NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS

Date: 10/26/26

Virtual Meeting

MARKET CONDUCT EXAMINATION GUIDELINES (D) WORKING GROUP
Wednesday, October 28, 2026
12:00 – 1:30 p.m. ET / 11:00 – 12:30 p.m. CT / 10: 00 – 11:30 a.m. MT / 9:00 – 10:30 a.m. PT

ROLL CALL

Brett Bache, Chair	Rhode Island	Ralph Boeckman	New Jersey
Danielle Torres, Vice Chair	Michigan	Elouisa Tyler	New Mexico
Katherine Jessen	Arizona	Sylvia Lawson	New York
Teri Ann Mecca	Arkansas	Teresa Knowles	North Carolina
Nick Gill	Connecticut	Colton Schulz	North Dakota
Sharon Shipp	District of Columbia	Rodney Beetch	Ohio
Elizabeth Nunes/ Paula Shamburger	Georgia	Landon Hubbart Cassie Soucy	Oklahoma Oregon
Chris Heisler	Illinois	Gary Jones/Paul Towsen	Pennsylvania
Will Speicher	Iowa	Gwendolyn Fuller McGriff/ Rachel Moore	South Carolina
Mary Lou Moran	Massachusetts	Stacie Parker	Texas
Teresa Kroll	Missouri	Karla Nuissl	Vermont
Peggy Willard-Ross/ Hermoliva Abejar	Nevada	Bryan Wachter Sandy Ray	Virginia Washington
Gregory S. Arce/ Victoria W. Fowler	New Hampshire	Jeremy White Darcy Paskey	West Virginia Wisconsin

NAIC Committee Support: Petra Wallace

AGENDA

1. Consider Adoption of the Aug. 18 Draft of Revised Chapter 21A—Conducting the Travel Insurance Examination for Inclusion in the *Market Regulation Handbook* (Handbook)—*Brett Bache (RI)* — Attachment 1
   A. American Property Casualty Insurance Association (APCIA)/U.S. Travel Insurance Association (USTIA): Aug. 18 Comments Chart
   B. APCIA/USTIA: Oct. 2 Joint Comments

2. Discuss the Oct. 20 Draft of the New Cybersecurity Event Response Coordination Framework—*Brett Bache (RI) and Miguel Romero (NAIC)* — Attachment 2
   A. NAIC Summary of Comments Received on Framework, May 14 Draft

3. Consider for Adoption the Aug. 18 Draft of the Accelerated Underwriting-Related Revisions to Chapter 20—General Examination Standards for Inclusion in the Handbook—*Brett Bache (RI)* — Attachment 3

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A. Accelerated Underwriting (A) Working Group Adopted Regulatory Guidance Document (Note: The Aug. 18 Chapter 20 revisions are based on this document.)
B. NAMIC/APCIA: Sept. 14 Joint Comments

4. Discuss the Aug. 18 Draft of a New Conducting the Pharmacy Benefit Manager Examination Chapter for Inclusion in the Handbook—*Brett Bache (RI)* Attachment 4
   A. Coalition: Sept. 17 Comments
   B. Coalition: Sept. 17 Executive Summary
   C. Coalition: Sept. 17 Redline Revisions to the Pharmacy Benefit Manager (PBM) Chapter

5. Discuss its 2026 Charges and Work Plan—*Brett Bache (RI)*

6. Discuss Any Other Matters Brought Before the Working Group—*Brett Bache (RI)*

7. Adjournment

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Chapter 21A—Conducting the Property and Casualty Travel Insurance Examination

IMPORTANT NOTE:
The standards set forth in this chapter are based on established procedures and/or NAIC models, not on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination process. Since it is based on NAIC models, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in the Foreword section of the handbook.

This chapter provides a format for conducting travel insurance company examinations. Procedures for conducting property/casualty (P/C) insurance company examinations and other types of specialized examinations, such as third-party administrators (TPAs) and surplus lines brokers, may be found in separate chapters.

The examination of travel insurance operations may involve any review of one or a combination of the following business areas:

A. Operations/Management
B. Complaint Handling
C. Marketing and Sales
D. Producer Licensing
E. Policyholder Service
F. Underwriting and Rating
G. Claims

When conducting an examination that reviews these areas, there are essential tests that should be completed. The tests are applied to determine if the ~~company~~ travel insurer is meeting standards. Some standards may not be applicable to all jurisdictions. The standards may suggest other areas of review that may be appropriate on an individual state basis.

A. Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

B. Complaint Handling

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

C. Marketing and Sales

Use the standards for this business area that are listed in Chapter 20—General Examination Standards and Chapter 21—Conducting the Property and Casualty Examination and the standards set forth below.

1. **Tests and Standards**

   The marketing and sales review includes, but is not limited to, the following standards addressing various aspects of the marketing and sales function. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
MARKETING AND SALES

Standard 1
Ensure the advertising and/or sales materials being utilized by the limited lines travel insurance producer and travel insurer: (i) provide the information required by Section 4(C) of the model law [or state equivalent]; (ii) are consistent with the travel protection plan being offered; (iii) are not deceptive or misleading; and (iv) otherwise comply with state law.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ The travel insurer's approved brochures or other written materials used in offering or disseminating travel insurance to prospective purchasers

_____ Policy forms and fulfillment materials are accurately represented in advertising and sales materials

_____ Producers' own advertising and sales materials, including travel retailers under the direction of a limited lines travel insurance producer

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request a listing of all marketing materials and select a sample according to the jurisdiction's sampling protocols. ~~If the examiner is unable to obtain the requested information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

Review specimen or actual copies of all of the brochures or other written materials in conjunction with the appropriate policy forms, endorsements, policies, rate filings~~,~~ and certificates of insurance. ~~There should be a notation indicating the manner and extent of distribution and the form number of every brochure advertised.~~ The examiner should review for compliance with applicable state form filing requirements.

~~All advertisements should be maintained in the file for a period of either at least three (3) years from the date the advertisement was first used or later if required by applicable state statutes, rules and regulations.~~ All advertisements should be maintained for at least the current calendar year and the two (2) preceding years, however examiners should review for compliance with applicable state record retention requirements.

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Materials should not:

- Misrepresent policy benefits, advantages or conditions by failing to disclose limitations, exclusions or reductions, or use terms or expressions that are misleading or ambiguous; ~~and~~
- Make false, deceptive or misleading statements or representations with respect to any person, company or organization; and
- Offer unlawful rebates. ***SEE Page 1 of Comment Chart, no change***

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Materials should:

- Clearly disclose the name and address of the travel insurer;
- If using a trade name, disclose the name of the insurer, an insurance group designation, name of the parent company of the travel insurer, name of a particular division of the travel insurer, service mark, slogan, symbol or other device or reference, if the advertisement would have the capacity or tendency to mislead or deceive as to the true identity of the travel insurer, or create the impression that a company other than the travel insurer would have any responsibility for the financial obligation under a policy;
- Clearly describe the type of policy being advertised;
- ~~Indicate that the travel protection plan being marketed is insurance; and~~ ***SEE Pages 1-2 of Comment Chart, language changed***
- Indicate that the travel protection plan being marketed contains insurance; and
- Comply with applicable statutes, rules and regulations.

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Determine if the travel insurer approves producer sales materials and advertising.

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STANDARDS
MARKETING AND SALES

Standard 2
The disclosures combinations of travel insurance, non-insurance travel assistance services~~,~~ and cancellation fee waivers are compliant with applicable statutes, rules and regulations.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Policy forms and fulfillment materials are accurately represented in advertising and sales materials

_____ Producers' own advertising and sales materials and travel retailers acting under the direction of a limited lines travel insurance producer

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard. ~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

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STANDARDS
MARKETING AND SALES

Standard 3
The limited lines travel insurance producer has established and maintains a register of each travel retailer that offers travel insurance on the producer's behalf.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ ~~Register of each travel retailer that offers travel insurance on the limited lines travel insurance producer's behalf~~ The limited lines travel insurance producer's register

_____ Policies and procedures for maintaining the accuracy of the register

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
~~*Unfair Trade Practices Act* (#880)~~

~~Examiners should request a copy of the register of each travel retailer that offers travel insurance on the producer's behalf from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard.~~ Examiners should request samples of the limited lines travel producer's register that is sufficient to determine compliance with this standard.

Examiners should ensure that the register is in the form required by the commissioner and includes all information required by statute, if applicable.

~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer. A random sample should be selected for review from the travel insurer's register.~~

~~Reconcile the information received for compliance, the register shall include the name, address, and contact information of the travel retailer and an officer or person who directs or controls the travel retailer's operations, and the travel retailer's Federal Tax Identification Number (FEIN).~~ Reconcile the information received for compliance. Confirm the register includes the name, address, and contact information of the travel retailer and an officer or person who directs or controls the travel retailer's operations, and the travel retailer's Federal Tax Identification Number (FEIN).

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STANDARDS
MARKETING AND SALES

Standard 4
The limited lines travel insurance producer has documentation sufficient to demonstrate compliance that the travel retailers (acting under the limited lines travel insurance producer's license) comply with 18 USC § 1033 ***Crimes by or affecting persons engaged in the business of insurance whose activities affect interstate commerce*****.**

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ ~~Travel insurer and department of insurance producer licensing records~~ ***SEE Page 2 of Comment Chart, language deleted***

_____ ~~Travel insurer and producer training materials~~ Travel insurer and producer training materials related to 18 USC § 1033 ***SEE Page 2 of Comment Chart, no change***

_____ ~~Travel insurer advertising and sales records~~

Others Reviewed

_____ 18 USC § 1033

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard.

~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

~~Review travel insurer and department of insurance producer licensing records for potential concerns and cross reference with department of insurance licensing records.~~ ***SEE Page 3 of Comment Chart, language deleted***

~~Evaluate the travel insurer's system for controlling advertisements. Every travel insurer should have and maintain a system of control over the content, form and method of dissemination of all advertisements of its policies. All advertisements, regardless of by whom written, created, designed or presented, are the responsibility of the travel insurer.~~

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~~Ensure the travel insurer maintains, at its home or principal office, a complete file containing a specimen copy of every printed, published or prepared advertisement of its individual policies and specimen copies of typical printed, published or prepared advertisements of its blanket, franchise and group policies. There should be a notation indicating the manner and extent of distribution and the form number of every policy advertised. All advertisements should be maintained in the file for a period of either at least three years from the date the advertisement was first used or later if required by applicable state statutes, rules and regulations.~~

~~Review advertising materials in conjunction with the appropriate policy form.~~

~~Examiners should ensure that travel insurer practices do not violate any state specific unfair trade practices as outlined in applicable state statutes, rules and regulations.~~

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STANDARDS
MARKETING AND SALES

Standard 5
Determine that consumers were provided with information and an opportunity to learn more about the pre-existing condition exclusions: (i) at any time prior to the purchase; and (ii) in the fulfillment materials.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Policy form, fulfillment materials, advertising/sales materials, and disclosures

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Determine that information about pre-existing condition exclusions is provided prior to the time of purchase, including whether the purchaser of travel insurance: (i) has the ability to waive the pre-existing condition exclusion; (ii) under what circumstances it can be waived; and (iii) whether the purchaser of travel insurance has been advised that the coverage for pre-existing conditions can be purchased, if applicable.

Determine that the fulfillment materials provide information about pre-existing condition exclusions.

Determine that the policies or certificates and fulfillment materials clearly define pre-existing conditions as intended in the exclusions.

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STANDARDS
MARKETING AND SALES

Standard 6
Determine that descriptions of the following are provided to the purchasers of travel insurance: (i) the material or actual terms of the insurance coverage; (ii) the process for filing a claim; (iii) the review or cancellation process for the travel insurance policy; and (iv) the identity and contact information of the travel insurer and limited lines travel insurance producer.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard. ~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

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STANDARDS
MARKETING AND SALES

Standard 7
The limited lines travel insurance producer has an adequate training program in place, containing instructions on the types of insurance offered, ethical sales practices, and required consumer disclosures, that is required of each employee and authorized representative of the travel retailer whose duties shall include offering and disseminating travel insurance.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Limited lines travel insurance producer's policies and procedures, including the standards for product training

_____ Limited lines travel insurance producer's instruction/training files and training materials for travel retailer employees and authorized representatives offering or disseminating travel insurance

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Review policies and procedures to ensure that the limited lines travel insurance producer has adequate procedures in place to provide instruction and training that is appropriate for and consistent with the type(s) of travel insurance being offered. Review the limited lines travel insurance producer's procedures used to inform travel retailers of the regulated entity's standards for travel insurance product training and of applicable state statutes, rules or regulations regarding the solicitation and sale of travel insurance products.

Determine that the limited lines travel insurance producer has adequate procedures in place to verify that the employees and authorized representatives of a travel retailer have completed necessary training, as required by applicable state statutes, rules and regulations, before allowing the employees and authorized representatives to sell travel insurance for that insurer.

Contact other state insurance regulators that may have conducted a recent review of the training standards.

Determine if the training materials are appropriate and accurately reflect the coverage provided by the travel insurance product.

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Review a regulated entity's records to determine if, when and how training occurred prior to the employees or authorized representatives of a travel retailer's recommendation of a travel insurance product.

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STANDARDS
MARKETING AND SALES

Standard 8
~~**The limited lines travel insurance producer has designated a "Designated Responsible Producer."**~~

The limited lines travel insurance producer has designated one of its employees who is a licensed individual producer as the person (a "Designated Responsible Producer" or "DRP") responsible for the compliance with the Travel Insurance laws and regulations applicable to the Limited Lines Travel Insurance Producer and its registrants.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ ~~Copy of agency manual~~ Copy of agency written procedures and/or manual

_____ ~~Copy of travel insurer operations manual~~Copy of travel insurer written procedures and/or operations manual ***SEE Page 4 of Comment Chart, no change***

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Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
~~*Unfair Trade Practices Model Act* (#880)~~

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard. ~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

~~Ensure that the agency and travel insurer operations manuals include the process, criteria and procedure pursued to determine the "Designated Responsible Producer" or "DRP."~~ Ensure that the agency and travel insurer written procedures and/or operations manuals include the process, criteria and procedure pursued to determine the "Designated Responsible Producer" or "DRP."

~~Ensure the agency and travel insurer operations manuals include the fingerprinting requirements applicable to insurance producers in the resident state of the Limited Lines Travel Insurance Producer.~~ Ensure the agency and travel insurer written procedures and/or operations manuals include applicable state regulations' requirements which may include fingerprinting of insurance producers in the resident state of the limited lines travel insurance producer.

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STANDARDS
MARKETING AND SALES

Standard 9
Sales practices do not include "negative option or opt out."

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ ~~Sales and marketing~~Advertising/sales materials

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Review a sampling of marketing materials and policies to confirm that customers were not offered or sold a policy through negative option or opt out.

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STANDARDS
MARKETING AND SALES

Standard 10
Blanket coverage is not marketed or described as "free" coverage.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ All marketing/sales material related to blanket coverage

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Review the use of the words/phrases "free," "no cost," "without cost," "no additional cost," "at no extra cost," or words/phrases of similar import. Such words/phrases should not be used with respect to any benefit or service being made available with a policy, unless true.

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STANDARDS
MARKETING AND SALES

Standard 11
~~If any website provides a short summary of the coverage, determine that the consumer has access to the full provisions of the policy by electronic means.~~
If the travel insurer's and/or the aggregator's websites provide a short summary of the coverage, determine that the consumer has access to the full provisions of the policy by electronic means.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ ~~All online locations where the travel insurer's products are marketed, including aggregators' websites~~ Travel insurers' and/or aggregators' websites where the travel insurer's products are marketed

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard.

~~Examiners should confirm that the aggregator's website does not violate applicable state statutes, rules and regulations relating to Model #880 and any other law applicable in [insert applicable] state. This includes verifying that an accurate summary or short description of coverage is provided on the web page, so long as the consumer has access to the full provisions of the policy through electronic means.~~ ~~Examiners should confirm that the travel insurer's and/or the aggregator's websites do not violate applicable state statutes, rules and regulations relating to Model #880 and any other law applicable in [insert applicable] state.~~ ***SEE Page 4 of Comment Chart, previous sentence deleted*** The examiner should verify that if an accurate summary or short description of coverage is provided on the web page, the consumer has access to the full provisions of the policy through electronic means.

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~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

~~Review the travel insurer's website or sources provided by others through an aggregator site to determine how travel insurance is marketed.~~ ~~Review the travel insurer's and/or aggregator's websites to confirm there is a short summary of the coverage with access to the full policy.~~ ***SEE Page 5 of Comment Chart, the previous sentence was replaced with the following sentence. This issue was not present in either of the APCIA or the USTIA August 2025***

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comment letters. Review the travel insurer's and/or aggregator's websites to determine if there is a short summary of the coverage and confirm there is access to the full policy.

~~Request information from the travel insurer which includes the disclosure in the policy documentation and fulfillment materials whether the travel insurance is primary or secondary to other applicable coverage.~~

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D. Producer Licensing

Use the standards for this business area that are listed in Chapter 20—General Examination Standards, ~~and~~ Chapter 21—Conducting the Property and Casualty Examination and the standard~~s~~ set forth below.

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STANDARDS
PRODUCER LICENSING

Standard 1
Determine that the travel insurer or limited lines travel insurance producer has provided the information required in ~~Section 4(B)(1) [or state equivalent]~~ Section 4(B)(1) and applicable state statutes, rules and regulations to the purchasers of travel insurance.

SEE Pages 5-6 of Comment Chart, the above exam standard is to be replaced with the following exam standard (added "Section 4(B)(1) [or state equivalent]" back in and removed "Section 4(B)(1) and applicable state statutes, rules and regulations".)

Determine that the travel insurer or limited lines travel insurance producer has provided the information required in Section 4(B)(1) [or state equivalent] to the purchasers of travel insurance.

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Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Determine if the requested coverage is issued.

Examiners should request proof from the travel insurer or limited lines travel insurance producer sufficient to demonstrate that the actual information was provided. ~~If the examiner is unable to obtain proof from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

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E. Policyholder Service

Use the standards for this business area that are listed in Chapter 20—General Examination Standards, ~~and~~ Chapter 21—Conducting the Property and Casualty Examination and the standards set forth below.

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STANDARDS
POLICYHOLDER SERVICE

Standard 1
Fulfillment materials were provided to the policyholder or ~~certificate holder~~certificateholder, as required.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ All applications

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request documentation from the travel insurer or limited lines travel insurance producer that is sufficient to demonstrate that the fulfillment documents were provided to the purchasers of travel insurance.

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STANDARDS
POLICYHOLDER SERVICE

Standard 2
The policy documents disclosed whether the travel insurance was primary or secondary to other coverage.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ All applications

_____ Policy contract terms related to payment terms

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Examiners should request documentation from the travel insurer or limited lines travel insurance producer that is sufficient to demonstrate that the policy documents state whether the coverage provided is primary or secondary to other coverage.

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F. Underwriting and Rating

Use the standards for this business area that are listed in Chapter 20—General Examination Standards, ~~and~~ Chapter 21—Conducting the Property and Casualty Examination and the standard~~s~~ set forth below.

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STANDARDS
UNDERWRITING AND RATING

Standard 1
~~**Minimum data collection standards to ensure proper allocation for payment of premium tax have been established.**~~

The travel insurer has established minimum data collection standards to ensure proper allocation for payment of premium tax.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ All applications

_____ Premium tax payment documentation from the travel insurer

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard. ~~If the examiner is unable to obtain the information from the travel insurer or the limited lines travel insurance producer, the examiner may request the information directly from the travel retailer.~~

Confirm that the travel insurer is paying premium tax, as provided in [insert applicable state]'s existing premium tax provision on travel insurance premiums paid by any of the following:

- An individual primary policyholder who is a resident of [insert applicable state];
- A primary certificateholder who is a resident of [insert applicable state] who elects coverage under a group travel insurance policy; or
- A blanket travel insurance policyholder that is a resident in, or has its principal place of business or the principal place of business of an affiliate or subsidiary that has purchased blanket travel insurance in [insert applicable state] for eligible blanket group members, subject to any apportionment rules which apply to the travel insurer across multiple taxing jurisdictions or that permit the travel insurer to allocate premium on an apportioned basis in a reasonable and equitable manner in those jurisdictions.

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Confirm the travel insurer provides the following:

- Document the state of residence or principal place of business of the policyholder or certificateholder, as required in applicable state statutes, rules and regulations relating to Model #632; and
- Report as premium only the amount allocable to travel insurance and not any amounts received for travel assistance services or cancellation fee waivers.

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G. Claims

Use the standards for this business area that are listed in Chapter 20—General Examination Standards, Chapter 21—Conducting the Property and Casualty Examination~~,~~ and the standard~~s~~ set forth below.

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STANDARDS
CLAIMS

Standard 1
The policies issued contain benefits for which a claim and claim payment could have been made.

Apply to: All property and casualty travel insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

____ Review policy forms and endorsements

_____ Claim files

_____ Claim complaint records

_____ Claim procedure/underwriting manuals

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Travel Insurance Model Act (#632)
Unfair Trade Practices Act (#880)
Unfair Property/Casualty Claim Settlement Practices Model Regulation (#902)

Review Procedures and Criteria

To determine compliance with this requirement, examiners will: (i) review a sample set of policies to confirm that benefits are being offered under the policies issued and a payment for a claim could have been made; and (ii) review a sample of denied claims to confirm that the denials were appropriate based on the policy language.

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AMERICAN PROPERTY CASUALTY INSURANCE ASSOCIATION & U.S. TRAVEL INSURANCE ASSOCIATION August 15 & 14, 2025 Comments

Section	APCIA (Their contention shown in red) (Their proposed resolution shown in green)	USTIA (Their contention shown in red) (Their proposed resolution shown in green)	Changes/Rationale
Marketing and Sales Standard 1 Rebating	**Standard 1—4th Paragraph under Review Procedures and Criteria** The Review Procedures and Criteria address "unlawful rebate[s]." As stated in APCIA's March 12, 2025 letter, this is not addressed in the Model Act and should be removed. The Draft states, "Indicate that the travel protection plan being marketed is insurance." APCIA's concerns with the statement remain as the language creates a discrepancy as the definition of a travel protection plan per the Act includes non-insurance benefits, travel assistance services and waivers as is acknowledged in the next standard, Standard 2.	**Standard 1—4th Paragraph under Review Procedures and Criteria** The Review Procedures and Criteria still provide that the materials should not "[o]ffer unlawful rebates," despite UStiA and the American Property Casualty Insurance Association ("APCIA") requesting in their March 12, 2025, letters that the language be removed. The stated rationale for keeping this language is that "1) [u]nlawful rebating is listed in Section I. Rebates of Model 880 (the Unfair Trade Practices Model Act), which is referenced in this exam standard, and 2) Model 880 applies to travel insurance." Draft Revisions, Attachment 1 at 2-3. UStiA is not aware of any rebating complaints or concerns specifically related to travel insurance. Thus, it is inappropriate to highlight this specific issue in an examination of travel insurance. Model 880 lists seventeen (17) other types of unfair trade practices. UStiA has not been made aware of the basis for singling out rebating among these practices. Further, Model 880 only applies to travel insurance if it is not in conflict with specific provisions of the NAIC Travel Insurance Model Act ("Model Act"). *See* Model Act §§ 2C, 7A.	***No change*** ***The SMEs appreciate the recommendation; no additional changes are needed. SMEs feel rebating is the most potentially likely of the unfair trade practices listed in Model 880 that apply to travel insurance***
Marketing and Sales Standard 1 Rebating	**Standard 1—4th Bullet in the "Materials should" paragraph under Review Procedures and Criteria—"Indicate that the travel protection plan being marketed is insurance"** The Draft states, "Indicate that the travel protection plan being marketed is insurance." APCIA's concerns with the	**Standard 1—4th Bullet in the "Materials should" paragraph under Review Procedures and Criteria—"Indicate that the travel protection plan being marketed is insurance"** Additionally, the Draft Revisions retain the provisions stating that materials should "[i]ndicate that the travel	***Language changed*** ***The SMEs agree in part with the APCIA/USTIA comments, and have revised "Indicate that the travel protection plan being marketed is insurance" to***

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	statement remain as the language creates a discrepancy as the definition of a travel protection plan per the Act includes non-insurance benefits, travel assistance services and waivers as is acknowledged in the next standard, Standard 2.	protection plan being marketed is insurance." APCIA previously requested that this language be removed and UStiA agrees. This language creates a discrepancy as a travel protection plan includes non-insurance benefits, which is acknowledged in Standard 2. Although UStiA requests that the provision be deleted entirely, the language should, at a minimum, be amended to read: "Indicate that the travel protection plan being marketed *contains insurance and other components*."	***"Indicate that the travel protection plan being marketed contains insurance"***
Marketing and Sales Standard 4 Compliance with 18 U.S.C. §1033	**Standard 4—Documents to be Reviewed—"Travel insurer and department of insurance producer licensing records"** As we asserted in our March 12, 2025 letter, this standard relates to the section of the Model Act (Section 4(B)(2)) that requires that "[t]he limited lines travel insurance producer shall also certify that the travel retailer registered complies with 18 U.S.C. § 1033." Documents to be Reviewed include "Travel insurer and department of insurance producer licensing records." Per the Model Act, it is the limited lines travel insurance producer who will certify that the travel retailer registered complies with 18 USC §1033. It is the limited lines travel insurance producer who will maintain the 1033 certification. **Standard 4—Documents to be Reviewed— "Travel insurer and producer training materials related to 18 U.S.C. 1033"** **No equivalent in APCIA letter**	**Standard 4—Documents to be Reviewed— "Travel insurer and department of insurance producer licensing records"** **No equivalent in USTIA letter** **Standard 4—Documents to be Reviewed— "Travel insurer and producer training materials related to 18 U.S.C. 1033"** UStiA is grateful that the Working Group incorporated certain of UStiA's requested changes in the Draft	***Language deleted*** ***SMEs agree with the APCIA comment and deleted the Document to be Reviewed "Travel insurer and department of insurance producer licensing records", as this examiner guidance is in Chapter 20-General Exam Standards*** ***No change*** ***The SMEs appreciate the recommendation; no additional changes are needed. The Market Regulation***

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		Revisions for Standard 4. However, UStiA believes that the following language under Documents to be Reviewed should be removed: "Travel insurer and producer training materials related to 18 U.S.C. 1033." There is no requirement that any training materials contain a reference to 18 U.S.C. 1033. Model Act Section 4B(2) only requires that the travel retailer registered complies with 18 U.S.C. 1033. Moreover, training is addressed in Model Section 4B(6), and that section does not mention 18 U.S.C. 1033. UStiA therefore believes this reference to the federal statute is inappropriate and goes beyond the Model Act.	***Handbook (MRH) provides guidelines for examiners; examiners need to follow their applicable state-specific statutes, rules and regulations, if a state has not adopted the Travel model. The SMEs want to leave this open-ended; regulators need to look at what is applicable for their consumers, taking into consideration each state's specific statutes, rules and regulations. Additionally, requesting an insurer's policies and procedures is a standard part of market conduct examination procedure***
	Standard 4—Review Procedures and Criteria (3rd paragraph) Under Review Procedures and Criteria, APCIA again suggests deleting all but the first paragraph – "Examiners should request information from the travel insurer or limited lines travel insurance producer that is sufficient to determine compliance with this standard." Review of insurer records, again, will not provide information germane to this standard as it is the limited lines travel insurance producer who certifies that travel retailers comply with 18 USC §1033.	**Standard 4—Review Procedures and Criteria (3rd paragraph)** **No equivalent in USTIA letter**	***Language deleted*** ***SMEs agree with the APCIA comment and deleted the paragraph "Review travel insurer and department of insurance producer licensing records for potential concerns and cross reference with department of insurance licensing records."***

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Marketing and Sales Standard 8 Designated Responsible Producer	**Standard 8—3rd Document to be Reviewed** **No equivalent in APCIA letter**	**Standard 8— 3rd Document to be Reviewed—"Copy of travel insurer written procedures and/or operations manual"** Rather than revise the Documents to be Reviewed to remove "[c]opy of travel insurer operations manual," as UStiA requested in its March 12, 2025 letter, the Draft Revisions amend this Standard to now read: "Copy of travel insurer written procedures and/or operations manual." It is not clear what is intended by "written procedures and/or operations manual," and in any event, this provision creates a new substantive requirement that goes beyond the Model Act. Accordingly, UStiA again respectfully requests the Working Group remove this language.	***No change*** ***The SMES appreciate the recommendation; no additional changes are needed.***
Marketing and Sales Standard 11 Consumer has access to the full provisions of the travel policy (if a travel and/or aggregator's websites provide a short coverage summary)	**Standard 11—Review Procedures and Criteria** **2nd Paragraph—"Examiners should confirm that the travel insurer's and/or aggregator's websites do not violate…through electronic means"** **No equivalent in APCIA letter**	**Standard 11—Review Procedures and Criteria** **2nd Paragraph—"Examiners should confirm that the travel insurer's and/or aggregator's websites do not violate…through electronic means"** UStiA continues to believe that the following language under Review Procedures and Criteria is exceedingly broad: "Examiners should confirm that the travel insurer's and/or aggregator's websites do not violate applicable state statutes, rules, and regulations relating to Model #880 and any other law in [insert applicable] state." The provision appears to require a sweeping review of the travel insurer and aggregator's websites. Model Act Section 7(C)(5) provides that it is not an unfair trade practice or other violation of law to provide an accurate summary or short description of the coverage	***Language deleted*** ***SMEs agree with the UStiA comment and deleted the sentence "Examiners should confirm that the travel insurer's and/or the aggregator's websites do not violate…" from the 2nd paragraph.***

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		on the website, so long as the consumer has electronic access to the full policy. UStiA does not understand the rationale for such a sweeping review mandate for examiners and thus maintains its request that the language be removed.	
Marketing and Sales Standard 11 Review Procedures and Criteria "Review the travel insurer's and/or aggregator's websites to confirm there is a short summary of the coverage with access to the full policy"	**Not in the APCIA letter** **2nd sentence of 4th Paragraph of the Review Procedures and Criteria section—"Review the travel insurer's and/or aggregator's websites to confirm there is a short summary of the coverage with access to the full policy"**	**Not in the UStiA letter** **2nd sentence of 4th Paragraph of the Review Procedures and Criteria section —"Review the travel insurer's and/or aggregator's websites to confirm there is a short summary of the coverage with access to the full policy"**	***Language changed*** ***SMES noted an item not referenced in the APCIA and UStiA's August 2025 comments in their review of Standard 11. The 2nd sentence of the fourth paragraph "Review the travel insurer's and/or aggregator's websites to confirm there is a short summary of the coverage with access to the full policy" was updated to be consistent with the language of the Travel model to: "Review the travel insurer's and/or aggregator's websites to determine if there is a short summary of the coverage and confirm there is access to the full policy"***
Producer Licensing Standard 1—Exam Standard Language	**Standard 1—Exam Standard** **No equivalent in APCIA August 14 letter** The below is copied from the APCIA March 12 comments (copied here, since USTIA mentioned it in their Aug. 14 comments):	**Standard 1—Exam Standard** UStiA continues to oppose the expansive requirements in this Standard which go beyond the Model Act, for the reasons stated in UStiA and APCIA's March 12, 2025, letters. *See* Model Act §§ 2C, 7A. Moreover, as APCIA	***Language changed*** ***The SMEs added "Section 4(B)(1) [or state equivalent]" back in and removed "Section 4(B)(1) and applicable state***

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	APCIA requests that the changes suggested to this standard be rejected. The Model Act provides clear producer licensing requirements in Section 4(B)(1) that specifically spells out the information required to be provided.	explained in its March 12 letter, Model Act Section 4B(1) provides clear requirements for what the limited lines travel insurance producer and travel retailer must provide to purchasers of travel insurance. The below is copied from the USTIA March 12 comments (copied here, since USTIA mentioned it in their Aug. 14 comments): The proposed revision to insert "applicable state statutes, rules and regulations" should be rejected as beyond the Standard and the Model Act. The current Standard directs the examiner to review whether the travel insurer or limited lines travel insurance producer has provided the information required in Section 4(B)(1) of the Model Act to purchasers of travel insurance. Although there are other disclosures and information that must be provided (e.g., Model Act Sections 4(C), 7(C)(2), etc.), broadening the Standard in this way would seem to give the examiner less guidance as to what to look for, and may cause the examiner to apply general provisions of law that are inapplicable to travel insurance. (See, e.g., Sections 2(C) and 7(A), which most of the thirty-seven (37) states have incorporated into their insurance laws.)	***statutes, rules and regulations" so the exam standard now reads: "Determine that the travel insurer or limited lines travel insurance producer has provided the information required in Section 4(B)(1) [or state equivalent] to the purchasers of travel insurance."***

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October 2, 2026

VIA EMAIL

Petra Wallace
Senior Market Regulation Specialist
NAIC Central Office
1100 Walnut Street, Suite 1500
Kansas City, MO 64106-2197
pwallace@naic.org

Re: August 18, 2026 Draft Revisions to Chapter 21A—Conducting the Property/Casualty Travel Insurance Examination of the *Market Regulation Handbook*

Dear Ms. Wallace:

We are writing on behalf of the U.S. Travel Insurance Association ("USTIA")[1] and the American Property Casualty Insurance Association ("APCIA")[2] regarding changes to Chapter 21A—Conducting the Property/Casualty Travel Insurance Examination, of the National Association of Insurance Commissioners ("NAIC") Market Regulation Handbook ("Handbook") as revised on August 18, 2026, by the NAIC Market Conduct Examination Guidelines (D) Working Group ("Working Group") ("Revised Draft").

The USTIA and APCIA appreciate the efforts of the Working Group and its further consideration and incorporation of many of the revisions suggested in the USTIA's and APCIA's previous comments.[3] The USTIA would like to highlight two additional proposed revisions that were not accepted by the Working Group, as it continues to believe that the revisions are warranted.

[1] The USTIA is the national association of the travel insurance industry. Its members include insurance carriers, third-party administrators, insurance agencies, and related businesses that develop, administer, and market travel insurance and travel assistance products. USTIA members represent 90% of the travel insurance marketplace.
[2] APCIA is the primary national trade association for home, auto, and business insurers. APCIA promotes and protects the viability of private competition for the benefit of consumers and insurers, with a legacy dating back 150 years. APCIA members represent all sizes, structures, and regions-protecting families, communities, and businesses in the U.S. and across the globe.
[3] On March 12, 2025, the USTIA and APCIA submitted comments on the initial proposed revisions to Chapter 21 A of the Handbook. On August 14, 2025, the USTIA submitted comments on the July 17, 2025 draft revisions to Chapter 21 A of the Handbook. On August 15, 2025, APCIA submitted comments on the July 17, 2025 draft revisions.

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Marketing and Sales Standards

Standard 1

Under the Review Procedures and Criteria, examiners are directed to request a list of all marketing materials and to review specimen or actual copies of all of the brochures or other written materials in conjunction with policy rate and form filings. The Review Procedures and Criteria then state that "[m]aterials should not ... offer unlawful rebates." In the American Property Casualty Insurance Association & U.S. Travel Insurance Association August 15 & 14, 2025 Comment chart, the text provides, "The SMEs appreciate the recommendation; no additional changes are needed. SMEs feel rebating is the most potentially likely of the unfair trade practices listed in Model 880 that apply to travel insurance." There is no other support provided for retaining this reference to "unlawful rebating."

The USTIA and APCIA are not aware of unlawful rebating being an issue specific to travel insurance. For example, we are not aware of any evidence of unlawful rebating in travel insurance exams, DOI complaints, or litigation. The USTIA and APCIA believe that directing examiners to review travel insurance brochures and materials will incorrectly suggest such an issue and complaints do exist, causing examiners to expend resources to identify them or "prove the negative," and thus misdirect and expand exams.

We also note that the NAIC Travel Insurance Model Act ("Model Act"), enacted in 44 states, expressly permits the sale of travel insurance with assistance services and/or cancellation fee waivers as a combined "travel protection plan." These different features that make up a travel protection plan are defined in the Model Act, and their combined sale is specifically authorized therein, along with specific consumer protections and disclosures associated with the sale. Although this bundling has caused no confusion in the marketplace, it may nonetheless confuse examiners directed to look for unlawful rebating in travel insurance. Because these non-insurance services or waivers normally fall outside the filed insurance form regulators review, an examiner could mistake it for valuable consideration that induces the purchase of insurance—even though these legally permissible travel protection plans have always been ubiquitous in the marketplace. In short, directing examiners to look for illegal rebating runs the risk of confusing the legally permitted sale of travel protection plans with illegal rebating. For this additional reason, references to rebating should be removed.

We believe the Handbook otherwise sufficiently directs examiners to review such materials for misrepresentations or false, deceptive, or misleading statements. Accordingly, the USTIA and APCIA respectfully request that this item be removed from the Review Procedures and Criteria of the Revised Draft. If SMEs are aware of problems in this area, the USTIA and APCIA would very much like to engage in dialogue with those SMEs to learn more about what they are seeing.

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Standard 4

The Revised Draft, in the "Documents to be Reviewed" section, continues to have the language, "[t]ravel insurer and producer training materials related to 18 U.S.C. § 1033." The explanation for including this language is that "[t]he SMEs want to leave this open-ended; regulators need to look at what is applicable for their consumers, taking into consideration each state's specific statutes, rules and regulations. Additionally, requesting an insurer's policies and procedures is a standard part of market conduct examination procedure."

We respectfully request the Working Group remove this language from the Revised Draft, unless insurer and producer training materials related to 18 U.S.C. § 1033 exist in other chapters of the Handbook. Otherwise, the Model Act, in § 4(B)(6), requires the program of instruction and training to contain adequate instructions on the types of insurance offered, ethical sales practices, and required disclosures to prospective customers. Because the Model Act requires no training specific to 18 U.S.C. § 1033, the proposed Handbook language would incorrectly imply such a requirement for travel insurance and thus, as noted above regarding rebating, retaining this language would misdirect examiner resources and unnecessarily expand exams.

* * * *

Thank you for considering our comments. Please do not hesitate to reach out to me at (212) 547-5388 or mbyrne@mcdermottlaw.com if you have questions.

Sincerely,



Michael Byrne
Counsel, USTIA

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Cybersecurity Event Response Coordination Framework

1. Purpose~~, Scope,~~ and Use of This Framework

Continuing cybersecurity events have directed a national spotlight on the need for a regulatory framework to enhance coordination efforts in response to cybersecurity events of national significance in the insurance sector.

The Market Regulation and Consumer Affairs (D) Committee, the Innovation, Cybersecurity and Technology (H) Committee, and the Financial Condition~~s~~ (E) Committee have responsibility for developing standards and guidance on cybersecurity preparedness and post-incident actions of regulated entities.

This document recommends establishing a structured response framework built around a coordinating lead-state concept with support to be provided by several groups as suggested below. ~~The document also concludes with several discussions aimed at driving regulator input on key design choices should a framework receive further consideration.~~

This ~~framework~~ Framework ~~includes detailed responsibilities for each~~ describes the role each committee will take in providing oversight of the coordination process, coordination mechanisms for complex events that cross jurisdictional boundaries, and specific implementation recommendations to formalize these procedures. ~~–~~The ~~F~~framework is designed to drive coordination particularly for information gathering to both enhance regulatory responses and reduce duplicative requests to industry in the wake of cybersecurity events.

By establishing a structured approach, the NAIC can ensure consistent, effective responses to cybersecurity events while protecting both consumers and the stability of the insurance market.

Relationship to the Cybersecurity Event Response Plan

The Cybersecurity Event Response Plan (CERP) is a foundational resource that may be utilized for cybersecurity event response. A department of insurance (DOI) that receives notification under Section 6 of the NAIC Insurance Data Security Model Law (#668), (hereinafter referred to as Model #668) or that otherwise becomes aware of a cybersecurity event at a regulated entity, may consult the CERP in navigating the DOI's response. In

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practice, a DOI may follow a response plan specific to their state but for ease of reference, this document will refer to the CERP.

This Framework builds on the CERP by adding a framework for -coordination for the limited subset of events that warrant a coordinated multistate regulatory response.

What This Framework Does Not Do

Application of this Framework:

- does not expand the information a licensee is required to report beyond that described in Section 6(B), absent an examination or investigation brought under Section 7 of Model #668 or under other applicable state authority;
- does not confer on the NAIC, or on any state, authority that the state does not otherwise possess; and
- does not alter any state's confidentiality obligations or any licensee's ability to assert privilege or trade secret protection.

Where this Framework is applied, participating states will work to coordinate communication with the affected entity through the Coordinating Lead State. The reduction of duplicative regulatory requests is both a purpose of this Framework and a commitment of the states participating in it.

2. Evaluation and Response Process

As cybersecurity events take place, the Cybersecurity (H) Working Group (CWG) (hereinafter referred to as the CWG) will evaluate events and will engage with domestic regulators to see if the events would benefit from a coordinated response.

Generally, this Framework, and thus NAIC support, would apply to events that potentially affect policyholders across 5 or more states.

The evaluation of whether an event would benefit from the use of the Framework to guide coordination will also include consideration of the following criteria:

- The number of states in which consumers, policyholders, or operations are affected.
- The number of licensees affected by a common underlying event, including an event originating at a third-party or affiliated service provider or other shared technology dependency.

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- Operational impact to the affected licensee or licensees, including any impairment of claims handling, premiums processing, provider payment, or the ability to communicate with policyholders
- Direct Premium Written for company impacted
- Nature of the event and type of data involved
- ~~# of Policyholders affected~~
- ~~# of States involved~~
- # of companies affected (in cases where a singular event affects multiple entities)
- Operational impact ~~to~~to the company affected
- Whether the company operates internationally and if so, how international regulators are responding

The criteria in this section govern the coordination of regulatory responses among states. They do not establish, modify, or inform any threshold for a licensee's obligation to notify a commissioner of a cybersecurity event.

Response Protocol

Ongoing Activity - Monitoring

Over the course of the year, NAIC staff will work with the Cybersecurity (H) Working Group (CWG) and other regulators to determine if any cybersecurity event could benefit from a coordinated response through the Framework, based on consideration of the criteria listed above. Such information gathering should take place within 30 business days of the identification of an event and rely on public information as much as possible.

Paths to Consideration

An event may come before the Working Group for consideration under this Framework by any of the following paths, each of which is independent of the others:

1. Referral by the domiciliary regulator, or by a state previously identified as Lead State, under the CERP.
2. Request by any other state in which the affected licensee is licensed or operating, including any state that receives notification under a provision comparable to Section 6(A)(2) of Model #668.
3. Recommendation of the CWG leadership.

Step 1. Event Identification / Recommendation

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After initial and preliminary information gathering, NAIC staff will provide an event summary to the CWG.

NAIC staff, domestic regulators (as appropriate), and the CWG will work to ~~:~~d

~~I.~~Document a recommendation as to whether the Framework should apply for a given incident.

~~II.~~ The recommendation will summarize the event, explain the impact and reasoning to apply the framework, and will reach a preliminary assessment as to whether the event is one that should be treated primarily as a market conduct inquiry, financial inquiry, or as an industry ~~-~~event.

I.

II. The recommendation will also identify the presumed Coordinating Lead State and, where an alternate is proposed, the basis for the proposal.

~~a.~~

Step 2. Initial Communication

~~2.~~ Communicate the recommendation to the leadership of the:

~~a.~~I. Market Regulation and Consumer Affairs (D) Committee
~~b.~~II. Financial Condition (E) Committee
~~c.~~III. Innovation, Cybersecurity, and Technology (H) Committee
~~d.~~IV. Other Committee leadership as appropriate

Step 3. Activation and Lead State Identification

Based on responses received, NAIC staff and CWG leadership will identify a coordinating lead state as described in Section 3 of the Framework.

Step 4. Operation of the Framework

~~3.~~ ~~and work~~The Lead State, with support from the Cybersecurity (H) Working Group and NAIC staff will work together to facilitate coordinated inquiries of the affected company and facilitate information sharing, as appropriate, on the following:

I. Operational
   a. Status of resolution for any remediation of operational impacts including:
      i. ~~m~~Monitoring claims-paying ability
      ii. Ability to receive and process premium payments

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iii. Ability for policyholders to access coverage information

~~a.~~II. Market Conduct

~~i.~~a. Examining consumer data exposure and notification requirements

~~ii.~~b. Assessing market conduct implications

~~iii.~~c. Reviewing compliance with privacy regulations

~~iv.~~d. Coordinating multi-state market conduct examinations

~~v.~~e. Monitoring consumer complaint patterns

~~vi.~~f. Evaluating producer licensing impacts

~~vii.~~g. Developing consumer protection measures

~~b.~~II. Financial Condition / Solvency Event – Assessment of financial impact

~~i.~~a. Evaluating financial impact of the breach

~~ii.~~b. Assessing capital adequacy implications

~~iii.~~c. Reviewing business continuity capabilities

~~iv.~~d. Assessing risk management systems

~~v.~~e. Determining potential rating implications

~~c. I. Operational (Both) –~~

~~i. a. Status of resolution for any remediation of operational impacts including monitoring claims-paying ability~~

The ~~coordinating l~~Lead ~~state~~ State will work with NAIC staff and CWG leadership to provide communication via:

- ~~All state calls~~ Calls with all states / calls among affected states
- Regulator briefings
- Regulator only communications, and/or
- Summary response documentation ~~providing~~ with talking points in case of external inquiries as to how regulators are responding to the event

Communication and updates may consist of information explaining the cybersecurity event, impact to the insurer, impact to consumers, and may later provide insights on lessons learned as a result of responding to the cybersecurity event.

3. Coordinating Lead State Selection

Every insurance holding company system has individual characteristics that make it unique. Therefore, an evaluation of traits is required to determine how ~~examinations~~ regulatory responses ~~responding~~ to a cybersecurity event should be coordinated and which individual state, known as the Coordinating Lead State (Lead State), should assume the leadership role

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in a cybersecurity event response. The Lead State ~~is leading~~leads the state insurance regulatory response ~~primarily consisting of~~ with information gathering and dissemination of such information.

Presumption

In most situations to date, a Lead State may have already been identified pursuant to the protocols overseen by either the Market Regulation and Consumer Affairs (D) Committee or the Financial Condition (E) Committee and any of their supporting groups.

The domiciliary regulator, or a state previously identified as Lead State under those protocols, is presumed to serve as Coordinating Lead State under this Framework.

While deference should be given to previously selected Lead States, there may be circumstances driven by capacity or other circumstances where a different Lead State may need to be selected. Factors that may be considered when determining the Lead State are:

- State with the largest number of domestic insurance companies in the group.
- State of large or largest premium volume or exposure.
- Domiciliary state of top-tiered insurance company in an insurance holding company system.
- Physical location of the main corporate offices or the largest operational offices of the group.
- Authority to take action and respond to the event including adoption of the ~~Insurance Data Security~~ Model Law ~~(~~#668~~)~~
- Expertise in the area of concern and specialized experience of a state's staff members
- Ability to perform duties and responsibilities of a ~~lead~~ Lead ~~state~~State

Because each company or group has its own unique characteristics and similarly each cybersecurity event is unique, it may be appropriate to select a Lead State that differs from the Lead State otherwise selected for market or financial supervision purposes.

While Lead State selection will consider the adoption of the Model Law, it will not preclude the selection of non-adopting states as Lead States or from participating if states are able to ensure the confidentiality of information gathered in operating the Framework.

As the NAIC deploys this framework, after action meetings may take place allowing lessons learned to inform future revisions to the Framework.

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4. Coordinating Lead State Responsibilities

The Coordinating Lead State (Lead State) has the overall responsibility of facilitating communication and coordinating activities in an efficient manner. The Lead State is the key contact with the regulated entity under review. In coordination with the Cybersecurity (H) Working Group and other groups as appropriate, Lead State duties include:

- Convening the sStates for initial strategy planning to determine the appropriate course of action and scope of issues to be addressed.
- Requesting that participating states work to gather information jointly, as appropriate.
- Prior to each NAIC national meeting and following any material event, providing status updates on the coordinated state response and on the cybersecurity event.
- Scheduling regular meetings and conference calls with the regulated entity to ensure that the process continues to be efficient and effective, and notifying the participating states as appropriate.
- As requested by any participating state the Lead State will work with NAIC staff to schedule conference calls. Calls will be open to all participating states where the current status of the cybersecurity event and coordinated response will be described, and any documents shared. All participating states will have an opportunity to ask questions.
- Working with participating states to ensure information shared is properly held confidential, as appropriate.
- Determining, in conjunction with participating states, if violations occurred and the extent of any violations found.
- Determining and coordinating an appropriate corrective action by the regulated entity to ensure that further similar violations are prevented.
- Determining, in conjunction with participating states, if a plan of remediation is necessary and its scope.
- Determining whether any post-action reporting by the regulated entity is needed.
- Determining the scope of post-action monitoring necessary by the Lead State.
- Determining, in conjunction participating states, when the coordination process and related inquiry should be concluded.
- Serving as the single point of contact for the affected entity, and receiving notice of any information request a participating state proposes to make outside the coordinated process.
- Maintaining the shared record of the coordinated response in the environments described under Section 6 “Confidentiality” below.

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Working through the Lead State to request information, the Framework should assist in reducing duplicative requests allowing states to gather information jointly.

Participating State Responsibilities

A state participating in a coordinated response under this Framework:

- Executes the information sharing and confidentiality agreement described under "Confidentiality" below, or identifies the limits its own law places on its participation;
- Directs information requests to the affected entity through the Coordinating Lead State, and gives the Coordinating Lead State notice of any request it must make independently;
- Shares with participating states, to the extent its own law permits, information it receives regarding the event;
- Identifies a point of contact for the duration of the coordinated response; and
- Maintains shared information consistent with its own confidentiality obligations and with the terms of the agreement.

Participation is voluntary. A state may participate in a coordinated response without ~~relinquished~~relinquishing any authority, and may decline to participate without prejudice to any action it takes independently.

5. NAIC Support Responsibilities

The support that NAIC provides may vary from event to event depending on state needs. However, NAIC staff may be asked to:

- Assist in gathering and reviewing publicly available information on a cybersecurity event.
- Assist in the logistics of coordination calls including scheduling and provisioning of meeting notices.
- Advising state insurance regulators on technical subject matters relating to the Information Data Security Model Law or examination authority.
- Limited review and assessment of technical information intended to support state cybersecurity event responses.

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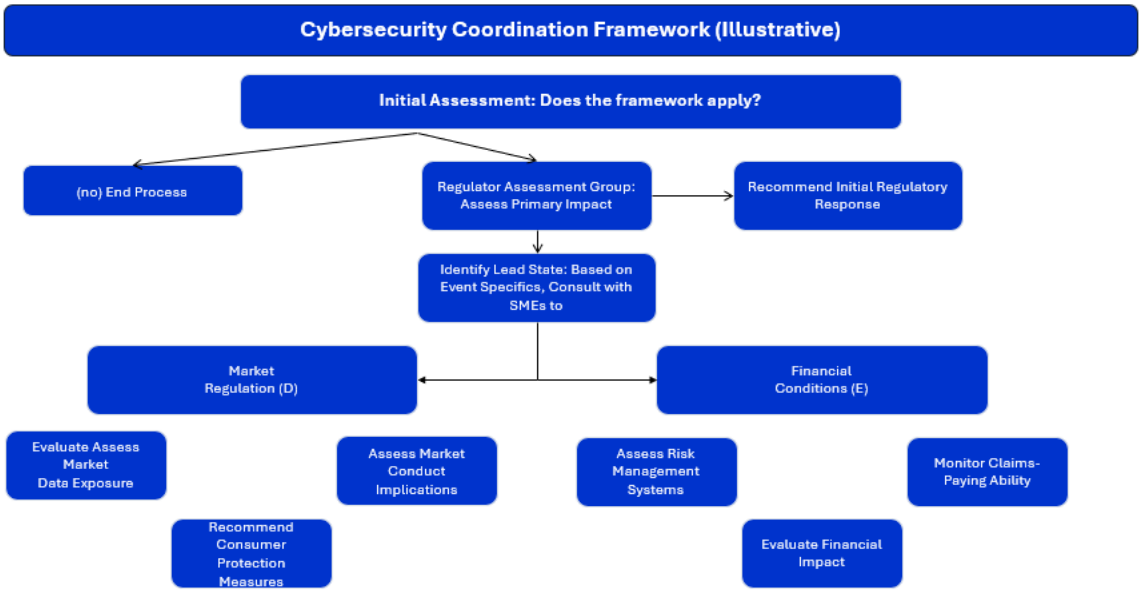
6. Confidentiality

As states are requesting information, states will ensure confidentiality of information specific to each situation. States will generally rely on the authority afforded to states via their implementation of either the Model Law #668 and the authority to investigate cybersecurity events it provides, or the state examination authority.

Confidentiality will depend on the states involved and on the information being gathered. Information on how each Lead State will provide confidentiality for requested information will be addressed on a ~~case by case~~case-by-case basis.

7. Cybersecurity Coordination Framework in Operation – ~~Illustrative~~Illustrations

~~5.~~ To assist in explaining the operation of the Framework, the following illustrations were created depicting key concepts.

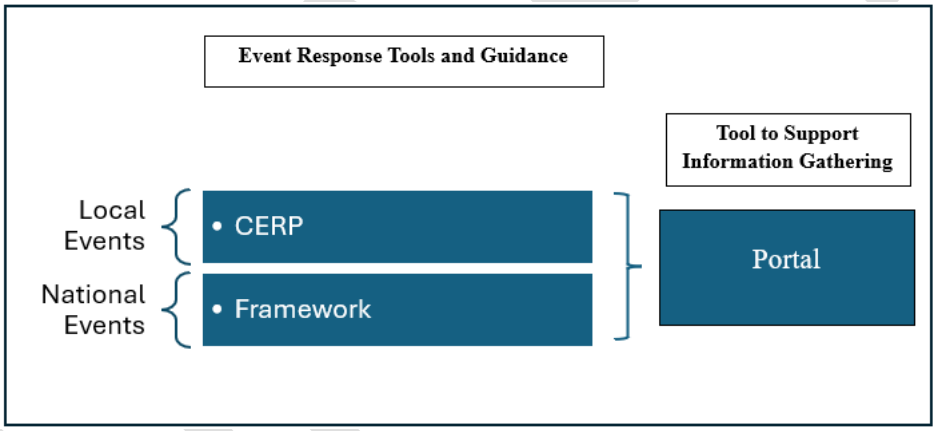


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~~6.~~8. Relationship to other documents and projects

This Framework operates within a larger context that includes other NAIC documents, laws, and regulations. However, there are three documents/projects which play a more central role relative to responding to cybersecurity events. These are:

- The Cybersecurity Event Response Plan which is a resource that assists states responding to cybersecurity events ~~happening within~~ affecting their domestic insurers.
- The Cybersecurity Event Response Coordination Framework described throughout this document.
- The Cybersecurity Event Notification Portal which is a tool that supports all regulatory responses whether for larger, national events, or for events where coordination is not as pivotal.



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Comment Summary and Summary of Changes

To assist stakeholders in understanding the changes to the latest version of the Cybersecurity Coordination Framework, NAIC staff have prepared this summary with notations for how the Framework has been updated to reflect the input received.

Who commented

- **Information Technology Examination (E) Working Group**
- **NAMIC**
- **California DOI**
- **New York DFS**
- **ACLI**
- **AHIP**
- **APCIA**
- **BCBSA**

Key themes and how the revision responds

1. Support for coordinating, with a narrow scope. Nearly every commenter backed the lead-state idea as a way to cut duplicate requests. Stakeholders expressed input ranging from support for the idea without material changes to workable to expressing caution against creating a "51st state" or a central supervisory layer.

- *Revision:* A new "What This Framework Does Not Do" section says the Framework adds no reporting duties, gives no state or NAIC new authority, and changes no confidentiality or privilege protections.

2. Activation criteria and scope. Stakeholders said the catch-all clause left no real threshold with some asking for objective criteria based on material impact. Other stakeholders asked about the Framework's purpose and intended uses.

- *Revision:* The catch-all clause is gone. The Framework now generally applies to events that may affect policyholders in 5 or more states, with clearer factors to weigh.

3. Confidentiality and information sharing. Several stakeholders raised concerns about how sensitive information would be protected as it moves between states and NAIC staff.

- *Revision:* Additional language on confidentiality has been added.

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4. Portal access and states without Model #668. Several stakeholders all raised the problem that the Portal is limited to states that adopted Model #668 and to whether a lead state that hasn't adopted Model #668 would be disqualified.

- *Revision:* Not adopting Model #668 doesn't automatically stop a state from leading or participating, as long as it can keep information confidential. Additional text distinguishing the Portal as a tool from the Framework as a process of coordination was added. The edits further add that there are many ways that a Department of Insurance may learn about an event.

5. Choosing the lead state and its role. Stakeholders posed numerous questions about lead state selection with several also suggesting a default rule. Stakeholders also suggested that the lead state function as the main point of contact in discussions with the affected insurance company.

- *Revision:* The domiciliary regulator, or an existing lead state, is presumed to lead. Participating states will route communication through the lead state.

7. NAIC staff role. Stakeholders asked for more clarity on the NAIC's role in this framework.

- *Revision:* A new section describes NAIC staff's supporting role has been added.

8. Clarity of the Process. Stakeholders offered input that the actual process of coordination was unclear.

- Revision: Several edits aimed at clarifying the progression of coordination were added.

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Chapter 20—General Examination Standards

IMPORTANT NOTE:
The standards set forth in this chapter are based on established procedures and/or NAIC models, not on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination process. Since it is based on NAIC models, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in the Foreword section of the handbook.

The examination of the insurance operations of a regulated entity may involve reviewing one or more of the following business areas:

A. Operations/Management
B. Complaint Handling
C. Marketing and Sales
D. Producer Licensing
E. Policyholder Service
F. Underwriting and Rating
G. Claims

When conducting an examination that reviews these areas, there are essential tests that should be completed. The tests are applied to determine if the regulated entity is meeting standards. Some standards may not be applicable to all jurisdictions. The standards may suggest other areas of review that may be appropriate on an individual state basis.

When an examination involves a depository institution or their affiliates, the bank may also be regulated by federal agencies, such as the Office of the Comptroller of the Currency, the Federal Reserve Board, the Office of Thrift Supervision or the Federal Deposit Insurance Corporation. In addition, banks may also be regulated at the state level. Many states have executed an agreement to share complaint information with one or more of these federal or state agencies. If the examination results find adverse trends or a pattern of activities that may be of concern to a federal or state agency and there is an agreement to share information, it may be appropriate to notify the agency of the examination findings.

This chapter contains examination standards that are relevant to nearly all types of examinations. Chapters 21 through 32 contain standards that are specific to various product lines and specialized entities.

A. Operations/Management

1. Purpose

The Operations/Management portion of the examination is designed to provide a view of what the regulated entity is and how it operates. It is not based on sampling techniques; it is more concerned with structure. This review is not intended to duplicate a financial examination review, but is important in providing the market conduct examiner with an understanding of the examinee. Many troubled companies have become so because management has not been structured to recognize and address the problems that can arise in the insurance industry. The areas to be considered in this kind of review include:

a. History;
b. Profile;
c. Subcontractor oversight;
d. Internal audits;
e. Antifraud initiatives;
f. Certificates of authority;

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g. Disaster recovery plan;
h. Computer systems;
i. Minutes from all meetings attended by the board of directors; and
j. Privacy.

2. Techniques

Typically, the items to be reviewed here can be prepared by the regulated entity and provided at the pre-examination conference. Supplemental information, including history and profile may be available in the insurance department files. Other items suggest an active review of regulated entity files relating to managing general agent (MGA) or subcontractor oversight, internal audits, procedure manuals, record management, computer systems controls and antifraud plans. The latter category of items should have substantial supporting documentation.

The absence of subcontractor oversight, internal audit functions, written procedures or an antifraud plan should be specifically noted when preparing the examination report.

a. History

The examiner should prepare for the examination report a very brief history of the regulated entity, including its formation; its type; its structure, including the parent corporation and other members of the group; and any major changes that are relevant to the current examination.

b. Profile

The profile includes an overview of the regulated entity's operations, including management structure, type of carrier, states where the regulated entity is licensed and the entity's major line(s) of business. A total change in the management team may generate the need to review the regulated entity on an abbreviated time cycle.

The examiner should review Market Action Tracking System (MATS) findings from prior examinations, Regulatory Information Retrieval System (RIRS) results, complaint index reports and reports from other NAIC applications and databases to determine if other regulators have expressed concerns that may require additional attention during the examination. RIRS and MATS information should not be included in the examination report.

The total written premiums for the major lines of business should be compared to the total writing in a given state to determine the market share. The loss, expense and combined ratios can be obtained from the expense exhibit attached to the annual statement or the NAIC Financial Analyst Workbench (FAW) system and may be calculated for the specific jurisdiction. Review IRIS ratios, which can be an indicator of market conduct problems. The surplus ratio should also be examined and noted for the period under review. Substantial shifts in the geographical area of operation and kinds of business written and volume should be noted, questioned and described.

c. Subcontractor Oversight

The jurisdiction's statutes on MGAs and other subcontractors are sources of tests for this oversight. The aim is to ensure that a regulated entity using subcontractors engages in a realistic level of oversight. Contracts should be reviewed to ensure compliance with the MGA statutes governing contract content and oversight features. The focus is on the oversight impacting records and actions considered in a market conduct examination such as, but not limited to, trade practices, claims practices, policy selection and issuance, rating, complaint handling, etc. Examiners should pay particular attention to a subcontractor's dealings with policyholders and claimants.

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d. Internal Audits

A regulated entity that has no internal audit function lacks the ready means to detect structural problems until after problems have occurred. Any questionable findings about the internal audit function should be referred to the Examiner-in-Charge.

e. Antifraud Plans

The regulated entity should have antifraud plans which are reasonably calculated to detect, prosecute and prevent fraudulent insurance acts. Written procedural manuals or guides and antifraud plans should provide sufficient detail to enable employees to perform their functions in accordance with the goals and direction of management. In addition, insurers may be required by law to establish antifraud plans, and examiners should be aware of any state-specific legal requirements pertaining to antifraud measures.

The guidelines set forth in the *Antifraud Plan Guideline* (#1690), adopted by the NAIC in March 2011, are intended to provide a road map for state fraud bureaus, insurers' Special Investigative Units (SIU)s or contracted SIU vendors for preparation of an antifraud plan.

Flexibility should be allowed for each insurer to develop a plan that meets its individual needs and still meet state compliance standards. The *Antifraud Plan Guideline* does not preempt other state laws or preempt or amend any guidance previously published by the NAIC Antifraud (D) Task Force or in the *Fraud Prevention Model Act* (#680).

f. Certificates of Authority

The examiner should determine if the regulated entity's operations conform with the regulated entity's certificates of authority.

g. Disaster Recovery Plan

It is essential that the regulated entity has a formalized disaster recovery plan that will detail procedures for continuing operations in the event of any type of disaster. The examiners should determine if the regulated entity maintains separate backups of all records and facilities to continue operations.

h. Computer Systems

The examiners should determine the types of controls, safeguards and procedures for protecting the integrity of the computer information. The focus in this case is on those records subject to a market conduct examination that are maintained in electronic format, such as, but not limited to, underwriting files, claim files, rate and form filings, complaint files, statistical data used to support rates, etc.

The regulated entity should identify the location(s) of all websites maintained by or for and authorized by the regulated entity and all approved producer sites.

In addition, an Internet search using the regulated entity's name should be conducted using a search engine such as Yahoo, Google or a metasearch (aggregator) search engine such as WebCrawler. If any additional sites are located that the regulated entity did not identify, it should be specifically noted when preparing the examination report. The examiner should be mindful that some searches may produce a large volume of "hits." In such a situation, the examiner should employ sampling techniques to determine the regulated entity's general practices on the Internet.

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i. Minutes from All Meetings Attended by the Board of Directors

A review of the minutes of meetings with the board of directors should be conducted to ensure the board has proper oversight of the company's operations and activities. Note: When a credit company is the subject of an examination, examiners should be aware that there may be statutes, rules, and regulations with specific requirements regarding the organization and structure of credit organizations.

j. Privacy

The NAIC has adopted several sets of privacy requirements, and examiners will need to determine which requirement(s) the state imposes to conduct an examination. The first is the *NAIC Insurance Information and Privacy Protection Model Act* (#670) (hereinafter, the 1982 Model Act). The second NAIC approach was the *Health Information Privacy Model Act* (#55), which, according to NAIC records, as of April 2015 had not been adopted by any state, although a few states have related laws.

The NAIC then adopted a model titled *Privacy of Consumer Financial and Health Information Regulation* (#672) (hereinafter, the 2000 Model Privacy Regulation) to assist states with promulgation of regulations to comply with certain requirements of Title V of the federal Gramm-Leach-Bliley Act (GLBA) (PL 102-106), enacted by Congress in 1999. And, in 2002, the *Standards for Safeguarding Customer Information Model Regulation* (#673) (hereinafter, the 2002 Model Information Security Regulation) was adopted to assist states in establishing standards for development and implementation of safeguards by insurers to protect customer information, also required by Title V of GLBA.

In some cases, a state may have one or more of these measures, or a combination thereof, in force. NAIC records indicate that as of April 2015, 39 states plus the District of Columbia and Puerto Rico have enacted regulations/laws based on the 2000 Model Privacy Regulation.

1982 Model Act (#670)
The 1982 Model Act is focused primarily on the insurance application process, underwriting, policy issuance and related transactions. It requires various disclosures to applicants regarding the insurer's practices (e.g., that an investigative consumer report may be obtained and that information may be disclosed to insurance support organizations which, in turn, may retain and later re-disclose the information to others) and the applicant's rights (e.g., that the applicant has a right to obtain a copy of any investigative consumer report and that the applicant has the rights of access to and correction of information about him/her).

Notices providing these disclosures may be required at application and whenever there is a "change of status"—e.g., at renewal or reinstatement—if new or additional information is to be collected from a source other than the applicant. There is no requirement for annual notices. If an insurer intends to disclose information for the marketing of a product or service, the customer must be given an opportunity to opt out. Operations/Management Examination Standards #10 and #11 in this chapter are applicable only for those states that have enacted the 1982 Model Act or substantially similar privacy requirements.

2000 Model Privacy Regulation (#672)
The 2000 Model Privacy Regulation was adopted to implement certain privacy provisions of the Gramm-Leach-Bliley Act. Title V of GLBA addressed the confidentiality of information about customers of "financial institutions," a term that includes insurance companies, banks and depository institutions, broker-dealers, investment companies, registered investment advisors and a variety of other kinds of businesses. Title V, as further implemented by the 2000 Model Privacy Regulation, requires that financial institutions establish and implement a privacy policy and provide

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notices to customers describing such policies and the customer's rights to opt out of disclosures other than those allowed by the exceptions in Sections 14 through 16 (Section 17B of the 2000 Model Privacy Regulation sets forth exceptions for the customer authorization requirement for certain health information disclosures). The adoption of regulations and guidelines was delegated to the functional regulators of the various financial institutions.

The federal functional regulators (including, among others, the Securities and Exchange Commission, the Office of the Comptroller of Currency and the Federal Trade Commission) and the NAIC have taken substantially similar positions in their regulations regarding the disclosure of customer personal information and notices. The federal regulations are nearly identical to each other, with very minor differences to reflect the different financial products and services involved and related business practices. The 2000 Model Privacy Regulation is very similar to the federal regulations with respect to the treatment of financial information, with appropriate changes for insurance products and services, as well as established business practices and relationships.

The notices required by the 2000 Model Privacy Regulation include initial, revised and annual privacy notices, which must reflect the privacy policy, including financial information disclosure practices, of the insurance regulated entity or other licensee. It should be noted that privacy policies differ from insurer to insurer, from insurer to other licensee, etc. There is no set format required for privacy notices, although they must be "clear and conspicuous" as that term is defined in the regulation. The regulation does, however, list the topics that the privacy notice must address. Since a privacy notice reflects a specific insurer's or other licensee's own particular financial information privacy practices, notices will legitimately differ.

The 2000 Model Privacy Regulation differs from the federal agency regulations in that the model includes protections for certain health information. In general, a licensee must get an individual's approval (opt-in) prior to disclosing nonpublic personal health information, unless the disclosure falls under an exception listed in Subsection 17B or the licensee is in compliance with the health privacy regulation promulgated by the U.S. Department of Health and Human Services (HHS) pursuant to the federal Health Information Portability and Accountability Act (HIPAA). Even if the licensee is not subject to HIPAA, the 2000 Model Privacy Regulation allows the option of complying with the HHS standards as an alternative to the NAIC standards.

Operations/Management Examination Standards #12, #13, #14, #15 and #16 in this chapter are applicable for examination of compliance with the 2000 Model Privacy Regulation regarding the disclosure of customer information.

2002 Model Information Security Regulation (#673)

The 2002 Model Information Security Regulation was adopted to establish standards regarding safeguarding of customer information, also required by Title V of GLBA. It should be noted that the 2002 Model Information Security Regulation requires that a licensee establish an information security program "appropriate to the size and complexity of the licensee," as well as appropriate to the "nature and scope of (the licensee's) activities." The regulation provides illustrative examples of various factors that a licensee may consider when developing its information security program. Operations/Management Examination Standard #17 in this chapter is applicable for examination of compliance with the 2002 Model Information Security Regulation for security standards.

Insurance Data Security Model Law (#668)

Operations/Management Examination Standard #17 in this chapter is also applicable for examination of compliance with the *Insurance Data Security Model Law* (#668). Note: When reviewing a regulated entity's information security program for compliance with applicable state statutes, rules or regulations relating to Model #668, in the absence of a "Cybersecurity Event," as defined in applicable state statutes, rules or regulations, please refer to the Insurance Data Security Pre-Breach Checklist found in the Reference Documents of the *Market Regulation Handbook*. Regulators may access Reference Documents on StateNet at the link Market Regulation Handbook,

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Handbook Updates and Reference Documents. Non-regulators may access Reference Documents via their login credentials on NAIC Account Manager at *https://www.naic.org/account_manager.htm*.

When reviewing a regulated entity's information security program and response to a "Cybersecurity Event" for compliance with applicable state statutes, rules or regulations relating to the *Insurance Data Security Model Law* (Model #668), after a Cybersecurity Event has occurred, as defined in applicable state statutes, rules or regulations, please refer to the Insurance Data Security Post-Breach Checklist provided as Addendum A to Operations/Management Examination Standard 17 in this chapter.

3. Tests and Standards

The operations and management review includes, but is not limited to, the following standards addressing various aspects of a regulated entity's operations. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 1
The regulated entity has an up-to-date, valid internal or external audit program.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Audit plan and regulated entities' procedural manuals

_____ Audit reports and results

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Consumer Credit Insurance Model Regulation (#370), Section 12
Model Regulation to Require Reporting of Statistical Data by Property and Casualty Insurance Companies (#751), Section 11
Best Practices Organizations White Paper

Review Procedures and Criteria

Review audit reports to determine if the function is providing meaningful information to management. If external, obtain an explanation.

Determine how management is using the reports.

Determine if the regulated entity responds to internal audit recommendations to correct, modify and implement procedures.

Determine if accuracy of internal statistical data and information systems is periodically tested by the regulated entity's audit program.

Determine if the regulated entity conducts periodic reviews of creditors with respect to their credit insurance business with such creditors.

Determine if the regulated entity has adopted edit and audit procedures to screen and check data submitted by the regulated entity's statistical agent.

Determine if the regulated entity has adopted edit and audit procedures to screen and check data provided by the regulated entity's insurance support organizations.

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Note: The examiner should be mindful of the proprietary nature of internal audit reports. Administrative action should not be recommended by the examiner based on results of internal audit findings for which the regulated entity has taken appropriate corrective action.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 2
The regulated entity has appropriate controls, safeguards and procedures for protecting the integrity of computer information.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Electronic records control, recovery/backup plan and regulated entity's procedural manuals; whether the records are electronic

_____ ~~Negotiated contracts~~ Regulated entity negotiated contracts and regulated entity written procedures related to privacy and protection of consumer data

Others Reviewed

_____ _____

_____ _____

NAIC Model References

NAIC Insurance Information and Privacy Protection Model Act (#670)
Health Information Privacy Model Act (#55)
Standards for Safeguarding Consumer Information Model Regulation (#673)

Review Procedures and Criteria

Review regulated entity records, central recovery and backup procedures. The plan and procedures should be valid and up-to-date.

Review computer security procedures.

If the regulated entity permits changes to be made to policies either electronically or verbally, check what security procedures the regulated entity has established to permit these changes. These may include who has authority to make those changes, and what verification is done by the regulated entity with the insured after changes are made.

Ensure there is adequate security of applicant/insured data during the electronic transference of information. Identify any areas where the applicant's/insured's privacy is not properly protected.

Review regulated entity negotiated contracts with insurance support organizations and/or regulated entity written procedures to determine compliance with applicable state statutes, rules and regulations, including protection of consumer personal information.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 3
The regulated entity has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraudulent insurance acts.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity antifraud plan and procedural manuals

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Antifraud Plan Guideline (#1690)
Stranger-Originated Annuity Transactions (STOA) NAIC Sample Bulletin

Review Procedures and Criteria

Review the regulated entity's antifraud initiatives in conjunction with applicable statutory requirements. Antifraud initiatives may include fraud investigators, who may be insurer employees or independent contractors, and an antifraud plan.

Verify that the insurer, if required by applicable state statutes, rules and regulations, submits its antifraud plan to the insurance commissioner:

- Within ninety days of receiving a certificate of authority;
- Every five years thereafter; and
- Within thirty days of a material change made to the antifraud plan.

Determine if the plan is adequate, up-to-date and in compliance with statutes, rules and regulations.

Review the regulated entity's implementation (staffing, support, etc.) of its plan and, if necessary, discuss with management.

Note: An SIU antifraud plan may cover several insurer entities within a regulated entity, if one SIU has the fraud investigation mission for all entities.

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Verify that the insurer's antifraud plan includes the following five sections:

1. General Requirements
    - An acknowledgment that the SIU has established criteria that will be used for the investigation of acts of suspected insurance fraud relating to the different types of insurance offered by that insurer;
    - An acknowledgement that the insurer or SIU shall record the date that suspected fraudulent activity is detected, and shall record the date that reports of such suspected insurance fraud were sent directly to the insurance department or other applicable state regulatory agency within a specific time frame;
    - A provision stating whether the SIU is an internal unit or an external or third-party unit;
    - If the SIU is an internal unit, provide a description of whether the unit is part of the insurer's claims or underwriting departments, or whether it is separate from such departments;
    - A written description or chart outlining the organizational arrangement of the insurer's antifraud positions responsible for the investigation and reporting of possible fraudulent insurance acts:
        - If the SIU is an internal unit, the insurer shall provide general contact information for the company's SIU;
        - If the SIU is an external unit, the insurer shall provide (1) the name of the company or companies used; (2) contact information for the company; and (3) a company organizational chart. The insurer shall specify the person or position at the insurer responsible for maintaining contact with the external SIU company; and
        - If an external SIU is employed for purposes of surveillance, the insurer shall include a description of the policies and procedures implemented;
    - A provision where the insurer provides the appropriate NAIC individual and group code numbers;
    - A statement as to whether the insurer has implemented a fraud awareness or outreach program. If the insurer has an awareness or outreach program, a brief description of the program shall be included; and
    - If the SIU is a third-party unit, a description of the insurer's policies and procedures for ensuring that the third-party unit fulfills its contractual obligations to the insurer and a copy of the contract with the third-party vendor.

    Note: States that do not mandate fraud reporting should revise or remove inapplicable requirements from this section.

2. Prevention, Detection and Investigation of Fraud
    - A description of the insurer's corporate policies for preventing fraudulent insurance acts by its policyholders;
    - A description of the insurer's established fraud detection procedures (i.e. technology and other detection procedures);
    - A description of the internal referral criteria used in reporting suspicious claims of insurance fraud for investigation by the SIU;
    - A description of the SIU investigation program (i.e. by business line, external form claims adjustment, vendor management Statement of Positions (SOPs); and
    - A description of the insurer's policies and procedures for referring suspicious or fraudulent activity from its claims or underwriting departments to the SIU.

3. Reporting of Fraud
    - A description of the insurer's reporting procedures for the mandatory reporting of possible fraudulent insurance acts to the insurance commissioner or applicable state regulatory agency pursuant to applicable state statutes, rules and regulations;

    - A description of the insurer's criteria or threshold for reporting fraud to the insurance commissioner; and

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- A description of the insurer's means of submission of suspected fraud reports to the insurance commissioner (e.g., the NAIC Online Fraud Reporting System (OFRS), National Insurance Crime Bureau (NICB), National Health Care Anti-Fraud Association (NHCAA), electronic state system or other).

Note: States that do not mandate fraud reporting should revise or remove inapplicable requirements from this section.

Note: The examiner should be aware of any applicable state statutes, rules and regulations regarding state antifraud mandatory reporting methods.

4. Education and Training
    - If applicable, a description of the insurer's plan for antifraud education and training initiatives of any personnel involved in antifraud related efforts. This description shall include:
        - The internal positions the insurer offers regular education and training, such as underwriters, adjusters, claims representatives, appointed agents, attorneys, etc.;
        - If the training will be internal and/or external;
        - Number of hours expected per year; and
        - If training includes ethics, false claims or other legal-related issues.

5. Internal Fraud Detection and Prevention
    - A description of insurer's internal fraud detection policy for employees, consultants or others, such as underwriters, claims representatives, appointed agents, etc.; and
    - A description of the insurer's internal fraud reporting system.

Determine if the regulated entity has procedures in place to prevent persons convicted of a felony involving dishonesty or breach of trust from participating in the business of insurance.

Determine if the regulated entity has procedures in place to provide information regarding fraudulent insurance acts to the insurance commissioner and in a manner prescribed by the insurance commissioner.

Examiners may wish to remind insurers that sell annuities of the existence of the *Stranger-Originated Annuity Transactions (STOA) NAIC Sample Bulletin* because sales of stranger-originated annuities may be an indicator of potentially fraudulent transactions.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 4
The regulated entity has a valid disaster recovery plan.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Description of the regulated entity's disaster recovery plan, procedural manuals and controls

_____ Description of protective devices for various hazards and procedures/controls for protection from those hazards

_____ Negotiated contracts

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Market Conduct Record Retention and Production Model Regulation (#910)

Review Procedures and Criteria

Determine that the regulated entity's database(s) are protected from various hazards, including environmental hazards.

Review the regulated entity's documents. Any additional areas or lack of information should be discussed with the regulated entity's management. The disaster recovery plan should be valid, specific and operational, with procedures for implementation and should also be current. Failure of the regulated entity to adequately plan for the future means the standard was not met.

Failure of the regulated entity to adequately (on an ongoing basis) provide for off-site backup, failure of the regulated entity to provide adequate controls and, in the case of a catastrophe, failure to provide for recovery, means the standard was not met.

Operations/Management Examination Standard #2 in this chapter also addresses disaster recovery issues.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 5
Contracts between the regulated entity and entities assuming a business function or acting on behalf of the regulated entity, such as, but not limited to, managing general agents (MGAs), general agents (GAs), third-party administrators (TPAs) and management agreements, must comply with applicable licensing requirements, statutes, rules and regulations.

Apply to All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Contracts

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Service Contracts Model Act (#685)
Managing General Agents Act (#225)
Registration and Regulation of Third-Party Administrators, An NAIC Guideline (#1090)
Third Party Administrator Statute (#90)

Review Procedures and Criteria

Review the contract to determine compliance with state statutes and rules.

The contract should specify the responsibilities of the subcontractor regarding recordkeeping and responsibilities of the regulated entity for conducting audits.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 6
The regulated entity is adequately monitoring the activities of any entity that contractually assumes a business function or is acting on behalf of the regulated entity.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Contracts

_____ Audit reports

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Managing General Agents Act (#225), Section 5
Registration and Regulation of Third-Party Administrators, An NAIC Guideline (#1090)
Third Party Administrator Statute (#90), Section 6
Consumer Credit Insurance Model Regulation (#370), Section 12
Variable Life Insurance Model Regulation (#270)

Review Procedures and Criteria

Entities can include an MGA, GA or TPA. Suppliers of consulting, investment, administrative, sales, marketing, custodial or other services with respect to variable life insurance operations are also considered entities (*Variable Life Insurance Model Regulation* (#270), Section 3E).

Review entity contracts to determine compliance with statutes, rules and regulations. The contract should specify the responsibilities of the MGA, GA and TPA concerning recordkeeping and responsibilities of the regulated entity for conducting audits.

Review audit reports to determine whether the regulated entity is adequately monitoring the activities of the contracted entity.

Review activities of entities to ensure compliance with applicable statutes and rules.

For credit insurance, each insurer is responsible for conducting a thorough periodic review of creditors with respect to their credit insurance business. The review should ensure compliance with statutes, rules and regulations. Written records of the reviews must be maintained by the insurer.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 7
Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ All records, files and documents

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Model Regulation for Complaint Records to be Maintained Pursuant to the NAIC Unfair Trade Practices Act (#884)
Market Conduct Record Retention and Production Model Regulation (#910)
Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Model Law on Examinations (#390), Section 4
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
The Use of Social Media in Insurance White Paper

Review Procedures and Criteria

Evaluate the orderly organization, legibility and structure of files.

Review state record retention requirements to determine regulated entity compliance.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 8
The regulated entity is licensed for the lines of business that are being written.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Certificate of authority or other similar documents

_____ Access NAIC financial system

_____ Regulated entity system

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Service Contracts Model Act (#685)
Nonadmitted Insurance Model Act (#870)
Unauthorized Transaction of Insurance Criminal Model Act (#890)

Review Procedures and Criteria

Review certificates of authority; compare writings with authorized lines.

Review financial annual statement submitted to the NAIC; compare writings with authorized states.

Obtain explanation of any discrepancies.

Access regulated entity system to verify that writings are in line with written premium reported in the financial annual statement.

Automation Tip:
The Financial Applications section of NAIC iSite+ contains the annual statement financial information for insurance companies that report to the NAIC. The most useful for market conduct examiners would be the annual statement Pick-a-Page. The State Page Exhibit displays the direct written premiums in any particular state for any particular year.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 9
The regulated entity cooperates on a timely basis with examiners performing the examinations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations, especially insurance examination law

_____ All records, files and documents

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Model Law on Examinations (#390)

Review Procedures and Criteria

Monitor regulated entity's cooperation during the course of the examination; this may be noted in the examination report.

Automation Tip:
Requests for information or "crits" can be monitored using either a database or spreadsheet. The information that should be captured includes: area of review, type of request, contact person, date given, date due and date received. Databases and spreadsheets contain functions that will calculate the number of days between two dates. The information can be easily sorted and reviewed to see what is still outstanding and if the regulated entity is responding in a timely fashion.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 10
The regulated entity has procedures for the collection, use and disclosure of information gathered in connection with insurance transactions so as to minimize any improper intrusion into the privacy of applicants and policyholders.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Written procedures of regulated entity for maintaining personal information and privileged information of applicants and policyholders

_____ The "Notice of Information Practices" required to be provided to applicants and policyholders

_____ Disclosure authorization forms

_____ Written procedures for the correction, amendment or deletion of recorded personal information

Others Reviewed

_____ _____

_____ _____

NAIC Model References

NAIC Insurance Information and Privacy Protection Model Act (#670)
Health Information Privacy Model Act (#55)
Unfair Discrimination Against Subjects of Abuse in Property and Casualty Insurance Model Act (#898)
Unfair Discrimination Against Subjects of Abuse in Life Insurance Model Act (#896)
Unfair Discrimination Against Subjects of Abuse in Health Benefit Plans Model Act (#895)
The Use of Social Media in Insurance White Paper

Review Procedures and Criteria

Determine if the regulated entity appropriately provides a "notice of information practices" that contains the required information.

Determine if the content of disclosure authorization forms meet content standards.

Determine if the regulated entity properly handles the use of investigative consumer reports.

Determine if the regulated entity's procedures appropriately limit access to personal information.

Determine if the regulated entity provides specific and accurate reasons for adverse underwriting decisions.

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Determine if the regulated entity's procedures properly allow for the correction, amendment or deletion of personal information.

Determine if the regulated entity appropriately notifies insurance support organizations when information an insurance support organization has provided to the regulated entity is corrected, amended or deleted by request of an individual or commissioner.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 11
The regulated entity has developed and implemented written policies, standards and procedures for the management of insurance information.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity procedure manual

_____ Regulated entity training manual

_____ Internal regulated entity claim audit procedures

_____ Regulated entity bulletins regarding insurance information

_____ Contractual arrangements between the carrier and a person other than the covered person

_____ The "Notice of Information Practices" required to be provided to applicants and policyholders

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Health Information Privacy Model Act (#55), Section 5
NAIC Insurance Information and Privacy Protection Model Act (#670), Sections 4-9

Review Procedures and Criteria

Review regulated entity procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state law.

Review contractual arrangements between the regulated entity and other persons to determine if the contracts address privacy procedures and standards for the person with whom the regulated entity is contracting.

Review the regulated entity's methods for handling, disclosing, storing and disposing of insurance information. The examiners should determine whether there are procedures in place to ensure proper authorization is obtained prior to disclosure of insurance information.

Review the regulated entity's training manual to determine whether the regulated entity's employees are properly trained on the handling of insurance information.

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Verify that the regulated entity provides a "Notice of Information Practices" to all applicants or policyholders or has procedures in place for the producer to deliver the notice. The examiner should determine whether the notice contains all provisions required by applicable state law.

Verify that the regulated entity specifies those questions designed to obtain information solely for marketing or research purposes.

Verify that the regulated entity has implemented reasonable procedures to address investigative consumer reports and personal interviews.

Verify that the regulated entity has established procedures to address access to, correction, amendment or deletion of recorded personal information, including providing appropriate notice of any correction, amendment or fact of deletion of personal information to insurance support organizations that provided the personal information.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 12
The regulated entity has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity privacy policies and procedures

_____ Other regulated entity manuals/instruction books

_____ Communication provided by the regulated entity to employees and producers subject to the regulated entity's privacy policies

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Privacy of Consumer Financial and Health Information Model Regulation (#672)

Review Procedures and Criteria

Review the regulated entity's policies, practices and procedures regarding protection and disclosure of nonpublic personal information of customers, former customers and consumers who are not customers, to verify that they comply with applicable state laws regarding privacy.

Review employee procedures regarding the treatment of nonpublic personal information to verify that they comply with the regulated entity's privacy policies, practices and procedures and with applicable state laws regarding privacy.

As applicable, verify that the regulated entity/licensee has provided a copy of its privacy notice to its producers.

Determine that the regulated entity does not unfairly discriminate against customers and consumers who are not customers who (1) have opted out from the disclosure of nonpublic personal financial information to nonaffiliated third parties; and (2) have not authorized disclosure of nonpublic personal health information, if applicable.

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Review all privacy-related consumer complaints and inquiries.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 13
The regulated entity provides privacy notices to its customers and, if applicable, to its consumers who are not customers regarding treatment of nonpublic personal financial information.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity privacy policies and procedures

_____ Sample notices to customers: initial, annual, revised and simplified, if applicable

_____ Sample notices to consumers that are not customers, if applicable: initial (standard and short-form) notices and revised notice

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Privacy of Consumer Financial and Health Information Model Regulation (#672)

Review Procedures and Criteria

Review the content of the regulated entity's initial, annual and revised notices.

Verify that these notices are clear and conspicuous and accurately reflect privacy policies and practices.

Notices should include the following:

- Identification of the regulated entity, if applicable;
- The categories of nonpublic personal financial information that the regulated entity collects;
- The categories of nonpublic personal financial information that the regulated entity discloses, if applicable;
- The categories of affiliates and nonaffiliated third parties to whom the regulated entity discloses nonpublic personal financial information, other than disclosures permitted under Sections 15 and 16 of Model #672, if applicable;
- The categories of nonpublic personal financial information about the regulated entity's former customers that the regulated entity discloses and the categories of affiliates and nonaffiliated third parties to whom the regulated entity discloses nonpublic personal financial information about the regulated entity's former customers, other than disclosures permitted under Sections 15 and 16 of Model #672, if applicable;

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- If a regulated entity discloses nonpublic personal financial information to a nonaffiliated third party under Section 14 of Model #672, a separate description of the categories of information the regulated entity discloses and the categories of third parties with whom the regulated entity has contracted;
- An explanation of the consumer's right to opt out of the disclosure of nonpublic personal financial information to nonaffiliated third parties, including the methods by which the consumer may exercise that right, if applicable;
- Any disclosures that the regulated entity may make under Section 603(d)(2)(A)(iii) of the federal Fair Credit Reporting Act (15 USC Section 1681a(d)(2)(A)(iii) (i.e., notices regarding the ability to opt out of disclosures of information among affiliates, other than transaction and experience information);
- The regulated entity's policies and practices with respect to protecting the confidentiality and security of nonpublic personal information; and
- If a regulated entity only discloses nonpublic personal financial information as authorized under Sections 15 and 16 of Model #672, a statement that indicates the regulated entity makes disclosures to other affiliated or nonaffiliated third parties, as applicable, as permitted by law.

Review the content of the regulated entity's simplified notice, if applicable, which shall include:

- Identification of the regulated entity and affiliates or subsidiaries, if applicable;
- The categories of nonpublic personal financial information that the regulated entity collects;
- The regulated entity's policies and practices with respect to protecting the confidentiality and security of nonpublic personal information; and
- That the regulated entity only discloses nonpublic personal financial information to affiliates and nonaffiliated third parties, as applicable, as authorized under Sections 15 and 16 of Model #672.

Review the content of the regulated entity's short-form notice for consumers who are not customers, if applicable, which shall state that the regulated entity's privacy notice is available upon request and provide a reasonable means by which the consumer may obtain a full notice.

Verify that the regulated entity's process for delivery of notices includes:

- Initial notice, if applicable, to consumers who are not customers;
- Initial notice to all customers, as required;
- Annual notice to all customers, as required;
- Revised notice to customers and consumers who are not customers entitled to notice, if applicable;
- Where applicable, simplified notices to customers, if the regulated entity only discloses nonpublic personal financial information about customers and former customers to affiliates and nonaffiliated third parties as authorized under Sections 15 and 16 of Model #672 (or the applicable sections under state law regarding privacy); and
- Short-form notices to consumers who are not customers, in lieu of initial notices, if applicable.

Verify that a notice is delivered to the regulated entity's customers at or prior to the time the regulated entity establishes a customer relationship (initial notice), and at least once in any period of 12 consecutive months or once in each calendar year thereafter (annual notice) during the continuation of the customer relationship, if appropriate. If initial notice was provided to customers after the customer relationship was established, verify that the notice was delivered within a reasonable time after the customer relationship was established and (1) establishing the customer relationship was not at the customer's election; or (2) providing notice at or prior to the establishment of the relationship would have substantially delayed the customer's transaction and the customer agreed to receive the notice at a later time.

Verify that if the regulated entity discloses any consumer's nonpublic personal financial information to any nonaffiliated third party, other than as authorized under Section 15 or 16 of Model #672 (or the applicable sections under state laws regarding privacy), the regulated entity delivers a notice before disclosing the information.

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Verify that individuals deemed consumers under applicable law are provided with an initial notice where applicable (such as where a licensee discloses a claimant's nonpublic personal financial information outside Sections 14 through 16 of Model #672 or its equivalent under state laws regarding privacy).

Verify that a notice was delivered to the regulated entity's customers and, if applicable, to consumers who are not customers in a manner that can reasonably be expected to provide actual notice.

Verify that a notice was provided to the regulated entity's customers and, if applicable, to consumers who are not customers, in writing, or, if the licensee provides and if the consumer has agreed, electronically.

Verify that the regulated entity has provided customers with clear and conspicuous initial, annual and revised notices in a manner that allows the customer to retain the notices or obtain them later in writing or, if the customer has agreed, electronically.

If the regulated entity is an excess lines insurer and does not disclose nonpublic personal financial information to nonaffiliated third parties, except as authorized under Sections 15 and 16 of Model #672, verify that the notice set forth in Section 4Q(3)(ii) of Model #672 has been delivered to all customers at the time the regulated entity established ongoing relationships with the customers. If the regulated entity makes disclosures other than as authorized under Sections 15 and 16 of Model #672, the regulated entity is required to comply with applicable initial, annual and revised notice requirements and the opt-out requirements.

Review the regulated entity's notice content and notice delivery procedures to verify that the regulated entity complies with applicable statutes, rules and regulations regarding privacy.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 14
If the regulated entity discloses information subject to an opt-out right, the regulated entity has policies and procedures in place so that nonpublic personal financial information will not be disclosed when a consumer who is not a customer has opted out, and the regulated entity provides opt-out notices to its customers and other affected consumers.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity privacy policies and procedures

_____ Sample notices to customers: initial, annual and, if applicable, revised

_____ Sample notices to consumers who are not customers, if applicable

_____ Sample opt-out notice, if applicable

_____ Regulated entity records of consumers and other customers who have opted out, if applicable

_____ Communication of customers' and consumers who are not customers' opt-out elections to producers of record

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Privacy of Consumer Financial and Health Information Model Regulation (#672)

Review Procedures and Criteria

Determine whether the regulated entity discloses nonpublic personal information relating to customers or consumers who are not customers beyond the scope permitted under Sections 14, 15 and 16 of Model #672.

- Verify that consumers who may be affected by such disclosures have been offered the opportunity to opt out before the disclosures are made. Continue with Steps 1 through 5 below.
- If not, verify that any communications the regulated entity makes regarding opt-out rights are accurate and are in compliance with applicable law.
    1. If applicable, verify that the regulated entity has policies and procedures in place so that customers and other affected consumers may opt out of the disclosure of their nonpublic personal financial

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information to nonaffiliated third parties, except to the extent such disclosure is permitted under Sections 14, 15 and 16 of Model #672.

2. If applicable, review the regulated entity's policies and procedures to verify that the regulated entity has the capability to keep nonpublic personal financial information from being unlawfully disclosed to nonaffiliated third parties when a consumer has opted out.

3. If applicable, verify that the regulated entity does not disclose, directly or through any affiliate, unless authorized or permitted by applicable federal and/or state law or regulations, nonpublic personal financial information about a consumer or to a nonaffiliated third party except when:
   - The regulated entity has provided a notice to the consumer;
   - The regulated entity has provided an opt-out notice to the consumer;
   - The regulated entity has given the consumer a reasonable opportunity to opt out of the disclosure before the regulated entity discloses the consumer's nonpublic personal financial information to a nonaffiliated third party; and
   - The consumer does not opt out.

4. As applicable, determine that the regulated entity's initial, annual, revised and short-form notices accurately explain the consumer's right to opt-out, including the methods by which the consumer may exercise that right at any time, in accordance with applicable law and the regulated entity's policies and procedures.

5. If applicable, review the content of the regulated entity's opt-out notice to determine if it is clear and conspicuous and includes, either on the form or on the initial privacy notice:
   - A statement that the regulated entity discloses or reserves the right to disclose nonpublic personal financial information about its consumer to a nonaffiliated third party;
   - A statement that the consumer has the right to opt out of that disclosure; and
   - A reasonable means by which the consumer may exercise the opt-out right.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 15
The regulated entity's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity privacy policies and procedures

_____ Joint marketing agreements, if any

_____ Sample service agreements, if any, with nonaffiliated third parties involved in the regulated entity's marketing activities

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Privacy of Consumer Financial and Health Information Model Regulation (#672)

Review Procedures and Criteria

If the regulated entity discloses nonpublic personal financial information of its customers or consumers who are not customers to nonaffiliated third parties for joint marketing purposes, verify that all such disclosures are in compliance with Model #672:

- Verify that the regulated entity has provided initial notices to its customers and other affected consumers that include the required information regarding the regulated entity's joint marketing and servicing activities; and
- Review joint marketing agreements, where applicable, to verify that they prohibit the nonaffiliated third party from disclosing or using the nonpublic personal financial information received from the regulated entity other than to carry out the purposes for which the regulated entity disclosed the information, including use under an exception in Sections 15 or 16 of Model #672.

Verify that the regulated entity does not disclose nonpublic personal financial information that it receives from a nonaffiliated financial institution, except in compliance with Model #672.

Review sample service agreements under which a third party markets a licensee's own products and services, if any, to verify inclusion of non-disclosure requirements.

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Verify that the regulated entity prohibits disclosure of policy numbers or similar forms of access numbers or access codes for a consumer's policy or transaction account to any nonaffiliated third party, except as permitted by applicable law or regulation regarding privacy.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 16
In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the regulated entity has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity privacy policies and procedures

_____ Sample authorizations used by the regulated entity to permit disclosure of nonpublic personal health information, if applicable

_____ Regulated entity records of customer and other consumer authorizations

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Privacy of Consumer Financial and Health Information Model Regulation (#672)

Review Procedures and Criteria

If applicable, verify that the regulated entity has policies and procedures in place to secure authorizations from its customers and consumers who are not customers before disclosing their nonpublic personal health information to nonaffiliated third parties, except to the extent such disclosure is permitted under Subsection 17B of Model #672.

If applicable, verify that the regulated entity has obtained valid authorizations from customers and consumers who are not customers before disclosing their nonpublic personal health information, except to the extent such disclosures are permitted under Subsection 17B of Model #672. A valid authorization shall include:

- The identity of the consumer who is the subject of the nonpublic personal health information;
- A general description of the types of nonpublic personal health information to be disclosed;
- A general description of the parties to whom the licensee discloses nonpublic personal health information;
- A general description of the purpose of the disclosure of the nonpublic personal health information;
- A general explanation of how the nonpublic personal health information will be used;

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- The signature of the consumer who is the subject of the nonpublic personal health information or the individual who is legally empowered to grant disclosure authority and the date signed;
- A notice of the length of time for which the authorization is valid; and
- A notice that the consumer may revoke the authorization at any time, and an explanation of the procedure for making a revocation.

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 17
Each licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity written materials describing its information security program

_____ Regulated entity policies, procedures and other materials it uses to implement its information security program

_____ Prior to conducting an examination, the examiner should review the state's definition of "customer" and "consumer" to determine appropriate usage of the terms. The examiner should also review the various exceptions and exclusions contained in the state's privacy act/regulation.

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Standards for Safeguarding Customer Information Model Regulation (#673)
Insurance Data Security Model Law (#668)

Review Procedures and Criteria

Note: When reviewing a regulated entity's information security program for compliance with applicable state statutes, rules or regulations relating to the *Insurance Data Security Model Law* (Model #668), in the absence of a Cybersecurity Event, as defined in applicable state statutes, rules or regulations, please refer to the Insurance Data Security Pre-Breach Checklist found in the Reference Documents of the *Market Regulation Handbook*. Regulators may access Reference Documents on StateNet at the link Market Regulation Handbook, Handbook Updates and Reference Documents. Non-regulators may access Reference Documents via NAIC Account Manager at *https://www.naic.org/account_manager.htm*.

Note: When reviewing a regulated entity's information security program and response to a Cybersecurity Event for compliance with applicable state statutes, rules or regulations relating to the *Insurance Data Security Model Law* (Model #668), after a Cybersecurity Event has occurred, as defined in applicable state statutes, rules or regulations, please refer to the Insurance Data Security Post-Breach Checklist provided as Addendum A to Operations/Management Examination Standard 17 in Chapter 20—General Examination Standards.

Review the regulated entity's written information security program to determine whether the security program includes administrative, technical and physical safeguards.

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Determine whether, when developing safeguards, the regulated entity took into consideration the:

- Size and complexity of the regulated entity; and
- Nature and scope of regulated entity's activities.

In making the assessment above, consider factors such as: (1) the products and services offered by the regulated entity; (2) the methods of distribution for the products and services; (3) the types of information maintained by the regulated entity; (4) the size of the regulated entity (which may include the number of employees and the volume of business, etc.); (5) the marketing arrangements; and (6) the extent to which, or methods by which, the regulated entity communicates electronically with customers, producers and other third parties.

Evaluate whether the regulated entity's information security program is designed to:

- Ensure the security and confidentiality of customer information;
- Protect against any anticipated threats or hazards to the security or integrity of the information; and
- Protect against unauthorized access to or use of the information that could result in substantial harm or inconvenience to any customer.

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ADDENDUM A TO OPERATIONS/MANAGEMENT STANDARD 17
CHAPTER 20—GENERAL EXAMINATION STANDARDS
MARKET REGULATION HANDBOOK
INSURANCE DATA SECURITY POST-BREACH CHECKLIST

Supplemental Incident Response Plan Investigation (Post-Breach) and Notification Cybersecurity Event Checklist for Operations/Management Standard #17
Model #668, Sections 5 and 6

Company Name	
Period of Examination	
Examination Field Date	
Prepared By	
Date	

GUIDANCE
Insurance Data Security Model Law (#668)

The guidance that follows should only be used in states that have enacted the *Insurance Data Security Model Law* (#668) or legislation, which is substantially similar to Model #668. Moreover, in performing work during an exam in relation to Model #668, it is important that the examiners first obtain an understanding and leverage the work performed by other units in the department, including but not limited to, financial examination-related work.

OVERVIEW
The purpose and intent of Model #668 is to establish standards for data security and standards for the investigation of and notification to the Commissioner or Director of Insurance of a Cybersecurity Event affecting Licensees.

REVIEW GUIDELINES AND INSTRUCTIONS

When reviewing a Licensee's Information Security Program (ISP) for compliance with Model #668 for the prevention of a Cybersecurity Event, as defined in Model #668, please refer to the pre-breach examination checklist in the Reference Documents of the *Market Regulation Handbook* . Regulators can access the pre-breach examination checklist on the Market Regulation Handbook Reference Documents web page on StateNet. Non-regulators may access the pre-breach examination checklist at *https://www.naic.org/account_manager.htm*.

When reviewing a Licensee's ISP and response to a Cybersecurity Event for compliance with Model #668 subsequent to a suspected and/or known Cybersecurity Event, as defined in Model #668, please refer to both the pre-breach examination checklist and the post-breach examination checklist.

When considering whether to underake such a review, refer to Section 9 of Model #668, which provides certain exceptions to compliance for licensees with fewer than 10 employees; licensees subject to the Health Insurance Portability and Accountability Act (HIPAA) (Pub.L, 104–191, 110 Stat. 1936, enacted Aug. 21, 1996); and certain employees, agents, representatives, or designees of licensees who are in themselves licensees.

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ADDENDUM A TO OPERATIONS/MANAGEMENT STANDARD 17
CHAPTER 20—GENERAL EXAMINATION STANDARDS
MARKET REGULATION HANDBOOK
INSURANCE DATA SECURITY POST-BREACH CHECKLIST, CONT'D

Supplemental Incident Response Plan Investigation (Post-Breach) and Notification Cybersecurity Event Checklist for Operations/Management Standard #17
Model #668, Sections 5 and 6

Company Name	
Period of Examination	
Examination Field Date	
Prepared By	
Date	

POST-EVENT INVESTIGATION BY LICENSEE (Section 5)

REVIEW CRITERIA	**NOTES *(YES, NO, NOT APPLICABLE, OTHER)***
1. Did the Licensee conduct a prompt investigation of the Cybersecurity Event? (Section 5A)	
2. Did the Licensee appropriately determine the nature and scope of the Cybersecurity Event? (Section 5B)	

NOTICE TO COMMISSIONER/DIRECTOR OF INSURANCE (Section 6)

REVIEW CRITERIA	**NOTES *(YES, NO, NOT APPLICABLE, OTHER)***
3. Did the Licensee provide timely notice (no later than 72 hours) to the Commissioner or Director of Insurance following the Cybersecurity Event? (Section 6A)	
4. Did the notification to the Commissioner or Director of Insurance include the following information, to the extent reasonably available? (Section 6B)	
4a. The date of the Cybersecurity Event, or the date upon which it was discovered?	
4b. A description of how the Nonpublic Information was exposed, lost, stolen or breached, including the specific roles and responsibilities of Third-Party Service Providers, if any?	
4c. How the Cybersecurity Event was discovered?	
4d. Whether any lost, stolen or breached Nonpublic Information has been recovered, and if so, how this was done?	
4e. The identity of the source of the Cybersecurity Event?	
4f. Whether the Licensee has filed a police report or has notified any regulatory, government or law enforcement agencies? *(If YES, did the Licensee provide the date(s) of such notification(s)?)*	
4g. A description of the specific types of Nonpublic Information acquired without authorization?	
4h. The period during which the Information System was compromised by the Cybersecurity Event?	
4i. A best estimate of the number of total Consumers in this state and globally affected by the Cybersecurity Event?	
4j. The results of any internal review of automated controls and internal procedures and whether or not such controls and procedures were followed?	

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ADDENDUM A TO OPERATIONS/MANAGEMENT STANDARD 17
CHAPTER 20—GENERAL EXAMINATION STANDARDS
MARKET REGULATION HANDBOOK
INSURANCE DATA SECURITY POST-BREACH CHECKLIST, CONT'D

Supplemental Incident Response Plan Investigation (Post-Breach) and Notification Cybersecurity Event Checklist for Operations/Management Standard #17
Model #668, Sections 5 and 6

Company Name	
Period of Examination	
Examination Field Date	
Prepared By	
Date	

NOTICE TO COMMISSIONER/DIRECTOR OF INSURANCE (Section 6) (CONT'D)

REVIEW CRITERIA	**NOTES *(YES, NO, NOT APPLICABLE, OTHER)***
4k. A description of efforts being undertaken to remediate the circumstances which permitted the Cybersecurity Event to occur?	
4l. A copy of the Licensee's privacy policy and a statement outlining the steps the Licensee will take to investigate the Cybersecurity Event and to notify affected Consumers?	
4m. The name of a contact person familiar with the Cybersecurity Event and authorized to act for the Licensee?	
5. Did the Licensee provide timely updates to the initial notification and-Questions 4a–4m above? (Section 6B)	

OTHER NOTIFICATIONS (Section 6)

REVIEW CRITERIA	**NOTES *(YES, NO, NOT APPLICABLE, OTHER)***
6. Did the Licensee provide timely and sufficient notice of the Cybersecurity Event to Consumers? (*If YES, did the Licensee provide a copy of the notification to the Commissioner(s)/Directors of all affected states?)* (Section 6C)	
7. Did the reinsurer Licensee provide timely and sufficient notice of the Cybersecurity Event to ceding insurers? (Section 6E)	
8. Did the Licensee provide timely and sufficient notice of the Cybersecurity Event to independent insurance producers and/or producers of record of affected Consumers? (Section 6F)	

THIRD-PARTY SERVICE PROVIDERS

REVIEW CRITERIA	***NOTES (YES, NO, NOT APPLICABLE, OTHER)***
9. Did the Cybersecurity Event occur at a Third-Party Service Provider? *(If YES, did the Licensee fulfill its obligations to ensure compliance with this law, either directly or by the Third-Party Service Provider?)* (Sections 5C and 6D)	

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ADDENDUM A TO OPERATIONS/MANAGEMENT STANDARD 17
CHAPTER 20—GENERAL EXAMINATION STANDARDS
MARKET REGULATION HANDBOOK
INSURANCE DATA SECURITY POST-BREACH CHECKLIST, CONT'D

Supplemental Incident Response Plan Investigation (Post-Breach) and Notification Cybersecurity Event Checklist for Operations/Management Standard #17
Model #668, Sections 5 and 6

Company Name	
Period of Examination	
Examination Field Date	
Prepared By	
Date	

POST-EVENT ANALYSIS

REVIEW CRITERIA	***NOTES (YES, NO, NOT APPLICABLE, OTHER)***
10. What changes, if any, are being considered to the Licensee's ISP as a result of the Cybersecurity Event and the Licensee's response?	

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STANDARDS
OPERATIONS/MANAGEMENT

Standard 18
All data required to be reported to departments of insurance is complete and accurate.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Claim files

_____ Underwriting files

_____ Regulated entity's medical professional liability closed claim reports (if applicable)

_____ Regulated entity's Market Conduct Annual Statement (MCAS) submissions

_____ Regulated entity's responses to state-specific data requests

Others Reviewed

Statutory or regulatory authority for state-specific data requests

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Medical Professional Liability Closed Claim Reporting Model Law (#77)
Market Conduct Surveillance Model Law (#693)

Review Procedures and Criteria

Interview the regulated entity's personnel who prepare loss statistical reports, medical professional liability loss reports, MCAS data and state-specific data requests; analyze regulated entity's internal communications between various departments which report same.

Determine that the regulated entity reviews data errors and subsequent changes are made.

Determine if the regulated entity's medical professional liability closed claims reports are accurate and reported within the required time frame.

Request that the regulated entity reconcile closed claims reports, state-specific data requests and MCAS data with the State Page of the annual statement to include payments, case reserves, and defense cost containment expenses, and explain differences.

Request that the regulated entity reconcile closed claims reports to data provided on the standardized data request.

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B. Complaint Handling

1. Purpose

The NAIC definition of a complaint is "any written communication that expresses dissatisfaction with a specific person or entity subject to regulation under the state's insurance laws. An oral communication, which is subsequently converted to a written form, would meet the definition of a complaint for this purpose." The examiner should review the regulated entity's procedures for processing consumer or other related complaints. Specific problem areas may necessitate an overall review of a particular segment of the regulated entity's operation.

If a regulated entity is using social media, the examiner should review the regulated entity's policies and procedures with regard to regulated entity handling of complaints received via social media, in which the regulated entity is active.

2. Techniques

A review of complaint handling should incorporate both consumer direct complaints to the regulated entity and those complaints filed with the insurance department. The examiner should reconcile the regulated entity's complaint register with a list of complaints from the insurance department. A random sample of complaints should be selected for review from the regulated entity's complaint register. If such a register is not maintained, alternative methods of isolating complaints may be implemented.

The examiner should review the frequency of similar complaints and be aware of any pattern of specific type of complaints. The examiner should take into consideration the increase of complaints that typically follows a catastrophe. Should the type of complaints generated be cause for unusual concern, specific measures should be instituted to investigate other areas of the regulated entity's operations. This may include modifying the scope of examination to examine specific regulated entity behavior.

The examiner should review the NAIC Complaints Database System (CDS) to determine the regulated entity's complaint index, along with any adverse trends in complaint volume. The examiner may wish to review complaint trends and the complaint index for the preceding three years.

The examiner should review the final disposition of the complaints and determine if the regulated entity has taken adequate steps to finalize the complaint. The examiner should determine if the actions taken are in compliance with statutes, rules and regulations.

In states that have established a statutory or regulatory standard of promptness, a study should be conducted to determine how promptly the regulated entity responds to complaints, the adequacy of the responses and what, if any, actions were taken to resolve the problems.

If the examination involves a depository institution or their affiliates, it may also be regulated by a federal agency, such as the Office of the Comptroller of the Currency, the Federal Reserve Board, the Office of Thrift Supervision or the Federal Deposit Insurance Corporation. In addition, banks may also be regulated at the state level. If the state has signed an agreement to share complaint information with these agencies, any adverse trends or pattern of concern to the examiners may be identified and relayed to the agency.

3. Tests and Standards

The complaint handling review includes, but is not limited to, the following standards addressing various aspects of a regulated entity's operations. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
COMPLAINT HANDLING

Standard 1
All complaints are recorded in the required format on the regulated entity's complaint register.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity complaint register

_____ Insurance department's complaint records

_____ Direct consumer complaints

_____ Complaints received electronically (i.e., via Internet or email)

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Model Regulation for Complaint Records to be Maintained Pursuant to the NAIC Unfair Trade Practices Act (#884)
Consumer Complaints White Paper
Unfair Trade Practices Act (#880), Section 4K

Review Procedures and Criteria

All of the above should be reviewed to make sure the regulated entity is:

- Recording all complaints (both consumer direct and insurance department); and
- Recording required information in the regulated entity complaint register.

Determine if the regulated entity complaint register meets minimum standards as required by law. At a minimum, the complaint register should include:

- Line of business;
- Function (underwriting, marketing and sales, claims, policyholder services or miscellaneous); and
- Reason for complaint (underwriting, application, cancellation, recission, nonrenewal).

Automation Tip:
Most companies maintain this information in some sort of PC-based spreadsheet format, such as Lotus or Excel. Request that this spreadsheet be copied in its usual format for comparison with insurance department records. Do not specify which data to be supplied, but instead go with exactly what the regulated entity tracks. A review can be made to see if they contain the information that should be collected from each complaint. Then, a sample can be pulled to review individual complaints to see if the regulated entity's procedures are being followed.

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Obtain complaint data file from the insurance department (in whatever format available; e.g., ASCII text file, Microsoft Access, etc.). Convert the data file to a format compatible to the spreadsheet/database from the regulated entity. Compare the complainant name, claim number, policy number, etc., in both files to determine if all of the insurance department complaints were correctly logged by the regulated entity.

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STANDARDS
COMPLAINT HANDLING

Standard 2
The regulated entity has adequate complaint handling procedures in place and communicates such procedures to policyholders.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Complaint handling procedure manuals

_____ Policy files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Complaints White Paper

Review Procedures and Criteria

Review the regulated entity's manuals to verify that complaint procedures exist.

Determine whether there are sufficient procedures in place to require satisfactory handling of complaints received, as well as internal procedures for analysis in areas developing complaints.

Determine whether there is a method for distribution of and obtaining and recording responses to complaints. This method should be sufficient to allow response within the time frame required by state law.

The regulated entity should provide a telephone number and address for consumer inquiries.

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STANDARDS
COMPLAINT HANDLING

Standard 3
The regulated entity takes adequate steps to finalize and dispose of the complaint in accordance with applicable statutes, rules and regulations and contract language.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Interstate Insurance Product Regulation Commission (Compact) uniform standards for products approved by the Compact)

_____ Regulated entity complaint register

_____ Complaint letter or email and regulated entity complaint response

_____ Supporting documentation (claim files, underwriting files, etc.)

_____ Regulated entity correspondence

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Complaints White Paper

Review Procedures and Criteria

Review complaints documentation to determine if the regulated entity response fully addresses the issues raised. If the regulated entity did not properly address/resolve the complaint, the examiner should ask the regulated entity what corrective action it intends to take.

Criteria for reviewing complaint responses:

- The response is timely;
- The response is complete and responds to all issues raised;
- The response includes adequate documentation to support the respondent's position;
- The respondent's actions are appropriate from a business practice standpoint;
- The respondent's actions comply with all applicable statutes, rules and policy or contract provisions; and
- The appropriate remedies for the consumer are identified.

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STANDARDS
COMPLAINT HANDLING

Standard 4
The time frame within which the regulated entity responds to complaints is in accordance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Complaint letter or email

_____ Regulated entity response and supporting documentation

_____ Regulated entity complaint register

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Complaints White Paper

Review Procedures and Criteria

Review complaints to ensure regulated entity is maintaining adequate documentation.

Determine if the regulated entity's response is timely. The examiner should refer to state laws for the required time frame.

Automation Tip:
Most companies maintain this information in some sort of PC-based spreadsheet format, such as Lotus or Excel. Request that this spreadsheet be copied in its usual format for comparison with insurance department records. Using either an Excel spreadsheet or a Microsoft Access database, calculate the number of days between the date the complaint was received and the date a final resolution was sent to the complainant. Use the features of either application to identify those complaints where the number of days to resolve the complaint exceeds the statutory standard.

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C. Marketing and Sales

1. Purpose

The Marketing and Sales portion of the examination is designed to evaluate the representations made by the regulated entity about its product(s) or services. It is not typically based on sampling techniques. The areas to be considered in this kind of review include all media (radio, television, videotape, electronic medium, social media, etc.), written and verbal advertising and sales materials.

2. Techniques

This area of review should include all advertising and sales material and all producer sales training materials to determine compliance with statutes, rules and regulations. Information from other jurisdictions may be reviewed, if appropriate. The examiner may contact policyholders, producers and others to verify the accuracy of information provided or to obtain additional information.

As with all of its advertising, regardless of the medium, every regulated entity is required to have procedures in place to establish and, at all times, maintain a system of control over the content, form and method of dissemination of all of its advertisements. All of these advertisements maintained by or for the regulated entity and authorized by the regulated entity are the responsibility of the regulated entity.

The exact same regulations and statutes (such as the *Unfair Trade Practices Act* (#880)) that apply to conventional advertising also apply to Internet advertising. Bearing that in mind, when the examiner is reviewing a regulated entity's Internet advertisements, it is important to also review the safeguards implemented by the regulated entity.

All advertisements are required to be truthful and not misleading in fact or by implication. The form and content of an advertisement of a policy shall be sufficiently clear so as to avoid deception. The advertisement shall not have the capacity or tendency to mislead or deceive. Whether an advertisement has the capacity or tendency to mislead or deceive shall be determined upon reviewing the overall impression that the advertisement reasonably may be expected to create upon a person of average education or intelligence within the segment of the public to which the advertisement is directed.

3. Tests and Standards

The marketing and sales review includes, but is not limited to, the following standards addressing various aspects of the marketing and sales function. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
MARKETING AND SALES

Standard 1
All advertising and sales materials are in compliance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ All regulated entity advertising and sales materials, including radio and audiovisual items such as television commercials, telemarketing scripts, pictorial materials, social media or other electronic medium

_____ Policy forms as they coincide with advertising and sales materials

_____ Producer's own advertising and sales materials

_____ Regulated entity policies and procedures

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Trade Practices Act (#880)
Advertisements of Life Insurance and Annuities Model Regulation (#570), Section 3B
Risk-Based Capital (RBC) for Insurers Model Act (#312), Section 8B
Life Insurance Disclosure Model Regulation (#580), Section 8C
Life and Health Insurance Guaranty Association Model Act (#520), Section 19A
Long-Term Care Insurance Model Act (#640)
Life Insurance Illustrations Model Regulation (#582)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Model Act (#171), Section 7(H)(1)(a)(I)
Advertisements of Accident and Sickness Insurance Model Regulation (#40)
Individual Health Insurance Portability Model Act (#37), Section 5
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Home Service Disclosure Model Act (#920)
Marketing Insurance Over the Internet White Paper
Group Health Insurance Standards Model Act (#100)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
The Use of Social Media in Insurance White Paper
Insurance Holding Company System Regulatory Model Act (#440), Section 8G

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Compact Uniform Standard References

Compact Standards for Individual Long-Term Care Advertising Materials (applicable to individual long-term care (LTC) products and associated advertising materials submitted and/or approved by the Compact)

Review Procedures and Criteria

Review advertising materials in conjunction with the appropriate policy form. If statistics are included, proper citation should be included in the documentation.

Materials should not:

- Misrepresent the dividends or share of the surplus to be received on any policy;
- Make a false or misleading statement as to the dividends or share of the surplus previously paid on the policy;
- Misrepresent any policy as being shares of stock;
- Misrepresent policy benefits forms or conditions by failing to disclose limitations, exclusions or reductions or use terms or expressions that are misleading or ambiguous;
- Make unfair or incomplete comparisons with other policies;
- Make false, deceptive or misleading statements or representations with respect to any person, regulated entity or organization in the conduct of insurance business; and
- Offer unlawful rebates or inducements.

Materials should:

- Disclose the name and address of insurer;
- Comply with applicable statutes, rules and regulations; and
- Cite the source of statistics used by the regulated entity.

Determine if the regulated entity approves producer sales materials and advertising. Determine if advertisements or lead-generating calls falsely project the image that they were sent by a government agency.

Review the regulated entity's and producer's websites with the following questions in mind:

- Does the website disclose who is selling/advertising/servicing for the website?
- Does the website disclose what is being sold or advertised?
- If required by statutes, rules or regulations, does the website reveal the physical location of the regulated entity/entities?
- Does the website reveal the jurisdictions where the advertised product is (or is not) approved, or use some other mechanism (including, but not limited to, identifying persons by geographic location) to accomplish an appropriate result?

For the review of Internet advertisements:

- Run an inquiry with the regulated entity's name;
- Review the regulated entity's home page;
- Identify all lines of business referenced on the regulated entity's home page;
- Research the ability to request more information about a particular product and verify the information provided is accurate; and
- Review the regulated entity's procedures related to producers advertising on the Internet and ensure the regulated entity requires prior approval of the producer pages, if the regulated entity name is used.

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For the review of social media:

- Perform a search of social media sites with the regulated entity's name;
- Identify social media sites in which the regulated entity is active;
- Review identified social media sites and verify any product information provided by the regulated entity is accurate;
- Review the regulated entity's policies and procedures to identify the personnel involved in monitoring the regulated entity's marketing and sales-related social media activity;
- Review the regulated entity's policies and procedures for tracking marketing and sales-related social media requiring regulated entity review; and
- If the regulated entity requires preapproval of producer advertising on the Internet, review the regulated entity's preapproval procedures to determine whether the regulated entity identifies marketing and sales-related social media as also requiring regulated entity preapproval.

Automation Tip:
Enter a summary of all marketing materials of whatever description in an Excel spreadsheet. Capture the regulated entity's name of the material; the form number, if any; the edition date, if any; source, if applicable; and media, such as Internet or direct mail. Include fields to note exceptions, such as unsupported statistics or possible misleading statements. Insert each possible violation/exception in a separate field.

Statistics and statements are likely to be repeated in more than one "piece" of marketing material. It is also possible that one piece of marketing material will contain more than one violation/exception.

The spreadsheet will make it easier to track any repeated statements and to identify any marketing material containing apparent multiple violations/exceptions.

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STANDARDS
MARKETING AND SALES

Standard 2
Regulated entity internal producer training materials are in compliance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity's producer training manuals, videos and sales scripts

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Producer Licensing Model Act (#218)
Life Insurance Disclosure Model Regulation (#580), Section 5A(2)
Advertisements of Life Insurance and Annuities Model Regulation (#570)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Individual Health Insurance Portability Model Act (#37), Sections 11D and 11E
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Advertisements of Accident and Sickness Insurance Model Regulation (#40)
Group Health Insurance Standards Model Act (#100)
Long-Term Care Insurance Model Act (#640)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the Medicare Supplement Insurance Minimum Standards Model Act (#651)

Review Procedures and Criteria

Review all producers' training materials for compliance with state statutes, rules and regulations.

Review materials for references to employing unfair discrimination tactics or avoiding statutory compliance.

Determine whether producers' prepared materials are permitted and, if so, under what conditions and controls.

The examiners should be aware of the results of the review of common consumer complaints against the regulated entity, as that could point toward problems in this area.

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Automation Tip:
Enter a summary of all training materials of whatever description in an Excel spreadsheet. Capture the regulated entity's name of the material; the form number, if any; the edition date, if any; source, if applicable; and media, such as video, sales script, etc. Include fields to note exceptions, such as incomplete disclosure or possible misleading statements. Insert each possible violation/exception in a separate field.

Statistics and statements are likely to be repeated in more than one "piece" of training material. It is also possible that one piece of training material will contain more than one violation/exception.

The spreadsheet will make it easier to track any repeated statements and to identify any training material containing apparent multiple violations/exceptions.

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STANDARDS
MARKETING AND SALES

Standard 3
Regulated entity communications to producers are in compliance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Bulletins, newsletters and memos

_____ Organizational chart of marketing division

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Trade Practices Act (#880)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Group Health Insurance Standards Model Act (#100)
Long-Term Care Insurance Model Act (#640)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the Medicare Supplement Insurance Minimum Standards Model Act (#651)

Review Procedures and Criteria

Review written and electronic communication between the regulated entity and producers in accordance with applicable statutes, rules and regulations.

Determine if communication includes references to new rates, rules and regulations.

Determine if communication conforms to Marketing and Sales Examination Standard #1 in this chapter when referencing advertising and sales.

Determine if the regulated entity uses email to communicate with producers. The examiner should ask to review saved, stored or archived email that was broadcast to the sales force.

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Automation Tip:
Enter a summary of all producer communications of whatever description in an Excel spreadsheet. Capture the regulated entity's title or subject line for the communication, the date of the communication, source of the communication, etc. Include fields to note exceptions, such as misleading statements or instructions to producers that are in conflict with statutes or regulations. Insert each possible violation/exception in a separate field.

Statistics and statements are likely to be repeated in more than one regulated entity communication. It is also possible that a single regulated entity communication will contain more than one violation/exception.

The Excel spreadsheet will make it easier to track any repeated statements and to identify any regulated entity communications containing apparent multiple violations/exceptions.

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D. Producer Licensing

1. Purpose

The producer licensing portion of the examination is designed to test a regulated entity's compliance with state producer licensing laws and rules. The focus of the standard relating to producer accounts current is to aid in the detection of fraud or misuse of funds held by the producer in a fiduciary capacity.

2. Techniques

The examiner should review and compare information obtained from insurance departments and regulated entity records pertaining to licenses held by individuals or entities soliciting business on behalf of the regulated entity. Information related to producer licensing may be obtained from the NAIC State Producer Licensing Database (SPLD). In addition to aggregate listings of licensed/appointed/terminated producers, compliance with producer licensing statutes should be verified during the review of individual policy files, which take place during other portions of the examination (see Section F Underwriting and Rating in this chapter).

The examiner should compare information obtained from insurance departments and regulated entity records pertaining to the licenses held by individuals or entities soliciting business on behalf of the regulated entity. Insurance department records may be obtained through the NAIC SPLD, if the state is actively submitting information to the database. The SPLD contains information about a producer's license and any appointments they have with a regulated entity.

3. Tests and Standards

The producer licensing review includes, but is not limited to, the following standards related to producer licensing. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
PRODUCER LICENSING

Standard 1
Regulated entity records of licensed and appointed (if applicable) producers and in jurisdictions where applicable, licensed company or contracted independent adjusters agree with insurance department records.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Insurance department listing of producers and, if applicable, adjusters or the SPLD (State Producer Licensing Database)

_____ Regulated entity listing of currently licensed and/or appointed producers and, if applicable, adjusters

_____ Regulated entity listing of commissions

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Mass Marketing of Property and Liability Insurance Model Regulation (#710)
Producer Licensing Model Act (#218)
Title Insurance Agent Model Act (#230)
Independent Adjuster Licensing Guideline (#1224)

Review Procedures and Criteria

Reconcile above regulated entity lists with corresponding insurance department lists to determine any discrepancies. If the state is actively participating in the State Producer Licensing Database (SPLD), the examiner should validate the producer's or adjuster's licensure status through the SPLD in lieu of obtaining a hardcopy of the producer's or adjuster's license.

Determine that any producer writing business in connection with a mass marketing plan is appropriately licensed.

Refer discrepancies to appropriate divisions within the insurance department.

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Automation Tip:
Obtain from the regulated entity a list of all producers licensed and appointed at any time during the examination period, and, where applicable, all company or contracted independent adjusters licensed at any time during the examination period. Include the producer's or adjuster's National Producer Number (NPN) or, if unavailable, Social Security number, Federal Employer Identification number, name, address, licensed date, appointed date, type of license, and internal regulated entity or employee number for the producer. Obtain from the insurance department's licensing division a similar list. Obtain from the regulated entity a list of all producers who received commission during the examination period. Include the producer's National Producer Number (NPN) or, if unavailable, Social Security number, Federal Employer Identification number, name, address, licensed date, appointed date, type of license, date first commission received and internal regulated entity or employee number for the producer. Obtain from the regulated entity a list of all new business written during the examination period. Include the date the policy was issued and the producer's internal regulated entity or employee number.

- Compare the regulated entity's producer and adjuster licensing list to the insurance department's licensed producers list by comparing National Producer Numbers (NPN) or, if unavailable, Social Security numbers, Federal Employer Identification numbers, extracting any producers on the regulated entity's list who are not on the insurance department's list;
- Compare the regulated entity's commissions list to the insurance department's licensed producers list by comparing National Producer Numbers (NPN) or, if unavailable, Social Security numbers, Federal Employer Identification numbers, extracting any producers on the regulated entity's list who are not on the insurance department's list. Also compare commission first earned dates to the insurance department's license/appointment dates to see if commissions were earned prior to license/appointment date; and
- Compare the regulated entity's new business written list to the insurance department's licensed producers list by comparing National Producer Numbers (NPN) or, if unavailable, Social Security numbers, Federal Employer Identification numbers or internal regulated entity/employee numbers), extracting any producers on the regulated entity's list who are not on the insurance department's list. Also compare policy issued date to the insurance department's license/appointment dates to see if policies were written prior to license/appointment date. This may need to be cross-referenced with the regulated entity's licensed producer list to correlate the producer's National Producer Number (NPN) and the internal regulated entity/employee number.

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STANDARDS
PRODUCER LICENSING

Standard 2
The producers are properly licensed and appointed and have appropriate continuing education (if required by state law) in the jurisdiction where the application was taken.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ New business application

_____ Insurance department listing of licensed and/or appointed producers or the State Producer Licensing Database (SPLD)

_____ Copy of producer's license or electronic verification of producer's license via the State Producer Licensing Database (SPLD)

_____ Regulated entity listing of all currently licensed and/or appointed producers

_____ Notice of appointment

_____ Regulated entity procedures for appointing a producer

_____ Regulated entity list of commissions paid by line of business

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Producer Licensing Model Act (#218)
Title Insurance Agent Model Act (#230)
Unfair Trade Practices Act (#880)
Long-Term Care Insurance Model Act (#640)

Review Procedures and Criteria

Review the regulated entity's procedures for the appointment of producers.

Review the producer's license and the appointment records. Determine if the appointment was effective within 15 days of the producer writing business on behalf of the regulated entity.

Review the producer's authority for the types of business he/she is eligible to solicit. Determine if the producer is acting within the scope of that authority.

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Determine that the producer has met continuing education requirements and, if appropriate, has met the producer training requirements for selling long-term care insurance (LTCI).

Identify the producer of each selected policy and determine proper licensure and appointment (if required).

Automation Tip:
Obtain from the regulated entity a list of all producers licensed and appointed at anytime during the examination period. Include the producer's National Producer Number (NPN) or, if unavailable, Social Security number or Federal Employer Identification number, name, address, licensed date, appointed date, type of license and internal regulated entity or employee number for the producer. Obtain from the insurance department's licensing division a list of all producers licensed and appointed at any time during the examination period. Include the producer's National Producer Number (NPN) or, if unavailable, Social Security number or Federal Employer Identification number, name, address, licensed date, appointed date, applicable jurisdictions and type of license. Obtain from the regulated entity a list of all applications taken during the examination period. Include the date the application was taken, the producer's internal regulated entity or employee number and the jurisdiction where the application was taken. Compare these files using National Producer Numbers (NPN) or, if unavailable, Social Security numbers or Federal Employer Identification numbers and internal regulated entity/employee number for the producer and jurisdictions. Extract any producers who took applications from jurisdictions where they were not licensed/appointed.

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STANDARDS
PRODUCER LICENSING

Standard 3
Termination of producers complies with applicable standards, rules and regulations regarding notification to the producer and notification to the state, if applicable.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity/agency contracts

_____ Regulated entity listing of producer terminations for examination review period

_____ Regulated entity listing of commissions

_____ Insurance department listing of terminations

_____ Copies of individual termination notifications sent to terminated producers

_____ Copies of individual termination notifications sent to insurance department

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Producer Licensing Model Act (#218)
Title Insurance Agent Model Act (#230)

Review Procedures and Criteria

Reconcile the regulated entity's listing of producer terminations with the listing of commissions paid to determine if payouts are being made properly to terminated producers.

Review individual termination notices from the regulated entity to producers to determine compliance with termination notification periods and allowance for renewal commissions.

Refer any discovery of terminated producers still submitting new business to appropriate divisions within the insurance department.

Review the regulated entity's contract with producers to determine how commissions are paid to producers who have been terminated (e.g., vesting provisions).

Compare the regulated entity's listing of producer terminations with the National Insurance Producer Registry (NIPR) to ensure accuracy in reporting.

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STANDARDS
PRODUCER LICENSING

Standard 4
The regulated entity's policy of producer appointments and terminations does not result in unfair discrimination against policyholders.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Listing of appointments and terminations for examination review period

_____ Listing of producer appointments by line of business (if applicable) by producer's business ZIP code

_____ Listing of terminations by line of business (if applicable) by producer's business ZIP code

_____ Regulated entity market plan or synopsis

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Compare the number of appointments/terminations for the current review period with previous review period and, if difference is significant, determine the reason(s).

Review the regulated entity's marketing plan.

Review ZIP code listings to determine the placement of producers and if there is evidence of under-served or over-served geographical areas.

Automation Tip:
Obtain from the regulated entity a list of all producers licensed and appointed at any time during the examination period. Include the producer's National Producer Number (NPN) or, if unavailable, Social Security number, Federal Employer Identification number, name, address, county, ZIP code, licensed date, appointed date, termination date, type of license and internal regulated entity or employee number for the producer. Extract a list of all producers that were licensed/appointed and/or terminated during the examination period. Run a count on the number of producers that are licensed/appointed by ZIP code or county and a count on the number of producers terminated by ZIP code or county. Also run a count on the original file by ZIP code or county. A comparison of the counts may show ZIP codes or counties that are under-served or over-served.

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STANDARDS
PRODUCER LICENSING

Standard 5
Records of terminated producers adequately document reasons for terminations.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity listings of terminated producers for examination review period

_____ Regulated entity individual files of terminated producers

_____ Insurance department's list of acceptable reasons for terminations

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Producer Licensing Model Act (#218)
Title Insurance Agent Model Act (#230)

Review Procedures and Criteria

Determine reasons for producer terminations.

Review all or sample of individual terminated producer files.

Review above documents for inadequately or inaccurately documented termination reasons. If necessary, refer to the appropriate division within the insurance department.

Compare the regulated entity's listing of producer terminations with NIPR to ensure accuracy in reporting.

Determine if the insurance department is notified of termination for cause (if applicable).

Automation Tip:
Obtain from the regulated entity a list of all producers terminated at any time during the examination period. Include the producer's National Producer Number (NPN) or, if unavailable, Social Security number, Federal Employer Identification number, name, address, termination date and reason for termination. Review the regulated entity's files for these producers to determine if the terminations were adequately documented.

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STANDARDS
PRODUCER LICENSING

Standard 6
Producer account balances are in accordance with the producer's contract with the insurer.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Listing of producer accounts current exceeding contract limits

_____ Producer and/or agency contracts

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Producer Licensing Model Act (#218)
Title Insurance Agent Model Act (#230)
Unfair Trade Practices Act (#880)
Insurance Fraud Prevention Model Act (#680)

Review Procedures and Criteria

Review listing of producer accounts current.

Discuss excessive balances with the regulated entity.

Accounts current exceeding contract limits may indicate producer mishandling of funds.

Refer to appropriate division within the insurance department.

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E. Policyholder Service

1. Purpose

The policyholder service portion of the examination is designed to test a regulated entity's compliance with statutes regarding notice/billing, delays/no response, and premium refund and coverage questions.

2. Techniques

While larger companies may have a full staff to handle policyholder service, smaller companies may well do policyholder service as a function of the claims or underwriting department.

Policyholder service departments vary from regulated entity to regulated entity. Some companies do only what is required of them by state statute (i.e., notification of the toll-free number or policyholder complaint telephone number). In contrast, some actually contact policyholders that have had occasion to deal directly with the regulated entity, such as presenting a claim or requesting a policy change.

It is important that the examiner check with the examination coordinator to determine where the policyholder service function lies and then apply the following tests to determine the effectiveness of the unit.

3. Tests and Standards

The policyholder service review includes, but is not limited to, the following standards related to the adequacy and level of policyholder service provided by the regulated entity. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
POLICYHOLDER SERVICE

Standard 1
Premium notices and billing notices are sent out with an adequate amount of advance notice.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Underwriting files

_____ Underwriting procedure manuals

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Improper Termination Practices Model Act (#915)
Property Insurance Declination, Termination and Disclosure Model Act (#720)
Automobile Insurance Declination, Termination and Disclosure Model Act (#725)
Universal Life Insurance Model Regulation (#585), Section 7F

Review Procedures and Criteria

Check renewal business to determine if the regulated entity's procedures for handling renewals are in accordance with state guidelines.

Check underwriting files to determine if premium notices for endorsements were sent timely, and not at audit or policy expiration.

Check mailroom for billings sent out by the regulated entity to ensure timeliness.

Automation Tip:
Obtain from the regulated entity a data file of all cancellations due to nonpayment. Include in the file the policy number, the date the notice was generated/mailed and the effective date of the cancellation. Using either a spreadsheet or database (if the file is quite large, use ACL), calculate the number of days between the date the regulated entity represents the notice was generated/mailed and the effective date of the cancellation. Using ACL or some other sampling software, select a sample of cancellation and premium notices that appear to conform to state requirements. Request documentation that the notice was mailed on the date reported by the regulated entity. Also extract a report of all notices, which apparently fail to comply with state requirements and submit to the regulated entity for explanations.

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STANDARDS
POLICYHOLDER SERVICE

Standard 2
Policy issuance and insured-requested cancellations are timely.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Underwriting manuals

_____ Insured's request for cancellation

_____ Cancellation notices

_____ Procedure manuals

_____ Underwriting files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Trade Practices Act (#880)

Review Procedures and Criteria

Determine if insured-requested cancellations are handled in a timely manner without excessive paperwork requirements for the insured.

Perform a time study on policy issuance to determine that policies and endorsements are issued in a timely manner.

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STANDARDS
POLICYHOLDER SERVICE

Standard 3
All correspondence directed to the regulated entity is answered in a timely and responsive manner by the appropriate department.

Apply to: **All regulated entities**

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity correspondence files

_____ Electronic correspondence

_____ Policy/Underwriting files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

NAIC Insurance Information and Privacy Protection Model Act (#670)
Unfair Claims Settlement Practices Act (#990)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)

Review Procedures and Criteria

Review correspondence to ensure that the response was made by the appropriate department.

Ensure the original question or problem was properly addressed in a timely manner.

Determine if the regulated entity responds to inquiries from the applicant regarding the specific reason(s) for adverse underwriting decisions.

Review correspondence contained in the policy files from the regulated entity to determine appropriateness and timeliness of handling.

Confirm that reasons for any adverse underwriting decisions, including rejections or declinations, are provided to the consumer in language understandable by the typical consumer.

Verify that the information provided to consumers regarding adverse underwriting decisions is consistent with applicable state statutes, rules and regulations.

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Confirm that records are maintained to demonstrate timely responses to correspondence and communication of adverse underwriting decisions.

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STANDARDS
POLICYHOLDER SERVICE

Standard 4
Whenever the regulated entity transfers the obligation of its contracts to another regulated entity pursuant to an assumption reinsurance agreement, the regulated entity has gained prior approval of the insurance department, and the regulated entity has sent the required notices to affected policyholders.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Assumption reinsurance agreements

_____ Order of insurance commissioner approving assumption reinsurance agreement

_____ Notice of transfer sent to policyholders, producers and brokers

_____ Response card sent to policyholders

_____ Written regulated entity procedures for handling inquiries regarding the assumption transaction and for processing the policyholders' response cards

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Assumption Reinsurance Model Act (#803)

Review Procedures and Criteria

According to the model act, "assumption reinsurance agreement" means any contract which both:

- Transfers insurance obligations and/or risks of existing or in force contracts of insurance from a transferring insurer to an assuming insurer; and
- Is intended to affect a novation of the transferred contract of insurance with the result that the assuming insurer becomes directly liable to the policyholders of the transferring insurer.

Determine if any assumption reinsurance agreements exist.

Obtain a list of policyholders covered by any assumption reinsurance agreements in order to determine sample.

Determine if the class of policyholder or type of product was covered by the assumption reinsurance agreement.

Determine if affected policyholders received the notice of transfer and the response card and that each includes appropriate language.

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Determine whether the regulated entity appropriately handled a policyholder's right to reject the transfer.

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STANDARDS
POLICYHOLDER SERVICE

Standard 5
Policy transactions are processed accurately and completely.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Regulated entity correspondence files

_____ Policy underwriting files involving nonforfeiture, surrenders, benefit changes, existing policy changes and other post-issue transactions

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Modified Guaranteed Annuity Model Regulation (#255), Section 6B(1)(b)
Consumer Credit Insurance Model Act (#360)

Review Procedures and Criteria

Ensure proper documentation is maintained for the following:

- Cash surrenders;
- Policy loans;
- Bank draft acceptance and clearance; and
- Beneficiary changes.

Ensure that policyholder requests are processed as soon as reasonably possible.

Ensure that matured endowments are processed when due. Determine if the regulated entity takes appropriate steps to notify policyholders of guaranteed options to purchase additional insurance.

Premium refunds for modified guaranteed life products. Special requirements may exist, under policy provisions or state law, for calculation of refunds involving "10-day right to return" periods for life products, which include a separate account.

For credit insurance, if a debt is refinanced prior to the scheduled maturity date, the in force insurance must be terminated before any new insurance is issued.

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STANDARDS
POLICYHOLDER SERVICE

Standard 6
Reasonable attempts to locate missing policyholders or beneficiaries are made.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Schedule F of the annual statement

_____ Policies scheduled for matured endowments

_____ Underwriting files

_____ Unpaid payees of returned benefit checks

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Review Procedures and Criteria

Determine if the regulated entity has made reasonable attempts to locate beneficiaries, policyholders and recipients of unclaimed properties.

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STANDARDS
POLICYHOLDER SERVICE

Standard 7
Unearned premiums are correctly calculated and returned to the appropriate party in a timely manner and in accordance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Policy contract

_____ Notice of cancellation/nonrenewal

_____ Refund check or complete documentation of refund, if canceled check information is maintained on the computer system

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Consumer Credit Insurance Model Regulation (#370)
Universal Life Insurance Model Regulation (#585)

Review Procedures and Criteria

Calculate the unearned premium (short rate, pro rata or sum of digits method) in accordance with policy provisions or state law.

Verify that refunds provided to producers are properly distributed.

Verify that unearned premiums were returned to the insured in a timely manner.

Verify that the regulated entity adheres to applicable "free look" periods.

For credit insurance:

- If the creditor has opened a line of credit for a debtor and is charging for the line of credit rather than the amount of debt (i.e., credit cards), at the debtor's death the insured amount due is the amount of established credit against premium was last charged;
- If a debtor prepays the debt in full, any credit insurance shall be terminated and an appropriate refund of premium shall be paid or credited to the debtor; and
- In the event of termination, no charge may be made for the first 15 days of a month and a full month may be charged for over 16 days.

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F. Underwriting and Rating

1. Purpose

These standards, in general, apply to insurance companies, although some or all of these standards may be applicable to other regulated entities to the extent that they address functions that have been delegated to them by insurance companies.

The underwriting portion of the examination is designed to provide a view of how the regulated entity treats the public and whether that treatment is in compliance with applicable statutes, rules and regulations. It is typically determined by testing a random sampling of files and applying various tests to the sampled files. It is concerned with compliance issues. The areas to be considered in this kind of review include:

a. Rating practices;
b. Underwriting practices;
c. Use of correct and properly filed and approved forms and endorsements;
d. Termination practices;
e. Unfair discrimination;
f. Use of proper disclosures, buyers' guides and delivery receipts;
g. Reinsurance; and
h. Statistical coding.

2. Techniques

During an examination, it is necessary for examiners to review a number of information sources, including:

- Rating manuals and rate cards;
- Rate classifications;
- Symbol manuals or tables;
- Rating systems filed with regulators;
- Payment plans;
- Minimum premiums;
- Policy fees;
- Discounts;
- Dividend rating plans;
- Regulated entity automated rating systems;
- Rating materials provided to producers;
- Reinsurer policies/treaties;
- Reinsurer guidelines and manuals;
- Documentation of required disclosures and delivery receipts;
- Premium statements and billing statements;
- Premium refund documentation;
- Replacement and conservation materials;
- Underwriting manuals, guidelines and classification manuals;
- Medical underwriting manuals;
- Issued and renewed policy and certificate files;
- Canceled and nonrenewed policy and certificate files;
- Declined applications and notices;
- Individual and group lapsed policy files and notices;
- Individual and group nonforfeiture files and notices;
- Rescission files;
- Underwriting guidelines;

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- Sample of premium audit files;
- Applicable policy forms and endorsements and summaries;
- Producer licensing information;
- Group trust and association arrangements where applicable;
- Producer compensation agreements where applicable;
- Statistical reporting requirements; and
- Underwriting files content and structure.

For purposes of this chapter, "underwriting file" means the file or files containing the new business application; renewal application; rate calculation sheets; billings; audits, including binders; engineering reports; inspection reports; risk or hazard investigative or evaluation reports; motor vehicle reports (MVRs); credit reports; all underwriting information obtained or developed; policy declaration page; endorsements; premium finance agreements with regulated entities activities; cancellation or reinstatement notices; correspondence; and any other documentation supporting selection, classification, rating or termination of the risk.

In selecting samples for testing, personal lines should generally not be combined with commercial lines. These two areas are generally not homogeneous, and conclusions or inferences to be made from the results of sampling may not be valid if combined. The examiner should be familiar with any statutory or regulatory distinctions made between personal lines and commercial lines as respects the various tests to be developed. Then examiners also should be familiar with the process for gathering and processing underwriting information, and the quality controls for the issuance of policies, endorsements and premium statement/billings. The list of files from which a sample is to be drawn may be generated through a computer run or in some cases through a policy register covering the period of time selected in the notice or call of examination.

Determine the regulated entity's policy population (policy count) by line of business. Review a random selection of business for application of a particular test or apply specific tests to a census population using automated tools. (In the event specific files are chosen for a target review, the examiner must be certain the examination results are clearly identified as being from the target selection.) The examiner should maintain a list of the various tests to be applied to each file in the sample. This will aid in consistency by ensuring that each test is considered for each file in the sample.

If exceptions are noted, the examiner must determine if the exception is caused by such practices as use of faulty automated rating systems, or development of improperly or vaguely worded manuals or guidelines. When exceptions are noted, it is advisable to determine the scope and extent of the problem. The examiner responses should maximize objectivity; the examiner should avoid replacing examiner judgment for regulated entity judgment.

a. Rating Practices

   It is necessary to determine if the regulated entity is in compliance with rating systems that have been filed with, and, in some cases, approved by the various state insurance departments. Where rates are not required to be filed with an applicable regulatory agency, it is prudent to determine if rates are being applied consistently and in accordance with the regulated entity's own rating methods. In general, rates should not be unfairly discriminatory. Wide-scale application of incorrect rates by a regulated entity may raise financial solvency questions or be indicative of inadequate management oversight. Deviation from established rating plans may also indicate a regulated entity is engaged in unfair competitive practices. Inconsistent application of rates, individual risk premium modifications, modification factors and deviations can result in unfair discrimination.

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The procedure for determining adherence to rates filed or used by a regulated entity varies between personal lines and commercial lines. There can also be considerable variation by kind of insurance. The examiner should become familiar with the regulated entity's policy form numbers or other identification procedures, inasmuch as references may be made to such numbers or procedures in lieu of having the particular form attached. If policies are issued by an automated system, the examiner should manually rate policies based on a selection of various classes and various territories to verify that the computer has been programmed correctly. Once this has been established, the examiner should check only the input data for other policies against the information included in the inspection report or from information obtained from other sources in order to determine that they have been rated correctly. If rating exceptions are noted, the examiner must determine if the exception is caused by such practices as use of faulty automated rating systems, or development of improperly or vaguely worded rating manuals. When exceptions are noted, it is advisable to determine the scope and extent of the problem.

When possible, the examination team should make use of audit software to verify correct application of specific rating components. This allows for a more thorough review and can save time during the examination process. All new automated audit applications that are developed should be submitted to the NAIC File Repository, in order to assist in building a comprehensive set of audit programs.

Rating practices of renewal policies, as well as newly issued policies, should be reviewed. By reviewing renewal policies, the examiner can verify whether the regulated entity is updating rating components, such as vehicle-identification number (VIN) symbol changes or property protection class changes. The examiner can look for cases where initial year premium rates were set at artificially low levels for competitive reasons.

The complexity of rating systems varies greatly from line to line. Some lines require little in the way of documentation focused on the appropriate use of the rating system. Some systems are so complex that appropriate determination is difficult if a worksheet is not maintained. This is generally more true of commercial lines than it is for personal lines. The examiner should ensure that the underwriting files contain sufficient information to support the rates that have been applied to a policy. Inherent in the more complex systems is the concern for unfair discrimination.

Examiners may wish to review situations involving multiple related companies under common underwriting management for issues involving unfair discrimination between similarly situated policyholders.

Restraint of trade issues also may be involved if there are indications of two or more unrelated companies attempting to conspire to monopolize an insurance market.

b. Underwriting Practices

The examiner should review relevant underwriting information; e.g., the regulated entity's underwriting guidelines, underwriting bulletins, declination procedures, agency agreements and correspondence with producers. Interoffice memoranda and regulated entity minutes, which may furnish evidence of anti-competitive behavior, may also be requested. In addition to reviewing the content of the above information for indications of unfairly discriminatory practices, the examination team also will use the above information to determine regulated entity compliance with its own manuals and guidelines. The examiner should confirm that the regulated entity's underwriters and producers consistently apply the regulated entity's guidelines for all business selected or rejected. The examination team should verify that the regulated entity has correctly classified insured individuals.

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File documentation should also be sufficient to support underwriting decisions made. Underwriting decisions that are adequately documented generally afford management of the regulated entity the opportunity to know what business it has selected through its underwriters and producers. The examiner should verify that properly licensed and appointed (where applicable) producers have been used in the production of business.

Underwriting guidelines may vary by geographic areas in the jurisdiction and, therefore, such guidelines should be reviewed for each regional office being examined.

Any practice suggesting anti-competitive behavior may involve legal considerations that should be referred to insurance department counsel. Ultimately, the information so obtained may be useful in drafting legislation or regulations.

In some lines of business, a survey of nonstandard (e.g., surplus lines markets and consent-to-rate filings) and residual markets (e.g., FAIR—Fair Access to Insurance Requirements Plan, JUA—Joint Underwriting Association and high-risk health pools) may provide some insight into general industry underwriting practices.

c. Use of Correct and Properly Filed Forms and Endorsements

The examination team should verify that all policy forms and endorsements used have been filed with the appropriate regulatory authority, if applicable. Additionally, the examination team should verify the consistent and correct use of policy forms and endorsements. The examiner should also be mindful of possible outdated forms or endorsements. If coverages and riders requested by the applicant are not issued, proper notification should be provided to the applicant. In some cases, supplemental applications are appropriate.

If the forms have been approved by the Compact, the examiner should verify that the compacting state was included in the Compact-approved product filing and the form being marketed has a prefix of "ICCxx" (where "xx" represents the appropriate year the form was submitted for filing). If Compact-approved forms are being used or mixed and matched with forms approved by the compacting state, the examiner may wish to verify the forms approved by the compacting state were identified on the statement of intent schedule, which is required to be submitted, updated and maintained by the insurer in the product filing submitted to the Compact. Compacting states have access through the NAIC System for Electronic Rates and Forms Filing (SERFF) to product filings submitted to the Compact for approval and use in their respective state or jurisdiction and can use the export tool in SERFF to extract relevant information.

d. Termination Practices

The examiner should review the regulated entity's declination, cancellation and nonrenewal of policy practices to determine compliance with applicable statutes, rules and regulations and to determine conformance with regulated entity rules, guidelines and policy provisions.

The review of cancellation and nonrenewal practices in a particular line of insurance should involve a request for the underwriting file for each policy selected from the random sample of canceled policies. For nonrenewals, the examiner should select the sample from the expiration list. Cancellations of specific lines of business have unique requirements. The sampling should be completed separately for each product line in order to get a fair sampling for each line of business to be reviewed. The examiner should review material submitted to determine that the cancellations comply with statutory provisions and policy provisions.

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Cancellation processing for nonpayment of premium should include a formal notice to the insured. Some companies use the last billing notice as the cancellation notice. If this is the case, that billing notice must clearly state the effective date of termination of coverage, the insured's rights to an explanation, as provided by statutes where required, and a concise statement of the reason for termination of coverage. Make sure that the loss payee is receiving a copy of the same notice, or separate notice from the regulated entity, to advise that coverage is being terminated. Refer to the specific statute and rule that applies.

The accuracy of return premiums on canceled policies and, in particular, pro rata vs. short rate return of premiums should be verified. When coverage other than homeowners is canceled at the request of the insured, short rate methodology should be used. Cancellations initiated by the regulated entity and all homeowner cancellations should be pro rata.

The examination team should review reinstatement offers and determine what the regulated entity practice is for offering reinstatement. Additionally, the examination team should be mindful of billing practices that may encourage policy lapses.

e. Declination Practices

The examiner should review the regulated entity's declination of policy practices to determine compliance with applicable statutes, rules and regulations and to determine conformance with regulated entity rules and guidelines. "Declination" includes only refusal of an insurer to issue a policy upon receipt of a written nonbinding application or written request for coverage from a producer or an applicant, or the refusal of a producer or broker to transmit to an insurer a written nonbinding application or written request for coverage.

Insurers should maintain declination files and producers should maintain files on declinations made on behalf of the regulated entity. The applicant must be provided with a written, specific reason for the declination.

The review of declination practices in a particular line of insurance should involve a request for the underwriting file for each policy selected from the random sample of declinations. The sampling should be completed separately for each product line in order to get a fair sampling for each line of business to be reviewed. The examiner should review material submitted to determine that the declinations are in compliance with the applicable rules and regulations and in conformance with the rules and guidelines for the specific line of business.

f. Reinsurance

Most state statutes include a feature that for many lines of business the regulated entity is not permitted to place more than 10 percent of its surplus to policyholders at risk on any one placement of insurance. While this is primarily a solvency issue, it is one that market conduct examiners are in an ideal position to test in view of the sampling of underwriting files utilized for other tests.

Adherence to the requirement is easy to test but requires familiarity with the structure and content of the reinsurance treaties covering the business written by the regulated entity. This item is particularly important for companies that hold minimal policyholder surplus accounts (i.e., surplus of less than $10 million). It may also reflect on the care the regulated entity's management places on its selection of business, and represent a danger to the financial health of the regulated entity. Errors in this area should result in alerts to the insurance department's financial examiners. Any tests of this type must be coordinated with the state's financial examiners.

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3. Tests and Standards

The underwriting and rating review includes, but is not limited to, the following standards addressing various aspects of the regulated entity's underwriting activities. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
UNDERWRITING AND RATING

Standard 1
The rates charged for the policy coverage are in accordance with filed rates (if applicable) or the regulated entity's rating plan.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ New business application

_____ All underwriting information obtained

_____ Rating manuals

--------- Underwriting models used to rate applicants

_____ Policy declaration page

_____ Underwriter's file or notes on a system log

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Property and Casualty Model Rating Law Guideline (File and Use Version) (#1775)
Property and Casualty Model Rating Law Guideline (Prior Approval Version) (#1780)
Property and Casualty Commercial Rate and Policy Form Model Law (Condensed) (#777)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Stop Loss Insurance Model Act (#92)
Individual Health Insurance Portability Model Act (#37), Sections 5A–H, 5J, 5K, 7 and 9
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Verify all rating factors, including class, territory, symbol assignment, surcharges, deductible factors and increased limit factors.

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If no source document application exists, review what procedures the regulated entity has in place to determine the accuracy of the information that was given to issue the policy.

Calculate the policy premium to verify it is in accordance with filed rates.

Verify that the proper rules are being used.

Verify that the filed implementation date is used uniformly, including at different branches.

Confirm that rates in use were filed and approved prior to use, where required.

Confirm that rates in use have been submitted as required, if system is other than prior approval.

Verify the basis of premium is correct.

Verify that the protection classes and other rating factors are correct.

Verify that the rating rules are properly utilized. The examiner should be alert for incorrect interpretation of rating rules.

Confirm how the regulated entity obtains any external data or information used as part of its underwriting program.

Verify that the underwriting model(s) the regulated entity uses are based on sound actuarial principles.

Verify that the regulated entity addresses potential unfair discrimination by ensuring that external consumer data's correlation to risk is not outweighed by any correlation to a protected class(es).

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

Automation Tip:
Obtain from the regulated entity a data file that contains new business written during the examination period. The file should contain policy number, policy form, address, territory code or any other rating factor that is standardized by the regulated entity. Obtain from the regulated entity a data file that contains these standardized rating factors. For example, if the regulated entity underwrites by county, then obtain a data file that contains the county codes and a new business file that contains the policyholder's county. Compare the two files to see if the appropriate rating code is being applied. Since variations can happen, ask for explanations only in areas where the error rate is unacceptable.

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STANDARDS
UNDERWRITING AND RATING

Standard 2
All mandated disclosures are documented and in accordance with applicable statutes, rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Underwriting or policy files

_____ Lapsed policies

_____ Rating/Quote information provided electronically

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Cancer Insurance Shopper's Guide
*Model Regulation to Implement the Small Employer Insurance Portability Model Ac*t (#119)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Accident and Sickness Insurance Minimum Standards Model Act (#170), Section 5
Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act (#171), Sections 8A(10) and 8A(11)
Consumer Credit Insurance Model Act (#360)
Individual Health Insurance Portability Model Act (#37), Section 11
Unfair Trade Practices Act (#880)
Long-Term Care Insurance Model Act (#640)
Long-Term Care Insurance Model Regulation (#641)
Life Insurance Disclosure Model Regulation (#580), Section 5A(1)
Life Insurance Illustrations Model Regulation (#582)
Consumer Credit Insurance Model Regulation (#370)
Charitable Gift Annuities Model Act (#240)
Charitable Gift Annuities Exemption Model Act (#241)
Bulletin pertaining to Voluntary Expedited Filing Procedures for Insurance Applications Developed to allow Depository Institutions to meet their Disclosure Obligations under Section 305 of the Gramm-Leach-Bliley Act
Group Life Insurance Definition and Group Life Insurance Standard Provisions Model Act (#565)
Military Sales Practices Model Regulation (#568)
Group Health Insurance Standards Model Act (#100)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)

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Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Verify that written notice of Medicare supplement replacements are provided to applicants and existing insurers and that appropriate buyer's guides are used.

Verify that appropriate notices regarding credit-related coverages are documented.

Verify that notices regarding the existence of health insurance pools are provided, where applicable.

Review other notices and disclosures required by various jurisdictions.

Determine if state law requires that telephone help numbers be provided, including state insurance department telephone numbers and addresses.

Determine if changes in coverage are disclosed in a timely manner.

Determine if the regulated entity underwriting guidelines comply with applicable statutes, rules and regulations.

Determine if mandated optional coverages are disclosed and documented.

Verify that quotations are made accurately and in a timely manner.

Verify that delivery receipts are obtained where necessary.

Verify that changes in rates are disclosed in a timely manner and in accordance with applicable statutes, rules, regulations and policy provisions.

Determine if the regulated entity is in compliance with rules related to fair marketing.

Verify that the *Shopper's Guide to Cancer Insurance* complies with required disclosures and policy limitations.

Ensure disclosures to consumers represent the applicable consumer protections required by state law, including:

- Limits on preexisting condition exclusions;
- Prohibitions on discrimination based on health status and related factors;
- Guaranteed renewals for all policies, with certain exceptions;
- Limits on the factors that can be used to establish and change premium rates; and
- Descriptive information about all available health benefit plans.

Ensure the regulated entity maintains complete and detailed descriptions of its rating and underwriting practices for individuals and small groups at its principal place of business.

Verify that the regulated entity provides a copy of all disclosures given to applicants regarding its underwriting program.

Verify that disclosures are written in language understandable by the typical consumer and include all required information.

Confirm that the regulated entity maintains records of disclosures provided, including dates and recipients, to demonstrate compliance with applicable state statutes, rules and regulations.

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Where required, individual accident and sickness insurance policies shall include with delivery or application an outline of coverage, in a prescribed format. Outlines of coverage delivered in connection with individual hospital confinement indemnity, specified disease or limited benefit health insurance coverages to persons eligible for Medicare by reason of age shall contain language that indicates "This policy IS NOT A MEDICARE SUPPLEMENT policy. If you are eligible for Medicare, review the Medicare Supplement Buyer's Guide available from the regulated entity."

Insurers shall give any person applying for specified disease insurance a buyer's guide approved by the insurance commissioner. Direct response insurers shall provide the buyer's guide upon request, but not later than the time the policy is delivered.

Credit disability income products

Ensure the debtor is provided a disclosure with the following information prior to the election to purchase insurance:

- That the purchase of consumer credit insurance is optional and not a condition of obtaining credit approval;
- If more than one kind of consumer credit insurance is being made available to the debtor, whether the debtor can purchase each kind separately or the multiple coverages only as a package;
- The conditions of eligibility;
- That, if the consumer has other insurance that covers the risk, he or she may not want or need credit insurance;
- That within the first 30 days after receiving the individual policy or group certificate, the debtor may cancel the coverage and have all premiums paid by the debtor refunded or credited. Thereafter, the debtor may cancel the policy at any time during the term of the loan and receive a refund of any of the unearned premium. However, only in those instances where insurance is a requirement for the extension of credit, the debtor may be required to offer evidence of alternative insurance acceptable to the creditor at the time of cancellation;
- A brief description of the coverage, including a description of the amount, the term, any exceptions, limitations and exclusions, the insured event, any waiting or elimination period, any deductible, any applicable waiver of premium provision, to whom the benefits would be paid and the premium rate for each coverage or for all coverages in a package; and
- That, if the premium or insurance charge is financed, it will be subject to finance charges at the rate applicable to the credit transaction.

LTC products

Verify that written notice of LTC replacements is provided to applicants and existing insurers, suitability worksheets are completed and submitted and that appropriate buyer's guides and contract or policy summaries are used.

Ensure the entity maintains, at its home office or principal office, a complete file containing one specimen copy of each disclosure document authorized and used by the entity (i.e., buyer's guide, contract, outline of coverage, statement of policy information for applicant, etc.). The file should contain one copy of each authorized form for a period of 3 years following the date of its last authorized use. Many jurisdictions have repealed the requirement for policy summaries if the product is declared to be marketed with an illustration that meets the requirements of statutes, rules and regulations.

Workers' compensation products

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

Compact-approved products

If the forms and advertisements have been approved by the Compact, please note that the notices and disclosures required to be included within the approved forms and advertisements are governed by the Compact uniform standards and not state law. State law that requires notices and disclosures during the sale, underwriting and claims processes are still applicable to products and advertisements approved by the Compact, provided such state law

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requirements do not pertain to or affect the content or approval of the Compact-approved products and advertisements.

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STANDARDS
UNDERWRITING AND RATING

Standard 3
The regulated entity does not permit illegal rebating, commission-cutting or inducements.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Complaint files/logs

_____ Underwriting files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Trade Practices Act (#880)
Producer Licensing Model Act (#218)
Interest-Indexed Annuity Contracts Model Regulation (#235)
Consumer Credit Insurance Model Regulation (#370)
Individual Health Insurance Portability Model Act (#37), Section 11
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)

Review Procedures and Criteria

Check commission schedule for inappropriate variances.

Determine that producer commissions adhere to the commission schedule and, if not, verify that the file documentation reflects reasons for the variance.

Check billings and invoices for varying commission percentages.

Check regulated entity advertising for indications of illegal commission-cutting or inducements.

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STANDARDS
UNDERWRITING AND RATING

Standard 4
The regulated entity's underwriting practices are not unfairly discriminatory. The regulated entity adheres to applicable statutes, rules and regulations and regulated entity guidelines in the selection of risks.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ New business and renewal applications

_____ All underwriting information obtained

_____ Regulated entity underwriting guidelines

_____ Underwriting bulletins

_____ Declination procedures

_____ Agency agreements and correspondence with producers

_____ Interoffice memoranda and regulated entity minutes

_____ Policy declaration page

_____ Underwriter's file or notes on a system log

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Model Regulation on Unfair Discrimination in Life and Health Insurance on the Basis of Physical or Mental Impairment (#887)
Model Regulation on Unfair Discrimination on Basis of Blindness or Partial Blindness (#888)
Unfair Trade Practices Act (#880)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Military Sales Practices Model Regulation (#568)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Group Health Insurance Standards Model Act (#100)
Stranger-Originated Annuity Transactions (STOA) NAIC Sample Bulletin

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Review Procedures and Criteria

Review relevant underwriting information to ensure that no unfair discrimination is occurring according to the state's definition of unfair discrimination.

Determine if the regulated entity is following its underwriting guidelines, and that the guidelines conform to state laws and are not unfairly discriminatory.

Determine, if required, that the regulated entity's underwriting guidelines have been filed with the insurance department.

Review interoffice memoranda for evidence of anti-competitive behavior.

Underwriting guidelines may vary by geographic areas in the jurisdiction and, therefore, such guidelines should be reviewed for each regional office being examined.

Verify that data inputs used in underwriting are transparent, accurate and reliable.

Verify that data is evaluated for potential unfair discrimination before being used in underwriting decisions.

Confirm that the regulated entity provides documentation of all source data used in underwriting, including third-party or internal sources.

Verify that external data sources, algorithms or underwriting models are based on sound actuarial principles, with a rational explanation of why rating variables or combinations of variables are correlated to expected loss or expense, and why that correlation aligns with expected outcomes.

Verify that underwriting models or machine learning algorithms accurately assess and price risk.

Verify that underwriting models or machine learning algorithms achieve outcomes that are not unfairly discriminatory.

Confirm that the regulated entity provides documentation or summaries of underwriting models, algorithms or machine learning tools used in underwriting.

Confirm that underwriting programs and guidelines demonstrate proper use of data elements in risk selection.

Verify that the regulated entity audits its data sets, underwriting models and machine learning algorithms to ensure accuracy, reliability, and that underwriting decisions do not result in unfairly discriminatory outcomes.

Verify that external data used in underwriting is not correlated to protected classes in a way that outweighs its correlation to actual risk.

Confirm the specific external data or information about insurance applicants used in the underwriting process.

Ensure that the regulated entity does not discriminate against individuals by using any of an individual's past lawful travel or future lawful travel plans to refuse life insurance, refuse to continue existing life insurance, or limit the amount, extent or kind of life insurance available to an individual.

Ensure that the regulated entity's procedures are in compliance with the Genetic Information Nondiscrimination Act (GINA).

Some indication of industry underwriting practices may be obtained by a survey of residual markets (FAIR Plan and JUA), surplus lines markets and consent-to-rate filings.

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Inconsistent handling of rating or underwriting practices, even if not intentioned, can result in unfair discrimination, including requests for supplemental information.

Examine new business and renewal applications for the required fraud warning statement.

Review whether the insurer has established a system of STOA-related oversight (underwriting criteria). If not, discuss the existence of the STOA bulletin with the insurer. The examiner should be mindful that the provisions within the bulletin may not be legally required by their applicable jurisdiction.

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STANDARDS
UNDERWRITING AND RATING

Standard 5
All forms, including policies, contracts, riders, amendments, endorsement forms and certificates are filed with the insurance department, if applicable.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ New business application

_____ Policy or contract determination page

_____ Regulated entity's approval register

_____ Insurance department's approval for all forms, including policies, contracts, riders, amendments, endorsements and certificates (Note: All forms submitted to the Compact for approval in the applicable compacting state can be verified through SERFF or by contacting the designated Compact representative(s) within the compacting state)

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Health Policy Rate and Form Model [Act] [Regulation] (#165)
Individual Health Insurance Portability Model Act (#37*)*, Sections 7 and 9
Insurance Fraud Prevention Model Act (#680)
Unfair Trade Practices Act (#880)
Group Health Insurance Standards Model Act (#100)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Determine if the forms and endorsements have been filed. Where required, determine that either prior approval has been obtained or that applicable waiting periods following the filing have been met.

Determine if the regulated entity lists, on the summary page, all forms that constitute a part of the contract.

Examine new business applications for the required fraud warning statement.

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When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
UNDERWRITING AND RATING

Standard 6
Policies, contracts, riders, amendments and endorsements are issued or renewed accurately, timely and completely.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Underwriting files

_____ Application

_____ Underwriting procedure manuals

_____ Underwriting and binding guidelines

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Anti-Arson Application Model Bill (#715)
Improper Termination Practices Model Act (#915)
Property Insurance Declination, Termination and Disclosure Model Act (#720)
Automobile Insurance Declination, Termination and Disclosure Model Act (#725)
Consumer Credit Insurance Model Regulation (#370)
Consumer Credit Insurance Model Act (#360)
Health Policy Rate and Form Model [Act] [Regulation] (#165)
Uniform Individual Accident and Sickness Policy Provision Law (#180), Sections 2A(7), 2B(5) and 5C
Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act (#171), Sections 6G and 8A(2)
Administrative Procedure Relative to Renewability and Cancellation Provisions in the Approval of Accident and Health Policies Drafted In Accordance with the Uniform Individual Accident and Sickness Provision Law, Section 8
Individual Health Insurance Portability Model Act (#37), Sections 6, 7, 8 and 11
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Group Health Insurance Standards Model Act (#100)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

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Review Procedures and Criteria

~~Determine if policies and endorsements are issued in appropriate time frames.~~ Verify that policies, contracts, riders, amendments and endorsements are issued or renewed accurately, completely and in a timely manner.

Verify how much time elapses between completion of the application and issuance of coverage.

Review new issues prior to mailing to ensure correct procedures, forms, disclosures, etc., are used.

Confirm that any external data or information used in the issuance or renewal of insurance policies, including data from underwriting programs, is documented and applied correctly.

Verify that the regulated entity's processes ensure that all policy terms, coverage and endorsements are consistent with submitted applications and underwriting decisions.

Confirm that any adjustments or corrections resulting from external data review are properly incorporated before issuance or renewal of the policy.

Note that this standard may need flexibility or special application when dealing with assigned risk plans, joint insurance arrangements, anti-arson applications, FAIR (Fair Access to Insurance Requirements) plans or other involuntary business.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
UNDERWRITING AND RATING

Standard 7
Rejections and declinations are not unfairly discriminatory.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Policy contract

_____ Notice of declination

_____ Regulated entity guidelines for cancellation/nonrenewal/declination

_____ ~~Producer records/issued policies and declinations~~ Regulated entity/producer records

_____ Underwriting models, external data sources and algorithms used to rate applicants

_____ Documentation of regulated entity audits, data sets, underwriting models and outputs

Others Reviewed

_____ The Genetic Information Nondiscrimination Act (GINA)

_____ _____

NAIC Model References

NAIC Insurance Information and Privacy Protection Model Act (#670), Sections 10-12
Small Employer and Individual Health Insurance Availability Model Act (#35)
Group Health Insurance Standards Model Act (#100)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Unfair Trade Practices Act (#880)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Determine if the regulated entity provides valid reasons for rejection/declination when required.

Determine if the regulated entity responds to inquiries from the applicant regarding the specific reason(s) for adverse underwriting decisions. Was the adverse underwriting decision based on previous adverse underwriting decisions?

Determine if the regulated entity uses valid reasons for rejection/declination and documents these reasons.

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Review the regulated entity's procedures for rejection/declination to determine if the regulated entity is following its own guidelines.

Determine if the regulated entity monitors agency rejection/declination for appropriate practices.

Review for any unfairly discriminatory practices.

Verify appropriate refund has been made to the applicant.

Verify that data inputs used to make rejection or declination decisions are transparent, accurate, reliable, and evaluated for potential unfair discrimination.

Verify that external data sources, algorithms or underwriting models used in rejection or declination decisions are based on sound actuarial principles, including a rational explanation for correlations between rating variables and expected loss or expense.

Confirm that the regulated entity provides clear reasons for an adverse underwriting decision, including rejections or declinations, along with the information used to make the decision, in language understandable to the typical consumer and consistent with applicable state statutes, rules and regulations.

Confirm that underwriting programs and guidelines demonstrate the proper use of data elements in making rejection or declination decisions.

Confirm that the regulated entity provides documentation of source data used in rejection or declination decisions, whether obtained from third parties or generated internally.

Verify that the regulated entity audits its data sets, underwriting models and machine learning algorithms to ensure accuracy, reliability, and that rejection or declination decisions do not result in unfairly discriminatory outcomes.

Verify that external data used in rejection or declination decisions is not correlated to protected classes in a way that outweighs its correlation to actual risk.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
UNDERWRITING AND RATING

Standard 8
Cancellation/nonrenewal, discontinuance and declination notices comply with policy and contract provisions, state laws and the regulated entity's guidelines.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations (Note: Reference applicable Compact uniform standards for products approved by the Compact)

_____ Policy contract

_____ Notice of cancellation/nonrenewal

_____ Agent's/MGA's/Underwriter's file or notes on a system log

_____ Producer records/notices issued

_____ Insured's request (if applicable)

_____ Regulated entity cancellation/nonrenewal guidelines

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Property Insurance Declination, Termination and Disclosure Model Act (#720)
Automobile Insurance Declination, Termination and Disclosure Model Act (#725)
Improper Termination Practices Model Act (#915), Section 8A
Unfair Trade Practices Act (#880)
Group Coverage Discontinuance and Replacement Model Regulation (#110)
Individual Health Insurance Portability Model Act (#37), Section 11
Long-Term Care Insurance Model Act (#640)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Small Employer and Individual Health Insurance Availability Model Act (#35)
Group Health Insurance Standards Model Act (#100)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

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Review Procedures and Criteria

Determine if the reason for cancellation/nonrenewal or declination was valid according to policy provisions and state law.

Review the regulated entity's procedures for cancellation/nonrenewal and declinations to determine if the regulated entity is following its own guidelines.

Review regulated entity-initiated cancellations and consider a separate sample for insured-initiated cancellation.

Determine if the regulated entity monitors agency cancellation, declination and nonrenewals for appropriate practices.

Review for any unfairly discriminatory practices.

Review declinations, including declinations made by producers on behalf of the regulated entity. Declinations shall, as required, include the specific reasons for the declination.

Review notice of cancellation/nonrenewal to determine that it was mailed or delivered by the insurer to the first named insured's last known address.

Verify that cancellations, nonrenewals, discontinuances and declinations comply with policy and contract provisions, applicable state statutes, rules and regulations and the regulated entity's internal guidelines.

Confirm that the regulated entity provides clear and understandable notice to policyholders or applicants regarding cancellations, nonrenewals, discontinuances or declinations.

Verify that the regulated entity identifies and documents any external data or information used in decisions to cancel, nonrenew, discontinue or decline coverage.

Verify that the regulated entity provides a process or recourse for applicants or policyholders to contest or appeal a cancellation, nonrenewal, discontinuance or declination decision.

Verify that the regulated entity provides a process for applicants or policyholders to correct errors in external data or information used in cancellation, nonrenewal, discontinuance or declination decisions.

Verify that any underwriting models, algorithms or underwriting tools used to support cancellation, nonrenewal, discontinuance or declination decisions are based on sound actuarial principles.

Verify that the regulated entity ensures that decisions related to cancellations, nonrenewals, discontinuances or declinations do not result in unfairly discriminatory outcomes, ensuring correlations to risk are not outweighed by correlations to protected classes.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

Automation Tip:
Obtain from the regulated entity a data file of all cancellations/nonrenewals and declinations during the examination period. Include in the file the policy number, the date the notice was generated/mailed and the effective date of the cancellation/nonrenewal or declination. Using either a spreadsheet or database (if the file is quite large, use ACL), calculate the number of days between the date the regulated entity represents the notice was generated/mailed and the effective date of the cancellation/nonrenewal or declination. Using ACL or some other sampling software, select a sample of cancellation and premium notices that appear to conform to state requirements. Request documentation

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that the notice was mailed on the date reported by the regulated entity. Also extract a report of all notices which apparently fail to comply with state requirements and submit to the regulated entity for explanations.

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STANDARDS
UNDERWRITING AND RATING

Standard 9
Rescissions are not made for non-material misrepresentation.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ List of rescinded policies

_____ Underwriting files and supporting documentation, including claim files

Others Reviewed

_____ Case law for state impacted

_____ _____

_____ _____

NAIC Model References

Improper Termination Practices Model Act (#915)
Unfair Trade Practices Act (#880)
Long-Term Care Insurance Model Act (#640)
Medicare Supplement Insurance Minimum Standards Model Act (#650)
Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act (#651)
Group Health Insurance Standards Model Act (#100)

Review Procedures and Criteria

Determine if rescinded policies indicate a trend toward post-claim underwriting practices.

Determine if decisions to rescind policies are made in accordance with applicable statutes, rules and regulations.

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G. Claims

1. Purpose

These standards, in general, apply to insurance companies, although some or all of these standards may be applicable to other regulated entities to the extent that they address functions that have been delegated to them by insurance companies. The claims portion of the examination is designed to provide a view of how the regulated entity treats claimants and whether that treatment is in compliance with applicable statutes, rules and regulations. It is determined by testing a random sampling of files and applying various tests to open and closed claims.

For purposes of this chapter, "claim file" means the file or files containing the notice of claim, claim forms, proof of loss, medical records, health facility pre-admission certification or utilization review documentation, settlement demands, accident reports, police reports, adjusters' logs, claim investigation documentation, inspection reports, supporting bills (including electronic payment records, estimates and valuation worksheets), correspondence to and from insureds and claimants or their representatives, complaint correspondence, copies of claim checks and/or check numbers and amounts, releases, all applicable notices and correspondence used for determining and concluding claim payments or denials, subrogation and salvage documentation, and any other documentation necessary to support claim-handling activity.

The review is concerned with the regulated entity's claims practices by line of business for compliance with statutes, rules and regulations and policy provisions. The areas to be considered in this kind of review include:

a. Time studies to measure acknowledgment, investigation and settlement times;
b. General handling study;
c. Total loss valuation survey;
d. Closed without payment survey;
e. Subrogation survey;
f. Litigation survey;
g. Unfair claims practices survey;
h. Claims form review;
i. Loss statistical reporting survey;
j. Time study on canceled checks; and
k. Review of other procedures, as deemed necessary.

2. Techniques

Each area of claims review involves selecting a sample of claims (open, closed without payment, closed, denied). However, it is not necessary to use different samples to review timeliness of payment, conformity to policy language or adequacy of proof.

A general approach to examination would be to:

- Define the scope of the examination in terms of the lines of business and type of claims covered. Lines of business should be defined as specifically as possible; e.g., physical damage coverage rather than automobile coverage.
- Become familiar with the regulated entity's claim handling procedures for the line of business identified. Review corresponding policy forms for coverage, exclusions and nonstandard provisions. Review the methods for processing claims from notification to conclusion. Review with the claim manager or other appropriate personnel the maintenance of claim records and draft and settlement authority.

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- Select a representative sample of files to be reviewed. Chapter 17—Sampling of this handbook should be reviewed. If field sizes are relatively small and the regulated entity's records appear complete, representative samples or a census should be selected. In the case of large field sizes and incomplete or complicated records, the use of audit software should be considered. Care should be taken that no adverse selection occurs.
    a. Time studies to measure acknowledgment, investigation and settlement times

        Record the date of loss/claim, the date reported to the producer or regulated entity, the date sufficient information was available to determine the regulated entity's liability and the date the regulated entity accepted or rejected the claim. Record identifying data, such as the claim/policy number and the claimant's name.

        Determine for each claim the number of days the regulated entity took to accomplish each category. Compare days required by regulated entity to appropriate state standards and document those claims that exceed standards for inclusion in the report. Delays beyond the control of the regulated entity should be excluded; e.g., a delay caused by an uncooperative insured. Establish a mean and median time to acknowledge, investigate and accept/deny claims, if necessary, to determine a business practice.

        Caution: If a file has a violation of a standard with multiple tests, and the standard is the item measured, the file can only fail one time. If the individual test is the item measured, the file can fail each test. If failure of a standard or of a test ensures failure of another standard or test under another standard, then no substitution of the file need occur. The relationship, however, should be explained.

    b. General handling study

        Record identifying data such as claim/policy number, date of loss and claimant name. Files should be reviewed for adequate and accurate documentation. Correct application of deductibles, coinsurance and limits of coverage should be established. Mathematical accuracy should be determined. Reductions based on depreciation, obsolescence, etc., should be reviewed for fairness and accuracy.

        Checks or drafts should be reviewed for correct payees. Files should be reviewed for specific state requirements. Compliance with the regulated entity's own standards should be established.

    c. Closed without payment review

        This includes denied, rejected, incomplete and claims not paid for any other reason, including deductibles/waiting periods not met. Conduct tests similar to "General handling study" above. Record identifying data such as claim/policy number, date of loss and claimant name. Review specific state requirements for content and method of denial notification to the claimant. Note general handling by the regulated entity to determine validity of its action in the final disposition of these types of claims.

    d. Litigation survey

        Determine the extent of suits against the regulated entity. Separate first- and third-party actions. If a review is deemed appropriate, select a representative sample or census.

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Record identifying data such as claim/policy number, date of loss and claimant name. Files should be reviewed to determine the basis for suit and the regulated entity's position for denial or settlement offer. Closed litigated files should be reviewed to determine accuracy, regulated entity position and if punitive or bad faith judgments were rendered. Recognition of attorney-client privileged documents or work products should occur during the file review. A principal focus is compliance with unfair claims practices statutes and regulations.

e. Unfair claims practices review

Record identifying data such as claim/policy number, date of loss and claimant name. Review selected files for violations of specific state unfair claims practices, such as misrepresentation of policy provisions or concealment of coverage.

Calculate error ratios for the sample and field sizes. This is especially important in this study, since most unfair claims practices statutes make reference to "business practices."

f. Claim forms

Request copies of all claim forms in use for the lines of business being examined. Forms should be reviewed for content and appropriate usage. Inappropriate forms should be documented and included in the report. Claim forms also may be reviewed as they are encountered in the file reviews.

g. Review of canceled drafts/checks

This review should be considered if solvency is an issue, if the examiner determines delays in issuing a payment, or if consumer complaints indicated delays that are not supported by other time studies.

From the regulated entity's records, select a representative sample of the type of claims being reviewed. The selection should include drafts/checks reflecting a substantial payment amount on any one claim. Compare the date the regulated entity indicated the draft/check was forwarded to the claimant with the date the draft/check was presented for payment. If the review indicates significant and numerous delays in presenting drafts/checks for payment, additional investigation to determine the causes should be done.

Canceled checks should be reviewed to verify that the amount paid and the claim amount approved are the same, that payees are the same and that the information recorded in the computer system matches what is on the check (payee, amount, date of check, etc.).

h. Review of other procedures

Other review, as deemed necessary, should follow the same format for objectivity and sampling techniques as those already described. These reviews may be instituted by consumer complaints regarding specific claims practices and should be tailored to resolve specific issues.

3. Tests and Standards

The claims review includes, but is not limited to, the following standards addressing various aspects of the regulated entity's claim handling practices. The sequence of the standards listed here does not indicate priority of the standard.

STANDARDS

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CLAIMS

Standard 1
The initial contact by the regulated entity with the claimant is within the required time frame.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Internal regulated entity claims audit reports

_____ Claim files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's procedures, training manuals and bulletins to determine if regulated entity standards exist. Determine whether the regulated entity's standards comply with applicable statutes, rules and regulations.

Determine if initial contact procedures are in place and in compliance with the mandated time frame. Perform a time study of acknowledgment times.

Determine if initial contact with claimants meets required contract standards.

Determine if subsequent responses and claim handling delay notices comply with applicable statutes, rules and regulations.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 2
Timely investigations are conducted.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manual

_____ Internal regulated entity claims audit reports

_____ Claim bulletins

_____ Antifraud procedures

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Credit Insurance Model Act (#360)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state statutes.

Determine if investigations are initiated and concluded in compliance with state statutes.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 3
Claims are resolved in a timely manner.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Internal regulated entity claims audit reports

_____ Review of canceled claim checks

_____ Claim files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Credit Insurance Model Act (#360)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state statutes.

Determine if claim resolutions—i.e., liability, determinations, coverage questions and claims payment—are made in accordance with state requirements. Perform time studies to measure the settlement time of claims.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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Automation Tip:
Obtain from the regulated entity a listing of claims closed with payment or claims closed without payment by claim feature. Include in the file the claim number(s), date the claim was reported to the regulated entity, the first payment date (if applicable), and the date the claim feature was closed. Using ACL, a database or spreadsheet, calculate the number of days from the date the claim feature was closed to the date the claim was reported. Group the number of days in any appropriate time periods, for example, 1 to 15 days, 16 to 30 days, etc., and perform a count on each time period. Investigate any patterns of untimeliness.

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STANDARDS
CLAIMS

Standard 4
The regulated entity responds to claims correspondence in a timely manner.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Claim files

_____ Electronic claims correspondence

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Consumer Credit Insurance Model Act (#360)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state statutes.

Determine if correspondence related to claims is responded to in accordance with state requirements.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 5
Claim files are adequately documented.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Electronic records of claims activities

_____ Claims training manuals

_____ Internal regulated entity claims audit reports

_____ Claim bulletins

_____ Claim files

_____ Claim forms

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Title Insurers Model Act (#628)
Title Insurance Agent Model Act (#230)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state statutes.

Determine if quality of the claim documentation meets state requirements.

Determine if claim files retention/destruction program meets state requirements.

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Determine if claim files documentation is sufficient to support or justify the ultimate claim determination.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 6
Claims are properly handled in accordance with policy provisions and applicable statutes (including HIPAA), rules and regulations.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Internal regulated entity claims audit reports

_____ Claim bulletins

_____ Regulated entity claim forms manual

_____ Regulated entity subrogation and salvage logs

_____ Claim files

_____ Regulated entity depreciation schedules

_____ Auto—total loss evaluation procedures

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Retained Asset Accounts Sample Bulletin (#573)
Consumer Credit Insurance Model Regulation (#360)
Long-Term Care Insurance Model Act (#640)
Coordination of Benefits Model Regulation (#120)
Off-Label Drug Use Model Act (#148), Section 4
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

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Review Procedures and Criteria

Review regulated entity procedures, training manuals and claim bulletins to determine if regulated entity standards exist and whether standards comply with state statutes.

Determine if the regulated entity's procedures provide for the detection and reporting of fraudulent or potentially fraudulent insurance acts to the commissioner.

Determine if claim handling meets state-specific statutes and regulations as applied to total loss evaluations, sales tax payment, disposition of salvage, correct payees, improper release of claims, proper payment of non-disputed claims and proper referral of suspicious claims.

Determine if coverage was checked for proper application of deductible or appropriate exclusionary language.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 7
Regulated entity claim forms are appropriate for the type of product.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Claim forms for product being examined

_____ Electronic claims notification screens

_____ Claim files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Standardized Health Claim Form Model Regulation (#30)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Determine if claim form(s) include appropriate content and are used appropriately. Use of inappropriate forms should be documented and included in the examination report.

Review claim forms as they are encountered in the file reviews.

Examine all claim forms for the required fraud warning statement.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 8
Claim files are reserved in accordance with the regulated entity's established procedures.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Internal claims audit reports

_____ Individual claim file

_____ Average reserve data

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Review the regulated entity's claims procedure manuals for established reserving practices.

Determine if individual reserves are evaluated and posted.

Determine if reserve adjustments are made.

Determine if reserves are excessive/inadequate.

Determine if reserves are reduced, if a redundancy is apparent.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 9
Denied and closed without payment claims are handled in accordance with policy provisions and state law.

Apply to: All regulated entities

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Regulated entity claims procedure manuals

_____ Claims training manuals

_____ Internal regulated entity claims audit reports

_____ Claim bulletins

_____ Claim files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Insurance Fraud Prevention Model Act (#680)
Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)
Guidelines for the Filing of Workers' Compensation Large Deductible Policies and Programs (#1970)
Guidelines for Regulations and Legislation on Workers' Compensation Coverage for Professional Employer Organization Arrangements (#1950)

Review Procedures and Criteria

Determine if denied and closed without payment claims are based on policy provisions and applicable state statutes and regulations.

Determine if notices of claim denials reference specific policy provisions or exclusions.

Determine if the regulated entity provides claimants with a reasonable basis for the denial, when required by statutes, rules or regulations.

Where required, determine if claimants are provided with instructions for having rebuttals to denials reviewed by the insurance department or by the regulated entity.

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Determine if the regulated entity refers suspicious claims to a regulatory authority/law enforcement agency, when appropriate.

When conducting an examination on workers' compensation, it is recommended that separate samples be obtained for standard voluntary market, assigned risk (if applicable), large deductible (if applicable) and PEO accounts.

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STANDARDS
CLAIMS

Standard 10
Canceled benefit checks and drafts reflect appropriate claim handling practices.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Cashed benefit checks and drafts

_____ Regulated entity claims procedure manuals

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)

Review Procedures and Criteria

Perform a time study on canceled claim checks or drafts to ascertain whether claim proceeds are being promptly mailed or delivered.

Determine if canceled checks include the correct payee and are for the correct amount.

Ascertain whether payment checks indicate the payment is "final" when such is not the case.

Ascertain whether checks or drafts purport to release the insurer from total liability when such is not the case.

Review endorsements to see if they are consistent with the payee name listed on the check.

If drafts are used, ascertain whether there is prompt clearance by the insurer.

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STANDARDS
CLAIMS

Standard 11
Claim handling practices do not compel claimants to institute litigation, in cases of clear liability and coverage, to recover amounts due under policies by offering substantially less than is due under the policy.

Apply to: All regulated entities

Priority: Recommended

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Closed litigated claim files

_____ Regulated entity claims procedure manuals

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Unfair Claims Settlement Practices Act (#900)
Unfair Property/Casualty Claims Settlement Practices Model Regulation (#902)
Unfair Life, Accident and Health Claims Settlement Practices Model Regulation (#903)

Review Procedures and Criteria

Review a sample or entire population of closed litigated claim files, if feasible. Determine if litigated files indicate problematic claim handling practices. If warranted, notify the insurance department's financial examination division.

Note: The examiner should review applicable state statutes to determine which particular claims should adhere to this standard. For example, bodily injury claims may not readily fit this standard.

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Adopted by the Life Insurance and Annuities (A) Committee on August 14, 2024
Adopted by the Accelerated Underwriting (A) Working Group on August 6, 2024

Accelerated Underwriting in Life Insurance
Regulatory Guidance and Considerations

The Accelerated Underwriting (A) Working Group offers the following regulatory guidance for state Departments of Insurance (DOIs) to use when reviewing life insurer's use of accelerated underwriting programs. The regulatory guidance is designed to provide a framework for regulators to reference and is divided into three areas of focus: A) regulatory considerations; B) strategies for review; and C) requests for information.

Regulators should ensure that accelerated underwriting programs are fair, transparent, safe, and secure and in compliance with existing law. Making sure that the use of accelerated underwriting is fair to consumers is important because its use impacts the availability, access, and affordability of life insurance to consumers. Ensuring that insurers use accelerated underwriting in a transparent manner is important because consumers should understand what personal data is being accessed by insurers and how that data is being used. Insurers accessing sensitive consumer data have a duty to secure that data to protect consumers from the harm of unauthorized disclosure. And finally, it is critical that insurers' use of accelerated underwriting is in compliance with all applicable insurance laws and regulations.

A "Background" section has been included starting on page 5 to explain the history of the development of this regulatory guidance. A chronological list of the work product from other NAIC groups addressing similar or overlapping issues related to accelerated underwriting also has been included. While this entire body of work at the NAIC has influenced this guidance document, in the interest of clarity in this rapidly evolving area, this guidance document includes specific references to the definitions from other work product on which the regulatory guidance relies.

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Regulatory Guidance

A) Regulatory Considerations

The AUWG developed the following regulatory factors for DOIs to consider when reviewing a life insurer's use of Accelerated Underwriting[1] programs:

1. Data inputs are transparent, accurate, reliable, and the data itself is evaluated for potential unfair discrimination.

2. External data sources, Algorithms[2] or Predictive Models[3] are based on sound actuarial principles, including a rational explanation why a rating variable or combination of variables is correlated to expected loss or expense, and why that correlation is consistent with the expected direction of the relationship.[4]

3. Predictive Models or Machine Learning[5] Algorithm(s) within Accelerated Underwriting accurately assess and price risk.

4. Predictive Models or Machine Learning Algorithm(s) achieve an outcome that is not unfairly discriminatory.

5. Reason(s) for an Adverse Underwriting Decision,[6] along with information upon which the insurer based its Adverse Underwriting Decision, are provided to the consumer in language understandable by the typical consumer and consistent with applicable state and federal laws and regulations.

6. The insurer establishes and follows written procedures to protect the consumer's privacy and the consumer's data and provides a description of these procedures consistent with applicable state and federal laws and regulations to the consumer at the time of authorization.

7. The insurer has a mechanism in place to correct mistakes confirmed by records if found in consumer data.

8. The insurer has a process in place to assist a consumer in contacting the originator of a record that the consumer believes to be incorrect.

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[1] For purposes of this Regulatory Guidance, "Accelerated Underwriting" has the meaning set forth in the Life and Annuity Market Conduct Annual Statement (MCAS). See page 6 below "From 2022."
[2] For purposes of this Regulatory Guidance, "Algorithm" has the meaning set forth in the AI Model Bulletin (*See* Appendix 4).
[3] For purposes of this Regulatory Guidance, "Predictive Model" has the meaning set forth in the AI Model Bulletin (*See* Appendix 4).
[4] For clarity and consistency, this bullet borrows language from the Casualty Actuarial and Statistical (C) Task Force *Regulatory Review of Predictive Models White Paper* to describe this concept, replacing the language from the Accelerated Underwriting Educational Paper recommendation, which said: "External data sources, algorithms or predictive models are based on sound actuarial principles, including a valid explanation or rationale for any claimed correlation or causal connection."
[5] For purposes of this Regulatory Guidance, "Machine Learning" has the meaning set forth in the AI Model Bulletin (*See* Appendix 4).
[6] For purposes of this Regulatory Guidance, "Adverse Underwriting Decision" has the meaning articulated in the most recent draft of Model #674, which came from Model #670 and is consistent with the Fair Credit Reporting Act.

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8. The insurer will produce information upon request as part of regular filing submission reviews or market conduct examinations or actions.

9. The insurer has procedures in place to address consumer notice requirements anduse/restrictions on consumer data, consistent with applicable state and federal laws and regulations.

B) Strategies for Review

Using the regulatory considerations in A. above as a baseline for review, DOIs may consider the following:

1. Review a life insurer's underwriting programs/guidelines to confirm the proper use of data elements.

2. Request a life insurer provide Accelerated Underwriting data sources, Predictive Models, and Algorithms or summaries for analysis.

3. Request a life insurer provide additional information about how a particular Predictive Model or Machine Learning Algorithm is used in an Accelerated Underwriting program.

4. Request a life insurer provide information about source data used as part of its Accelerated Underwriting programs regardless of whether the data or score is provided by a third party or via a model.

5. Request a life insurer provide information about its auditing of data sets, Predictive Models, and Machine Learning Algorithms to ensure they are accurate, reliable, and do not result in unfairly discriminatory outcomes.

C) Requests for Information

The following are examples of questions and requests for information DOIs may want to submit to life insurers when reviewing Accelerated Underwriting programs:

1. What specific external data or information about life insurance applicants is being utilized by the Accelerated Underwriting program?

2. How does the company obtain any external data or information used as part of its life insurance Accelerated Underwriting program?

3. Explain and document in detail how the company discloses to applicants for life insurance what external information is used in its Accelerated Underwriting program and how this external information actually is used in the Accelerated Underwriting program.

4. Ask for a copy of all company disclosures provided to applicants regarding the company's Accelerated Underwriting program.

5. What process or recourse does the company provide to an applicant for life insurance should they receive an Adverse Underwriting decision based on external data or information?

6. What process or recourse does the company provide to applicants for life insurance to correct mistakes in the external data or information?

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7. How is external data or information about life applicants utilized, stored after the completion of the underwriting process, and ultimately destroyed?

8. How does the company validate, test, and/or audit data sets, Predictive Models, and Machine Learning Algorithms for accuracy and reliability, and for potential Adverse Consumer Outcomes[7]?

9. Does the company validate, test, and/or audit data sets, Predictive Models, and Machine Learning Algorithms internally or does it utilize a third-party to perform these functions?

10. How does the company ensure that the model(s) it uses are based on sound actuarial principles?

11. How does the company address potential unfair discrimination by ensuring that external consumer data's correlation to risk is not outweighed by any correlation to a protected class(es).

The AUWG offers this guidance to the state DOIs for consideration, while recognizing that there is more work to come. The AUWG anticipates that the work of the other NAIC groups on this topic will lead to additional guidance regarding Accelerated Underwriting in life insurance.

Background

The Accelerated Underwriting Working Group (AUWG) was created by the Life Insurance and Annuities (A) Committee at the NAIC 2019 Summer National Meeting. One of the original charges given to the Working Group was to "… consider the use of external data and data analytics in accelerated life underwriting . . . and, if appropriate, drafting guidance for the states." The Working Group has been considering the effects of accelerated underwriting in life insurance since 2019, and during that time the definitions of artificial intelligence and accelerated underwriting and their use in life insurance has evolved.

A significant portion of the early work of the AUWG benefitted from a multitude of presentations from the life insurance industry, actuarial consulting firms, a machine learning assurance company, and consumer advocate groups. These presentations are summarized in an educational paper (Appendix 1) adopted by the Life Insurance and Annuities (A) Committee at the NAIC 2022 Spring National Meeting.

The educational paper includes recommendations for insurers and regulators designed to ensure new technologies are utilized by life insurers in ways that comply with existing insurance law. While existing insurance laws vary from state to state, the recommendations acknowledge that most states: 1) require life insurance underwriting to be based on expected losses and expenses; 2) require insurers that collect consumer data to maintain that data in secure systems; and 3) prohibit unfair discrimination in insurance underwriting.

The AUWG presents regulatory guidance for State Departments of Insurance (DOIs) when reviewing Accelerated Underwriting programs used by life insurers. The regulatory guidance expounds on the recommendations the AUWG made in its educational paper and provides sample questions and areas for review for DOIs.

Also, the AUWG is making a referral (Appendix 2) to the Market Conduct Examination Guidelines (D) Working Group of the Market Regulation and Consumer Affairs (D) Committee with suggested additions to the NAIC's

[7] For purposes of this Regulatory Guidance, "Adverse Consumer Outcomes" has the meaning set forth in the Model AI Bulletin (See Appendix 4)..

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Market Regulation Handbook (MRH). The AUWG has concluded that it would be beneficial to include additional guidance in the NAIC's MRH that addresses questions involving Accelerated Underwriting in life insurance.

There are other NAIC groups working on similar or overlapping issues related to Accelerated Underwriting. The AUWG has considered and incorporated relevant content from the following:

From 2020:

- ***The National Association of Insurance Commissioners (NAIC) Principles on Artificial Intelligence (AI)***

On August 14, 2020, the NAIC membership adopted the *NAIC Principles on AI* (AI Principles) (Appendix 3). These AI Principles apply to insurance companies and all persons or entities facilitating the business of insurance that play an active role in the AI system life cycle, including third parties such as rating, data providers and advisory organizations (AI actors). The purpose of the principles is to inform and establish general expectations for AI actors and systems, emphasizing the importance of developing AI systems that are fair and ethical, accountable, compliant with insurance laws and regulations, transparent, and safe, secure, and robust. Both the educational paper and this regulatory guidance and referral rely on the expectations articulated in the AI Principles.[8]

From 2021:

- **The Casualty Actuarial and Statistical Task Force *Regulatory Review of Predictive Models White Paper*:**

The NAIC adopted the Casualty Actuarial and Statistical Task Force of Property and Casualty I Committee's *Regulatory Review of Predictive Models White Paper* (*Regulatory Review White Paper*) on April 14, 2021. The *Regulatory Review White Paper* was issued to help bring more consistency to the art of reviewing predictive models within property/casualty rate filings and make the review process more efficient.

From 2022:

- **The Market Conduct Annual Statement (MCAS) definition of Accelerated Underwriting**

The Market Conduct Annual Statement (MCAS) (D) Working Group under Market Regulation and Consumer Affairs (D) Committee is the national forum for states to define and revise the Market Conduct Annual Statement (MCAS) data elements and definitions. In 2022, the MCAS Working Group adopted additions to the Life and Annuity MCAS to collect basic information about products subject to Accelerated Underwriting, as well as the types of data the company uses in its Accelerated Underwriting. The MCAS includes the following:

> For this MCAS, data should be reported as Accelerated Underwriting when artificial intelligence and/or machine learning which utilizes, in whole or in part, Other Non-medical Third-party Data and/or FCRA Compliant Non-medical Third-party Data in the underwriting of life insurance is applied; including when that data is used in combination with Application Data or Medical Data.

The AUWG believes that the MCAS definition is consistent with the more detailed definition of Accelerated Underwriting that informed the educational paper.[9] Given that the AUWG regulatory guidance is contemplated

[8] The AUWG relied on the NAIC's AI Principles for the recommendations contained in its educational paper and believes that these AI Principles, coupled with the NAIC model references listed in the MRH Section F. Underwriting and Rating of Chapter 20—General Examination Standards, and Section F. Underwriting and Rating of Chapter 23—Conducting the Life and Annuity Examination, form the basis for additional examination review criteria that focus on Accelerated Underwriting in life insurance.

[9] AUWG's educational paper adopted the following definition: "Accelerated underwriting (AU) is the use of big data, artificial intelligence, and machine learning to underwrite life insurance in an expedited manner. The process generally uses predictive models and machine learning algorithms to analyze applicant data, which may include the use of non-traditional, non-medical data, provided either by the applicant directly or obtained through external sources. The process is typically used to replace

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for use by insurance departments during market conduct reviews and for inclusion in the MRH, the AUWG uses the MCAS definition for purposes of its regulatory guidance document to avoid any unintended confusion.

From 2023[10]:

- ***NAIC Model Bulletin: Use of Artificial Intelligence Systems by Insurers***

On December 4, 2023, the NAIC adopted the *NAIC Model Bulletin: Use of Artificial Intelligence Systems by Insurers* (AI Model Bulletin) (Appendix 4). The bulletin, when issued by a Department of Insurance: 1) reminds insurers that decisions or actions made or supported by AI must comply with all applicable insurance laws and regulations; 2) sets forth expectations as to how insurers will govern the development/acquisition and use of AI technologies and systems; and 3) also advises insurers of the type of information and documentation that the Department may request during an investigation or examination of any insurer regarding its use of AI technologies and systems.

The regulatory guidance follows the AI Model Bulletin. Specifically, the considerations, expectations, and questions about Accelerated Underwriting in life insurance contained in the regulatory guidance follow the expectations articulated in the first sentence of the AI Model Bulletin: "that decisions or actions impacting consumers that are made or supported by advanced analytical and computational technologies, including Artificial Intelligence (AI) Systems (as defined [in the bulletin]), must comply with all applicable insurance laws and regulations." The defined terms in the AI Model Bulletin also apply to the AUWG regulatory guidance.

Big Data and AI (H) Working Group 2023 Life Artificial Intelligence/Machine Learning Survey

The 2023 Life Artificial Intelligence/Machine Learning Survey (Life AI/ML Survey) was conducted to inform the work of the Big Data and Artificial Intelligence (H) Working Group in support of its charge to:

> Research the use of big data and artificial intelligence (AI) in the business of insurance, and evaluate existing regulatory frameworks for overseeing and monitoring their use. Present findings and recommended next steps, if any, to the Innovation and Technology (EX) Task Force, which may include model governance for the use of big data and AI for the insurance industry.

The results of the survey, summarized in a *Nov. 30, 2023 memorandum* (Appendix 5) and in the summary results chart (Appendix 6), confirm the importance of the development of regulatory guidance specific to the use of Accelerated Underwriting in life insurance.

In 2024 and ongoing…

- **Third-Party Data and Models (H) Task Force**

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all or part of traditional underwriting in life insurance and to allow some applicants to have certain medical requirements waived, such as paramedical exams and fluid collection."

[10] In 2023, Draft Model and Data Questions were developed and exposed for comment by the Big Data and AI (H) Working Group to help regulators assess whether, to what extent, and in what capacity AI and ML algorithms were used in insurer operations. The Questions are intended to help regulators perform regulatory oversight during an investigation or as related to rate model reviews. The document includes a spreadsheet to gather responses in a structured format. An initial draft was exposed for comment in 2023, however, the project was put on hold to focus efforts on developing the AI Model Bulletin.

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In 2024, the Third-Party Data and Models (H) Task Force was formed. The Task Force is charged to:

A. Develop and propose a framework for the regulatory oversight of third-party data and predictive models.
B. Monitor and report on state, federal, and international activities related to governmental oversight and regulation of third-party data and model vendors and their products and services. Provide recommendations to the Innovation, Cybersecurity, and Technology (H) Committee regarding responses to such activities.

The goal of this Task Force is to develop and propose an optimal regulatory framework for the regulatory oversight of third-party data and predictive models. The proposed regulatory framework may require new or modification of adopted model laws or regulations in 2025. The Third-Party Data and Models (H) Task Force will coordinate with other Innovation, Cybersecurity, and Technology (H) Committee activities and forums and place emphasis on transparency during the process.

- **Artificial Intelligence Systems Evaluation and Training Collaboration Forum**

The Innovation, Cybersecurity, and Technology (H) Committee established the concept of Collaboration Forums (CFs) as platforms for multiple NAIC groups to work together to identify and address foundational issues and develop a common framework that can inform the various workstreams across the NAIC Committee structure. CFs typically result in a series of events which may include webinars, or in-person components intended to advance an important policy matter.

An emerging CF is the Artificial Intelligence Systems Evaluation and Training Collaboration Forum, which includes several working groups and task force leads coming together for the purpose of developing exam standards for insurers using AI. The CF is also planning to oversee the development of AI training for regulators. The AUWG leadership is involved in this CF and in this role will help ensure that there is consistency around this topic across all lines of insurance.

- **The Privacy Protections (H) Working Group under the Innovation, Cybersecurity and Technology (H) Committee**

The Privacy Protections (H) Working Group is working on replacing the NAIC's Insurance Information and Privacy Protection Model Act (#670) and the Privacy of Consumer Financial and Health Information Regulation (#672) with one new model, *Consumer Privacy Protections Model Law* (#674). Model #674 is intended to address issues confronting state insurance regulators applying current model law and regulation requirements to consumer privacy notifications relative to insurance companies, insurance producers, and their third-party vendors access to consumer data via the internet, telematics, and other data tracking technology used in complex algorithms, including machine learning (ML) and artificial intelligence (AI). Although this group is addressing a unique set of issues, it will require coordination, especially with regard to definitions.

The AUWG supports the NAIC further developing regulatory guidance regarding the use of artificial intelligence in the insurance industry to help DOIs appropriately monitor the use of Accelerated Underwriting programs used by life insurers. As noted above, there is work currently underway which will inform future efforts on this topic.

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September 14, 2026

Brett Bache (RI), Chair
NAIC Market Conduct Examination Guidelines (D) Working Group
c/o Petra Wallace, Senior Market Regulation Specialist
Via email pwallace@naic.org

Re: Proposed Revisions to Market Regulation Handbook Chapter 20- General Examination Standards

Dear Chair Bache and Members of the Working Group,

The National Association of Mutual insurance Companies (NAMIC) and the American Property Casualty Insurance Association (APCIA) appreciate the opportunity to comment on the proposed revisions to Chapter 20- General Examination Standards of the NAIC Market Regulation Handbook.

NAMIC and APCIA recognize the NAIC's work on the Regulatory Guidance Document adopted by the Accelerated Underwriting (A) Working Group and subsequently adopted by the Life Insurance and Annuities (A) Committee at the 2024 NAIC Summer National Meeting. We support clear, appropriately tailored guidance for market conduct examiners reviewing life insurers' accelerated underwriting practices.

However, we respectfully recommend that this guidance be removed from Chapter 20 and instead be included in Chapter 23, Life Insurance Examination Standards. This placement would better align the guidance with its regulatory origin, subject matter, and intended application.

Chapter 20 is designed to establish examination standards relevant across nearly all regulated entities and lines of business, while Chapters 21 through 32 address standards specific to particular product lines and specialized entities. The accelerated underwriting guidance is focused on life insurance underwriting practices and was developed and adopted through NAIC life insurance and annuity policymaking processes. It is therefore more appropriately situated in the handbook's life insurance examination chapter.

Including the guidance in Chapter 20 could create uncertainty as to whether life-insurance-specific examination expectations are intended to apply to property/casualty insurers and other regulated entities. Moreover, Chapter 20 already provides examiners with a broad framework for evaluating underwriting and rating practices under applicable state law. It directs examiners to review underwriting guidelines, manuals, related records, and insurer compliance with their own standards, as well as potential unfair-discrimination issues. These generally applicable standards should remain distinct from specialized guidance developed for life insurance accelerated underwriting.

Accordingly, NAMIC and APCIA respectfully request that the NAIC relocate the proposed accelerated-underwriting market conduct examiner guidance from Chapter 20 to Chapter 23. Doing so would preserve the intended cross-line nature of Chapter 20, ensure that the guidance is clearly limited to its appropriate life insurance context, and support more focused and efficient market conduct examinations.

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Thank you for your consideration. We welcome the opportunity to discuss these comments further.

Respectfully Submitted,

Lisa Brown, JD, MCM
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Market Conduct and Counsel
APCIA

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Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:
The standards set forth in this chapter are based on state procedures, not on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination process. Since there are limits to state procedures and state laws vary, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in Chapter 1—Introduction.

This chapter provides a suggested format for conducting pharmacy benefit manager (PBM) examinations and reviews. In addition to this chapter, the examiner should be familiar with the NAIC white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (NAIC White Paper*)*.

Background, Scope and Types of Examinations

"Pharmacy Benefit Manager" is defined in the NAIC White Paper as entities that negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. Insurers, employers, other payors, and even other PBMs contract with PBMs to design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols). PBMs engage in negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

PBM examinations can be either comprehensive or targeted. A PBM examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the PBM's systems and procedures are similar, if not identical, for every state, the examination and resulting report should be acceptable in all states, regardless of which jurisdiction conducts the examination.

Unlike insurance company examinations, currently there are generally little, if any, "market analysis" procedures or tools developed to assist in the conduct of PBM examinations. Similarly, PBMs are not regulated for solvency. Rather, PBMs negotiate on behalf of insurers and other PBMs and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related items. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. In addition, PBMs contract directly with Pharmacy Services Administrative Organizations (PSAOs), who provide administrative services to independent pharmacies, including, but not limited to, contract negotiations with PBMs.

For additional information on background and scope, please refer to Chapter 12 and Chapter 13 of this handbook.
Key Terms:

Regulators must consider state specific definitions when conducting a PBM Examination.

340B Pharmacy – a pharmacy that dispenses outpatient drugs purchased at significant discounts by eligible "covered entities" such as safety-net hospitals, clinics, and health centers under the federal 340B Drug Pricing Program. These pharmacies are often excluded from additional drug manufacturer rebates for certain drug claims.

Note: The term "340B" is derived from the section of the Public Health Service Act (PHSA), 42 U.S.C. 256b, from which the 340B Program is defined.

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Affiliated Pharmacies – refers generally to pharmacies that are formally connected to or associated with a larger organization, such as a health system, hospital, or a PBM, through ownership, partnership, or contracted arrangement.

Biologic Drugs - are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, certain vaccines, and cell and gene therapies. Biologics are sometimes referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the U.S. Food & Drug Administration (FDA) to sell their products through a separate application process. Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.

Biosimilar Drugs - are FDA approved as having no clinically meaningful difference from the referenced product and may be produced following the expiration of the biologic's patent and exclusivity period. Biosimilar drugs are listed in the FDA Purple Book and are not considered "generic" of their brand referenced biologic product.

Brand Name Drugs - are medications discovered, developed, and marketed by a pharmaceutical company under a specific, patented, and trademarked name. These original, FDA-approved, or regulatory-approved drugs have exclusive marketing rights for a set period to recoup research costs, often making them more expensive than generic alternatives. Brand name drugs are often designated as the "Reference Listed Drug" in the FDA Orange Book.

Chain Pharmacy – Unless otherwise defined in the state, a chain pharmacy is owned, operated, or controlled by a corporate-owned entity, generally defined as four or more locations, often operating under a shared corporate banner and utilizing centralized management.

Covered Entity – means, as defined in 45 CFR 160.103, a health plan, a healthcare clearinghouse, or a health care provider who transmits health information electronically in connection with covered transactions.

Generic Drugs - are small molecule drugs that are therapeutically equivalent to their reference brand name drug. Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Like brand-name drugs, the FDA must approve a generic drug application called an Abbreviated New Drug Application to ensure its bioequivalence to the brand-name drug before it can be produced. Generic drugs comprise the largest portion of the pharmaceutical market.

Independent Pharmacy – unless otherwise defined in the state, a pharmacy that is privately and independently owned and operated by one or more pharmacists or under common ownership with not more than three pharmacies and whose primary function is to provide direct pharmaceutical care to patients. These services can include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling in a community setting.

Insurers – entities that contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees. Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management. In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including, but not limited to, utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks. Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

Long-Term Care (LTC) Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses medications and delivers them directly to a licensed long-term care facility, such as a nursing home, group home, or specialized health care facility, and generally does not provide medications to inpatient hospitals.

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Mail-Order Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses prescription medications and delivers them directly to a patient's home, workplace, or preferred location through the mail or courier service.

Payors - include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (individual, small group, large group, government programs) and the arrangement that the payor chooses. In this chapter, when PBM functions are referenced, payors may choose to do those tasks internally.

Pharmaceutical Manufacturers or Manufacturers - research, develop, produce, market, and sell prescription drugs to treat medical conditions. The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition. Pharmaceutical manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Pharmaceutical manufacturers may also purchase prescription drugs developed by other manufacturing companies to market as their own. Pharmaceutical manufacturers may also offer patient assistance programs and direct-to-consumer programs for some of the drugs they market.

Pharmacies - a place licensed by a state Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed. A pharmacy may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling, and other health care related functions, as permitted by the state in which the pharmacy is licensed.

Pharmacists - are licensed and trained health care providers that assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a medication to a patient to ensure patients do not receive the wrong drug or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals. Pharmacists are licensed by a State Board of Pharmacy and are permitted to conduct various levels of health care services in different states, depending on state licensure requirements.

Pharmacy and Therapeutics (P&T) Committee – are expert, multidisciplinary groups, which are usually comprised of physicians, pharmacists, and other health care professionals, that evaluate clinical, safety, and economic evidence for prescription drugs. P&T Committees determine which medications are covered, create formularies, and manage utilization policies, such as prior authorization.

Pharmacy Benefit Managers (PBMs) - provide claims processing services or other prescription drug services on behalf of insurers or administer an insurer's prescription drug coverage pursuant to its contract or under an employment relationship with an insurer or health plan that directly manages the prescription drug coverage provided by the insurer or health plan. Insurers determine through contractual delegation which activities a PBM may perform on their behalf, which may include negotiating and contracting with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs may also develop, negotiate, implement, or administer clinical, formulary, or other preferred lists for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers and other entities. PBMs may be delegated the responsibility of the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example ,drug coverage tiers, and utilization management protocols). PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

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PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews (DURs).

Pharmacy Benefit Manager Network –is a contracted, organized group of retail, mail-order, specialty, and other pharmacies established by a PBM to provide covered prescription drug services to health plan members. Pharmacies within the network have specific reimbursement rates, terms, and, in some cases, performance-based quality measures.

Pharmacy Services Administrative Organizations (PSAOs) - are organizations that provide administrative services to independent pharmacies. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly. The PSAO's overall administrative function is to assist with contract evaluation and execution with the PBM or wholesaler, customer service, central payment and reconciliation, and patient data evaluation. In many instances a PSAO is owned by a wholesaler.

Rebates or Manufacturer Rebates – are a post-purchase discount or price concession paid by pharmaceutical manufacturers directly or indirectly to rebate aggregators, group purchasing organizations (GPOs), PBMs, covered entities, or health insurers. These payments are typically negotiated in exchange for favorable placement of a drug on a health plans' formulary and may be described as reducing the overall cost of drugs for covered entities or payors.

Note: Rebates may also apply when speaking of wholesaler or pharmacy rebates, which are contractual incentives paid to pharmacies based on specific performance metrics. For purposes of this chapter unless otherwise specified, the term "rebates" includes "manufacturer rebates."

Specialty Drugs - is a term that generally refers to drugs and biologics that are typically high-cost, and can be complex to ship, or store, require specialized administration, subject to limited or exclusive distribution, or may require specialized clinical care, such as frequent dosage adjustments, intensive patient monitoring or counseling, or ongoing clinical support (i.e. high-touch).It often references medications used to treat rare, complex, life threatening, or chronic conditions. Because of this, these drugs often dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

Note: There is no unified regulatory definition of the term "specialty drug." Examiners should consult applicable state law and impacted health plan formulary definitions.

Specialty Pharmacy – is a type of pharmacy that dispenses specialty medications. Specialty pharmacies often hold limited-distribution contracts with a pharmaceutical manufacturer to be one of just a few pharmacies authorized to dispense a particular specialty medication. Specialty pharmacies may offer in-depth patient support such as clinical patient management.

Utilization Review – which is also known as utilization management or DUR, includes using predetermined criteria for appropriate drug therapy, utilizing patient-specific information to ensure safe and effective use of drug therapy to potentially lower the overall cost of health care. Types of utilization review include prospective, concurrent, and respective utilization review. PBMs and/or payors may develop utilization review standards to evaluate and approve or deny services when compared to clinical need, cost, and established national guidelines.

Wholesalers/Distributors - Wholesalers purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. Wholesalers own several of the largest PSAOs used by independent pharmacies.

Qualifications of Examiners

Information on qualifications, please refer to Chapter 14 of this handbook**.** In addition, states might want to include a pharmacist or other PBM-specific qualifications to the examination team.

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Types of Examinations

When planning the examination, it is helpful to first identify which services and products are regulated and the impact on regulated entities. A PBM examination can take the form of a comprehensive examination, a targeted examination, a risk-focused examination, a re-examination, a multistate cooperative examination or a desk examination. Most of the elements found in Chapter 13—Types of Examinations will apply to the PBM examination. Because most operations for these entities remain consistent in all states, it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Scheduling, Coordination and Planning Scope

The procedures discussed in this section are to assist the regulator in determining if an examination or other type of regulatory action needs to be scheduled. It will also assist in developing a plan for conducting examinations, investigations, desk audits, interrogatories, letters or interviews when deemed necessary.

1. Determine the jurisdiction's requirements for licensing and examining the PBM and determine if the jurisdiction is permitted to accept the examination report of another state;
2. Survey appropriate divisions within the insurance department to identify potential areas of concern or interest relating to PBMs operating in the jurisdiction.
3. For those PBMs for which a recent and current examination report has been made public and no unaddressed regulatory concerns exist, no additional analysis should be necessary. If analysis indicates that a market regulation action—such as a desk audit, letter, interrogatory, interview, investigation or examination—is appropriate, consider the possibility of coordinating with other jurisdictions with similar requirements or market regulation issues. Consider use of NAIC tools such as the Market Action Tracking System (MATS) for recording continuum types of regulatory responses and communicating with members of the Pharmacy Benefit Manager Examination Oversight (D) Working Group for multistate coordination of regulatory responses.
4. Survey the NAIC Research Division for relevant information to identify potential areas of concern in the evaluation process; and
5. Determine what specialists may be necessary to assist with the examination, such as a licensed pharmacist (ideally one with experience with the functions of a PBM or pharmacy operations).
6. Due to the complexity of pharmacy claims data, a comprehensive data dictionary shall be developed for all requested datasets. The data dictionary must clearly define all data fields, formats, and required inputs and shall be reviewed and finalized to ensure mutual understanding and agreement among all parties before data collection begins. The regulator may develop the data dictionary or may work with the PBM to develop the dictionary. The final regulator-approved data dictionary shall be used by the PBM. Any questions, clarifications, or necessary revisions must be addressed and resolved before data extraction occurs in order to minimize discrepancies, ensure data integrity, and prevent delays during the examination process.

For very narrow or specific regulatory issues, or for situations in which an examination is not required by statute, consider use of regulatory options other than an examination. For example, certain issues can be handled by a telephone call, letter or email; a data request; policy and procedure review; interrogatories; or desk audits. The remainder of this chapter is primarily written to facilitate examinations; however, certain information may be adaptable for the above-mentioned "continuum" type responses. An additional discussion of continuum of market actions is in Chapter 2 of this handbook.

Procedural Considerations

Although not an insurance company examination, the basic procedures for a market conduct examination in Chapter 20 of this handbook should be followed in a PBM examination:

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;

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- Notification of the examination;
- Preexamination procedures;
- On-site coordination, if applicable;
- Data calls;
- Sampling;
- Test procedures;
- Communication management;
- Post-examination procedures; and
- The examination report.

Where possible, each state's defined examination protocols applicable to the examination of insurers—such as time frames and report submissions—should be applied to PBM examinations, as well.

Writing the Examination Report
The report preparation elements as outlined in Chapter 19 of this handbook are generally applicable to PBM examinations. However, the following special considerations also apply:

- In addition to safeguarding the confidentiality of individual policyholder information, care should be taken to not disclose trade secret information of the examinees or insurers that are customers of the examinees (e.g., individual insurer information in class or territory detail, or the processes and procedures of the examinee). The PBM should be given the opportunity to mark exhibits and/or portions of the report as "confidential and proprietary," if such is allowed under state law and these are not subject to otherwise applicable public release laws outside the regulatory community; and
- The PBM should be given the opportunity to review the examination findings prior to issuing a final report, if such practice is consistent with the state's insurers' examination act or other applicable statute.

Use of Examination Standards
Each of the following examination standards may be applicable to specific functions performed by a PBM. The examination plan should indicate which standards for review will be used for each specific examination.

A. PBM Operations/Management
B. PBM Pricing and Methodologies
C. Contracts
D. Pharmacy Claims
E. Pharmaceutical Manufacturer Rebates
F. Pharmacy Network Adequacy
G. Utilization Review
H. Drug Formulary, Placement, and Specialty Drug
I. Complaints, Grievances, and Appeals
J. Pharmacy Audits

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A. PBM Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

The following standards would be the most applicable to a PBM examination.

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.
Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.
Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.
Standard 4 - The PBM has a valid disaster recovery plan.
Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.
Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.
Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.
Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.
Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.
Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.
Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.
Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.
Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

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B. PBM Pricing and Methodologies

STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 1
The PBM demonstrates it does not charge a covered entity, payor, or health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ Complete and unredacted contracts between the PBM and health plan.

_____ Complete and unredacted contracts between the PBM and pharmacy.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges.

_____ A schedule of claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to the covered entity, payor, or health plan for each prescription drug claim.

_____ Documentation of health plan billings during the exam period including a itemized breakdowns.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's

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policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 2
The PBM demonstrates the difference in its payment rates received by a covered entity, payor, or health plan compared to the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ An index of all policies and procedures relating to the PBM's payment to pharmacies.

_____ Complete and unredacted contracts between the PBM and health plan.

_____ Complete and unredacted contracts between the PBM and pharmacies.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to the covered entity, payor, or health plan for each prescription drug claim.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFIT MANANGERS
PBM PRICING METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent payment methodologies for reimbursement of all drugs that enable a pharmacy to understand the reimbursement amount for each claim prior to the pharmacy submitting the claim for reimbursement.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all policies and procedures relating to pharmacy reimbursement.

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to the pharmacy reimbursement method being examined. Request documents in an unredacted format.

_____ PBM contracts with pharmacies in an unredacted format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's pricing methods that it sends to pharmacies.

_____ All documents provided to pharmacies that support or describe the PBM's reimbursement amounts to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.

____ All contracts between the PBM and any third-party entities that may process prescriptions on behalf of the PBM or the PBM's clients, including but not limited to, any drug discount coupons or programs from manufacturers or drug discount entities.

_____ Contracts with the PBM and the insurer or employer group that include any references to the requirements for PBM's reimbursement to pharmacies and that describe the insurer's or employer group's oversight of the processes. Request the entire contract in an unredacted format.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing

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fee. For example, any claims processing fee applied to the claim.

- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

Others Reviewed

____ _____

____ _____

Review Procedures and Criteria

Review all contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, drug discount or manufacturer coupon contracts. Ensure all contractual language is transparent and sufficiently clear to enable the pharmacy to understand the payment rate prior to the pharmacy being paid.

- Assess how the PBM determines the drug pricing source it uses to reimburse each drug type including generic, brand and specialty drugs. Confirm the selection of the drug pricing source is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plain language.
- Assess the PBM's ability to change the drug pricing source selection, for example through application of the "lessor of logic" method. Confirm the "change" process is transparent and communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. If the PBM contract language gives the PBM authority to change this drug pricing source, assess how that change occurs, how often it occurs, how it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.
- Assess whether the PBM applies any "discounts" or other methods of reducing the amount of the selected drug pricing source. If the PBM does reduce the amount of the drug prior to paying the pharmacy, ensure that the "discount" reduction amount is transparent and communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.
- If the PBM does apply "discounts" or otherwise reduce the amount of the drug pricing source, ensure the contract language describes the extent of the PBM's ability to change this "discount," how that change occurs, how often it occurs, how and when it is communicated to the pharmacy, and whether the change can be done with or without the pharmacy's consent.

Review contracts between the PBM and the insurer or employer group to determine whether the pricing methodologies described to pharmacies are consistent with the PBM's requirements described in the insurer's or employer group's contract with the PBM.

Review a sample of (or all) claims to ensure the PBM follows its own policies and procedures regarding reimbursement of pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, LTC, 340B, specialty or affiliate. Review "discount" amounts applied

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for claims to assess whether the PBM's description of the "discounts" to pharmacies is consistent with the actual reimbursement amounts. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment should be consistent across pharmacies within the same network.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 4
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies or all brand effective rate (BER) policies. Request documents in an unredacted format.

_____ PBM contracts with pharmacies or PSAOs in an unredacted format.

_____ All notices, amendments, updates, or other communications describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.

_____ All documents provided to pharmacies that support or describe the PBM's effective rate reconciliation process and calculation to specific pharmacies, including but not limited to retail, mail order, specialty, or affiliate pharmacies.

_____ All reports or accounting documents provided to pharmacies or PSAOs showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and claims data.

_____ Request all claims data for a specified pharmacy and time period in a standardized template showing how each claim was "reconciled" by the PBM. Claims detail may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category;
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its initial payment to the pharmacy when the pharmacy submitted the claim.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.

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- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid the pharmacy when it submitted the claim; the amount should not include the dispensing fee).
- The total initial reimbursement of any dispensing fee.
- The reconciled percentage of "discount" applied to each claim or batch of claims.
- The total final reimbursement amount for each drug claim or batch of claims after reconciliation. This should not include the dispensing fee amount.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each drug. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO.
- The type of health coverage being reimbursed. For example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim. For example, paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.

_____ Contracts with the PBM and the insurer or employer group that include any references to the requirements for PBM's effective rate reconciliation process with pharmacies and that describe the carrier or employer group's oversight of the processes. Request the entire contract in an unredacted format.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, provider updates or manual amendments. Ensure all contractual language is transparent and sufficiently clear to enable the pharmacy to understand how the effective rate reconciliation process will be implemented prior to the PBM beginning the annual (or quarterly) reconciliation.

Request a listing of all network pharmacies or PSAOs that have an effective rate contract and all pharmacies or PSAOs that do not have one. Ensure the PBM is offering contracts to all similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer an effective rate contract to any specific pharmacies or pharmacy types, such as independent pharmacies. Understanding which pharmacies have an effective rate contract will assist the regulator in ensuring the PBM is compliant with state laws. For example, if a state requires NADAC payment for each drug, the regulator will not expect to see any effective rate contracts in that state.

Assess how the PBM determines which claims will be part of the reconciliation process, including categories of claims that are included and excluded in accordance with contract language. Confirm the selection of the claims is communicated to the pharmacies in clear and concise language.

Review all documents and communications sent from the PBM to the pharmacy as part of the reconciliation process. This should include but not be limited to any reconciliation reports, any claims data that is provided or can be requested by the pharmacy, any emails or other correspondence between the PBM and the pharmacy. Ensure all communications from the PBM provide sufficient detail to enable the pharmacy to understand the process and that all questions are appropriately addressed.

- If PBM provides any reports or charts to the pharmacy, ensure the document explains all use of acronyms and claims categories through use of a key.
- Review all documents describing the final reconciliation amount that may be owed to or from pharmacies or

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PSAOs. Does the PBM provide reasonably sufficient detail to ensure that pharmacies understand how and when they will receive payment or make payments, if applicable.

- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that it enables pharmacies to provide information to the PBM that may change the outcome of the reconciliation amount? Consider requesting specific examples of correspondence to review.

Review a sample of (or all) claims to ensure the PBM follows its own policies and procedures regarding reconciliation process. Compare the original "discount" and price paid to the pharmacy to the reconciled "discount" and price to determine if the reconciled "discount" applied to each claim or batch of claims is within the contractually stated "discount" amounts. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.

Review contracts between the PBM and the carrier or employer group to determine whether the reconciliation process as described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Consider verifying the accuracy of all the data and reports sent from the PBM with the pharmacy or pharmacy group. For example, if the PBM provides an annual report of all reconciled claims, did the pharmacy receive the same version?

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 5
The PBM demonstrates it has transparent payment methodologies for the dispensing fees of all drugs that enable a pharmacy to determine the dispensing fee amount paid for each claim.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all policies and procedures relating to pharmacy dispensing fees.

_____ All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted format.

_____ PBM contracts with pharmacies in an unredacted format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.

_____ All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to retail, mail order, specialty, or affiliate pharmacies.

_____ Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the insurer or employer group's oversight of the processes. Request the entire contract in an unredacted format.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category.
- The drug pricing source used for reimbursement of each claim at the time of adjudication.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source drug copay copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final ingredient cost reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.

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- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when the PBM reimbursed the pharmacy, to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons, including applicable rejection codes. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

**This information may be pared down if the regulator is only looking at dispensing fees and not all claims data. However, pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost lists, drug discount or manufacturer coupon contracts. Ensure all contractual language is transparent and sufficiently clear to enable the pharmacy to understand the dispensing fee payment prior to the pharmacy being paid.

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language.

Assess the PBM's ability to change the dispensing fee amount. Confirm the 'change' process is transparent & communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

Review contracts between the PBM and the carrier or employer group to determine whether the payment of dispensing fees described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Review a sample of (or all) claims to ensure the PBM follows its own policies and procedures regarding dispensing fees paid to pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, LTC, 340B, specialty or, if the pharmacy is affiliated or not affiliated with the PBM. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment of dispensing fees should be consistent across pharmacies within the same network.

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C. Contracts

STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACIES)

Standard 1
The PBM demonstrates that it exercises good faith and fair dealing in its contracting and contract negotiation processes with pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

_____ From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted format.

_____ A listing of all pharmacies in the PBM's network. The listing should also require the PBM to provide a listing of all contracts (including provider manuals) and contract amendments the PBM has in place with each pharmacy. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document.

_____ All documentation and correspondence, including but not limited to emails and red-lined documents, between pharmacies and the PBM that pertain to the contact and contact amendments. The documentation should provide examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, independent, mail order, LTC, 340B, specialty, or affiliate. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location. Standards should be applied in a non-discriminatory manner such that the PBM does not favor affiliate over non-affiliate pharmacies, for example.

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Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Examples include how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as who can submit the information and how i.e. via email, web portal or postal mail, any fees required. Ensure the PBM's contracting process is described to pharmacies in clear and concise language such that the pharmacies understand how to request changes to the contract terms.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for the PBM's review, how the PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review the documentation to assess whether the PBM is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with pharmacies.

Review the PBM communications to pharmacies to assess the PBM's responses to pharmacy negotiation requests. Ensure the PBM provides sufficient information to support or deny the pharmacy's requests. Ensure PBM contracting process is not unilateral or one-sided to prevent pharmacies from negotiating.

Review the PBM's communications to pharmacies to assess if the PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether the PBM appears to contract with certain pharmacy types and not others. For example, does the PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM to provide an explanation for such outcomes.

Assess how the PBM responds to pharmacy inquiries about the PBM's or the pharmacy's contractual obligations. For example, does the PBM have processes for pharmacies to initiate inquiries or obtain assistance from the PBM? Assess the PBM's responses to pharmacies during the inquiry process. Assess whether the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's response or final determination. Review specific examples of inquiries and follow-up from the PBM.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 2
The PBM demonstrates that it exercises good faith and fair dealing in implementing its contractual obligations with its vendors that work with its network pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all contracts with vendors that provide pharmacy benefits management services on behalf of the PBM and that interact with the pharmacy. The index should include a description of the services provided by each vendor and how the services impact pharmacies.

_____ From the index provided, review all policies and procedures that are applicable to the practices with the pharmacies being examined. Request documents in an unredacted format.

_____ Unredacted PBM contracts from vendors that provide pharmacy benefit management services on behalf of the PBM.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, independent, mail order, LTC, 340B, specialty, or affiliate. Standards should be applied in a non-discriminatory manner such that the PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example.

Review policies and procedures for providing information to pharmacies about vendors with whom the PBM contracts to perform certain functions. Review all documentation to assess if the PBM provides reasonably sufficient information to pharmacies such that they would understand the exact function of the vendor and how the pharmacy is to interact with the vendor.

Review contracts between the PBM and its vendors to ensure the PBM does not permit its vendors to engage in activities that are prohibited under state law. For example, if state law prohibits a PBM from charging fees to a pharmacy, the PBM should not have a contract with a vendor that allows the vendor to charge the prohibited fees.

Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its

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affiliate pharmacies over non-affiliated pharmacies.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 3
The PBM demonstrates that it has a reasonable and easily accessible dispute resolution process for pharmacies to address matters of conflict with the PBM.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ A data dictionary or list (and definitions) of all types of disputes that it considers "disputes." This may include but not be limited to complaints, independent third-party reviews, and arbitration.

_____ An index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.

_____ From the index provided, request all policies and procedures that are applicable to dispute resolution process being examined. Request documents in an unredacted format.

_____ PBM documentation showing how disputes are addressed and finalized. The PBM should provide examples of actual disputes and provide all documentation sent to or received by a pharmacy showing how the dispute was initiated, the correspondence between the PBM and pharmacy, any documentation that is exchanged, and documentation showing how the dispute is resolved.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding the PBM's dispute resolution process with pharmacies. Review criteria for the different types of disputes to assess whether the PBM has clear protocols, timeframes, and documentation requirements for addressing and resolving each type of dispute.

Review contracts and manuals for details provided to pharmacies about the dispute resolution process. Review how the PBM informs pharmacies of how disputes may be initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail, any fees required), the PBM's obligation to provide a justification for the final determination and timeframes for PBM response and resolution of the dispute.

Review contracts and manuals with details about the dispute resolution process to ensure the information provided to pharmacies is clear, concise, and easily understood.

Assess whether the PBM's requirements for pharmacies are convenient and accessible or whether the requirements create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute.

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Examples of requirements that may dissuade a pharmacy from initiating a dispute may include but are not limited to, requiring pharmacies to initiate disputes and send supporting documentation solely through postal mail or requiring exorbitant fee amounts to request or initiate a dispute resolution process.

Assess the PBM's responses to pharmacies during the dispute resolution process. Ensure the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's final determination.

Ensure the PBM's policies and procedures and implementation of those policies and procedures are consistent with state law.

Assess whether the PBM has staffing models to effectively resolve disputes.

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D. Pharmacy Claims

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY CLAIMS

Standard 1
The PBM demonstrates that it has timely and transparent claims submission and adjudication processes for pharmacy claims that enable pharmacies to understand the payment rate prior to claims submission.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format

_____ An index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ An index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.

_____ Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted format.

_____ Other than contracts and manuals, request all documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted format.

_____ All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format.

_____ All contacts with carriers or employer groups in an unredacted format.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.

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- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

_____ Regulatory actions

Others Reviewed

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Review Procedures and Criteria

Review policies and procedures related to the requirements for pharmacies to submit claims that may include but are not limited to the following:

- Claims processing software requirements.
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.
- Any applicable NCPDP standards.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:

- Dispensed as written codes
- Over-the-counter products
- Multi-ingredient compound processing
- Override
- Coordination of benefits
- Reversals
- Submission timeframes

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:

- The PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any "discount" the PBM may apply to reduce the reimbursement amount paid to the pharmacy
- The PBM should have clear criteria for claims approvals, denials or rejections at the point of sale.
- The PBM should have clear timeframes for claims adjudication either through payment or rejection of the claim.
- The PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is rejected, which may include providing reject codes that can be reviewed by the pharmacy.
- The PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or appeals for example, about any claims that are rejected or denied. *This would not include coverage appeals initiated by a consumer.*

Review all PBM policies and procedures to assess whether the PBM applies different standards to different types of claims such as self-funded, specialty drug, mail order, nonresident or discount card claims. Verify that any

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differing standards are consistent with state law.

Review all pharmacy contracts, including any Provider Manuals, to ensure the claims submission and adjudication processes are clearly and concisely described to pharmacies. The PBM should provide pharmacies with detailed information about:

- Each step necessary to submit a claim.
- The process and timeframe for the PBM to review and make a determination about whether a claim will be paid.
- How a pharmacy may submit an inquiry, appeal, or otherwise contest the PBM's response to a pharmacy's claim. Information should include timeframes for each step in the process and should describe an easily accessible process for the pharmacy.
- Ensure information describes how pharmacies are reimbursed in accordance with applicable laws that may dictate payment amount and applicable dispensing fees.

Review all documentation to assess whether the PBM provides reasonably sufficient information about its claims payment methodology to ensure that pharmacies understand what they will be paid prior to submitting claims. This should include but not be limited to:

- If the PBM publishes a Maximum Allowable Cost (MAC) list, the list is readily available and useful to pharmacies. Does the listing provide a "search" function to find a specific drug or is the list formatted in a way that requires the pharmacy to scroll through thousands of drugs to find a specific drug? The latter would not be reasonable.
- If the PBM applies a "discount" or other type of reimbursement reduction to the drug pricing source it uses to pay pharmacies, is that discount reasonably described in documentation to pharmacies such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a "discount" and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, is that process clearly described to pharmacies? Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Can the pharmacy "opt-in" or "opt-out" of any such programs? Does the PBM provide reasonably sufficient information such that the pharmacy will know its reimbursement level prior to submitting the claim?

When requesting claims data, require the PBM to submit ***all*** claims being examined, including a specific description of the claims being requested, including distribution channels (chain, independent, mail-order, LTC, 340B, or specialty), as well as lines of business (e.g. fully insured, Medicare, Medicaid, self-insured—ERISA, self-insured non-ERISA, etc.). In addition, consider including the scope of claims in the description (e.g. all pharmacies with physical locations in the state, member claims filled in the state, claims filled for members covered by health plans situsedin the state, or some other criteria). Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of a dispensing fee. Ensure the PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

Consider requesting the PBM provide a live demonstration of its claims adjudication process for a sample of each type of claim being examined which may include but not be limited to: claims that are approved, claims that are denied, claims that are rejected, claims that are mail order only, claims that are for self-funded employer groups, or claims that are for fully insured plans.

Review all, or a sample of PBM contracts with carriers/employer group to assess if the PBM is compliant with the claims payment requirements in those contracts and that those terms are consistent with in all messaging to pharmacies. For example, if pass-through pricing is required by the insurer contract, is that consistent with the payment method (and applicable description) to pharmacies?

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E. Pharmaceutical Manufacturer Rebates

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to aggregators, group purchasing organizations, or affiliated entities), administrative fees, credits, incentives and penalties are passed through to health plans, payors, patients, or covered entities as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ All policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans, payors, or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request document in unredacted format.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ A listing of all health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____ Complete and unredacted contracts between the PBM and all applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates, fees, and discounts received by the PBM and/or amounts remitted to health plans.

_____ All standard rebate reports provided to health plans during the examination period, including data

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dictionaries and field definitions.

_____ All claims data and rebate data for a specified time period in a standardized template sufficient to link:

- Pharmacy information including, but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The NDC and units are integral parts of the rebate transaction and must be included in the data dictionary.
- The rebate eligibility of the claim/drug.
- The rebate amount invoiced of the drug/claim.
- The rebate amount collected of the drug/claim.
- The rebate amount retained by the PBM.
- The rebate amount remitted to the health plan.
- The timing of each rebate transaction (claim versus rebate invoicing versus collection).

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates exist governing the identification, invoicing, collection, accounting, allocation, and remittance of manufacturer rebates, fees, and discounts, and whether those standards comply with state requirements.

Review contracts between the PBM and health plans, carriers, or employer groups to determine:

- Whether rebates are required to be passed through in full, in part, or retained by the PBM;
- If rebates are to be passed through in full or in part, are they allocated to the health plan, payor, and/or patient as authorized by law or contract;
- Whether administrative fees or other retained amounts are expressly permitted; and

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- Whether spread pricing or other pricing methodologies are authorized under the contract.

Review contracts between the PBM and pharmaceutical manufacturers or rebate aggregators to determine the types of remuneration received, the methodology used to calculate rebate amounts, and the timing of rebate payments.

Assess whether the PBM's descriptions of rebate practices in its contracts with health plans are consistent with its contractual arrangements with pharmaceutical manufacturers and affiliated rebate entities.

Determine whether the PBM has established processes to ensure that all rebate-eligible claims are accurately identified and included in manufacturer rebate submissions. Evaluate whether the PBM maintains controls to prevent the omission or misclassification of rebate-eligible claims.

Review all rebate transactions and associated pharmacy claims to verify that:

- The units for each NDC is applied appropriately and rebates are invoiced timely and appropriately in accordance with contractual and statutory requirements;
- Rebate amounts invoiced to manufacturers are supported by underlying claims data;
- Rebate amounts collected from manufacturers are consistent with contractual terms; and
- Rebate amounts remitted to health plans are calculated and transmitted in accordance with contractual and statutory requirements.

Assess whether rebates are remitted to health plans within required contractual or statutory timeframes and whether any delays are supported by documented reconciliation or dispute processes.

Where spread pricing is permitted under the contract between the PBM and the health plan, review claims and rebate data to determine whether the PBM's retention of spread or rebate amounts is consistent with the express terms of the contract and is accurately disclosed in required reporting to the health plan.

Review claims payment, pharmacy reimbursement, and rebate data collectively to ensure that drug ingredient cost, dispensing fees, administrative fees, alternative payment programs, discounts, accumulators, maximizers, spread pricing (if applicable), and manufacturer rebates are applied and reported in a consistent and transparent manner across all PBM financial transactions associated with a claim.

Assess whether the PBM provides health plans with reasonably sufficient detail in its reporting to enable the health plan to independently verify rebate calculations, collections, and remittances. Reports should allow reconciliation from manufacturer payment to claim-level utilization.

Determine whether the PBM applies differing rebate allocation methodologies across lines of business (e.g., fully insured, self-funded, independent, chain, LTC, specialty pharmacy) and verify that any such differences are permitted under applicable contracts and law.

Evaluate whether 340B pharmacies are included in rebate allocation and determine if permitted under applicable contracts and law.

Evaluate whether any affiliated pharmacies, specialty pharmacies, or PBM-owned entities are treated differently in rebate attribution or allocation and verify that such practices are disclosed and permitted under contract.

Where point-of-sale rebate crediting is used, review system logic, claims adjudication rules, and financial settlement processes to verify that rebate amounts applied at the point of sale are accurately calculated and reflected in both member cost sharing and health plan financial reporting.

Determine whether the PBM maintains adequate internal controls, audit trails, and reconciliation processes to ensure completeness and accuracy of rebate invoicing, collection, and remittance.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly reported to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ All policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request documents in unredacted format.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ A listing of all health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____Complete and unredacted contracts between the PBM and all applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates, fees, and discounts received by the PBM and/or amounts remitted to health plans.

_____ All standard rebate reports provided to health plans during the examination period, including data dictionaries and field definitions.

_____ All claims data and rebate data for a specified time period in a standardized template sufficient to link:

- National Drug Code (NDC);
- Claim identifier;
- Dispensing date;
- Rebate eligibility;

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- Rebate amount invoiced;
- Rebate amount collected;
- Rebate amount retained by the PBM;
- Rebate amount remitted to the health plan; and
- Timing of each rebate transaction.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the preparation of statutorily required reports exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the preparation of statutorily required reports.

Determine if the statutorily required reports to the regulator were complete, accurate, and timely filed.

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F. Pharmacy Network Adequacy

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for all pharmacies in its network and is able to demonstrate its credentially criteria from the beginning of the process to the end.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ Pharmacy contracts and manuals with the PBM's language relating to credentialing.

_____ An index of all internal policies and procedures for the credentialing process.

_____ All policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted format.

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for all pharmacies and pharmacy staff including but not limited to the pharmacist in charge (designated in different states as Supervising Pharmacist or Pharmacy Manager, etc), staff pharmacists, nationally certified and non-certified pharmacy technicians, and any customer service representatives/pharmacy clerks. Scope of practice and licensure are governed by the laws and regulations of each State Board of Pharmacy and should be reviewed as it pertains to that particular state. Review all exclusionary criteria such as requirements that pharmacists cannot be excluded or revoked by any licensing board.

Review any requirements for other personnel including but not limited to pharmacy owners, officers or directors. Review all exclusionary criteria that may apply.

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Review all requirements for pharmacies including but not limited to application documents, insurance requirements such as professional liability coverage, any required minimum stock of drugs, and technological capabilities such as claims submission platforms.

Review policies and procedures for providing information to pharmacies about the credentialing process, including how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as via email, web portal or postal mail, and any credentialing fees required.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for the PBM's review, how the PBM provides feedback to a pharmacy, how a pharmacy may correct deficiencies or provide additional information.

Review contracts and manuals for details provided to pharmacies about the credentialing process. The PBM should provide clear and concise information that is consistent with its own policies and procedures and should follow any applicable state or federal law for credentialing and recredentialing. Information provided to pharmacies should address all the requirements and steps for credentialing and should provide pharmacies with adequate time to provide all documentation and provide pharmacies with the ability to address any questions about the process.

Request a listing of all pharmacies and staff that went through the credentialing process during the examination period. Request the results of each process (i.e. was the pharmacy "approved" to be in the PBM's network or not). Request the reasoning for all approval or denials. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

Request *all correspondence* between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sample of those that went through the credentialing process. "Correspondence" may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM, any emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format. Ensure all correspondence from the PBM is clear and concise and provides reasonably sufficient information to pharmacies regarding the credentialing process and any decisions made by the PBM.

In any Summary of the PBM Network Adequacy that proceeds these standards, consider describing the difference between the *PBM's network* and *pharmacy networks*. The PBM's network encompasses all pharmacies with which it contracts in the state. The PBM may have multiple pharmacy networks that may be designed based on types of drugs dispensed, how drugs are dispensed (i.e. mail order or chain/independent), or geographic location and will likely have differing reimbursement levels.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any), insurer or employer contracts, or other reasonable criteria, that it creates and maintains a network of pharmacies in a transparent manner.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts and manuals. This should include all network contracts and forms. Request documents be provided in an unredacted format.

_____ An index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, Examiners should request all relevant policies and procedures for areas being examined. Request documents be provided in an unredacted format, including requiring all pricing information be unredacted.

_____ PBM and insurer or employer plan contracts. Request the entire contract, including any amendments, in an unredacted format.

_____ A listing of all the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, specialty, LTC, or 340B pharmacy), the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, whether the pharmacy is an affiliate pharmacy or not, whether the pharmacies' network participation changed at any time during the examination period and the reason for such change (i.e. PBM changed terms, pharmacy opted out, carrier requested change). Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ A state map or geo-maps identifying the location of each pharmacy.

_____ A description of the differences in each unique pharmacy network. For each pharmacy network, the PBM should identify the types of drugs dispensed, consumer access (such as mail order or chain/independent), the reimbursement levels including any "discounts" applied and dispensing fees provided, any criteria for participation and any participation limits or restrictions. Standards should be applied in a non-discriminatory manner such that the PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ A list of all insurers and employer groups and each plan for the entity for which the PBM administers prescription drug benefits. Require the PBM to identify every network associated with each plan. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ If required by state law, the PBM files with the department of insurance all required contract forms and any material changes to a contract proposed for use with its participating providers and intermediaries.

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Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal policies and procedures regarding PBM requirements for ensuring the PBM has appropriate number of pharmacies in applicable geographic areas to ensure network pharmacies provide appropriate access to consumers. Ensure the PBM is compliant with state law and any requirements within its contracts with insurers and employer groups.

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure the PBM has clear and concise requirements. The PBM internal requirements should include but not be limited to:

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy deserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its carrier/employer group clients.
- Requirements for pharmacy network reimbursement levels. Ensure these are applied consistently among all pharmacies in each network.
- Conditions under which a pharmacy may be terminated, including requirements on how the pharmacy is notified of the termination and payment for all unpaid claims at the time of the termination.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear, concise, and easily understandable. Areas to review include but are not limited to:

- Do contracts/manuals clearly describe the requirements for participation in each pharmacy network?
- How does the PBM change the terms of the pharmacy network requirements? Any changes should be made in a transparent manner and with timely notice to the pharmacies.
- Do the contracts/manuals clearly describe the reimbursement including dispensing fees for each network?

Review the pharmacy listing to assess how often the PBM made changes to the pharmacy network requirements and participation levels during the examination period. Ensure the specific reasons for such changes are reasonable. Request all correspondence with pharmacies impacted by any changes. Request all correspondence with insurers and employer groups about the network changes. Ensure the message conveyed to insurers and employer groups is consistent with the message provided to pharmacies.

Review the listing of pharmacies and description of pharmacy network differences to ensure compliance with state and federal requirements. Depending on the state's legal requirements, areas to consider include by are not limited to:

- Does the PBM have networks that are comprised solely of affiliate pharmacies?
- Does the PBM have networks that are comprised solely of mail order pharmacies?
- Are the reimbursement rates among the differing networks reasonable or do the rates show differing levels for affiliate only networks when compared to networks without affiliates?

In any Summary of the PBM Network Adequacy that proceeds these standards, consider reviewing the PBM's contracts and manuals with pharmacies as part of how to ask for specific information about "contracting."

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 3
The PBM demonstrates compliance with state law (if any) or other reasonable criteria, that it maintains a network of pharmacies that is sufficient in number and types of pharmacies to ensure that all services to covered persons will be accessible without unreasonable delay.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Policies and procedures for providing information to covered persons about pharmacy directories.

_____ Policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.

_____ Documentation regarding how the PBM makes its provider directory (that lists all providers who participate in its network) available to covered persons and how it makes available, on a timely and reasonable basis, updates to its directory.

_____ All documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how covered persons may contact the PBM with inquiries.

_____ A listing of all the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, LTC, or 340B pharmacy), the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand name, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ A state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Ensure the PBM has established and will maintain adequate arrangements to ensure reasonable proximity of participating pharmacies to the business or personal residence of covered persons. In determining whether a PBM has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

Review policies and procedures for providing information to covered persons about in-network pharmacies and emergency services.

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Review all information provided to covered persons to ensure the information is provided in a clear and concise manner and updated regularly. PBMs should have clear information that describes how consumers may contact the PBM with any inquiries about pharmacy options.

Review all consumer complaints submitted to the PBM and the regulator to assess whether consumers have issues with pharmacy access.

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G. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that insurers or payors and their designees, including PBMs, that provide or perform utilization review services comply with standards and criteria for the structure and operation of utilization review processes.

The areas to be considered in this kind of review include the insurer's or payor's utilization review policies and procedures, annual summary reports, timeliness in making utilization review decisions and handling appeals, communications with members about the program and oversight of delegated utilization review functions.

DUR is conducted in three primary forms: prospective, concurrent, and retrospective. Prospective DUR occurs prior to dispensing and is designed to identify potential issues such as drug–drug interactions, therapeutic duplication, or inappropriate dosing before the medication is provided to the patient. Concurrent DUR takes place during the course of treatment and is used to monitor ongoing therapy, such as reviewing refill patterns or emerging safety concerns while a patient is actively receiving a medication. Retrospective DUR is performed after dispensing and involves analyzing historical claims data to identify patterns of inappropriate prescribing, potential overutilization, or opportunities for provider or patient education.

2. Techniques

The analysis of utilization review activities should include an overview of the PBM's written utilization review policies, procedures and scripts, in addition to an overview of how utilization review activities are applied to individual cases. Utilization review issues may also surface during the examiners' inspection of claims, complaints and grievance procedures.

a. Examiners should request a written overview of the PBM's utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. The overview should also include if the PBM utilizes artificial intelligence (AI) in its utilization review, and if so, the extent of what is being reviewed by AI and what criteria determines that it moves from AI to PBM staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the PBM maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.

b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.

c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.

d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.

e. Obtain listings of utilization review determinations, including approvals or certifications, denials, and requests for

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reconsideration. Using appropriate sampling methodology, select a representative sample of cases for detailed review. For each sampled case, obtain the clinical criteria and review guidelines applied in the determination and evaluate whether the PBM's actions were consistent with its written policies, clinical standards, and established review procedures. Ensure that the examiner assigned to this review possesses sufficient clinical expertise to interpret the applicable criteria, understand the clinical context of the request, and assess whether determinations were made in accordance with the PBM's documented guidelines and utilization review protocols.

f. Obtain annual reporting by the PBM of its utilization review. Minimum standards should include:
- Number of requests by type (prior authorization, maximum unit, appeal, etc.).
- Number approved of each type.
- Number denied of each type.
- Number appealed of each type.
- Number approved after appeal of each type.
- Timeframe of each response of each type.
- Whether or not each of the above was derived from AI, clinical staff, or non-clinical staff.

3. Tests and Standards

The utilization review assessment includes, but is not limited to, the following standards related to the performance of utilization review activities by the PBM.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 1
The PBM operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations, including those related to mandated benefits and services.

_____Utilization review policies and procedures.

_____Utilization review program or plan documentation.

_____Medical criteria used to make utilization review determinations.

_____Job description of the staff position functionally responsible for day-to-day management.

_____Minutes of the PBM's board of directors.

_____Minutes of the PBM's utilization review committee.

_____Documentation of clinical staff credentialing maintenance and education requirements.

_____Program assessment reports.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a PBM that requires a request for benefits under the covered person's health benefit plan to be subjected to utilization review, implements a written utilization review program that describes all review activities, both delegated and nondelegated for:

- The filing of benefit requests;
- The notification of utilization review and benefit determinations; and
- The review of adverse determinations in accordance with applicable state statutes,

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- Verify that the PBM's written utilization review program document describes all the following:
  - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of pharmacy services;
  - Data sources and clinical review criteria used in decision-making;
  - Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
  - Data collection processes and analytical methods used in assessing utilization of pharmacy services;
  - Provisions for ensuring confidentiality of clinical and proprietary information;
  - If AI is used and in what capacity;
  - The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the insurer's or payor's governing body; and
  - The staff position functionally responsible for day-to-day program management.

- Verify that the PBM ensures that appropriate personnel have operational responsibility for conducting the insurer's or payor's utilization review program.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 2
The PBM operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed).

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM utilization review program uses documented clinical review criteria that are based generally accepted, independently-developed clinical standards published by the federal government or professional organizations and evaluated periodically to assure ongoing efficacy.

Note: The PBM may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the PBM makes its clinical review criteria available upon request to authorized government agencies.

Verify that the PBM ensures that qualified pharmaceutical professionals administer the utilization review program and oversee review decisions. Verify that the PBM has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the PBM issues utilization review decisions and benefit determinations in a timely and efficient manner pursuant to the requirements set forth in applicable state statutes, rules and regulations.

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Verify that the PBM has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the PBM conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the PBM's data systems are sufficient to support utilization review program activities and to generate management reports to enable the PBM to monitor and manage pharmacy services effectively.

If a PBM delegates any utilization review activities to a utilization review organization, verify that the PBM maintains adequate oversight, to include all the following:

- A written description of the utilization review organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the utilization review organization program by the PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the utilization review organization.

If a PBM delegates any utilization review activities to AI, a AI program, or a AI vendor, verify that the PBM maintains adequate oversight, to include all the following:

- A written description of the AI/AI organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the AI program by the PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the AI functionality.

Verify that the PBM coordinates its utilization review program activities with other medical management activity conducted by the insurer or payor, such as quality assurance, credentialing, provider contracting, data reporting, grievance procedures, claims adjudication, processes for assessing member satisfaction and risk management.

Verify that the PBM provides covered persons, or, if applicable, the covered person's authorized representatives and participating providers with access to its utilization review staff via a toll-free number or collect call telephone line.

Verify that the PBM, when conducting utilization review, collects only the information necessary, including pertinent clinical information, to make the utilization review or benefit determination.

Verify that PBM staff conducting each type of utilization review are qualified to make clinical determinations, i.e. non-clinical staff should not be making determinations on drug coverage based on detailed clinical criteria from information based on patient-specific laboratory or clinical findings when compared to national guidelines or predetermined criteria.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 3
The PBM discloses information about its utilization review and benefit determination procedures to covered persons, or, if applicable, the covered persons' authorized representative, in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Member materials.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM provides a clear and accurate summary of its utilization review and benefit determination procedures to the covered person's authorized representative.

Determine whether the PBM makes its utilization review criteria publicly available, including whether such criteria are posted on a website or otherwise maintained in a manner that allows covered persons and providers to easily access and obtain them upon request.

Verify that the PBM provides a clear and comprehensive description of its utilization review procedures, including the procedures for obtaining adverse review determinations, and a statement of rights and responsibilities of covered persons.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 4
The PBM makes standard utilization review and benefit determinations in a timely manner and as required by applicable state statutes, rules and regulations, as well as the provisions of HIPAA.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed).

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the PBM by the covered person, or, if applicable, the covered person's authorized representative, for benefits and for notifying the covered person, and, if applicable, the covered person's authorized representative, of its determinations with respect to these requests within the specified time frames required pursuant to applicable state statutes, rules and regulations.

State and federal law may contain specific criteria outlining mandates related to communication from the PBM to the patient or prescriber, such as time limitations of response, manner of communication (written notice, portal, etc.), and may contain different criteria related to different types of insurers/payors. The evaluation should take all state and federal guidelines for any/all types of insurers/payors.

For prospective review determinations, verify that the PBM makes the determination and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether the PBM certifies the provision of the benefit or not, within a reasonable period of time appropriate to the covered person's medical condition, but in no event later than the time as required by state or federal law after the date the PBM receives the request.

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Whenever the determination is an adverse determination, verify that the PBM makes the notification of the adverse determination in accordance with state or federal statutes, rules and regulations regarding procedures for standard utilization review and benefit determination.

Verify that if the PBM extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to the time required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the PBM has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the PBM expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the PBM issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Whenever the PBM receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the insurer's or payor's filing procedures, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of this failure and provides in the notice information on the proper procedures to be followed for filing a request.

Verify that the notice referenced in the previous paragraph is provided by the PBM as soon as possible, but in no event later than the time required by state or federal law following the date of the failure.

Verify that the PBM provides the notice orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to meet the insurer's filing procedures apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the PBM responsible for handling benefit matters; and

- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific pharmaceutical service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a PBM has certified an ongoing course of treatment to be provided over a period of time or number of treatments, examiners need to be aware that:

- Any reduction or termination by the PBM during the course of treatment before the end of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and

- The PBM shall notify the covered person, or, if applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state or federal statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the covered person's authorized representative, to file a grievance to:

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- Request a review of the adverse determination pursuant to state or federal statutes, rules and regulations; and
- Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

Verify that the pharmaceutical service or treatment that is the subject of the adverse determination is continued by the PBM without liability to the covered person with respect to the internal review request made pursuant to state statutes, rules and regulations.

For retrospective review determinations, verify that the PBM makes the determination within a reasonable period of time, but in no event later than the time as required by state or federal law after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the PBM provides notice of the adverse determination to the covered person, or, if applicable, the covered person's authorized representative, in accordance with applicable state statutes regarding procedures for standard utilization review and benefit PBM determination.

Verify that if the insurer extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to the time as required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the insurer has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the insurer expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the PBM issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Verify that the PBM calculates the time periods, within which a prospective or retrospective determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is received by the PBM in accordance with the insurer's procedures established pursuant to applicable state or federal statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to make the determination, verify that the PBM calculates the time period for making the determination to begin on the date on which the PBM sends the notification of the extension to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:

- The date on which the covered person, or, if applicable, the covered person's authorized representative, responds to the request for additional information; or
- The date on which the specified information was to have been submitted.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 5
The PBM provides written notice of an adverse determination of standard utilization review and benefit determinations in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed

_____ _____
_____ _____

Review Procedures and Criteria

Verify that the PBM issues notification of an adverse determination, in a manner calculated to be understood by the covered person, to include all the following:

- The specific reason or reasons for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to perfect the benefit request, including an explanation of why the material or information is necessary to perfect the request;
- A description of the PBM's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;
- If the PBM relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative, upon request;
- The PBM's policy on level of professional clinical license that is appropriate to conduct the adverse determination and if any secondary clinical staff was consulted prior to making an adverse determination;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination;
- The written statement of the scientific or clinical rationale for the adverse determination; and

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- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the PBM's grievance procedure process as provided under state statutes, rules and regulation, to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the PBM provides the notice in writing or electronically, when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 6
The PBM conducts expedited utilization review and benefit determinations in a timely manner and in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM has established written procedures pursuant to applicable state statutes, rules and regulations for receiving benefit requests from covered persons, or, if applicable, their authorized representatives, and for making and notifying the covered person, or, if applicable, the covered person's authorized representative, of expedited utilization review and benefit determinations with respect to urgent care requests.

Verify that the PBM, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the PBM's procedures for filing an urgent care request, notifies the covered person, or, if applicable, the covered person's authorized representative, of the failure and the proper procedures to be followed for filing the request.

Verify that the PBM's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the PBM's procedures for filing an urgent care request:

- Is provided to the covered person, or, if applicable, the covered person's authorized representative, as appropriate, as soon as possible, but not later than the time as required by state law after receipt of the request; and
- May be oral, unless the covered person, or, if applicable, the covered person's authorized representative, requests the notice in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the PBM's procedures for filing an urgent care request apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the PBM responsible for handling benefit matters; and

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- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific pharmaceutical service, treatment or provider for which approval is being requested.

For an urgent care request, unless the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the PBM to determine whether, or to what extent, the benefits requested are covered benefits or payable under the insurer's or payor's health benefit plan, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of the PBM's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, but in no event later than the time as required by state or federal law after the receipt of the request by the PBM.

If the PBM's determination is an adverse determination, verify that the PBM provides notice of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the health carrier to make a determination, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, either orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing of this failure and states what specific information is needed as soon as possible, but in no event later than the time as required by state law after receipt of the request.

Verify that the PBM provides the covered person, or, if applicable, the covered person's authorized representative, a reasonable period of time to submit the necessary information, taking into account the circumstances, but in no event less than the time as required by state or federal law after notifying the covered person, or, if applicable, the covered person's authorized representative, of the failure to submit sufficient information, pursuant to applicable state statutes, rules and regulations.

Verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible, but in no event more than 48 hours after the earlier of:

- The PBM's receipt of the requested specified information; or
- The end of the period provided for the covered person, or, if applicable, the covered person's authorized representative, to submit the requested specified information.

If the PBM's determination is an adverse determination, verify that the PBM provides notice of the adverse determination accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

For concurrent review urgent care requests involving a request by the covered person, or, if applicable, the covered person's authorized representative, to extend the course of treatment beyond the initial period of time or the number of treatments, if the request is made at least by the time as required by state law prior to the expiration of the prescribed period of time or number of treatments, verify that the PBM makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the covered person's medical condition, but in no event more than the time as required by state or federal law after the PBM's receipt of the request.

If the PBM's determination is an adverse determination, the PBM shall provide notice of the adverse determination or coordinate with the carrier in accordance with applicable state or federal statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

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Verify that the PBM calculates the time period within which a determination is required to be made pursuant to applicable state or federal statutes, rules and regulations, to begin on the date the request is filed with the either the insurer or PBM in accordance with the insurer's procedures established pursuant to applicable state or federal statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

Verify that the PBM's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative, to include all the following:

- The specific reason(s) for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to complete the request, including an explanation of why the material or information is necessary to complete the request;
- A description of the insurer's internal review procedures established pursuant to applicable state or federal statutes, rules and regulations including any time limits applicable to those procedures;
- A description of the PBM expedited review procedures established pursuant to applicable state statutes, rules and regulations;
- If the PBM relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative upon request;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- If applicable, instructions for requesting:
  - A copy of the rule, guideline, protocol, or other similar criterion relied upon in making the adverse determination, as set forth in applicable state statutes, rules and regulations; or
  - The written statement of the scientific or clinical rationale for the adverse determination, as set forth in applicable state or federal statutes, rules and regulations; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the health carrier's grievance procedure process as provided under applicable state or federal statutes, rules and regulations to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the PBM provides the notice orally, in writing or electronically.

If the PBM provides the notice of adverse determination orally, verify that the PBM also provides written or electronic notice of the adverse determination within the time as required by state or federal law following the oral notification when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 7
The PBM monitors the activities of the utilization review organization or entity with which the PBM contracts and ensures that the contracting organization complies with applicable state and federal provisions and accompanying regulations.

Apply to: PBMs contracting out utilization review services.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Contracts with organizations or entities.

_____Reports of entity reviews and audits (if any).

_____Periodic reports from the organization or entity.

_____Minutes of the PBM's board of directors

_____Minutes of the PBM's utilization review committee

_____Policies and procedures for oversight

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a PBM contracts to have a utilization review organization or other entity perform the utilization review functions required by the *Utilization Review and Benefit Determination Model Act (#73)* or applicable state statutes, rules and regulations, the PBM is responsible for monitoring the activities of the utilization review organization or entity with which the PBM contracts and for ensuring that the requirements of the *Utilization Review and Benefit Determination Model Act (#73)* and applicable state statutes, rules and regulations are met.

Verify that the PBM has policies and procedures in place that ensure the utilization review programs of designees comply with all applicable state and federal laws establishing confidentiality and reporting requirements.

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H. Drug Formulary, Placement, and Specialty Drug

The Drug Formulary, Placement and Specialty Drug review includes, but is not limited to, the following standards related to how the Formulary is managed and controlled by the PBM.

STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 1
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period.

_____All (P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formulary and drug placement-related systems utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the PBM formularies utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the PBM P&T Committee or other committee(s) decisions and statements are in compliance with all applicable state and federal statutes, rules and regulations.

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 2
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

_____ All policies, procedures, and other documentation relevant to drug utilization management, including but not limited to, all fail-first policies including step-therapy protocols, prior authorization requirements, and medical necessity guidelines.

_____Any and all list(s) of medications included in and excluded from the mail order benefit.

_____Any and all list(s) of medications allowed for a 90-day supply, and those only allowed for 30-day supply or less, for both mail order and retail pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to comply with all applicable state and federal statutes, rules and regulations.

Verify that all the PBM's formularies utilized during the examination period do not restrict access to drugs to select pharmacies in violation of any required and applicable state and federal statutes, rules or regulations.

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 3
The PBM defines and appropriately places any specialty drug on the formulary when a state has a specialty drug definition to comport with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

_____Specialty drug list(s)

_____All P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formulary and drug placement-related systems utilized during the examination period use the applicable definition in accordance with all applicable state and federal statutes, rules and regulations.

Verify that the PBM formularies utilized during the examination period have any drug that meets the definition of specialty placed appropriately and further that any drug that does not meet the definition tiered appropriately in accordance with all applicable state statutes, rules and regulations.

Verify that the PBM P&T Committee or other Committees decisions and statements use and apply the correct definition of specialty drug in compliance with all applicable state statutes, rules and regulations.

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I. Complaints, Grievances, and Appeals

1. Purpose

The purpose of complaints, grievances and appeals handling procedures is to provide a process for consumers or providers to address issues, and to evaluate how well a regulated entity complies with laws, resolves issues, and timely responds to dissatisfaction expressed by consumers or providers. This includes:

- Ensuring compliance with applicable statutes and/or regulations[1], including:
  - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
  - Establishing whether violations were committed; and
  - Monitoring future conduct for compliance;

- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers, providers, or pharmacies; and

- Identifying problem areas that may indicate broader operational issues.

All sections emphasize the importance of reviewing how concerns, whether classified as complaints, grievances, or appeals, are processed, documented, and used to improve consumer service.

2. Techniques

The examination approach for complaints, grievances, and appeals procedures include the following shared techniques:

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances, or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems.
- **Documentation Review:** Assessing written policies, procedures, contracts, provider manuals, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, providers, and pharmacies are informed of the procedures and their rights.

All procedures call for reviewing the frequency and nature of the issues raised and whether they were resolved in accordance with the applicable standards.

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, resolution).
- **Procedural Adequacy:** Verifying that the regulated entity has adequate written procedures for handling and resolving the issue, and that these are disclosed to consumers, providers, and pharmacies.
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law.
- **Compliance and Fairness:** Determine that responses:
  - Fully address the issue(s) that was raised.
  - Include adequate supporting documentation.

[1] The term statutes and/or regulations refers to all legally binding statutes, rules, regulations, policies or other documents promulgated by an entity with said power.

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- Are compliant with policy statutes and regulations.
- Provide appropriate remedies when necessary.

Complaints, Grievances, and Appeals stress maintaining records that are accessible to regulators and retaining them for appropriate time periods.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The PBM maintains a detailed, accessible register documenting each complaint, grievance, or appeal, in accordance with the applicable records retention schedule.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Regulated entity register.

_____Insurance department records.

_____Direct consumer or pharmacy complaint, grievance, or appeal.

_____Member evidence of coverage.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify accurate logging of the issue, date received, review actions, and resolution.

Verify that the register includes enough detail to support regulatory review.

Verify that the PBM retains the register for at least 3 years, or in accordance with applicable state or federal law, whichever is longer.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The PBM has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers, contracted providers, and contracted pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.

_____Member evidence of coverage.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the company maintains a complaint register.

Verify that the PBM included the complaint log and procedures that include the audit, credentialing, and network enrollment departments.

Verify that the PBM's procedures comply with applicable statutes and regulations.

Verify that the PBM's procedures are communicated to consumers and contracted providers

Verify that the PBM has filed procedures with the insurance commissioner where required.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 3
The PBM must resolve and respond to complaints, grievances, and appeals within prescribed timeframes.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____PBM register.

_____Test Sample.

_____Complaint, grievance, or appeal letter or email and PBM response.

_____Supporting documentation (claim files, extension requests, etc).

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review test sample to ensure the PBM is maintaining adequate documentation.

Determine if the PBM's response is timely in accordance with state and/or federal law. *Note:* Timing is measured from the date the issue is received.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The PBM actions taken in response to complaints, grievances, or appeals must comply with insurance laws, contracts, and regulations as well as address all identified concerns.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Contracts, including provider manuals.

_____PBM register.

_____Test Sample.

_____Complaint, grievance, or appeal letter or email and PBM response.

_____Supporting documentation (claim files, extension requests, etc).

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review documentation to determine if the PBM response fully addresses the issues raised. If the PBM did not properly address/resolve the complaint, the Examiner should ask the PBM what corrective action it intends to take.

For reviewing responses:
- Was the response timely.
- Was the response complete and responds to all issues raised.
- Does the response include adequate documentation to support the respondent's position.
- Were the respondent's actions appropriate from a business standpoint.
- Were the respondent's actions compliant with applicable statutes and regulations.
- Were the appropriate remedies for the consumer identified.

Document potential violations.

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J. Pharmacy Audits

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY AUDITS

Standard 1
The PBM demonstrates that it has reasonable and uniform criteria and procedures for pharmacy audits and demonstrates that it follows those standards.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted format.

_____ Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.

_____ A listing of all types of audits that may include but not be limited to on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)

_____ From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted format.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format.)

_____ A listing of parties who perform pharmacy audits on behalf of the PBM, including third-party vendors and credentials of auditor staff.

_____ A listing of all audits initiated or that were ongoing during the examination period. (As part of this request, the timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification and supporting documentation of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ All correspondence between the PBM and a pharmacy as part of audits during the examination period. (Consider whether to request information from all audits or just a sampling of the audits. 'Correspondence' may include but not be limited to all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM, any emails, notes from phone conversations, and any other communications about the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format.)

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_____ Summary of any use of artificial intelligence (AI) that it may use as part of auditing a pharmacy.

_____Policies and procedures associated with the use of AI.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review applicable state and federal law to ensure PBM policies and audits are compliant.

Review internal PBM policies and procedures regarding the PBM's audit process with pharmacies. Review criteria for the different types of audits to assess whether the PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit, including but not limited to processes for initiating, conducting, and resolving each type of audit.

Review contracts and manuals with details about the audit process to ensure the information provided to pharmacies is clear, concise, and easily understood. While the details of the audit process are important, the information must be provided in a clear and concise manner that will be understood by pharmacies.

Review contracts and manuals for details provided to pharmacies about the audit process. Review how the PBM informs pharmacies of how audits are initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail), any fees required by the PBM that are outside the audit finding, how the pharmacy may address and rectify potential findings, the PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

Assess whether the PBM's requirements for pharmacies are reasonable and provide pharmacies with the following:

- The scope, frequency (including the maximum annual amount) and method of all audits.
- Detailed guidelines, including metrics and data, used during audits.
- Advanced notice of an upcoming audit, and the day of the month the audit began.
- Sufficient time to prepare and collect required information.
- Convenient and accessible methods for corresponding with the PBM during the audit, for example does the pharmacy have a point of contact to ask questions and obtain clarification on the PBM's expectations.
- Sufficient time to review and correct any audit findings prior to the PBM's final determination.
- Sufficient input into the implementation of a corrective action plan (if applicable) and sufficient time to comply with the requirements of a corrective action plan.
- An appropriate dispute resolution process that pharmacies may use to dispute audit findings. The process for pharmacies should be convenient and accessible and should not create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute resolution process.

If the regulator feels the PBM's policies and procedures are reasonable, ensure the PBM also follows and implements its own policies and procedures. Review timeframe requirements, whether the PBM provides reasonable and concise information to pharmacies in response to any questions, and whether the PBM provides appropriate justifications in the draft and final audit reports.

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Review the results of all audits to determine if audits are conducted in a manner that appears reasonable for each of the individual pharmacies being audited and that there are no concerning trends with how the PBM conducts audits. For example, when conducting routine audits, are pharmacies selected randomly or does the PBM only audit non-affiliated, independent pharmacies? *The latter trend would be problematic.*

Verify that the PBM conducts pharmacy audits in compliance with applicable state laws and regulations. Ensure such methods are reasonable, utilized appropriately and consistent with any regulatory requirements (or prohibited if required by state law or regulation). For example, if use of auditing techniques such as extrapolation is prohibited by state law or regulation, the PBM should not apply the method in any audits.

Assess whether the PBM has staffing models to effectively initiate, conduct and finalize audits.

Assess the PBM's use of AI to ensure it is reasonable and that any results or findings from the use of AI are conveyed to the pharmacy in a clear and transparent manner.

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Coalition Comments and Redlines of the Draft "Conduct the Pharmacy Benefit Manager Examination" Chapter, as submitted to the PBM (D) Working Group

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Coalition Members:

The Cigna Group, CVS Health, Elevance Health, and UnitedHealth Group

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Coalition Comment Letter to PBM (D) Working Group

(April 3, 2026)

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April 3, 2026

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Pharmacy Benefit Management (D) Working Group
National Association of Insurance Commissioners
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Re: Comments on PBM Exam Standards DRAFT dated March 12, 2026

Dear Ms. Fix and Ms. Matthews:

The undersigned companies appreciate the opportunity to comment on the March 12, 2026 revised PBM Exam Standards Draft (the "draft standards") and the NAIC's willingness to work with us on refining the draft standards to be clear and consistent while remaining grounded in applicable state authority. As we have noted in the past, we support the creation of PBM exam standards and believe our suggested revisions will ultimately promote a more workable examination process for regulators and PBMs alike.

After reviewing the revised draft standards, our Coalition respectfully submits the following two priority recommendations intended to support efficient, predictable examinations and to promote consistent application across jurisdictions:

1. Clarify examination scope up front: Direct examiners to define the examination's scope consistent with applicable state law and jurisdictional authority and communicate that scope (including in-scope contracts and operations) to the examined entity at the outset, with the opportunity for response.
2. Right-size document production expectations: Update the document-production standards to focus requests on material, in-scope information; encourage statistically valid sampling where appropriate; and reduce the risk of unintended consequences and unnecessary administrative burden.

Below, we offer additional comments on these issues.

1. Clarify examination scope up front

While we appreciate that the examination standards themselves rightly reference applicable state statutes, rules, and regulations, the scope of the PBM contracts and data that are subject to examination has been broadened to potentially include any contract with an insurer or employer plan, regardless of who bears the risk (e.g., PBM Pricing Methodologies Standard 3). The scope has, further, been expanded to potentially include any line of business, including Medicare and Medicaid (e.g., Pharmacy Claims Standard 1).

Because market conduct examinations are intended to ensure compliance with a state's laws, establishing the scope at the onset is critical. This was raised in several interested parties' written and oral comments to the Working Group, including the importance of working through these issues up front.

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- ✓ **Recommended solution**: Update the reference to the NAIC White Paper to instruct examiners to also be familiar with the NAIC's *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* and *Guidance Document – ERISA Preemption and State PBM Laws* (once finalized and adopted). Add a reference to Chapter 16, Scheduling, Coordinating and Communicating, which details scope considerations, to the Scheduling, Coordination and Planning Scope section.

  Further, update the Procedural Considerations by adding language such as "When determining the scope of the examination, examiners should clearly outline which PBM contracts and which lines of business are subject to the state's insurance regulatory oversight and included in the examination. Examiners should consult applicable state law, federal law, and legal rulings relevant to federal preemption and provide the PBM the opportunity to raise concerns relevant to the scope as part of the preliminary examination information and in advance of the estimated commencement of the examination."

  Additionally, remove references to requesting Medicare data, which is preempted by federal law, and update references to Medicaid data to state the information is out of scope unless specifically subject to the state insurance regulator's oversight.

2. Right-size document production expectations

We understand from prior discussions that the intent of the draft standards is to provide the foundation for PBM examinations, which each state will adapt based on their priorities and laws. However, the document, as written, consistently requires all correspondence, all contracts, all amendments, all versions of materials, and all claims. This removes examiner discretion and conflicts with the NIAC Market Regulation Handbook's (Handbook) long-standing reliance on official correspondence, final documentation, sampling, and relevance.

While PBMs are distinct from health insurance issuers in that they are not risk-bearing entities, the approach to examination should be consistent across all regulated entities. The Handbook itself is designed with this in mind – general chapters that detail processes and standards that apply universally and specific chapters that outline examination standards for specific entities or lines of business.

We ask the drafting group to update the standards' document production requirements as detailed below.

a. Correspondence

The draft standards require production of all correspondence, including all emails, call notes, and informal communications, and redlined copies of documents. This represents a significant departure from established examination norms and standards across other lines of insurance and other regulated entities.[1]

[1] The current Handbook has narrow instances in which correspondence is required (e.g., Chapter 24, Conducting the Health Examination's credentialing process standards require correspondence to providers relating to the credentialing process). There are also limited instances where notes are expected (e.g., underwriter's notes on a system log in Chapter 26, Conducting the Long-Term Care Examination). Finally, email references are limited to broad communications (e.g., Chapter 27, Conducting the Consumer Credit Examination's request for saved, stored, or archived email that was

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As proposed, this expectation could unintentionally discourage and prevent efficient, informal communications with pharmacies as regulated entities seek to ensure all routine exchanges are captured for examination purposes. For example, if a pharmacy has a question regarding its contract, the standards may hinder the PBM's ability to connect the pharmacy with a live representative for guidance unless the PBM has built a system to record the call or call notes for production during examination.

We are, further, concerned that this would impose significant new burdens and could require new systems for compliance while slowing down analysis of records that are relevant to statutory compliance and increasing the likelihood that key compliance issues are obscured by inconsequential information.

- ✓ **Recommended solution**: Instead of requiring all official and unofficial correspondence, request an explanation or a walkthrough of the contracting and credentialing process used by the PBM that would outline timelines, standard documents and types of communications that are used in the process and require PBMs to provide policies and procedures relating to contracting, template contracts and amendments offered, final executed contracts, and provider manuals (e.g., PBM Pricing and Methodologies: Standard 4, PBM Provider/Pharmacy Relations: Standard 1, PBM Provider/Pharmacy Relations: Standard 2, PBM Pharmacy Network Adequacy: Standard 1, and PBM Pharmacy Audits: Standard 1). The standards should, further, note that additional materials could be requested when specific concerns are identified which indicate a potential violation of state law.

b. Sampling

The current Handbook rightfully treats sampling as a foundational examination methodology.[2] While we appreciate the revised draft standards reference sampling in the Procedural Considerations, the individual draft standards typically require production of "all" relevant materials.

This will slow both PBM production and, in some cases, regulator review without a clear demonstration that such breadth is warranted by a cost-benefit analysis. These expectations are also likely to lead to noncompliance findings and penalties if a regulated entity cannot respond timely or completely to requests, or if response timelines do not appropriately reflect the scope and complexity of the request.

We understand that examiners may find it appropriate to request 100% of a sample size at times; however, they should not be required to do so to align to the NAIC's examination standards. Chapter 17 (Sampling) details variations in sample sizes to reach statistically valid conclusions,

broadcast to the sales force) and complaint handling (e.g., Chapter 24A, Conducting the ACA Related Examination). We have not identified any references in the current Handbook requiring redlined versions of documents.

[2] *See* Standard Fourteen of the Core Competencies in Chapter 5 of the Handbook. There are, further, hundreds of references to sampling and requesting information relevant to the standard being reviewed throughout the Handbook. For example, Chapter 16 (Scheduling, Coordinating, and Communicating) discusses methods examiners will use to select the files for the sample or census review. Chapter 24's (Conducting the Health Examination) provider credentialing techniques instruct examiners to use the company's provider directory to select a sample of specific provider credential files, drawing from a variety of provider types and facilities, for further review and Chapter 24A's (Conducting the ACA Related Examination) grievance procedures require a sample of grievance documents to be reviewed.

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cautioning that regulators should carefully weigh the costs and benefits when making sampling decisions, such as whether gains in precision or higher confidence are merited by the cost of producing and investigating a larger sample of files.

- ✓ **Recommended solution**: Align with other chapters by leveraging broader language that permits examiner discretion consistent with core principles, such as "claim files" instead of "all claims data…" (e.g., PBM Pricing and Methodologies: Standard 2, 3, 4, 5; Pharmacy Claims: Standard 1), "pharmacy contracts" rather than "all pharmacy contracts" (e.g., Pharmacy Claims: Standard 1), and "network contracts" rather than "all network contracts" (e.g., Pharmacy Network Adequacy: Standard 2).

  Further, update the Procedural Considerations section to add a reference to Chapter 17, in addition to the current reference to Chapter 20, and language to encourage examiners to leverage rolling production timelines and good faith extensions, particularly for more complex or comprehensive data and document production requests.

c. Request, Receipt and Treatment of Proprietary and Confidential Information

We appreciate the draft standards' reference to Chapter 12 of the Handbook, which addresses confidentiality broadly, and language instructing examiners to take care not to disclose trade secret information and allowing PBMs to mark exhibits or portions of the examination reports as "confidential and proprietary" when state law permits. However, we are concerned that the draft standards do not adequately align with other NAIC-adopted protections for the request, receipt, and treatment of proprietary and trade secret information.

Current NAIC model laws on financial examinations and market conduct surveillance, and core licensing guidelines for PBMs, provide strong protections for regulated entities' competitively sensitive information, including treatment as confidential by law and privileged and protection from state open records laws, subpoena, discovery, or admissibility as evidence in any private civil action.[3] Further, the NAIC market regulation core competencies and financial regulation accreditation standards require departments of insurance to ensure contractors protect confidential information.[4] In addition, the current Handbook permits examiner discretion in request, receipt and treatment of proprietary and confidential information from a regulated entity.[5]

By requiring unredacted documents in all instances, the draft standards appear to limit examiner discretion to tailor document production to what is material to the examination's scope and objectives. PBM agreements, pricing methodologies, network and reimbursement terms, and other commercial and operational information frequently reflect negotiated, client-specific arrangements and trade secrets.

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[3] *See* Section 5F of the NAIC Model Law on Examinations (#390), Section 7 of the NAIC Model Law on Market Conduct Surveillance (#693), and the Enforcement portion of Section 2 (Core Licensing Guidelines for PBMs) in the Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators, as adopted at the Spring 2026 National Meeting. Model 390 and 693 are referenced in Chapter 12 of the Handbook, which is incorporated by reference in the draft standards.

[4] *See* Standard Six of the Core Competencies in Chapter 5 of the Handbook and Part C: Organizational and Personnel Practices of the Accreditation Program Manual, as amended at the Fall 2025 National Meeting.

[5] We have not identified any references in the current Handbook requiring unredacted copies of documents. Instead, for example, Chapter 8 (Enhancing State Market Analysis) makes note that many underwriting guidelines are considered trade secrets and/or proprietary in nature, stating that regulators must review confidentiality laws before issuing data requests.

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A default expectation of broad, unredacted production of relevant materials and data can increase the amount of competitively sensitive information collected and retained in examination files without a commensurate regulatory benefit, while increasing the risk of improper disclosure beyond the examination team (including through contractors/vendors, inadvertent handling errors, or public records processes). Such disclosure could materially harm the PBM and its clients. In addition, unredacted production of individual-level or role-identifying information (for example, Pharmacy and Therapeutics (P&T) Committee member information) may create unnecessary safety and privacy risks where the underlying identity information is not needed to evaluate compliance with state law.

These risks are not borne by PBMs and their clients alone. Over-collection and unclear confidentiality guardrails can also create material risks for state regulators and the markets they oversee. Improper disclosure (or even the perceived risk of disclosure) can undermine confidence in the examination process, delay production of relevant materials, and distort competition in the state's markets.

We believe a more balanced approach would ensure alignment with the NAIC's and state insurance regulators' longstanding commitment to protecting competitively sensitive information that could materially harm a regulated entity, its clients, and market competition if publicly released.

The standards should more clearly reflect the balance that state insurance regulators have long struck: regulator access to relevant information needed to assess compliance with applicable law that protects the trade secrets, proprietary business information, and other nonpublic information of the regulated entity, its clients, customers, and patients. Preserving that balance requires clear direction that examiner requests should be targeted to material, in-scope information and that unredacted production should be required only where necessary to determine compliance with the state law(s) being examined.

- ✓ **Recommended solution**: Align with other chapters by removing references to "unredacted" contracts and formats throughout (found in 43 instances throughout the standards) to reflect a relevance/materiality standard (e.g., "unredacted to the extent necessary to confirm compliance with applicable state law"). Further, add language in the Procedural Considerations to instruct examiners to (1) review and confirm the state's confidentiality protections before requesting highly sensitive information; and (2) when requesting unredacted information, identify (and document) why the unredacted information is necessary and relevant to the examination's scope and objectives and why less sensitive alternatives (e.g., sampling, summaries, targeted provisions, or redacted versions) are insufficient.

  Add language such as the following in the Procedural Considerations section:
  "If the examiner determines that unredacted production of data or documents is necessary, the examiner should document the specific examination objective and explain why the unredacted information is relevant and material to determining compliance with the state law(s) being examined and why reasonable alternatives (e.g., sampling, targeted provisions, or redacted production) are insufficient.

  The examiner must ensure the state's confidentiality laws provide that 'documents, materials or other information, including, but not limited to, all working papers, and copies

thereof, created, produced or obtained by or disclosed to the commissioner, or in the possession or control of the National Association of Insurance Commissioners and its affiliates and subsidiaries, or any other person in the course of an examination, or in the course of analysis by the commissioner of the financial condition or market conduct of a company, shall be confidential by law and privileged, shall not be subject to [insert open records, freedom of information, sunshine or other appropriate phrase], shall not be subject to subpoena, and shall not be subject to discovery or admissible in evidence in any private civil action. The commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the commissioner's official duties.'

If the state's confidentiality laws do not provide substantially the same protections for market conduct examinations, the examiner must coordinate with the PBM to access highly sensitive data relevant to the examination in a manner that appropriately safeguards the information.

These confidentiality expectations apply not only to the department, but also to any contract examiners and vendors, and reasonable steps must be taken to prevent unauthorized access, reproduction, disclosure, or distribution of confidential information."

* * *

We also recommend the Working Group incorporate the claims data template work completed in 2025 and are attaching as reference our October 2025 comments and draft of that template.

We believe that the above changes would preserve examiner access to essential information while ensuring consistency with state and federal law and the general procedures for market conduct examinations in NAIC model laws and the Handbook. Additionally, our suggested revisions would avoid document-production requirements that are unnecessarily burdensome or difficult to operationalize for both the examinee and the examiner.

We welcome the opportunity to discuss any of these recommendations in more detail and look forward to our continued collaboration.

Sincerely,

Franca D'Agostino
Director, Regulatory Affairs
The Cigna Group

Leanne D. Gassaway
VP State Government Affairs
CVS Health

Christine Cappiello
Sr. Director, State Affairs and NAIC
Elevance Health

Mollie Zito
Deputy General Counsel, Regulatory Affairs
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Attachment

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Attachment:
Claims Data Template Recommendations
(October 2, 2025)

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October 2, 2025

Ms. Joylynn Fix
Pharmacy Benefit Management (D) Working Group
National Association of Insurance Commissioners
444 North Capital Street, NW, Suite 700
Washington, DC 20001-1512
Forwarded via email: Jolie H. Matthews (jmatthews@naic.org)

RE: Submission of PBM Market Conduct Claims Data Template Recommendations

Dear Ms. Fix:

The undersigned Coalition of Pharmacy Benefit Managers (PBMs) and health insurers[1] is committed to assisting the Pharmacy Benefit Management (D) Working Group as it develops robust and transparent standards to enable consistent market regulation by state regulators. During our Coalition call with the drafting group, we discussed the importance of establishing a standard claims data template for regulators to leverage when requesting claims data from PBMs. A common template will streamline the data collection process, improve the comparability of information across states, mitigate the risk of inaccuracies due to interpretations, and facilitate a more effective review of market regulation data.

In the context of Market Conduct Examinations (MCEs), the definition of a "standard" claims data universe or layout must be grounded in how PBMs typically store, use, maintain and report data in the ordinary course of business. This objective is best served by leveraging existing operational data structures or commonly calculated values that align with standard reporting rather than imposing artificial reporting constructs that require logic, transformation, or calculation beyond what is routinely maintained or reported.

After reviewing several templates used in recent examinations, the Tennessee template, based on National Council for Prescription Drug Program (NCPDP) standards, offers a strong starting point for standardizing claims data collection. These standards are currently used throughout the PBM industry for claims processing, data reporting and for other purposes making data retrieval efficient and accurate. Further, it deliberately avoids Personally Identifiable Information (PII) concerns and is easily adaptable across various systems, supporting seamless implementation and integration.

While we support NCPDP standards as the basis of the initial request for claims data, the Coalition notes that due to the variances among state PBM laws, not all data fields in the

[1] The Cigna Group, CVS/Aetna, Elevance, UnitedHealth Group

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Tennessee template will be applicable in every state or should be the basis of a 100% claims data set. In the context of the Tennessee template, there are instances where deviations from the template make sense.

State Specific Data Requirements: Some data elements required by the Tennessee template do not apply broadly across all states. Moreover, these data fields do not have a corresponding NCPDP field and thus are not going to be standardized across PBMs. These fields include Low Volume Pharmacy Indicators, Sponsor Administrative Fee, Sponsor Amount and Cost Spread to PBM. The Coalition suggests that these, and other state-specific data elements, not be included in the NAIC template to preserve the integrity of a standard layout. State-specific compliance testing can be effectively addressed through:

- Targeted sampling, as endorsed in the NAIC Market Regulation Handbook; or
- Supplemental requests which allow regulators to explore specific issues without burdening all PBMs with non-standard reporting.

Data Elements Needing Calculation/Logic: Some data elements require additional calculations using business rules that are not uniformly applied and, therefore, are more appropriately and efficiently requested as part of an ad-hoc or sample-size claims request. As examples, these data elements include Accumulated Deductible Amount, Remaining Deductible Amount, Remaining Benefit Amount, Amount Applied to Periodic Deductibles and Amount Exceeding Periodic Benefit Maximum. This information cannot be automated and requires manual processes which will create inefficiencies and inaccuracies if applied broadly across all claims.

For your convenience, attached is a draft template for your consideration. Our recommendation is based on Tennessee's template and modified to allow for variances in state law. The data elements noted above are highlighted in the draft and those elements would therefore be done through either a sample-size methodology or some other type of agreeable process outside of the full claims dataset. We expect that states may have to supplement this template with other NCPDP standards to enforce their specific state laws, but those state-specific elements should not be included in the NAIC adopted template. To keep data operability across the industry, we would recommend that where deviations are necessary, they should be based on NCPDP standards wherever possible.

We appreciate the opportunity to contribute to this important initiative and look forward to working collaboratively with the working group to refine the template.

Sincerely,

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Christine Cappiello
Sr. Director, State Affairs and NAIC
Elevance Health

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UnitedHealth Group

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List of Pharmacy Claims

File Name: ClaimsWks[week numbers].xlsx. E.g., "ClaimsWks1and2.xlsx, ClaimsWks3and4.xlsx", etc.
Data should be submitted in bi-weekly files to manage file size.

The files should be downloaded from company system(s) and contain one record for each paid claim transaction submitted by pharmacies physically located in Tennessee, mail order pharmacies that served Tennessee residents, or specialty pharmacies that served Tennessee residents that the company processed within the scope of the audit.

Characters are required in all requested fields if applicable to a claim.

PBM may exclude information if the information pertains exclusively to plans in T.C.A. § 56-7-3102(1)(8).)

Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
503_F3	A	503-F3	Authorization Number	Number assigned by the processor to identify an authorized transaction.	
283	D	283	Original Claim Received Date	The date the pharmacy submitted the claim electronically for a paper claim- matching program.	MM/DD/YYYY
578	D	578	Adjudication Date	Date the claim or adjustment is processed.	MM/DD/YYYY
101_A1	A	101-A1	BIN Number	Card Issuer ID or Bank ID Number used for network routing.	
103_A3	A	103-A3	Transaction Code	Code identifying the type of transaction.	
104_A4	A	104-A4	Processor Control Number	Number assigned by the processor.	
201_B1	A	201-B1	Service Provider ID	NPI	The Service Provider ID should correspond to a NPI found on the Pharmacies Table
PhrmNme	A		Pharmacy Name		
Address1	A		Pharmacy Address Line 1		
Address2	A		Pharmacy Address Line 2 (if necessary)		
City	A		Pharmacy City		
State	A		Pharmacy State Abbreviation		
ZIPCode	A		Pharmacy Zip Code		
LwVolCrt	A		Low-Volume Pharmacy Indicator	Whether the pharmacy certified as a low-volume pharmacy with the PBM pursuant to Rule 0780-01-95-.10 for any portion of the calendar year	"Y"=Low Volume Pharmacy, "N"=Not a Low Volume Pharmacy
401_D1	D	401-D1	Date of Service	Identifies date the prescription was filled or professional service rendered or subsequent payer began coverage following Part A expiration in a long-term care setting only.	MM/DD/YYYY
332_CY	A	332-CY	Patient ID	ID assigned to the patient.	
302_C2	A	302-C2	Cardholder ID	Insurance ID assigned to the cardholder or identification number used by the plan.	
301_C1	A	301-C1	Group ID	ID assigned to the cardholder group or employer group.	
524_FO	A	524-FO	Plan ID	Assigned by the processor to identify a set of parameters, benefit, or coverage criteria used to adjudicate a claim.	
455_EM	A	455-EM	Prescription/Service Reference Number Qualifier	Indicates the type of billing submitted.	
402_D2	A	402-D2	Prescription/Service Reference Number	Reference number assigned by the provider for the dispensed drug/product and/or service provided.	
436_E1	A	436-E1	Product/Service ID Qualifier	Code qualifying the value in 'Product/Service ID' (407-D7).	
407_D7	A	407-D7	Product/Service ID	ID of the product dispensed or service provided.	
442_E7	N	442-E7	Quanity Dispensed	Quantity dispensed expressed in metric decimal units.	
403_D3	N	403-D3	Fill Number	The code indicating whether the prescription is an original or a refill.	
405_D5	N	405-D5	Days Supply	Estimated number of days the prescription will last.	
406_D6	A	406-D6	Compound Code	Code indicating whether or not the prescription is a compound.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
408_D8	A	408-D8	Dispense As Written (DAW)/Product Selection Code	Code indicating whether or not the prescriber's instructions regarding generic substitution were followed.	
414_DE	D	414-DE	Date Prescription Written	Date prescription was written.	MM/DD/YYYY
415_DF	N	415-DF	Number of Refills Authorized	Number of refills authorized by the prescriber.	
460_ET	N	460-ET	Quanity Prescribed	Amount expressed in metric decimal units.	
429_DT	A	429-DT	Unit Dose Indicator/Special Packaging Indicator	Code indicating the type of dispensing dose.	
600_28	A	600-28	Unit Of Measure	NCPDP standard product billing codes.	
461_EU	A	461-EU	Prior Authorization Type Code	Code clarifying the 'Prior Authorization Number Submitted' (462-EV) or benefit/plan exemption.	
462_EV	A	462-EV	Prior Authorization Number Submitted	Number submitted by the provider to identify the prior authorization.	
337_4C	A	337-4C	Coordination of Benefits/Other Payments Count	Count of other payment occurrences.	
338_5C	A	338-5C	Other Payer Coverage Type	Code identifying the type of 'Other Payer ID' (340-7C).	
339_6C	A	339-6C	Other Payer ID Qualifier	Code qualifying the 'Other Payer ID' (340-7C).	
340_7C	A	340-7C	Other Payer ID	ID assigned to the payer.	
443_E8	D	443-E8	Other Payer Date	Payment or denial date of the claim submitted to the other payer. Used for coordination of benefits.	MM/DD/YYYY
341_HB	N	341-HB	Other Payer Amount Paid Count	Count of the payer amount paid occurrences.	
342_HC	A	342-HC	Other Payer Amount Paid Qualifier	Code qualifying the 'Other Payer Amount Paid' (431-DV).	
431_DV	N	431-DV	Other Payer Amount Paid	Amount of any payment known by the pharmacy from other sources.	
409_D9	N	409-D9	Ingredient Cost Submitted	Submitted product component cost of the dispensed prescription. This amount is included in the 'Gross Amount Due' (430-DU).	
412_DC	N	412-DC	Dispensing Fee Submitted	Dispensing fee submitted by the pharmacy. This amount is included in the 'Gross Amount Due' (430-DU).	
477_BE	N	477-BE	Professional Service Fee Submitted	Amount submitted by the provider for professional services rendered.	
433_DX	N	433-DX	Patient Paid Amount Submitted	Amount the pharmacy received from the patient for the prescription dispensed.	
438_E3	N	438-E3	Incentive Amount Submitted	Amount represents a fee that is submitted by the pharmacy for contractually agreed upon services. This amount is included in the 'Gross Amount Due' (430-DU).	
478_H7	N	478-H7	Other Amount Claimed Submitted Count	Count of other amount claimed submitted occurrences.	
479_H8	A	479-H8	Other Amount Claimed Submitted Qualifier	Code identifying the additional incurred cost claimed in 'Other Amount Claimed Submitted' (480-H9).	
480_H9	N	480-H9	Other Amount Claimed Submitted	Amount representing the additional incurred costs for a dispensed prescription or service.	
426_DQ	N	426-DQ	Usual and Customary Charge	Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed.	
430_DU	N	430-DU	Gross Amount Due	Total price claimed from all sources. For prescription claim request, field represents a sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9). For service claim request, field represents a sum of 'Professional Services Fee Submitted' (477-BE), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Other Amount Claimed' (480-H9).	
423_DN	A	423-DN	Basis of Cost Determination	Code indicating the method by which 'Ingredient Cost Submitted' (Field 409-D9) was calculated.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
450_EF	A	450-EF	Compound Dosage Form Description Code	Dosage form of the complete compound mixture.	
451_EG	A	451-EG	Compound Dispensing Unit Form Indicator	NCPDP standard product billing codes.	
452_EH	A	452-EH	Compound Route of Administration	Code for the route of administration of the complete compound mixture.	
447_EC	N	447-EC	Compound Ingredient Component Count	Count of compound product IDs (both active and inactive) in the compound mixture submitted.	
488_RE	A	488-RE	Compound Product ID Qualifier	Code qualifying the type of product dispensed.	
489_TE	A	489-TE	Compound Product ID	Product identification of an ingredient used in a compound.	
448_ED	N	448-ED	Compound Ingredient Quantity	Amount expressed in metric decimal units of the product included in the compound mixture.	
449_EE	N	449-EE	Compound Ingredient Drug Cost	Ingredient cost for the metric decimal quantity of the product included in the compound mixture indicated in 'Compound Ingredient Quantity' (Field 448-ED).	
490_UE	A	490-UE	Compound Ingredient Basis of Cost Determination	Code indicating the method by which the drug cost of an ingredient used in a compound was calculated.	
545_2F	A	545-2F	Network Reimbursement ID	Field defined by the processor. It identifies the network, for the covered member, used to calculate the reimbursement to the pharmacy.	The Network Reimbursement ID should correspond to a NwkID found on the Network Table
568_J7	A	568-J7	Payer ID Qualifier	Code indicating the type of payer ID.	
569_J8	A	569-J8	Payer ID	ID of the payer.	
505_F5	N	505-F5	Patient Pay Amount	Amount that is calculated by the processor and returned to the pharmacy as the TOTAL amount to be paid by the patient to the pharmacy; the patient's total cost share, including copayments, amounts applied to deductible, over maximum amounts, penalties, etc.	
506_F6	N	506-F6	Ingredient Cost Paid	Drug ingredient cost paid included in the 'Total Amount Paid' (509-F9).	
507_F7	N	507-F7	Dispensing Fee Paid	Dispensing fee paid included in the 'Total Amount Paid' (509-F9).	
521_FL	N	521-FL	Incentive Amount Paid	Amount represents the contractually agreed upon incentive fee paid for specific services rendered. Amount is included in the 'Total Amount Paid' (509-F9).	
509_F9	N	509-F9	Total Amount Paid	Total amount to be paid by the claims processor (i.e. pharmacy receivable). Represents a sum of 'Ingredient Cost Paid' (506-F6), 'Dispensing Fee Paid' (507-F7), 'Flat Sales Tax Amount Paid' (558-AW), 'Percentage Sales Tax Amount Paid' (559-AX), 'Incentive Amount Paid' (521-FL), 'Professional Service Fee Paid' (562-J1), 'Other Amount Paid' (565-J4), less 'Patient Pay Amount' (505-F5) and 'Other Payer Amount Recognized' (566-J5).	
693	N	693	Total Gross Amount Due	Total sum of the gross amount due fields on the claim level.	
522_FM	A	522-FM	Basis of Reimbursement Determination	Code identifying how the reimbursement amount was calculated for 'Ingredient Cost Paid' (506-F6).	
512_FC	N	512-FC	Accumulated Deductible Amount	Amount in dollars met by the patient/family in a deductible plan.	
513_FD	N	513-FD	Remaining Deductible Amount	Amount not met by the patient/family in the deductible plan.	
514_FE	N	514-FE	Remaining Benefit Amount	Amount remaining in a patient/family plan with a periodic maximum benefit.	
517_FH	N	517-FH	Amount Applied to Periodic Deductible	Amount to be collected from a patient that is included in 'Patient Pay Amount' (505-F5) that is applied to a periodic deductible.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
518_FI	N	518-FI	Amount of Copay	Amount to be collected from the patient that is included in 'Patient Pay Amount' (505-F5) that is due to a per prescription copay.	
520_FK	N	520-FK	Amount Exceeding Periodic Benefit Maximum	Amount to be collected from the patient that is included in 'Patient Pay Amount' (505-F5) that is due to the patient exceeding a periodic benefit maximum.	
346_HH	A	346-HH	Basis of Calculation-Dispensing Fee	Code indicating how the reimbursement amount was calculated for 'Dispensing Fee Paid' (507-F7).	
347_HJ	A	347-HJ	Basis of Calculation-Copay	Code indicating how the Copay reimbursement amount was calculated for 'Patient Pay Amount' (505-F5).	
571_NZ	N	571-NZ	Amount Attributed to Processor Fee	Amount to be collected from the patient that is included in Patient Pay Amount (505-F5) that is due to the processing fee imposed by the processor.	
148_U8	N	148-U8	Ingredient Cost Contracted/Reimbursable Amount	Informational field used when Other Payer-Patient Responsibility Amount (352-NQ) or Patient Pay Amount (505-F5) is used for reimbursement. Amount is equal to contracted or reimbursable amount for product being dispensed.	
149_U9	N	149-U9	Dispensing Fee Contracted/Reimbursable Amount	Informational field used when Other Payer-Patient Responsibility Amount (352-NQ) or Patient Pay Amount (505-F5) is used for reimbursement. Amount is equal to contracted or reimbursable dispensing fee for product being dispensed.	
355_NT	N	355-NT	Other Payer ID Count	Count of other payers with payment responsibility.	
991_MH	A	991-MH	Other Payer Processor Control Number	A number that uniquely identifies the secondary, tertiary, etc. payer to the processor.	
356_NU	A	356-NU	Other Payer Cardholder ID	Cardholder ID for this member that is associated with the Payer noted.	
992_MJ	A	992-MJ	Other Payer Group ID	ID assigned to the cardholder group or employer group by the secondary, tertiary, etc. payer.	
142_UV	A	142-UV	Other Payer Person Code	Code assigned by the other payer to a specific person within a family.	
DrgNmS	A		Drug Name and Strength	Drug Name-The name under which the drug is marketed. I.e., the brand name if applicable or the generic name if the drug was not a brand name drug. Strength-How much of the active ingredient is present in each dosage.	
SpnsrFee	N		Sponsor Administrative Fee	Administrative fee charged to the plan sponsor	
SpnsrAmt	N		Sponsor Amount	Amount charged to the plan sponsor by the PBM for the cost of the drug or device	
SprdCst	N		Cost spread to the PBM	Amount charged to the plan sponsor by the PBM for the cost of the drug or device less the amount paid by the PBM.	

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Coalition Comment Letter to PBM (D) Working Group (January 30, 2026)

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January 30, 2026

Ms. Jolie Matthews
Pharmacy Benefit Management (D) Working Group
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700
Washington, DC 20001
EMAIL: JMatthews@naic.org

Re: Comments on PBM Exam Standards DRAFT dated November 25, 2025

Dear Ms. Matthews:

On behalf of our Coalition, we appreciate the opportunity to provide comments on the November 25, 2025, PBM Exam Standards Draft ("draft standards"). We appreciate the extensive work that went into developing the draft standards and value the NAIC's continued efforts to promote clarity, consistency, and applicability of examination standards across jurisdictions.

After reviewing the draft standards in detail, our Coalition proposes targeted revisions intended to increase language precision, promote regulatory consistency, align standards with existing statutory authority, and reduce operational burden without diminishing regulatory visibility.

Below is a consolidated, high-level summary of the key recommendations included in our submission. In addition to the summary below, we are also including a red-line version and a clean version of our suggested revisions to the draft standards.

Enhance overall clarity of standards.
Many of the revisions we made to the draft standards were to ensure that:

1. Standards are clear and actionable;
2. Requirements are tied to applicable state statutes and examinations are limited to fully insured plans and non-ERISA ASO; and
3. Obligations can be operationalized by both PBMs and regulators.

Where helpful, we also converted questions into standards or tightened language to reduce ambiguity.

Improve accuracy and consistency of PBM role descriptions and operational processes.
Our proposed revisions ensure the standards accurately reflect PBMs' delegated functions and distinguish them from activities retained by health plans. Several edits clarify that PBMs *support* health plans and non-ERISA ASOs but do not independently design or determine benefits. These revisions avoid misinterpretation of contractual roles and align terminology with other chapters of the Market Regulation Handbook (Handbook).

For the specialty drug and formulary sections, our revisions ensure the standards reflect how formulary committees operate, protect sensitive P&T committee information, and apply state definitions accurately. The language was refined to avoid requiring personal identifiable information beyond what is needed for compliance.

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Additionally, many edits correct assumptions or processes that do not reflect how PBMs operate today including:

1. Clarifying that effective rate reconciliation is not performed at the individual claim level;
2. Aligning claims-related standards with NCPDP requirements and state timelines; and
3. Adjusting language around network participation, contracting, vendor oversight, dispensing fees, and pharmacy audits to reflect operational realities and state variation.

Consolidate and streamline redundant text.
Throughout the draft standards, we identified repeated explanations (e.g., employer/Taft–Hartley definitions, glossary material, and examination procedure descriptions). We recommend removing duplicative language and consolidating background sections to improve readability and align the structure with other chapters included in the Handbook.

Clarify statutory vs. non-statutory requirements.
In many areas, the draft appeared to imply obligations not supported by state law or to apply insurer-centric concepts to PBMs (e.g., solvency, market analysis, concurrent review processes). Our revisions ensure the standards align with regulatory authority, clarify that certain requirements apply only where state law is applicable (e.g., fully insured and non-ERISA ASO plans), remove references to "covered entities" when statutory definitions may vary, and reduce the risk of inconsistent enforcement across states. Our edits clearly distinguish between:

1. PBM obligations established by state statute or regulation;
2. Plan-level requirements that cannot be imputed to PBMs; and
3. Optional examiner tools vs. mandatory review items.

Ensure safe treatment of confidential and proprietary information and adopt guidelines for the use of outside contracting firms/examiners.
Our revisions clarify where unredacted documents are appropriate and highlight the need for confidentiality protections—particularly around pricing terms, amendments, rebate contracts, and vendor agreements. Several edits emphasize that regulators should receive only the minimum necessary information to verify compliance, consistent with state public records laws. We also suggest incorporating recommendations on states' use of contract firms for consistency with the accreditation guidance adopted by the Financial Condition (E) Committee and Financial Regulation Standards and Accreditation (F) Committees in 2025.

Focus document requests on material, relevant information.
Many sections requested all contracts, all amendments, all correspondence, or all versions of network materials, which would generate enormous volumes of non-material data. Our revisions preserve examiner access to essential information while preventing burdensome, unmanageable audits. Our recommendations include:

1. Limiting requests for documentation and communication to in scope final, fully executed communications (rather than routine back and forth communication between contracting entities);
2. Allowing and encouraging sampling when large volumes of pharmacy contracts or audits exist;
3. Aligning claims-data requests to the subsets affected by state statute; and
4. Adding clarifying language to recognize that PSAOs—not PBMs—often control downstream communications to individual pharmacies.

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Align claims, reconciliation, and dispensing fee standards with industry practice and state law.
Our proposed revisions ensure:

1. Effective rate reconciliation is not treated as a claim-level or state specific process;
2. Dispensing-fee reviews are conducted only in states with explicit statutory requirements;
3. PBM processes are evaluated based on clear, concise communication requirements applicable under state laws; and
4. Examinations recognize that fee structures, unless prohibited, may differ for specialty, mail-order, and affiliate pharmacies.

Modernize network adequacy provisions.
When considering network adequacy standards, it is important to recognize that maintaining multiple networks is not an indicator that all networks were used or available for use in a certain state or type of client. For the network adequacy standards, we recommend revisions to:

1. Reflect that PBMs maintain multiple pharmacy networks with differing purposes;
2. Distinguish PBM network obligations from health plan adequacy obligations;
3. Ensure any adequate-access standard is tied directly to state law requirements; and
4. Remove comparisons that could misinterpret affiliate networks selected solely by a client.

Refine utilization review standards to reflect PBM functions.
Several sections of the draft standards referenced processes (e.g., concurrent review) that apply to medical benefit administration rather than PBM administration. In order to ensure that the standards reflect PBM functions we:

1. Aligned terminology with pharmacy-specific utilization review;
2. Ensured timelines and notification standards remain state-specific; and
3. Permitted disclosure of reviewer roles without requiring unnecessary personal information.

Standardize and clarify complaint, grievance, and appeals expectations.
For the complaint, grievance and appeals draft standards our Coalition recommends:

1. Aligning standards with existing state complaint-handling rules;
2. Focusing on PBM-specific responsibilities rather than insurer obligations;
3. Eliminating ambiguous standards (e.g., “easily understood”); and
4. Emphasizing accurate logging, timely response, and availability of documentation consistent with state law.

Improve audit standards for clarity and workability.
Our revisions regarding audit standards aim to ensure audits remain fair, efficient, and transparent while avoiding unnecessary administrative burdens. We suggested practical guardrails for audit-related documentation and addressed statutory limitations on audit methods such as extrapolation. Specifically, we recommend:

1. Limiting examiner requests to fully executed documents and final communications;
2. Eliminating production of informal, non-record communications;
3. Requiring clear PBM procedures for notice, documentation, timelines, and dispute processes; and
4. Ensuring audit standards reflect only those processes permitted or required under state law.

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Our Coalition appreciates the NAIC's willingness to work with us on refining the draft standards to enhance clarity, reduce ambiguity, and align them with established regulatory authority. As we have noted in the past, we support the creation of the standards and believe our suggested revisions will ultimately promote a more consistent and workable examination process for regulators and PBMs alike.

We welcome the opportunity to discuss any of these recommendations in more detail and look forward to our continued collaboration.

Sincerely,

Franca D'Agostino
Director, Regulatory Affairs
The Cigna Group

Leanne D. Gassaway
VP State Government Affairs
CVS Health

Christine Cappiello
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Elevance Health

Mollie Zito
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Draft 11/25/25

Comments are being requested on this draft on or before Jan. 16, 2026. Comments should be sent by email only to Jolie Matthews at jmatthews@naic.org.

Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:
The standards set forth in this chapter are not based on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination of Pharmacy Benefit Managers, as defined by state law. Since state laws vary, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in Chapter 1—Introduction.

This chapter provides a suggested format for conducting pharmacy benefit manager (PBM) examinations and reviews.

Background

Pharmacy Benefit Managers provide a variety of services to health plans including negotiating and contracting pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs work with a variety of clients including employers, health plans, and unions to help administer the benefits offered to members and may be contracted to develop, negotiate, implement, and administer formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example, drug coverage tiers and utilization management protocols). PBMs engage in negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

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Unlike insurance company examinations, there generally is little, if any, "market analysis" for Pharmacy Benefit Manager examinations. Similarly, Pharmacy Benefit Managers are not regulated for solvency.

Glossary of Terms

For general background, what follows is an explanation of key terms related to PBM examinations. Regulators however, must use state specific definitions when conducting a PBM Examination as the following general explanations do not replace, supersede, or modify definitions prescribed under applicable state or federal law, which remain the controlling authority.

Biologic Drugs - are distinct from traditional brand-name and generic drugs because they are made of living organisms. Examples include monoclonal antibodies, antitoxins, certain vaccines, and cell and gene therapies. Biologics are sometimes referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process. Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs. A biosimilar drug product is FDA-approved as having no clinically meaningful difference from the reference product and may be marketed following the

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expiration of the reference biologic's patent and exclusivity period. All FDA-approved biological products, including biosimilar and interchangeable biological products as well as a limited number of products available over the counter, are included in the FDA's ***Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*** (commonly known as the Purple Book). Certain biologics, including many biosimilars and cell and gene therapy products, are administered by health care providers and are typically covered under the medical benefit.

Statutory Definitions: Federal law defines key terms relevant to biologics, including biological product, reference product, biosimilar, and interchangeable biosimilar (42 U.S.C. §262). State pharmacy practice acts often include additional definitions, including when and under what conditions a pharmacist may substitute a generic for a brand name drug or a biosimilar for a biologic.

Brand-Name Drugs - are drugs sold by a manufacturer under a specific name or trademark that is protected by a patent. Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market. All FDA-approved brand-name drugs that are available by prescription, and some that are available over the counter, are included in the FDA's ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

Employers/Unions/Taft Hartley Trusts - have a variety of options available when designing the health benefits that they offer to their employees. They may choose a self-insured model, where the employer holds the risk. Regardless of the risk model payors sometimes contract with another entity, such as an insurance company, PBM, or other benefit manager, on a third-party basis to administer the benefits. These payors retain ultimate, discretionary control of the benefit plan design but may choose to delegate certain services, including carving out pharmacy benefit administration entirely, to one or more contracted benefits administrators.

Groups that are collectively bargained under ERISA Section 3(40), Taft-Hartley trusts established under 29 USC §186, and self-funded employer groups are not subject to state insurance regulations. Examiners may need to consult others in the insurance department or other regulatory agencies to correctly determine jurisdiction. Some states have enacted the NAIC Jurisdiction to determine Jurisdiction of Providers of Health Care Benefits Model Act which also provides guidance. Examiners may reference the NAIC Health and Welfare Plans Under the Employee Retirement Income Security Act (ERISA): Guidelines for State and Federal Regulation for more information about determining whether a state law is preempted by ERISA.

Generic Drugs - are small molecule drugs that are therapeutically equivalent (or bioequivalent) to their reference brand name drug products in dosage, safety, strength, and other factors and are only available after the brand-name drug is no longer patent-protected. Like brand-name drugs, the FDA must approve a generic drug application to ensure its equivalence to the brand-name drug before it can be produced. Prescription generic drugs comprise the largest portion of the U.S. pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers. All FDA-approved brand-name and generic drugs available by prescription, as well as certain products that are available over the counter, are listed in the ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

Health Plan refers to how state statutes define regulated fully-insured health benefit plans or non-ERISA Administrative Services Only (ASO) health benefit plans. Examiners should refer to those state definitions, but, generally, references to health plan in this chapter include any fully-insured arrangement or non-ERISA ASO under the regulatory authority of the state insurance department.

Insurers may choose to contract with PBMs to manage the pharmacy benefit portion of their health care benefits they provide to their insureds and enrollees. Insurers may choose to contract with PBMs because of the increasing complexity of prescription drug benefit management. In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their specific services that help manage or reduce costs, including utilization management, prescription drug rebates, negotiation of pharmacy dispensing fees and prescription drug

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reimbursements, and access to pharmacy networks. Ultimately, the scope of the PBM's role in administering the benefit depends on the insurer.

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

Statutory Definitions: Federal law includes definitions for key terms relating to health plans subject to state insurance regulation, including the Health Insurance Portability and Accountability Act (29 U.S.C. § 1191b) and the Public Health Service Act (42 U.S.C. § 300gg-9). In addition, each state has its own laws defining the entities (such as health carriers, health maintenance organizations, or health insurance issuers), products (such as health benefit plans or health insurance coverage), and markets (such as individual, small group, and large group health insurance markets) that are subject to state insurance regulation.

Manufacturers of pharmaceuticals research, develop, produce, market, and sell prescription drugs to treat medical conditions. The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition. Manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Manufacturers may also purchase prescription drugs developed by other manufacturers to market as their own.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Payors of health care services include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (e.g., individual, small group, large group or government program) and the arrangement that the payor chooses. In this handbook, when PBM functions are referenced, payors may choose to do those tasks internally.

Pharmacies offer a range of services to patients, including dispensing drugs, administering immunizations, performing health screenings, testing at point-of-care, and providing medication counseling. State laws often impose regulatory classifications and pharmacies, further, self-classify with the National Council for Prescription Drug Programs (NCPDP) based on various attributes, such as class (meaning their ownership structure, as explained herein) and the categories of prescription drugs dispensed and to what patient population (for example, specialty pharmacies, community/ retail pharmacies, compounding pharmacies, and long-term care pharmacies). The regulatory classifications, which vary by jurisdiction, create core parameters governing pharmacy operations.

PBMs and health plans use this information and may also use additional attributes, such as location (for example, urban, suburban, and rural), level of service, negotiated rates (for example, preferred v. non-preferred), network status (meaning in-network or out-of-network), or delivery mode to classify pharmacies. Unlike regulatory classifications, these categorizations are created for network management, reimbursement methodologies, and to administer benefit design.

A pharmacy chain typically refers to a third-party entity that engages in a business and that owns or operates four or more pharmacies under common ownership at which an individual consumer may have a prescription drug order filled.

Independent pharmacies generally include pharmacies that are privately and independently owned and operated by one or more pharmacists or under common ownership with no more than three pharmacies, and whose primary function is to provide direct pharmaceutical care to patients. in the community setting.

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Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). Federal law defines pharmacies as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Pharmacists are licensed and trained health care providers that assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a medication to a patient to ensure that the patients do not receive the wrong drug or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals. Pharmacists' permissible activities are subject to state scope of practice laws.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The DSCSA defines pharmacists as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Pharmacy Benefit Managers (PBMs) provide claims processing services or other prescription drug services on behalf of insurers to insureds or administer an insurer's prescription drug coverage pursuant to its contract or under an employment relationship with an insurer or health plan that directly manages the prescription drug coverage provided by the insurer or health plan. Insurers determine through contractual delegation which activities a PBM may perform on their behalf, which may include Negotiating and contracting with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network-related terms. PBMs may also develop, negotiate, implement, or administer clinical, formulary or other preferred lists for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example, drug coverage tiers, and utilization management protocols). PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews.

Pharmacy Benefits Manager Network means the group or groups of participating pharmacists or pharmacies providing pharmacy goods or services.

Pharmacy Services Administrative Organizations (PSAOs) are organizations that provide administrative services to independent pharmacies, who contract with PSAOs to perform services such as the evaluation, negotiation, and execution of a contract with PBMs or payors, or wholesalers. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly, for PBM network participation. The PSAO's also performs contract evaluation, negotiation of key terms like reimbursement rates, dispensing fees, billing requirements, payment frequency, effective rate reconciliations and value-based or quality payment adjustment terms and execution. PSAOs often perform credentialing services and may also offer their customers services such as, central payment and reconciliation, software, and patient data evaluation.[3]In many instances a PSAO is owned by a wholesaler, and most others facilitate business relationships with wholesalers to negotiate for, purchase, or deliver prescription drugs to their pharmacy clients.

Rebate means a formulary discount or pricing concession attributable to the utilization of prescription drugs in this state and that is paid by a manufacturer to a pharmacy benefits manager.

Statutory Definitions: While these programs are out of scope for purposes of state examinations, examiners should be aware that federal law establishes standards for certain rebates, including the Medicare Prescription Inflation Rebate Program (42 U.S.C. § 1395w-114a and -114b) and the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

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Specialty drugs - is a term that generally refers to drugs and biologics that are typically high-cost, and can be complex to ship, or store, require specialized administration, subject to limited or exclusive distribution or may require specialized clinical care such as frequent dosage adjustments, intensive patient monitoring or counseling, or ongoing clinical support (i.e. high-touch). It often references medications used to treat rare, complex, life threatening or chronic conditions. Because of this, these drugs often require dispensing through a specialty pharmacy, rather than traditional retail pharmacies.
There is no unified regulatory definition of the term specialty drug. Examiners should consult applicable state law and impacted health plan formulary definitions.

Wholesalers/Distributors purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. Wholesalers own several of the largest PSAOs used by independent pharmacies.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The Drug Supply Chain Security Act also establishes national standards for state licensing of wholesale drug distributors (21 U.S.C. § 353). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Qualifications of Examiners

Information on qualifications, please refer to Chapter 14 of the Market Regulation Handbook**.**

If a department elects to use contractors to complete a PBM examination, the department should demonstrate involvement of appropriate department personnel (i.e., department designees) during the course of the examination in accordance with the following guidelines and the department's policies and procedures. This should result in the department designee providing effective contractor oversight (e.g., status updates, budget oversight, approval of exam procedures), as well as understanding and assessing the overall quality of the work performed.

Use of Contract Personnel:

Standard: A department that utilizes contract personnel to assist in "Conducting the Pharmacy Benefit Manager Examination" should ensure that those hired in the capacity of a contractor are subject to standards that are comparable to or exceed those standards applicable to employees of the state, including disclosure of any conflicts of interest and agreeing to maintain confidentiality of examination records, proprietary data and other sensitive information they may be exposed to while under contract.

Results-Oriented Guidelines:

- The department should assess contractors used in performing examination and regulation activities to ensure the work being performed is commensurate with the department's processes and procedures.

Process-Oriented Guidelines:

- The department should have a process in place to consider qualifications, training and professional development of contractors performing PBM surveillance and market regulation activities.
- The department should have the authority to terminate a contract for services related to PBM surveillance and market regulation on the basis of poor performance.
- The department should have a process in place to consider any potential conflicts of interest among the contract personnel.
- The department should have a process in place to ensure the contract personnel will protect confidential information like PBM examination records, proprietary data and other sensitive information they may be exposed to while under contract.

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Types of Examinations

When planning the examination, it is essential to first identify which services and products are subject to regulatory oversight, the scope of clients impacted by those services and products, and the resulting implications on regulated entities. A Pharmacy Benefit Manager examination can take the form of a comprehensive examination, a targeted examination, a risk-focused examination, a re-examination, a multistate cooperative examination or a desk examination. Most of the elements found in Chapter 13—Types of Examinations will apply to the Pharmacy Benefit Manager examination. It is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Examiners should apply only those statutory and regulatory requirements that expressly govern PBMs. Requirements applicable to health plans—regardless of any delegation to a PBM—should not be treated as PBM compliance obligations. PBMs act in a support capacity, while compliance responsibility for plan level laws remains with the plan. PBMs contract with health plans to administer their pharmacy benefits in accordance with the plan's chosen benefit design. Each health plan retains the sole authority to design their pharmacy benefits and maintains discretionary control over the health plan's assets.

Scheduling, Coordination and Planning Scope

The procedures discussed in this section are to assist the regulator in determining if an examination or other type of regulatory action needs to be scheduled. It will also assist in developing a plan for conducting examinations, investigations, desk audits, interrogatories, letters or interviews when deemed necessary.

1. Determine the jurisdiction's requirements for licensing and examining the Pharmacy Benefit Manager and determine if the jurisdiction is permitted to accept the examination report of another state;
2. Survey appropriate divisions within the insurance department to identify potential areas of concern or interest relating to Pharmacy Benefit Managers operating in the jurisdiction;
3. For those Pharmacy Benefit Managers that have provided a current examination report and no unaddressed regulatory concerns exist, no additional analysis should be necessary. If analysis indicates that a market regulation action—such as a desk audit, letter, interrogatory, interview, investigation or examination—is appropriate, consider the possibility of coordinating with other jurisdictions with similar requirements or market regulation issues. Consider use of NAIC tools such as the Market Action Tracking System (MATS) for recording continuum types of regulatory responses and the Pharmacy Benefit Manager Examination Oversight (D) Working Group for multistate coordination of regulatory responses;
4. Survey the NAIC Research Division for relevant information to identify potential areas of concern in the evaluation process; and
5. Determine what specialists may be necessary to assist with the examination(ideally one with experience with the functions of a Pharmacy Benefit Manager).

For very narrow or specific regulatory issues, or for situations in which an examination is not required by statute, consider use of regulatory options other than an examination. For example, certain issues can be handled by a telephone call, letter or email; a data request; policy and procedure review; interrogatories; or desk audits. The remainder of this chapter is primarily written to facilitate examinations; however, certain information may be adaptable for the above-mentioned "continuum" type responses. An additional discussion of continuum of market actions is in Chapter 2 of this handbook.

For additional information on Market Conduct Examinations, please refer to Chapters 12 and 13 of the Market Regulation Handbook.

Procedural Considerations

Although not an insurance company examination, some of the basic procedures for a market conduct examination in Chapter 20 of this handbook should be followed in a Pharmacy Benefit Manager examination as

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noted below:

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;
- Notification of the examination;
- Preexamination procedures;
- On-site coordination;
- Communication management;
- Post-examination procedures; and
- The examination report.

Where possible, each state's defined examination protocols applicable to the examination of insurers—such as time frames and report submissions—should be applied to Pharmacy Benefit Manager examinations, as well.

Writing the Examination Report

The report preparation elements as outlined in Chapter 19 of this handbook are generally applicable to Pharmacy Benefit Manager examinations. However, the following special considerations also apply:

- In addition to safeguarding the confidentiality of individual policyholder information, care should be taken to not disclose trade secret information of the examinees or insurers that are customers of the examinees (e.g., individual insurer information in class or territory detail, or the processes and procedures of the examinee). The PBM should be given the opportunity to mark exhibits and/or portions of the report as "confidential and proprietary," if such is allowed under state law and these are not subject to otherwise applicable public release laws outside the regulatory community; and
- The PBM should be given the opportunity to review the examination findings prior to issuing a final report, if such practice is consistent with the state's insurers' examination act or other applicable statute.

Use of Examination Standards

Each of the following examination standards may be applicable to specific functions performed by a Pharmacy Benefit Manager. The examination plan should indicate which standards for review will be used for each specific examination.

A. Pharmacy Benefit Manager Operations/Management
B. PBM Pricing and Methodologies
C. Provider/Pharmacy Relations
D. Pharmacy Claims
E. PBM Pricing Methodologies
F. Pharmaceutical Manufacturer Rebates
G. Network Adequacy
H. Utilization Review
I. Drug Formulary, Placement and Specialty Drug
J. Complaints, Grievances, and Appeals
L. Audits

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A. Pharmacy Benefit Manager Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

The following standards would be the most applicable to a PBM examination.

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.
Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.
Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.
Standard 4 - The PBM has a valid disaster recovery plan.
Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.
Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.
Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.
Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.
Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.
Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.
Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.
Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.
Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 1

The PBM demonstrates it does not charge a health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug (i.e., spread pricing) as required by applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ c o p i e s o f contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

Copies of contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges, if applicable.

_ A schedule of only impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to a health plan for each prescription drug claim.

_____ Documentation demonstrating health plan billings and pharmacy reimbursement for a prescription drug claim during the exam period including an itemized breakdown if applicable, are identical.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and

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whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with state requirements.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 2
The PBM demonstrates the difference in its payment rates received by a health plan compared to the reimbursement paid to a pharmacy for a prescription drug if required by applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law,

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____An index of all policies and procedures relating to PBM's billing with health plans.

_____ An index of all policies and procedures relating to the PBM's payment to pharmacies.

_____ Copies of contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

Copies of contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total reimbursement amount charged to the health plan for each prescription drug claim.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM's pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

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Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.

_Based on information submitted with the policies and procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies all brand effective rate (BER) policies, state-specific policies. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM contracts with pharmacies or PSAOs in an unredacted format to the extent needed to confirm compliance with state law.

_____ All notices, material amendments, updates, or other informative documents applicable during the examination period describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.

_____ All documents provided to pharmacies applicable during the examination period that support or describe the PBM's effective rate reconciliation process to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.

_____ All reports or accounting documents provided to pharmacies or PSAOs applicable during the examination period showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and impacted claims data.

_____ Request all impacted claims data for a specified time period and in a standardized template showing whether each claim was 'reconciled' by the PBM in accordance with state law. Claims detail may include but is not limited to:

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Claim identifiers for all reconciled claims, to include retail, mail order, and specialty drug claims, including prescription number, date of service and product identifier.
- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid the pharmacy when it submitted the claim; the amount should not include the dispensing fee).

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- The total initial reimbursement of any dispensing fee.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each reconciled effective rate. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO for the reconciliation period(s) associated with the specified time period.

_____

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts or applicable material amendments thereto between the PBM and pharmacies in effect during the examination period, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, provider updates or manual amendments. Ensure all contractual language regarding the rate reconciliation process is clear and concise.

Request a listing of all network pharmacies or PSAOs that have an effective rate contract and all pharmacies or PSAOs that do not have one. If required by state law, ensure the PBM is offering contracts to all similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer a contract to any specific pharmacies or pharmacy types, such as independent pharmacies.

Assess how the PBM determines which claims will be part of the reconciliation process. Confirm the selection of the claims is communicated to pharmacies in clear and concise language.

Review all final and fully executed official documents and communications sent from the PBM to the pharmacy as part of the reconciliation process. This should include but not be limited to any reconciliation reports and any claims data that is provided or can be requested by the pharmacy. Ensure all communications from the PBM are clear, and concise, and reflect applicable state law. For example: provide sufficient detail to enable the pharmacy to understand the process and that all questions are appropriately addressed.

-
- Review all documents describing the final reconciliation amount that may be owed to or from pharmacies or PSAOs. Does the PBM provide reasonably sufficient detail to ensure that pharmacies understand how and when they will receive payment or make payments, if applicable? If a pharmacy is making a payment, are claims subject to an applicable state law prohibiting collection properly excluded?
- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that enables pharmacies to provide information to the PBM that may change the outcome of the reconciliation amount? Consider requesting specific examples of correspondence to review.

Review a sampling of claims to ensure the PBM follows its own policies and procedures regarding reconciliation process and how the claims sample fits into the final reconciliation. Where applicable, demonstrate that pharmacy claims that are reconciled through a contractually authorized program (i.e. effective rate or other performance-based program) allows the pharmacy to understand which claims have been included in the program and have been reconciled.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 4
The PBM demonstrates it has payment methodologies regarding the dispensing fees on a drug claim if required by statues, rules, and regulations.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ PBM to provide an index of all policies and procedures relating to pharmacy dispensing fees.

_____ All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.

_____ All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to mail order, specialty, or affiliate pharmacies.

_____ Contracts with the PBM and the health plan that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the health plan's oversight of the processes. Request the contract or applicable material amendments thereto in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims;
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
-
- The status of the claim for example paid, rejected, under appeal.
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.

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- If the claim was rejected or is under appeal, provide reasons.

**This information may be pared down if the regulator is only looking at dispensing fees and not all claims data. But pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*
***States have different requirements regarding dispensing fees paid to pharmacies in their jurisdiction.*

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts or material amendments thereto between the PBM and pharmacies in effect during the exam period, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost lists, drug discount or manufacturer coupon contracts. Ensure all contractual language regarding dispensing fees is clear and concise.

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language.

Assess the PBM's ability to change the dispensing fee amount. Confirm the 'change' process is transparent and communicated to pharmacies in clear and concise language. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

Review contracts between the PBM and the health plan to determine whether the payment of dispensing fees described to pharmacies is consistent with the PBM's requirements described in the health plan's contract with the PBM.

Review a sampling of claims to ensure the PBM follows its own policies and procedures regarding dispensing fees paid to pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. If required by state law, standards based on the type of pharmacy should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies and payment of dispensing fees should be consistent across pharmacies within the same network.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACY (AKA PROVIDER))

Standard 1
The PBM demonstrates that it exercises good faith and fair dealing in its contracting and contract negotiation processes with pharmacies.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ A listing of all pharmacies in the PBM's network. The listing should also require the PBM to provide a listing of all contracts (including provider manuals) and material contract amendments the PBM has in place with each pharmacy. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document.

_____ All final/fully executed documentation and correspondence between pharmacies and the PBM that pertain to the contract and material contract amendments. The Examiner may review documentation to assess the PBM and pharmacies' good faith negotiations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate to the extent such differentiated standards are prohibited by state law. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location if such limitations are permitted by law. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies to the extent required by state law.

Review policies and procedures for providing information to pharmacies about the contracting and contract

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negotiation processes. Examples include how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as who can submit the information and how i.e. via email, web portal or postal mail, any fees required. Ensure the PBM's contracting process, including requests for changes to contract terms, is described to pharmacies in clear and concise language.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review PBM communications to pharmacies to assess the PBM's responses to pharmacy negotiation requests. Ensure the PBM provides sufficient information to support or deny the pharmacy's requests. Ensure PBM contracting process is not unilateral or one-sided to prevent pharmacies from negotiating.

Review PBM's communications to pharmacies to assess if PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether PBM appears to contract with certain pharmacy types and not others. For example, does PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM explanation for such outcomes.

Assess how the PBM responds to pharmacy inquiries about the PBM's or the pharmacy's contractual obligations. For example, does the PBM have processes for pharmacies to initiate inquiries or obtain assistance from the PBM? Assess the PBM's responses to pharmacies during the inquiry process. Assess whether the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's response or final determination. Review specific examples of inquiries and follow-up from the PBM.

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**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 2
The PBM demonstrates that it exercises good faith and fair dealing in implementing its contractual obligations with its vendors that work with its network pharmacies.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all contracts with vendors that provide pharmacy benefits management services within scope on behalf of the PBM including a description of those services provided by each vendor and how the services impact pharmacies.

_____ From the index provided, review all policies and procedures that are applicable to the practices with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM contracts or applicable material amendments thereto with vendors that provide pharmacy benefit management services within scope on behalf of the PBM. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Standards should be applied in a non-discriminatory manner such that PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example, to the extent required by state law.

Review policies and procedures for providing information to pharmacies about vendors with whom the PBM contracts to perform certain functions. Review all documentation to assess whether the information that the PBM provides regarding its vendors is clear and concise.

Review contracts between PBM and its vendors to ensure the PBM does not permit its vendors to engage in activities that are prohibited under state law. For example, if state law prohibits a PBM from charging fees to a pharmacy, the PBM should not have a contract with a vendor that allows the vendor to charge the prohibited fees.

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Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its affiliate pharmacies over non-affiliated pharmacies.

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**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 3
The PBM demonstrates that it has a reasonable and easily accessible dispute resolution process for pharmacies to address matters of conflict with the PBM.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide a list (and definitions) of all categories of disputes that it considers 'disputes.' This may include but not be limited to complaints, independent third-party reviews, and arbitration.

_____ PBM to provide an index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.

_____ From the index provided, request all policies and procedures that are applicable to the dispute resolution process being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM documentation showing how disputes are addressed and finalized. PBM should provide examples of actual disputes and provide all documentation sent to or received by a pharmacy showing how the dispute was initiated and the final correspondence between the PBM and pharmacy and fully executed documentation showing how the dispute is resolved. Documentation should be consistent with other handbook standards regarding privacy and the sharing of PHI.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding the PBM's dispute resolution process with pharmacies. Review criteria for the different types of disputes to assess whether PBM has clear protocols, timeframes, and documentation requirements for addressing and resolving each type of dispute.

Review contracts or applicable material amendments thereto and manuals for details provided to pharmacies about the dispute resolution process. Review how PBM informs pharmacies of how disputes may be initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail, any fees required), PBM's obligation to provide a justification for the final determination and timeframes for PBM response and resolution of the dispute.

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Review contracts and manuals with details about the dispute resolution process to ensure the information provided to pharmacies is clear and concise.

Assess whether the PBM has provided pharmacies with a clear, transparent appeal process, including all information that must be shared or documented to support an appeal. Examples of requirements that may dissuade a pharmacy from initiating a dispute may include but are not limited to, requiring pharmacies to initiate disputes and send supporting documentation solely through postal mail or requiring exorbitant fee amounts to request or initiate a dispute resolution process.

Assess the PBM's responses to pharmacies during the dispute resolution process. Ensure the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's final determination.

Ensure PBM's policies and procedures and implementation of those policies and procedures are consistent with state law.

Assess whether PBM has staffing models to effectively resolve disputes.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PHARMACY CLAIMS

Standard 1
The PBM demonstrates that it has timely and transparent claims submission and adjudication processes for pharmacy claims that enable pharmacies to understand the payment rate prior to claims submission.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals that relate to the payment and adjudication of claims. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ PBM to provide an index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.

_____ Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ Other than contracts and manuals, request all documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted format to the extent needed to confirm compliance with state law.

_____ All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format to the extent needed to confirm compliance with state law..

_____ All impacted contacts with health plans in an unredacted format to the extent needed to confirm compliance with state law.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or

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dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
-
- The status of the claim (e.g., paid, rejected, under appeal).
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

_____ Regulatory actions

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures related to requirements for pharmacies to submit claims that may include but are not limited to the following:
- Claims processing software requirements.
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.
- Any NCPDP industry standards applicable.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:
- Dispensed as written codes.
- Over-the-counter products.
- Multi-ingredient compound processing.
- Override.
- Coordination of benefits.
- Reversals.
- Submission timeframes.

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:
- PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any reduction in reimbursement paid to the pharmacy.
- PBM should have clear criteria for claims approvals, denials or rejections.
- PBM should have clear timeframes for claims adjudication either through payment or denial/rejection of the claim in compliance with state claims timelines.
- PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is denied or rejected.
- PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or payment appeals for example, about any claims that are rejected or denied. This does not include benefit or coverage appeals that would be initiated by the member.

Review all PBM policies and procedures to assess whether the PBM applies different standards to different types

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of claims such as specialty drug, mail order, nonresident or discount card claims. Verify that any differing standards are consistent with state law.

Review all pharmacy contracts, including any Provider Manuals, to ensure the claims submission and adjudication processes are clearly and concisely described to pharmacies. The PBM should provide pharmacies with detailed information about:

- Each step necessary to submit a claim.
- The process and timeframe for the PBM to review and make a determination about whether a claim will be paid.
- How a pharmacy may submit an inquiry, appeal or otherwise contest the PBM's response to a pharmacy's claim. Information should include timeframes for each step in the process and should describe an easily accessible process for the pharmacy.
- Ensure information describes how pharmacies are reimbursed in accordance with applicable laws that may dictate payment amount and applicable dispensing fees.

Review all documentation to assess whether the PBM provides reasonably sufficient information about its claims payment methodology. This should include but not be limited to:

- If the PBM publishes a MAC list, the list is readily available and useful to pharmacies.
- If the PBM calculates payment from a drug pricing source it uses to pay pharmacies, any reduction is reasonably described in documentation to pharmacies.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, the process is clearly described to pharmacies.

When requesting claims data, require the PBM to submit ***all*** impacted claims being examined including mail order and specialty drug claims. Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of dispensing fee. Ensure PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

Consider requesting the PBM provide a live demonstration of its claims adjudication process for a sample of each type of claim being examined which may include but not be limited to: claims that are approved, claims that are denied, claims that are rejected, claims that are mail order only, or claims that are for fully insured insurers.

Review all, or a sampling of PBM contracts with health plans to assess if the PBM is compliant with the claims payment requirements in those contracts and that those terms are consistent with in all messaging to pharmacies. For example, if pass-through pricing is required by the health plan contract, is that consistent with the payment method (and applicable description) to pharmacies?

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to aggregators) are passed through to health plans if required by current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures within scope for this examination standard to the extent needed to confirm compliance with state law.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ Contracts or applicable material amendments thereto between the PBM and manufacturers within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals regarding manufacturer rebates for compliance with state laws.

Determine if applicable policies and procedures are implemented and applied.

Determine if manufacturer rebates received were properly forwarded to applicable health plans.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebates are passed through to health plans if required by current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates, fees and discounts.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures within scope for this examination standard to the extent needed to confirm compliance with state law.

_____ A listing of all health plans with which the PBM provides services in the state (for the applicable examination period).

_____ All impacted contracts or applicable material amendments thereto between the PBM and health plans within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates fees and discounts received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates, fees and discounts comply with state requirements.

Determine if applicable policies and procedures were implemented.

Determine if manufacturer rebates, fees and discounts received were properly forwarded to applicable health plans.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 3
The PBM demonstrates pharmaceutical manufacturer rebate payments are passed through directly to patients if required by current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.
Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ An index of all training manuals relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ Policies and procedures related to rebate crediting at the point of sale to the extent needed to confirm compliance with state law.

_____ A listing of all pharmacies that the PBM utilizes to pass rebates through to patients at the point of sale (for the applicable examination period).

_____ Contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent needed to confirm the PBM's compliance with applicable state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans or patients to monitor rebates received by the PBM and/or amounts passed through directly to patients.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates comply with state requirements.

Determine if applicable policies and procedures were implemented and applied.

Determine if manufacturer rebates received were passed through directly to patients.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 4
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly provided to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all training manuals relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all policies and procedures relating to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the PBM.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ Impacted contracts or material amendments thereto between the PBM and manufacturers. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of internal reports, certifications, or real-time systems used by employees in the preparation of statutorily required reports.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the preparation of statutorily required reports comply with state requirements.

Determine if applicable policies and procedures were communicated to employees responsible for the preparation of statutorily required reports.

Determine if the statutorily required reports were complete, accurate, and timely filed.

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for all pharmacies in its network is in compliance with applicable statutes, rules, and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ Pharmacy contracts and manuals relating to a PBM's language relating to credentialing.

_____ PBM to provide an index of all internal policies and procedures for the credentialing process.

_____ All policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for all pharmacies and pharmacy staff including but not limited to the pharmacist in charge (pharmacy manager), pharmacists, pharmacy technicians, and any customer service representatives. Review all exclusionary criteria such as requirements that pharmacists cannot be excluded or revoked by any licensing board.

Review any requirements for other personnel including but not limited to pharmacy owners, officers or directors. Review all exclusionary criteria that may apply.

Review all requirements for pharmacies including but not limited to application documents, insurance requirements such as professional liability coverage, any required minimum stock of drugs, and technological capabilities such as claims submission platforms.

Review policies and procedures for providing information to pharmacies about the credentialing process. Including

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how PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as via email, web portal or postal mail, any credentialing fees required.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy, how pharmacy may correct deficiencies or provide additional information.

Review contracts and manuals for details provided to pharmacies about the credentialing process. PBM should provide clear and concise information that is consistent with its own policies and procedures. Information provided to pharmacies should address all the requirements and steps for credentialing and should provide pharmacies with adequate time to provide all documentation and provide pharmacies with ability to address any questions about the process.

Request a listing of all pharmacies that went through the credentialing process during the examination period. Request the results of each process (i.e. was the pharmacy 'approved' to be in the PBM's network or not). Request the reasoning for all approval or denials.

Request final/fully executed correspondence between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sampling of those that went through the credentialing process. "Correspondence" may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM and any relevant and responsive emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy. Require documents to be provided in a readable format. Ensure all correspondence from the PBM is clear, concise and provides reasonably sufficient information to pharmacies regarding the credentialing process and any decisions made by the PBM to the extent required by law.

The PBM should describe the difference between the *PBM's network* and *pharmacy networks*. The PBM's network encompasses all pharmacies with which it contracts in the state. The PBM may have multiple pharmacy networks that may be designed based on types of drugs dispensed, how drugs are dispensed (i.e. mail order or retail), geographic location and will likely have differing reimbursement levels.

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any) that it creates and maintains a network of pharmacies in a transparent manner.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts or material amendments thereto and manuals. This should include all network contracts and forms. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____ PBM to provide an index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, examiners should request all relevant policies and procedures for areas being examined. Request documents be provided in an unredacted format, including requiring all pricing information be unredacted if needed to validate compliance with applicable state laws.

_____ PBM and health plan contracts within scope. Request the entire contract, including any material amendments, in an unredacted format if needed to validate compliance with applicable state laws.

_____ PBM to provide a listing of all the pharmacies with which it contracts. The listing should require PBM to identify each pharmacy's location (or identify if it is a mail order pharmacy), , the unique pharmacy network each pharmacy participates in, whether the pharmacy is an affiliate pharmacy or not, whether the pharmacies' network participation changed at any time during the examination period.

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy.

_____ PBM to provide a description of the differences in each unique pharmacy network. For each pharmacy network, the PBM should identify the types of drugs dispensed, consumer access (such as mail order or retail), the reimbursement levels including any 'discounts' applied and dispensing fees provided, any criteria for participation and any participation limits or restrictions. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ PBM to provide a sample list of all health plans within scope and each plan for the entity for which the PBM administers prescription drug benefits and which network is associated with each plan.

_____ If required by state law, the PBM files with the department of insurance all required contract forms and any material changes to a contract proposed for use with its participating providers and intermediaries.

Others Reviewed

_____ _____

_____ _____

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Review Procedures and Criteria

Review internal policies and procedures regarding PBM requirements for ensuring PBM is compliant with state network adequacy laws.

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure PBM has clear and concise requirements. PBM internal requirements should include but not be limited to:

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy desserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its health plan clients.
- Requirements for pharmacy network reimbursement levels in compliance with state law.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear and concise. Areas to review include but are not limited to:

- Do contracts/manuals clearly describe the requirements for participation in each pharmacy network?
- How does the PBM change the terms of the pharmacy network requirements? Any changes should be made in a transparent manner and with timely notice to the pharmacies.
- Do the contracts/manuals clearly describe the reimbursement including dispensing fees for each network?

Review the pharmacy listing to assess how often the PBM made changes to the pharmacy network requirements and participation levels during the examination period. Request all correspondence with pharmacies impacted by any changes. Request all correspondence with health plans within scope about the network changes. Ensure the message conveyed to health plans within scope is consistent with the message provided to pharmacies.

Review the listing of pharmacies and description of pharmacy network differences to ensure compliance with state and federal requirements. Depending on the state's legal requirements, areas to consider include by are not limited to:

- Does PBM have networks that are comprised solely of affiliate pharmacies?
- Does PBM have networks that are comprised solely of mail order pharmacies?

In any Summary of the PBM Network Adequacy that proceeds these standards, consider reviewing the PBM's contracts and manuals with pharmacies as part of how to ask for specific information about "contracting."

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 3
The PBM demonstrates that it maintains a network of pharmacies that is sufficient in number and types of pharmacies to ensure that all services to covered persons will be accessible without unreasonable delay if required by state law.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM policies and procedures for providing information to covered persons about pharmacy directories.

_____ PBM policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.

_____ PBM policies and procedures regarding availability of and updates to its provider network.

_____ All documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how the covered persons may contact the PBM with inquiries.

_____ PBM to provide a listing of all the pharmacies it contracts with. The listing should require PBM to identify each pharmacy's location or identify if it is a mail order pharmacy, the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Ensure the PBM has established and will maintain adequate arrangements to ensure reasonable proximity of participating pharmacies to the business or personal residence of covered persons. In determining whether a PBM has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

Review policies and procedures for providing information to covered persons about in-network pharmacies and emergency services.

Review all information provided to covered persons to ensure the information is provided in a clear and concise

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manner and updated regularly. PBMs should have clear information that describes how consumers may contact the PBM with any inquiries about pharmacy options.

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H. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that companies and their designees that provide or perform utilization review services comply with standards and criteria for the structure and operation of utilization review processes as required by state law.

The areas to be considered in this kind of review include the company's written utilization review policies and procedures, annual summary reports, timeliness in making utilization review decisions and handling appeals, communications with members about the program and oversight of delegated utilization review functions.

2. Techniques

The analysis of utilization review activities should include an overview of the pharmacy benefit manager's written utilization review policies, procedures and scripts, in addition to an overview of how utilization review activities are applied to individual cases. Utilization review issues may also surface during the examiners' inspection of claims, complaints and grievance procedures.

a. Examiners should request a written overview of the pharmacy benefit managers' utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the pharmacy benefit manager maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.

b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.

c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.

d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.

e. Obtain listings of utilization review approvals, denials and requests for reconsideration. Use sampling techniques to review specific cases. Evaluate handling for adherence to written guidelines and standards.

3. Tests and Standards

The utilization review assessment includes, but is not limited to, the following standards related to the performance of utilization review activities by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 1
The pharmacy benefit manager establishes and maintains a utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____Applicable statutes, rules and regulations, including those related to mandated benefits and services

_____Utilization review policies and procedures

_____Utilization review program or plan documentation

_____Medical criteria used to make utilization review determinations

_____Job description of the staff position functionally responsible for day-to-day management

_____Minutes of the Pharmacy Benefit Managers' board of directors

_____Minutes of the Pharmacy Benefit Managers' utilization review committee

_____Documentation of clinical staff credentialing maintenance and education requirements

_____Program assessment reports

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a Pharmacy Benefit Manager that requires a request for benefits under the covered person's health benefit plan to be subjected to utilization review, implements a written utilization review program that describes all review activities, both delegated and nondelegated for:

- The filing of benefit requests;

- The notification of utilization review and benefit determinations; and

- The review of adverse determinations in accordance with applicable state statutes,

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- Verify that the Pharmacy Benefit Manager's written utilization review program document describes all the following:
  - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of health care services;
  - Data sources and clinical review criteria used in decision-making;
  - Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
  - Data collection processes and analytical methods used in assessing utilization of health care services;
  - Provisions for ensuring confidentiality of clinical and proprietary information;
  - The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the health insurer's governing body; and
  - The staff position functionally responsible for day-to-day program management.

- Verify that the Pharmacy Benefit Manager ensures that appropriate personnel have operational responsibility for conducting the insurer's utilization review program.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 2
The pharmacy benefit manager operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager utilization review program uses documented clinical review criteria that are based on sound clinical evidence-based medicine and evaluated periodically to assure ongoing efficacy.

Note: The Pharmacy Benefit Manager may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the Pharmacy Benefit Manager makes its clinical review criteria available upon request to authorized government agencies.

Verify that the Pharmacy Benefit Manager ensures that qualified health care professionals administer the utilization review program and oversee review decisions. Verify that the Pharmacy Benefit Manager has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the Pharmacy Benefit Manager issues utilization review decisions and benefit determinations in a timely and efficient manner pursuant to the requirements set forth in applicable state statutes, rules and regulations.

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Verify that the Pharmacy Benefit Manager has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the Pharmacy Benefit Manager conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the Pharmacy Benefit Manager's data systems are sufficient to support utilization review program activities and to generate management reports to enable the Pharmacy Benefit Manager to monitor and manage health care services effectively.

If a Pharmacy Benefit Manager delegates any utilization review activities to a utilization review organization, verify that the Pharmacy Benefit Manager maintains adequate oversight, to include all the following:

- A written description of the utilization review organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the utilization review organization program by the Pharmacy Benefit Manager or respective insurer; and
- A process by which the Pharmacy Benefit Manager evaluates the performance of the utilization review organization.

Verify that the Pharmacy Benefit Manager coordinates its utilization review program activities with other medical management activity conducted by the health insurer, such as quality assurance, credentialing, provider contracting, data reporting, grievance procedures, claims adjudication, processes for assessing member satisfaction and risk management.

Verify that the Pharmacy Benefit Manager provides covered persons, or, if applicable, the covered person's authorized representatives and participating providers with access to its utilization review staff via a toll-free number or collect call telephone line.

Verify that the Pharmacy Benefit Manager, when conducting utilization review, collects only the information necessary, including pertinent clinical information, to make the utilization review or benefit determination.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 3
The Pharmacy Benefit Manager discloses information about its utilization review and benefit determination procedures to covered persons, or, if applicable, the covered persons' authorized representative, in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Member materials

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager provides a clear and accurate summary of its utilization review and benefit determination procedures to the covered person's authorized representative.

Verify that the Pharmacy Benefit Manager provides a clear and comprehensive description of its utilization review procedures, including the procedures for obtaining adverse review determinations, and a statement of rights and responsibilities of covered persons.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 4
The Pharmacy Benefit Manager makes standard utilization review and benefit determinations in a timely manner and as required by applicable state statutes, rules and regulations, as well as the provisions of HIPAA.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the Pharmacy Benefit Manager by the covered person, or, if applicable, the covered person's authorized representative, for benefits and for notifying the covered person, and, if applicable, the covered person's authorized representative, of its determinations with respect to these requests within the specified time frames required pursuant to applicable state statutes, rules and regulations.

For prospective review determinations, verify that the Pharmacy Benefit Manager makes the determination and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether the Pharmacy Benefit Manager certifies the provision of the benefit or not, within a reasonable period of time appropriate to the covered person's medical condition, but in no event later than 15 days after the date the Pharmacy Benefit Manager receives the request.

Whenever the determination is an adverse determination, verify that the Pharmacy Benefit Manager makes the notification of the adverse determination in accordance with state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination.

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Verify that if the Pharmacy Benefit Manager extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the Pharmacy Benefit Manager has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 15-day time period, of the circumstances requiring the extension of time and the date by which the Pharmacy Benefit Manager expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Whenever the Pharmacy Benefit Manager receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the health insurer's filing procedures, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of this failure and provides in the notice information on the proper procedures to be followed for filing a request.

Verify that the notice referenced in the previous paragraph is provided by the Pharmacy Benefit Manager as soon as possible, but in no event later than five days following the date of the failure.

Verify that the Pharmacy Benefit Manager provides the notice orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to meet the Pharmacy Benefit Manager's filing procedures apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and

- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a Pharmacy Benefit Manager has certified an ongoing course of treatment to be provided over a period of time or number of treatments, examiners need to be aware that:

- Any reduction or termination by the Pharmacy Benefit Manager during the course of treatment before the end of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and

- The Pharmacy Benefit Manager shall notify the covered person, or, applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the

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covered person's authorized representative, to file a grievance to:

- Request a review of the adverse determination pursuant to state statutes, rules and regulations; and
- Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

Verify that the health care service or treatment that is the subject of the adverse determination is continued by the Pharmacy Benefit Manager without liability to the covered person with respect to the internal review request made pursuant to state statutes, rules and regulations.

For retrospective review determinations, verify that the Pharmacy Benefit Manager makes the determination within a reasonable period of time, but in no event later than 30 working days after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination to the covered person, or, if applicable, the covered person's authorized representative, in accordance with applicable state statutes regarding procedures for standard utilization review and benefit Pharmacy Benefit Manager determination.

Verify that if the health insurer extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the health insurer has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 30-day time period, of the circumstances requiring the extension of time and the date by which the health insurer expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Verify that the Pharmacy Benefit Manager calculates the time periods, within which a prospective or retrospective determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is received by the Pharmacy Benefit Manager in accordance with the health insurer's procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to make the determination, verify that the Pharmacy Benefit Manager calculates the time period for making the determination to begin on the date on which the Pharmacy Benefit Manager sends the notification of the extension to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:

- The date on which the covered person, or, if applicable, the covered person's authorized representative, responds to the request for additional information; or
- The date on which the specified information was to have been submitted.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 5
The Pharmacy Benefit Manager provides written notice of an adverse determination of standard utilization review and benefit determinations in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager issues notification of an adverse determination, as required by state law. A description of the Pharmacy Benefit Manager's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;

Verify that the Pharmacy Benefit Manager provides the notice as required by state law if they are delegated to do so.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 6
The Pharmacy Benefit Manager conducts expedited utilization review and benefit determinations in a timely manner and in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager has established written procedures pursuant to applicable state statutes, rules and regulations for receiving benefit requests from covered persons, or, if applicable, their authorized representatives, and for making and notifying the covered person, or, if applicable, the covered person's authorized representative, of expedited utilization review and benefit determinations with respect to urgent care requests.

Verify that the Pharmacy Benefit Manager, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request, notifies the covered person, or, if applicable, the covered person's authorized representative, of the failure and the proper procedures to be followed for filing the request.

Verify that the Pharmacy Benefit Manager's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's as required by applicable state statues, rules, and regulations.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and
- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment or provider for which approval is being requested.

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For an urgent care request, unless the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the Pharmacy Benefit Manager to determine whether, or to what extent, the benefits requested are covered benefits or payable under the health insurer's health benefit plan, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of the Pharmacy Benefit Manager's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, and within the timeline required by applicable state statues, rules and regulations.

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the health insurer to make a determination, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, as required by applicable state statues, rules, and regulations around notification and timeframe.

Verify that the Pharmacy Benefit Manager provides the covered person, or, if applicable, the covered person's authorized representative, a reasonable period of time to submit the necessary information, taking into account the circumstances, pursuant to applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible and as required by applicable state statues, rules and regulations.

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the Pharmacy Benefit Manager's determination is an adverse determination, the Pharmacy Benefit Manager shall provide notice of the adverse determination or coordinate with the insurer in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

Verify that the Pharmacy Benefit Manager calculates the time period within which a determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is filed with the either the health insurer or Pharmacy Benefit Manager in accordance with the health insurer's procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

Verify that the Pharmacy Benefit Manager's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative as required by applicable state statutes, rules, and regulations. A description of the Pharmacy Benefit Manager expedited review procedures established pursuant to applicable state statutes, rules and regulations;

Verify that the Pharmacy Benefit Manager provides the notice orally, in writing or electronically.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 7
The Pharmacy Benefit Manager monitors the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and ensures that the contracting organization complies with applicable state provisions and accompanying regulations.

Apply to: PBMs contracting out utilization review services.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Contracts with organizations or entities within scope for this examination standard. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Reports of entity reviews and audits (if any) by health plan

_____Periodic reports from the organization or entity, if required by contract or state law. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's board of directors. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's utilization review committee. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

_____Policies and procedures for oversight within scope. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a Pharmacy Benefit Manager contracts to have a utilization review organization or other entity perform the utilization review functions required by the Utilization Review and Benefit or applicable state statutes, rules and regulations, the Pharmacy Benefit Manager is responsible for monitoring the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and for ensuring that the requirements of the Utilization Review and applicable state statutes, rules and regulations are met.

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Verify that the Pharmacy Benefit Manager has policies and procedures in place that ensure the utilization review programs of designees comply with all applicable state and federal laws establishing confidentiality and reporting requirements.

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The Drug Formulary, Placement and Specialty Drug review includes, but is not limited to, the following standards related to how the Formulary is managed and controlled by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 1
The pharmacy benefit manager establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Formularies and formulary templates used during the examination period.

All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period are compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period are compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other committee decisions and statements comply with all applicable state statutes, rules and regulations.

The identification of members of a P&C Committee shall not be publicly disclosed.

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STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 2
The pharmacy benefit manager establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period.

_____ All policies, procedures, and other documentation relevant to drug utilization management; including but not limited to, all fail-first policies including step-therapy protocols, prior authorization requirements, and medical necessity guidelines.

_____Any and all list(s) of medications included in and excluded from the mail order benefit.

_____Any list(s) of all medications allowed for a 90-day supply and those only allowed for 30-day supply or less, for both mail order and retail pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to comply with all applicable state statutes, rules and regulations.

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period are compliant with applicable state statutes, rules or regulations.

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STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 3
The pharmacy benefit manager defines specialty drug and executes specialty drug formulary placement in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations that are applicable to Pharmacy Benefit Managers

_____Formularies and formulary templates used during the examination period.

_____Utilization review policies and procedures

_____Specialty drug list(s)

_____All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period are compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period that places specialty and non-specialty drugs on formularies in compliance with all applicable state statutes, rules, and regulations.

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other committee decisions and statements use and apply the state statute definition of specialty drug to in compliance with all applicable state statutes, rules and regulations.

The identification of members of a P&C Committee shall not be publicly disclosed.

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J. Complaints, Grievances, and Appeals

1. Purpose

The purpose of complaints, grievances and appeals handling procedures is to provide a process for consumers or providers to address issues, and to evaluate how well a regulated entity complies with laws, resolves issues, and timely responds to dissatisfaction expressed by consumers or providers. This includes:

- Ensuring compliance with applicable statutes and/or regulations[1], including:
    - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
    - Establishing whether violations were committed; and
    - Monitoring future conduct for compliance;

- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers or providers; and

- Identifying problem areas that may indicate broader operational issues.

All sections emphasize the importance of reviewing how concerns-whether classified as complaints, grievances or appeals-are processed, documented, and used to improve consumer service.

2. Techniques

The examination approach for complaints, grievances, and appeals procedures include the following shared techniques:

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems.
- **Documentation Review:** Assessing written policies, procedures, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, and providers are informed of the procedures and their rights.

All procedures call for reviewing the frequency and nature of the issues raised and whether they were resolved in accordance with the applicable standards

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, resolution)
- **Procedural Adequacy:** Verifying that the regulated entity has adequate written procedures for handling and resolving the issue, and that these are disclosed to consumers
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law
- **Compliance and Fairness:** Determine that responses:

[1] The term statutes and/or regulations refers to all legally binding statutes, rules, regulations, policies or other documents promulgated by an entity with said power.

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- Fully address the issue(s) that was raised.
- Include adequate supporting documentation.
- Are compliant with policy statutes and regulations.
- Provide appropriate remedies when necessary.

Complaints, Grievances and Appeals stress maintaining records that are accessible to regulators and retaining them for appropriate time periods.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The pharmacy benefit manager maintains a detailed, accessible register documenting each complaint, grievance, or appeal, in accordance with applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Regulated entity register

_____Insurance department records

_____Direct consumer complaint, grievance, or appeal

_____Member evidence of coverage

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify accurate logging of the issue, date received, review actions, and resolution

Verify that the register includes enough detail to support regulatory review

Verify that the PBM retains the register for at least 3 years if required by state law.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The pharmacy benefit manager has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers and contracted providers.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.

_____Member evidence of coverage.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM maintains a complaint register.

Verify that the PBM's procedures comply with applicable statutes and regulations.

Verify that the PBM's procedures are communicated to consumers and contracted providers.

Verify that the PBM has filed procedures with the insurance commissioner where required.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 3
The pharmacy benefit manager must resolve and respond to complaints, grievances, and appeals within prescribed timeframes required by applicable statues, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review test sample to ensure the PBM is maintaining adequate documentation.

Determine if the PBM's response is timely. The Examiner should refer to state laws and regulations for the required time frame. *Note:* Timing is measured from the date the issue is received.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The pharmacy benefit manager actions taken in response to complaints, grievances, or appeals must comply with applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations

_____Complaint, grievance, and appeal procedure manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review documentation to determine if the PBM response fully addresses the issues raised. If the PBM did not properly address/resolve the complaint, the Examiner should ask the PBM what corrective action it intends to take.

For reviewing responses:
- Was the response timely.
- Was the response complete and responds to all issues raised.
- Does the response include adequate documentation to support the respondent's position.
- Were the respondent's actions appropriate from a business standpoint.
- Were the respondent's actions compliant with applicable statutes and regulations.
- Were the appropriate remedies for the consumer identified.

Document potential violations.

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STANDARDS
PHARMACY BENEFITS MANAGERS
AUDITS

Standard 1
The PBM demonstrates that it has documented policies and procedures for pharmacy audits and demonstrates that it conducts the pharmacy audit in compliance with its policies and procedures and in compliance with appliable statutes, rules, and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.

_____ Listing of all types of audits that may include but not be limited to, on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)

_____ From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted format to the extent needed to confirm compliance with state law.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format to the extent needed to confirm compliance with state law.)

_____ Listing of all audits initiated or that were ongoing during the examination period. (As part of this request, require a timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal.

_____ A*ll correspondence* within scope between the PBM and a pharmacy as part of audits during the examination period. (Consider whether to request information from all audits or just a sampling of the audits. 'Correspondence' may include all final and fully executed documents and communications sent by the PBM to the pharmacies andby the pharmacies to the PBM as part of the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format to the extent needed to confirm compliance with state law.)

_____.

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_____.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal PBM policies and procedures regarding the PBM's audit process with pharmacies. Review criteria for the different types of audits to assess whether PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit including but not limited to processes for initiating, conducting and resolving each type of audit.

Review contracts and manuals with details about the audit process to ensure the information provided to pharmacies is clear, and concise.

Review contracts and manuals for details provided to pharmacies about the audit process. Review how PBM informs pharmacies of how audits are initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail), any fees required by the PBM that are outside the audit finding, how the pharmacy may address and rectify potential findings, PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

Assess whether the PBM's pharmacy audit requirements are compliant with state law and provide pharmacies with the following:

- The scope, frequency (including the maximum annual amount) and method of all audits.
- Detailed guidelines, including metrics and data, used during audits.
- Advanced notice of an upcoming audit.
- Sufficient time to prepare and collect required information.
- Convenient and accessible methods for corresponding with the PBM during the audit, for example does the pharmacy have a point of contact to ask questions and obtain clarification on the PBM's expectations.
- Sufficient time to review and correct any audit findings prior to the PBM's final determination.
- Sufficient input into the implementation of a corrective action plan (if applicable) and sufficient time to comply with the requirements of a corrective action plan.
- An appropriate dispute resolution process that pharmacies may use to dispute audit findings. The process for pharmacies should be convenient and accessible and should not create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute resolution process.

If the regulator feels the PBM's policies and procedures are compliant with state law, ensure the PBM also follows and implements its own policies & procedures. Review timeframe requirements, whether the PBM provides reasonable and concise information to pharmacies in response to any questions, and whether the PBM provides appropriate justifications in the draft and final audit reports.

Review the results of all audits to determine there are no concerning trends with how the PBM conducts audits. For example, when conducting routine audits, are pharmacies selected randomly or does the PBM only audit non-affiliated, independent pharmacies?

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Verify that the PBM conducts pharmacy audits in compliance with applicable state laws and regulations. Ensure such methods are reasonable, utilized appropriately and consistent with any regulatory requirements (or prohibited if required by state law or regulation). For example, if use of auditing techniques such as extrapolation is prohibited by state law or regulation, the PBM should not apply the method in any audits.

Assess whether PBM has staffing models to effectively initiate, conduct and finalize audits.

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Draft 11/25/25

Comments are being requested on this draft on or before Jan. 16, 2026. Comments should be sent by email only to Jolie Matthews at jmatthews@naic.org.

Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:
The standards set forth in this chapter are ~~based on state procedures, not~~not based on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination ~~process~~of Pharmacy Benefit Managers, as defined by state law. Since ~~there are limits to state procedures and~~ state laws vary, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in Chapter 1—Introduction.

This chapter provides a suggested format for conducting pharmacy benefit manager (PBM) examinations and reviews. ~~In addition to this chapter, the examiner should be familiar with the NAIC white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (NAIC White Paper).~~

Background~~, Scope and Types of Examinations~~

~~"Pharmacy Benefit Manager" is defined in the NAIC White Paper as entities that negotiate and contract~~Pharmacy Benefit Managers provide a variety of services to health plans including negotiating and contracting ~~with all the various types of~~ pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs work with a variety of clients including employers, health plans, and unions to help administer the benefits offered to members and may be~~are~~ contracted to develop , negotiate, implement, and administer ~~manage~~ formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated ~~are responsible for~~ the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example, drug coverage tiers~~, out of pocket responsibilities for patients~~ and utilization management protocols). PBMs engage in negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

Commented [A1]: Refined PBM role description to accurately reflect the PBM's role of working with clients rather than being solely responsible for activities such as plan design, etc.

~~Examinations of Pharmacy Benefit Manager can be either comprehensive or targeted. A Pharmacy Benefit Manager examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the Pharmacy Benefit Manager's systems and procedures are similar, if not identical, for every state, the examination and resulting report should be acceptable in all states, regardless of which jurisdiction conducts the examination.~~

Commented [A2]: Recommend deletion as this is addressed in "Types of Examinations" below.

Unlike insurance company examinations, there generally is little, if any, "market analysis" for Pharmacy Benefit Manager examinations. Similarly, Pharmacy Benefit Managers are not regulated for solvency. ~~Rather, Pharmacy Benefit Manager negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.~~

Commented [A3]: Recommend deletion of language as it is redundant to language in the first paragraph.

~~**For additional information on background and scope, please refer to chapter 12&13 of the Market Regulation Handbook.**~~

Commented [A4]: Recommend moving this language to "Scheduling, Coordination, and Scope."

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~~Definitions~~Glossary of Terms~~:~~

For general background, what follows is an explanation of key terms related to PBM examinations. ***Regulators ~~may want to consider~~ however, must use state specific definitions when conducting a PBM Examination as the following general explanations do not replace, supersede, or modify definitions prescribed under applicable state or federal law, which remain the controlling authority*.**

Biologic Drugs - ~~Biologic drugs~~ are distinct from traditional brand-name and generic drugs because they are made of living organisms. Examples include, ~~cells, such as~~ monoclonal antibodies, antitoxins, ~~and~~ certain vaccines, and cell and gene therapies.~~[16]~~ Biologics are sometimes referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process.~~[17]~~ Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.~~[18]~~ A biosimilar drug product is FDA-approved as having no clinically meaningful difference from the reference product and may be marketed~~produced~~ following the expiration of the reference biologic's patent and exclusivity period. All FDA-approved biological products, including biosimilar and interchangeable biological products as well as a limited number of products available over the counter, are included in the FDA's ***Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*** (commonly known as the Purple Book). Certain biologics, including many biosimilars and cell and gene therapy products, are administered by health care providers and are typically covered under the medical benefit.

Statutory Definitions: Federal law defines key terms relevant to biologics, including biological product, reference product, biosimilar, and interchangeable biosimilar (42 U.S.C. §262). State pharmacy practice acts often include additional definitions, including when and under what conditions a pharmacist may substitute a generic for a brand name drug or a biosimilar for a biologic.

Brand-Name Drugs - ~~Manufacturers who produce brand-name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name~~ are drugs sold by a manufacturer under a specific name or trademark that is protected by a ~~receive~~ patent.~~nts and exclusivities from the FDA.~~[12] Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market. All FDA-approved brand-name drugs that are available by prescription, and some that are available over the counter, are included in the FDA's ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

Employers/Unions/Taft Hartley Trusts - ~~Employers~~ have a variety of options available when designing the health benefits that they offer to their employees. They may choose a self-insured model, where the employer holds the risk. Regardless of the risk model, ~~but~~ payors sometimes contract with ~~hires~~ another entity, such as an insurance company, PBM, or other benefit manager , on a third party basis t~~o~~ administer the benefits. ~~Employers~~ These payors retain ultimate, discretionary control of the benefit plan design but may choose to delegate certain services, including carving out pharmacy benefit administration entirely, to one or more ~~choose how much of the benefits they will allow a~~ contracted benefits administrators. ~~to design and may choose to "carve out" the pharmacy administration and have external entities perform different functions.~~

Groups that are collectively bargained under ERISA Section 3(40), Taft-Hartley trusts established under 29 USC §186, and self-funded employer groups are not subject to state insurance regulation. Examiners may need to consult others in the insurance department or other regulatory agencies to correctly determine jurisdiction. Some states have enacted the NAIC Jurisdiction to determine Jurisdiction of Providers of Health Care Benefits Model Act which also provides guidance. Examiners may reference the NAIC Health and Welfare Plans Under the Employee Retirement Income Security Act (ERISA): Guidelines for State and Federal Regulation for more information about determining whether a state law is preempted by ERISA.

Commented [A5]: This has been updated to improve consistency with the approach of other Handbook chapters and to reflect that these terms are not based on an NAIC Model Law. The proposed changes reflect the goal of providing general background information/ context while referring examiners to state or federal law for how to define specific terms during the examination process. Where possible, references to specific federal statutes have been added.

Commented [A6]: Removing numbers that appear to be unlinked references throughout and instead inserting federal law citations, consistent with other health-related Handbook chapters.

Commented [A7]: Many state pharmacy practice laws reference the Orange and Purple Books.

Commented [A8]: This is a general explanation taken from Healthcare.gov's glossary of terms, available at Brand name (drugs) - Glossary | HealthCare.gov. FDA also has a glossary of terms, available at Drugs@FDA Glossary of Terms | FDA

Commented [A9]: Many state pharmacy practice laws reference the Orange and Purple Books.

Commented [A10]: Edits to attempt to improve consistency with how TPA is explained in Ch. 30 (Conducting the TPA Examination). Please note that the terms union and Taft Hartley Trusts are not used throughout the standards that follow.

Commented [A11]: Added for consistency with the explanation of "Exempt Benefit Plans" in Ch. 24 (Conducting the Health Examination).

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Generic Drugs - ~~Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing~~ are small molecule drugs that are therapeutically equivalent ~~generic~~(or bioequivalent) to their reference brand name ~~-~~drug products in dosage, safety, strength, and other factors and are only available after the brand-name drug is no longer patent-protected. Like brand-name drugs, the FDA must approve a generic drug application to ensure its equivalence to the brand-name drug before it can be produced.~~13~~ ~~G~~ Prescription generic drugs comprise the largest portion of the U.S. pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers~~.~~. All FDA-approved brand-name and generic drugs available by prescription, as well as certain products that are available over the counter, are listed in the ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

Commented [A12]: This was included because many state pharmacy practice laws reference the Orange and Purple Books.

Health Plan refers to how state statutes define regulated fully-insured health benefit plans or non-ERISA Administrative Services Only (ASO) health benefit plans. Examiners should refer to those state definitions, but, generally, references to health plan in this chapter include any fully-insured arrangement or non-ERISA ASO under the regulatory authority of the state insurance department.

Insurers may choose to ~~—Insurers~~ contract with PBMs to manage the pharmacy benefit portion of their health care benefits they provide~~d~~ to their insureds and enrollees.~~4~~ Insurers may choose to contract with PBMs because of the increasing complexity of prescription drug benefit management.~~5~~ In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their specific services that help manage or reduce costs, including utilization management, prescription drug rebates, ~~and~~ negotiation of pharmacy dispensing fees and prescription drug reimbursements, and access to pharmacy networks.~~6~~ Ultimately, the scope of the PBM's role in administering~~managing~~ th~~eis~~ benefit depends on the insurer. ~~7~~

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

Statutory Definitions: Federal law includes definitions for key terms relating to health plans subject to state insurance regulation, including the Health Insurance Portability and Accountability Act (29 U.S.C. § 1191b) and the Public Health Service Act (42 U.S.C. § 300gg-9). In addition, each state has its own laws defining the entities (such as health carriers, health maintenance organizations, or health insurance issuers), products (such as health benefit plans or health insurance coverage), and markets (such as individual, small group, and large group health insurance markets) that are subject to state insurance regulation.

Manufacturers ~~—P~~ of p~~harmaceutical~~s ~~manufacturers~~ research, develop, produce, market, and sell prescription drugs to treat medical conditions.~~8~~ The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition.~~9~~ Manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Manufacturers may also purchase prescription drugs developed by other manufacturers to market as their own.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Payors ~~—Payors~~ of health care services include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (e.g., individual, small group, large group or government program) and the arrangement that the payor chooses. In this ~~paper~~handbook, when PBM functions are referenced, payors may choose to do those tasks internally.

Pharmacies offer a range of services to patients, including dispensing drugs, administering immunizations, performing health screenings, testing at point-of-care, and providing medication counseling. State laws often

Commented [A13]: Revisions attempt to better reflect how the examiner should view pharmacies and the various classifications a PBM may utilize for pharmacies.

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impose regulatory classifications and pharmacies, further, self-classify with the National Council for Prescription Drug Programs (NCPDP) based on various attributes, such as class (meaning their ownership structure, as explained herein), and the categories of prescription drugs dispensed and to what patient population (for example, specialty pharmacies, community/ retail pharmacies, compounding pharmacies, and long-term care pharmacies). The regulatory classifications, which vary by jurisdiction, create core parameters governing pharmacy operations.

PBMs and health plans use this information and may also use additional attributes, such as location (for example, urban, suburban, and rural), level of service, negotiated rates (for example, preferred v. non-preferred), network status (meaning in-network or out-of-network), or delivery mode to classify pharmacies. Unlike regulatory classifications, these categorizations are created for network management, reimbursement methodologies, and to administer benefit design.

A pharmacy chain typically refers to a third-party entity that engages in a ~~retail~~ business and that owns or operates four or more pharmacies under common ownership ~~multiple retail outlets~~ at which an individual consumer may have a prescription drug order filled. ~~Retail outlets may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling.~~

Commented [A14]: This edit reflects the NCPDP Dispenser Class Code definition.

Commented [A15]: Deleted as this is now covered at the lead-in

~~**Independent**~~

Independent pharmacies generally include ~~refer to~~ pharmacies that are privately and independently owned and operated by one or more pharmacists or under common ownership with no more than three pharmacies, and whose primary function is to provide direct pharmaceutical care to patients. ~~These services include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling~~ in the community setting.

Commented [A16]: NCPDP defines an independent pharmacy as one to three pharmacies under common ownership.

Commented [A17]: Moved to lead-in as most pharmacies offer these services, not just independent pharmacies.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). Federal law defines pharmacies as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Pharmacists are licensed and trained health care providers that ~~. The basic duty of a community pharmacist is to~~ assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a ~~the~~ medication to a~~the~~ patient~~s~~ to ensure that the patients do not receive the wrong drug~~s~~ or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals. Pharmacists' permissible activities are subject to state scope of practice laws.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The DSCSA defines pharmacists as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Pharmacy Benefit Managers (PBMs) ~~. PBMs~~ provide claims processing services or other prescription drug services on behalf of insurers to insureds or administer an insurer's prescription drug coverage pursuant to its contract or under an employment relationship with an insurer or health plan that directly manages the prescription drug coverage provided by the insurer or health plan. Insurers determine through contractual delegation which activities a PBM may perform on their behalf, which may include N~~n~~egotiating~~e~~ and contracting with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network ~~-~~related terms.~~23~~ PBMs may also develop~~design~~, negotiate, implement, or ~~-~~administer clinical, formulary or other preferred lists~~designs~~ for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers.~~24~~ PBMs may be delegated ~~are responsible for~~ the design and implementation of preferred and non-preferred pharmacy networks, metric-

Commented [A18]: Edits attempt to clarify the role of PBMs and the broad range of services they may offer.

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based payment arrangements, and formulary design elements (for example, drug coverage tiers, and utilization management protocols).[25] ~~PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.~~ PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews.

Pharmacy Benefits Manager Network – means ~~a network of~~ the group or groups of participating pharmacists or pharmacies ~~that are offered by an agreement or contract to~~ providing~~e~~ pharmacy goods or services.

Pharmacy Services Administrative Organizations (PSAOs) ~~– Pharmacy Services Administrative Organizations (PSAOs)~~ are organizations that provide administrative services to independent pharmacies, who contract with PSAOs ~~to~~ perform services such as ~~support~~ the evaluation, negotiation, and execution of a contract with PBMs or payors, or wholesalers. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly, for PBM network participation. The PSAO's ~~overall administrative function is to assist with~~ also performs contract evaluation, negotiation of key terms like reimbursement rates, dispensing fees, billing requirements, payment frequency, effective rate reconciliations and value-based or quality payment adjustment terms and execution~~,~~. PSAOs often perform credentialing services and may also offer their customers services such as, central payment and reconciliation, software, and patient data evaluation.[30] In many instances a PSAO is owned by a wholesaler and most others facilitate business relationships with wholesalers to negotiate for, purchase, or deliver prescription drugs to their pharmacy clients.

Rebates ~~–~~ means a formulary discount or ~~other~~ pric~~e~~ing concession~~, or payment that is both of the following: 1. Based on~~ attributable to the utilization of ~~a~~ prescription drugs in this state~~. 2.~~ and that is ~~P~~paid by a manufacturer ~~or third party, directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with~~ to a pharmacy benefits manager.

Statutory Definitions: While these programs are out of scope for purposes of state examinations, examiners should be aware that federal law establishes standards for certain rebates, including the Medicare Prescription Inflation Rebate Program (42 U.S.C. § 1395w-114a and -114b) and the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

Specialty drugs - is a term that generally refers to drugs and biologics that are typically high-cost, and can be complex~~,~~ to ship, or store, require specialized administration, subject to limited or exclusive distribution or may require specialized clinical care such as frequent dosage adjustments, intensive patient monitoring or counseling, or ongoing clinical support (i.e. high-touch). It often references ~~-~~medications used to treat rare, complex, life threatening or ~~or~~ chronic conditions. Because of this, t~~T~~hese drugs often require ~~specialized handling, administration, and~~ dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

There is no unified regulatory definition of the term specialty drug. Examiners should consult applicable state law and impacted health plan formulary definitions.

Wholesalers/Distributors ~~–Wholesalers~~ purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. ~~About 92 percent of prescription drugs in the United States are distributed through wholesalers, with three companies accounting for more than 90 percent of wholesale drug distribution in the United States.~~ Wholesalers own several of ~~the~~ largest PSAOs used by independent pharmacies.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The Drug Supply Chain Security Act also establishes national standards for state licensing of wholesale drug distributors (21 U.S.C. § 353). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

Commented [A19]: Updated for greater consistency with The Health Benefit Plan Network Access and Adequacy Model Act #74.

Commented [A20]: Attempted to simplify this explanation

Commented [A21]: Deleting since this irrelevant for a handbook and can change over time.

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Qualifications of Examiners

Information on qualifications, please refer to Cehapter 14 of the Market Regulation Handbook.

If a department elects to use contractors to complete a PBM examination, the department should demonstrate involvement of appropriate department personnel (i.e., department designees) during the course of the examination in accordance with the following guidelines and the department's policies and procedures. This should result in the department designee providing effective contractor oversight (e.g., status updates, budget oversight, approval of exam procedures), as well as understanding and assessing the overall quality of the work performed.

Use of Contract Personnel:

Standard: A department that utilizes contract personnel to assist in "Conducting the Pharmacy Benefit Manager Examination" should ensure that those hired in the capacity of a contractor are subject to standards that are comparable to or exceed those standards applicable to employees of the state, including disclosure of any conflicts of interest and agreeing to maintain confidentiality of examination records, proprietary data and other sensitive information they may be exposed to while under contract.

Results-Oriented Guidelines:

- The department should assess contractors used in performing examination and regulation activities to ensure the work being performed is commensurate with the department's processes and procedures.

Process-Oriented Guidelines:

- The department should have a process in place to consider qualifications, training and professional development of contractors performing PBM surveillance and market regulation activities.
- The department should have the authority to terminate a contract for services related to PBM surveillance and market regulation on the basis of poor performance.
- The department should have a process in place to consider any potential conflicts of interest among the contract personnel.
- The department should have a process in place to ensure the contract personnel will protect confidential information like PBM examination records, proprietary data and other sensitive information they may be exposed to while under contract.

Types of Examinations

When planning the examination, it is essentialhelpful to first identify which services and products are subject to regulatoryed oversight, the scope of clients impacted by those services and products, and the resulting implications impact on regulated entities. A Pharmacy Benefit Manager examination can take the form of a comprehensive examination, a targeted examination, a risk-focused examination, a re-examination, a multistate cooperative examination or a desk examination. Most of the elements found in Chapter 13—Types of Examinations will apply to the Pharmacy Benefit Manager examination. Because most operations for these entities remain consistent in all states, I it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Examiners should apply only those statutory and regulatory requirements that expressly govern PBMs. Requirements applicable to health plans—regardless of any delegation to a PBM—should not be treated as PBM compliance obligations. PBMs act in a support capacity, while compliance responsibility for plan level laws remains with the plan. PBMs contract with health plans to administer their pharmacy benefits in accordance with the plan's chosen benefit design. Each health plan retains the sole authority to design their pharmacy benefits and maintains discretionary control over the health plan's assets.

Commented [A22]: The following recommendations relating to states' use of contract firms is consistent with handbook and accreditation guidance adopted by the Financial Condition (E) Committee and Financial Regulation Standards and Accreditation (F) Committee in 2025.

Commented [A23]: It is crucial for regulators to know impacts of law, not to product/services but clients in scope as well.

Commented [A24]: It is important to make this distinction

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Scheduling, Coordination and Planning Scope

The procedures discussed in this section are to assist the regulator in determining if an examination or other type of regulatory action needs to be scheduled. It will also assist in developing a plan for conducting examinations, investigations, desk audits, interrogatories, letters or interviews when deemed necessary.

1. Determine the jurisdiction's requirements for licensing and examining the Pharmacy Benefit Manager and determine if the jurisdiction is permitted to accept the examination report of another state;
2. Survey appropriate divisions within the insurance department to identify potential areas of concern or interest relating to Pharmacy Benefit Managers operating in the jurisdiction;
3. For those Pharmacy Benefit Managers that have provided a current examination report and no unaddressed regulatory concerns exist, no additional analysis should be necessary. If analysis indicates that a market regulation action—such as a desk audit, letter, interrogatory, interview, investigation or examination—is appropriate, consider the possibility of coordinating with other jurisdictions with similar requirements or market regulation issues. Consider use of NAIC tools such as the Market Action Tracking System (MATS) for recording continuum types of regulatory responses and the Pharmacy Benefit Manager Examination Oversight (D) Working Group for multistate coordination of regulatory responses;~~.~~
4. Survey the NAIC Research Division for relevant information to identify potential areas of concern in the evaluation process; and
5. Determine what specialists may be necessary to assist with the examination~~, such as an actuary~~ (ideally one with experience with the functions of a Pharmacy Benefit Manager).

Commented [A25]: The addition of specialists increases costs for conducting exams – we suggest a trigger to initiate when a specialists' involvement is warranted (ex. Large-scale claim analysis where spread pricing or rebate pass through model analysis is necessary).

For very narrow or specific regulatory issues, or for situations in which an examination is not required by statute, consider use of regulatory options other than an examination. For example, certain issues can be handled by a telephone call, letter or email; a data request; policy and procedure review; interrogatories; or desk audits. The remainder of this chapter is primarily written to facilitate examinations; however, certain information may be adaptable for the above-mentioned "continuum" type responses. An additional discussion of continuum of market actions is in Chapter 2 of this handbook.

For additional information on Market Conduct Examinations, please refer to Chapters 12 and 13 of the Market Regulation Handbook.

Procedural Considerations

Although not an insurance company examination, some of the basic procedures for a market conduct examination in Chapter 20 of this handbook should be followed in a Pharmacy Benefit Manager examination as noted below:

Commented [A26]: Basic procedures for a MCE in Chapter 20 of the handbook are not well aligned to PBMs. Recommend that PBM-specific protocols be adopted as many of the insurer centric standards in Chapter 20 do not apply to PBMs and will be burdensome to incorporate.

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;
- Notification of the examination;
- Preexamination procedures;
- On-site coordination;
- Communication management;
- Post-examination procedures; and
- The examination report.

Where possible, each state's defined examination protocols applicable to the examination of insurers—such as time frames and report submissions—should be applied to ~~PBM~~ Pharmacy Benefit Manager examinations, as well.

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Writing the Examination Report
The report preparation elements as outlined in Chapter 19 of this handbook ~~of the report~~ are generally applicable to Pharmacy Benefit Manager examinations. However, the following special considerations also apply:

- In addition to safeguarding the confidentiality of individual policyholder information, care should be taken to not disclose trade secret information of the examinees or insurers that are customers of the examinees (e.g., individual insurer information in class or territory detail, or the processes and procedures of the examinee). The PBM should be given the opportunity to mark exhibits and/or portions of the report as "confidential and proprietary," if such is allowed under state law and these are not subject to otherwise applicable public release laws outside the regulatory community; and
- The PBM should be given the opportunity to review the examination findings prior to issuing a final report, if such practice is consistent with the state's insurers' examination act or other applicable statute.

Use of Examination Standards
Each of the following examination standards may be applicable to specific functions performed by a Pharmacy Benefit Manager. The examination plan should indicate which standards for review will be used for each specific examination.

A. Pharmacy Benefit Manager Operations/Management
B. PBM Pricing and Methodologies
C. Provider/Pharmacy Relations
D. Pharmacy Claims
E. PBM Pricing Methodologies
F. Pharmaceutical Manufacturer Rebates
G. Network Adequacy
H. Utilization Review
I. Drug Formulary, Placement and Specialty Drug
J. Complaints, Grievances, and Appeals
L. Audits

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A. Pharmacy Benefit Manager Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

The following standards would be the most applicable to a PBM examination.

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.
Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.
Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.
Standard 4 - The PBM has a valid disaster recovery plan.
Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.
Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.
Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.
Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.
Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.
Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.
Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.
Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.
Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 1
The PBM demonstrates it does not charge a ~~covered entity or~~ health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug (i.e., spread pricing) as required by applicable statutes, rules and regulations. ~~AKA SPREAD PRICING.~~

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ ~~Complete and unredacted~~ copies of contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

~~Complete and unredacted~~ Copies of contracts or material amendments thereto between the PBM and pharmac~~y~~ies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges, if applicable.

_ A schedule of only impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total ~~reimbursement~~ amount ~~paid to the pharmacy~~charged to a health plan for each prescription drug claim.

_____ Documentation demonstrating ~~of~~ health plan billings ~~in comparison to~~and pharmacy reimbursement ~~at a claim level~~for a prescription drug claim during the exam period including an itemized breakdown~~s~~ if applicable, are identical.

Others Reviewed

_____ _____

_____ _____

Commented [A27]: References to "covered entity" have been removed throughout as this does not align to the terminology used in the glossary.

Commented [A28]: Edits to contract-related documents are intended to reflect that contracts regularly involve multiple documents that may not be co-located as amendments are made over time and, further, to clarify that material that is not relevant to the examination standard is redactable to protect sensitive/ proprietary information.

Commented [A29]: Claims data should only be requested for claims that are related to spread pricing as defined under state law.

Commented [A30]: Added "if applicable" language to documents to be reviewed as every plan may not require real-time monitoring or periodic reports.

Commented [A31]: Revised language to align with processes.

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Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent ~~contracts between the PBM and the health plan and are consistent~~ with state requirements.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 2
The PBM demonstrates the difference in its payment rates received by a ~~covered entity or~~ health plan compared to the reimbursement paid to a pharmacy for a prescription drug ~~as~~ if required by applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law,

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____An index of all policies and procedures relating to PBM's billing with health plans.

_____ An index of all policies and procedures relating to the PBM's payment to pharmacies.

_____ ~~Complete and unredacted~~ Copies of contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

~~Complete and unredacted~~ Copies of contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

Commented [A32]: See previous comments on concerns with unredacted documents.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total reimbursement amount charged to the ~~covered entity or~~ health plan for each prescription drug claim.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM's pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

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Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.

_Based on information submitted with the policies ~~&~~ and procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies ~~or~~ all brand effective rate (BER) policies, state-specific policies. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM contracts with pharmacies or PSAOs in an unredacted format to the extent needed to confirm compliance with state law.

_____ All notices, material amendments, updates, or other informative documents applicable during the examination period describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.

_____ All documents provided to pharmacies applicable during the examination period that support or describe the PBM's effective rate reconciliation process to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.

_____ All reports or accounting documents provided to pharmacies or PSAOs applicable during the examination period showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and impacted claims data.

_____ Request all impacted claims data for a specified time period and in a standardized template showing ~~how~~ whether each claim was 'reconciled' by the PBM in accordance with state law. Claims detail may include but is not ~~be~~ limited to:

- Pharmacy information including but not limited to name, ~~NPN~~NPI, and address.
- Pharmacy network name associated with each claim.
- Claim identifiers for all reconciled claims, to include ~~R~~retail, mail order, and specialty drug claims, including prescription number, date of service and product identifier.~~;~~
- ~~The drug pricing source used for reimbursement of each claim when~~
- ~~The percentage *and* actual amount of any 'discount' or other price reduction from the drug~~

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~~pricing source that the PBM applied as part of its initial payment to the pharmacy when the pharmacy submitted the claim.~~

- ~~The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.~~
- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid the pharmacy when it submitted the claim; the amount should not include the dispensing fee).
- The total initial reimbursement of any dispensing fee.~~,~~
- ~~The reconciled percentage of 'discount' applied to each claim.~~
- ~~The total final reimbursement amount for each drug claim after reconciliation. This should not include the dispensing fee amount.~~
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each ~~drug~~reconciled effective rate. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO for the reconciliation period(s) associated with the specified time period.

_____ ~~Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's effective rate reconciliation process with pharmacies and that describe the carrier or employer group's oversight of the processes. Request the entire contract in an unredacted format.~~

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts or applicable material amendments thereto between the PBM and pharmacies in effect during the examination period, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, provider updates or manual amendments. Ensure all contractual language regarding the rate reconciliation process is clear and concise. ~~is transparent and sufficiently clear to enable the pharmacy to understand how the effective rate reconciliation process will be implemented prior to the PBM beginning the annual (or quarterly) reconciliation.~~

Request a listing of all network pharmacies or PSAOs that have an effective rate contract and all pharmacies or PSAOs that do not have one. If required by state law, e~~E~~nsure the PBM is offering contracts to all similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer ~~an effective rate~~a contract to any specific pharmacies or pharmacy types, such as independent pharmacies.

Assess how the PBM determines which claims will be part of the reconciliation process. Confirm the selection of the claims is communicated to ~~the~~ pharmacies in clear and concise language. ~~that is easily understandable and cannot be misinterpreted to mean more than the plane language.~~

Review all final and fully executed official documents and communications sent from the PBM to the pharmacy as part of the reconciliation process. This should include but not be limited to any reconciliation reports~~,~~ and any claims data that is provided or can be requested by the pharmacy~~, any emails or other correspondence between the PBM and the pharmacy~~. Ensure all communications from the PBM are clear, and concise, and reflect applicable state law. For example: provide sufficient detail to enable the pharmacy to understand the process and that all questions are appropriately addressed.

- ~~If PBM provides any reports or charts to the pharmacy, ensure the document explains all use of acronyms and use of differing claims categories for example, through use of a key.~~
- Review all documents describing the final reconciliation amount that may be owed to or from pharmacies or

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Commented [A33]: Removed documentation that is not related to effective rate reconciliation.

Commented [A34]: Removed this documentation request as effective rate reconciliation is not performed at the claim level.

Commented [A35]: Added language to clarify that the time period sampled may or may not align with how a pharmacy is reconciled and could span multiple reconciliations.

Commented [A36]: Removed this document as PBM contracts with health plans do not typically reference effective rate reconciliation with pharmacies.

Commented [A37]: We recommend that, to make this more manageable for the regulator and the PBM, document reviews should be limited to a sample of final/fully executed documents and communications.

Unless there is a statutory requirement to provide routine, informal communications, this sample should be limited to a sample of final/fully executed communications and not routine back and forth, which is not relevant to examination for compliance with state law.

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PSAOs. Does the PBM provide reasonably sufficient detail to ensure that pharmacies understand how and when they will receive payment or make payments, if applicable~~.~~? If a pharmacy is making a payment, are claims subject to an applicable state law prohibiting collection properly excluded?

- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that enables pharmacies to provide information to the PBM that may change the outcome of the reconciliation amount~~.~~? Consider requesting specific examples of correspondence to review.

Review a sampling of ~~(or all)~~ claims to ensure the PBM follows its own policies and procedures regarding reconciliation process and how the claims sample fits into the final reconciliation. Where applicable, demonstrate that pharmacy claims that are reconciled through a contractually authorized program (i.e. effective rate or other performance-based program) allows the pharmacy to understand which claims have been included in the program and have been reconciled. ~~Compare the original 'discount' and price paid to the pharmacy to the reconciled 'discount' and price to determine if the reconciled 'discount' applied to each claim is within the contractually stated 'discount' amounts.~~

~~Review a sample of contracts between the PBM and the pharmacy services administration organization or group pharmacy contract carrier or employer group to determine whether the reconciliation process as described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.~~

~~Consider verifying the accuracy of all the data and reports sent from the PBM with the pharmacy or pharmacy group. For example, if the PBM provides an annual report of all reconciled claims, did the pharmacy receive the same version?~~

Commented [A38]: Removed this documentation requirement as effective rate reconciliation is not governed by client agreements.

Commented [A39]: Revised language as the current language does not accurately reflect the rate reconciliation process.

Commented [A40]: Removed this documentation requirement as PBMs do not know what was sent to the pharmacy - that goes from the PSAO to the pharmacy (not the PBM).

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STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 4
The PBM demonstrates it has ~~transparent~~ payment methodologies ~~for~~ regarding the dispensing fees on a drug claim if required by statues, rules, and regulations. ~~f all drugs that enable a pharmacy to understand dispensing fee amount for each claim~~

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ PBM to provide an index of all policies and procedures relating to pharmacy dispensing fees.

_____ All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ ~~PBM contracts with pharmacies in an unredacted format.~~

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.

_____ All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to mail order, specialty, or affiliate pharmacies.

_____ Contracts with the PBM and the ~~carrier or employer group~~health plan that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the ~~carrier or employer group's~~ health plan's oversight of the processes. Request the ~~entire~~ contract or applicable material amendments thereto in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims;
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.~~;~~
- ~~The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-~~

Commented [A41]: Limit to jurisdictions where there are requirements defining what a dispensing fee is and what is to be paid.

Commented [A42]: Delete as duplicative to #2 above

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~~funded vs. fully insured;~~

- The status of the claim for example paid, rejected, under appeal.
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. ~~*The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*~~

**This information may be pared down if the regulator is only looking at dispensing fees and not all claims data. But pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*
***States have different requirements regarding dispensing fees paid to pharmacies in their jurisdiction.*

Others Reviewed

____ _____

____ _____

Review Procedures and Criteria

Review all contracts or material amendments thereto between the PBM and pharmacies in effect during the exam period, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost lists, drug discount or manufacturer coupon contracts. Ensure all contractual language ~~is transparent and sufficiently clear to enable the pharmacy to understand the~~regarding dispensing fees ~~payment prior to the pharmacy being paid~~is clear and concise.

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language ~~that is easily understandable and cannot be misinterpreted to mean more than the plane language~~.

Assess the PBM's ability to change the dispensing fee amount. Confirm the 'change' process is transparent and~~&~~ communicated to pharmacies in clear and concise language ~~that is easily understandable and cannot be misinterpreted to mean more than the plane language~~. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

Review contracts between the PBM and the ~~carrier or employer group~~health plan to determine whether the payment of dispensing fees described to pharmacies is consistent with the PBM's requirements described in the ~~carrier or employer group's~~ health plan's contract with the PBM.

Review a sampling of ~~(or all)~~ claims to ensure the PBM follows its own policies and procedures regarding dispensing fees paid to pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. If required by state law, ~~S~~standards based on the type of pharmacy should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies~~, for example.~~ and p~~P~~ayment of dispensing fees should be consistent across pharmacies within the same network.

Commented [A43]: Removed to reflect that the documentation requested should only include information for plans subject to state DOI regulatory authority (i.e., fully-insured and non-ERISA ASO plans).

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STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACY (AKA PROVIDER))

Standard 1
The PBM demonstrates that it exercises good faith and fair dealing in its contracting and contract negotiation processes with pharmacies.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ A listing of all pharmacies in the PBM's network. The listing should also require the PBM to provide a listing of all contracts (including provider manuals) and material contract amendments the PBM has in place with each pharmacy. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document.

_____ All final/fully executed documentation and correspondence~~, including but not limited to emails and red-lined documents,~~ between pharmacies and the PBM that pertain to the contract and material contract amendments. ~~The documentation should provide examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses.~~ The Examiner ~~should~~ may review ~~the~~ documentation to assess ~~whether~~ the PBM ~~is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with~~and pharmacies' good faith negotiations.

Commented [A44]: Revised to limit to final/fully executed documentation. The proposed requirement to provide all documents including "red-lined documents" between the pharmacy and the PBM pertaining to contract amendments is extremely burdensome as this is not typically available in a centralized database and instead would require manual processes that increase the risk of error. This level of documentation may, further, include privileged communications.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate to the extent such differentiated standards are prohibited by state law. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location if such limitations are permitted by law. Standards should be applied in a non-discriminatory

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manner such that PBM does not favor affiliate over non-affiliate pharmacies to the extent required by state law.~~, for example.~~

Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Examples include ~~Including how~~ how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as who can submit the information and how i.e. via email, web portal or postal mail, any fees required.~~-~~ Ensure the PBM's contracting process, including requests for changes to contract terms, is described to pharmacies in clear and concise language~~ such that the pharmacies understand how to request changes to the contract terms~~.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review PBM communications to pharmacies to assess the PBM's responses to pharmacy negotiation requests. Ensure the PBM provides sufficient information to support or deny the pharmacy's requests. Ensure PBM contracting process is not unilateral or one-sided to prevent pharmacies from negotiating.

Review PBM's communications to pharmacies to assess if PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether PBM appears to contract with certain pharmacy types and not others. For example, does PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM explanation for such outcomes.

Assess how the PBM responds to pharmacy inquiries about the PBM's or the pharmacy's contractual obligations. For example, does the PBM have processes for pharmacies to initiate inquiries or obtain assistance from the PBM? Assess the PBM's responses to pharmacies during the inquiry process. Assess whether the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's response or final determination. Review specific examples of inquiries and follow-up from the PBM.

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**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 2
The PBM demonstrates that it exercises good faith and fair dealing in implementing its contractual obligations with its vendors that work with its network pharmacies.

Apply to: All PBMs if services are delegated by the health plan

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all contracts with vendors that provide pharmacy benefits management services within scope on behalf of the PBM including a description of those services provided by each vendor and how the services impact pharmacies.

_____ From the index provided, review all policies and procedures that are applicable to the practices with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ ~~Unredacted~~ PBM contracts ~~from~~ or applicable material amendments thereto with vendors that provide pharmacy benefit management services within scope on behalf of the PBM. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Standards should be applied in a non-discriminatory manner such that PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example, to the extent required by state law.

Review policies and procedures for providing information to pharmacies about vendors with whom the PBM contracts to perform certain functions. ~~-~~Review all documentation to assess ~~if~~ whether the ~~PBM provides reasonably sufficient information to pharmacies such that they would understand the exact function of the vendor and how the pharmacy is to interact with the vendor~~information that the PBM provides regarding its vendors is clear and concise.

Review contracts between PBM and its vendors to ensure the PBM does not permit its vendors to engage in activities that are prohibited under state law. For example, if state law prohibits a PBM from charging fees to a pharmacy,

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the PBM should not have a contract with a vendor that allows the vendor to charge the prohibited fees.

Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its affiliate pharmacies over non-affiliated pharmacies.

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**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 3
The PBM demonstrates that it has a reasonable and easily accessible dispute resolution process for pharmacies to address matters of conflict with the PBM.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide a ~~data dictionary or~~ list (and definitions) of all categories ~~types~~ of disputes that it considers 'disputes.' This may include but not be limited to complaints, independent third-party reviews, and arbitration.

_____ PBM to provide an index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.

_____ From the index provided, request all policies and procedures that are applicable to the dispute resolution process being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM documentation ~~of~~ showing how disputes are addressed and finalized. PBM should provide examples of actual disputes and provide all documentation sent to or received by a pharmacy showing how the dispute was initiated and~~,~~ the final correspondence between the PBM and pharmacy~~, any documentation that is exchanged,~~ and fully executed documentation showing how the dispute is resolved. Documentation should be consistent with other handbook standards regarding privacy and the sharing of PHI.

Commented [A45]: Revised to limit to final correspondence and fully executed documentation as the broader language would result in an unmanageable volume of documents.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding the PBM's dispute resolution process with pharmacies. Review criteria for the different types of disputes to assess whether PBM has clear protocols, timeframes, and documentation requirements for addressing and resolving each type of dispute.

Review contracts or applicable material amendments thereto and manuals for details provided to pharmacies about the dispute resolution process. Review how PBM informs pharmacies of how disputes may be initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail, any fees required), PBM's obligation to provide a justification for the final determination

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and timeframes for PBM response and resolution of the dispute.

Review contracts and manuals with details about the dispute resolution process to ensure the information provided to pharmacies is clear~~, concise, and easily understood~~ and concise.

Assess whether the PBM has provided pharmacies with a clear, transparent appeal process, including all information that must be shared or documented to support an appeal. ~~'s requirements for pharmacies are convenient and accessible or whether the requirements create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute.~~ Examples of requirements that may dissuade a pharmacy from initiating a dispute may include but are not limited to, requiring pharmacies to initiate disputes and send supporting documentation solely through postal mail or requiring exorbitant fee amounts to request or initiate a dispute resolution process.

Assess the PBM's responses to pharmacies during the dispute resolution process. Ensure the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's final determination.

Ensure PBM's policies and procedures and implementation of those policies and procedures are consistent with state law.

Assess whether PBM has staffing models to effectively resolve disputes.

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STANDARDS
PHARMACY BENEFITS MANAGERS
PHARMACY CLAIMS

Standard 1
The PBM demonstrates that it has timely and transparent claims submission and adjudication processes for pharmacy claims that enable pharmacies to understand the payment rate prior to claims submission.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals ~~in an unredacted format~~ that relate to the payment and adjudication of claims. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ PBM to provide an index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.

_____ Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ Other than contracts and manuals, request all documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted format to the extent needed to confirm compliance with state law.

_____ All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format to the extent needed to confirm compliance with state law..

_____ All impacted contacts with ~~carriers or employer groups~~health plans in an unredacted format to the extent needed to confirm compliance with state law.

_____ Request all impacted claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims.~~;~~
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or

Commented [A46]: We recommend limiting to related documents; otherwise, this will result in an unmanageable volume of documents to produce or review.

Commented [A47]: We recommend the NAIC look to NCPDP for industry standards regarding policies and procedures review rather than create new process or standards

Consider adding to Review Criteria below.

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dispensing fee. For example, any claims processing fee applied to the claim.

- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee~~:~~.
- ~~The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured;~~
- The status of the claim ~~for example~~(e.g., paid, rejected, under appeal).
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

_____ Regulatory actions

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures ~~for pharmacy requirements to be able~~ related to requirements for pharmacies to submit claims that may include but are not limited to the following:

- Claims processing software requirements.
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.
- Any NCPDP industry standards applicable.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:

- Dispensed as written codes.
- Over-the-counter products.
- Multi-ingredient compound processing.
- Override.
- Coordination of benefits.
- Reversals.
- Submission timeframes.

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:

- PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any ~~"discount" the PBM may apply to~~ reduction in reimbursement~~e the price~~ paid to the pharmacy.
- PBM should have clear criteria for claims approvals, denials or rejections.
- PBM should have clear timeframes for claims adjudication either through payment or denial/rejection of the claim in compliance with state claims timelines.
- PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is denied or rejected.
- PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or payment appeals for example, about any claims that are rejected or denied. This does not include benefit or coverage appeals that would be initiated by the member.

Commented [A48]: Delete language where state DOIs do not have jurisdiction (Medicare, Medicaid, Self-funded).

Examiners may encounter documents in the course of a health plan examination that refer to "ERISA plans." Many health carriers perform administrative functions on behalf of self-funded employers, union trusts and other collectively bargained groups (under ERISA Section 3(40)) that are not subject to state insurance regulation," 2024 *Market Regulation Handbook*, p. 570.

Commented [A49]: Revise language to reflect that it is a reduction in reimbursement.

Commented [A50]: Suggest revising to reflect state claims timeline standards.

Commented [A51]: Revised to clarify - actions of pharmacy v. member

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Review all PBM policies and procedures to assess whether the PBM applies different standards to different types of claims such as ~~self funded,~~ specialty drug, mail order, nonresident or discount card claims. Verify that any differing standards are consistent with state law.

Review all pharmacy contracts, including any Provider Manuals, to ensure the claims submission and adjudication processes are clearly and concisely described to pharmacies. The PBM should provide pharmacies with detailed information about:

- Each step necessary to submit a claim.
- The process and timeframe for the PBM to review and make a determination about whether a claim will be paid.
- How a pharmacy may submit an inquiry, appeal or otherwise contest the PBM's response to a pharmacy's claim. Information should include timeframes for each step in the process and should describe an easily accessible process for the pharmacy.
- Ensure information describes how pharmacies are reimbursed in accordance with applicable laws that may dictate payment amount and applicable dispensing fees.

Review all documentation to assess whether the PBM provides reasonably sufficient information about its claims payment methodology ~~to ensure that pharmacies understand what they will be paid prior to submitting claims~~. This should include but not be limited to:

- If the PBM publishes a MAC list, ~~is~~ the list is readily available and useful to pharmacies.~~?~~ ~~Does the listing provide a 'search' function to find a specific drug or is the list formatted in a way that requires the pharmacy to scroll through thousands of drugs to find a specific drug? The latter would not be reasonable.~~
- If the PBM calculates payment from a ~~applies a 'discount' to the~~ drug pricing source it uses to pay pharmacies, ~~is that~~any reduction ~~discount~~ is reasonably described in documentation to pharmacies.~~?~~ ~~such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a 'discount' and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.~~
- If the PBM uses a third-party vendor for processing and/or payment of any claims, ~~is that~~the process is clearly described to pharmacies.~~?~~ ~~Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Does the pharmacy have the ability to 'opt0in' or 'opt out' of any such programs? Does the PBM provide reasonably sufficient information such that the pharmacy will know its reimbursement level prior to submitting the claim?~~

When requesting claims data, require the PBM to submit ***all*** impacted claims being examined including mail order and specialty drug claims. ~~*Regulators have had challenges getting mail order and specialty drug claims from some PBMs.*~~ Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of dispensing fee. Ensure PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

Consider requesting the PBM provide a live demonstration of its claims adjudication process for a sample of each type of claim being examined which may include but not be limited to: claims that are approved, claims that are denied, claims that are rejected, claims that are mail order only, ~~claims that are for self-funded employer groups,~~ or claims that are for fully insured insurers~~carriers~~.

Review all, or a sampling of PBM contracts with ~~carriers/employer group~~health plans to assess if the PBM is compliant with the claims payment requirements in those contracts and that those terms are consistent with in all messaging to pharmacies. For example, if pass-through pricing is required by the ~~carrier~~ health plan contract, is that consistent with the payment method (and applicable description) to pharmacies?

Commented [A52]: Revise language to accurately reflect process.

Commented [A53]: Remove language - may be inconsistent with state law.

Commented [A54]: Revised to set standards rather than questions.

Commented [A55]: Suggest limiting live demos to a sample to reduce administrative burden while accurately demonstrating the data being requested.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to aAggregators) are passed through to health plans ~~or covered entities as applicable to~~if required by current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures ~~related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company~~health planwithin scope for this examination standard to the extent needed to confirm compliance with state law.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ C~~omplete and unredacted c~~ontracts or applicable material amendments thereto between the PBM and manufacturers within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals ~~to determine if internal standards~~ regarding ~~the forwarding of~~ manufacturer rebates ~~exist and whether those standards comply~~for compliance with state ~~requirements~~laws.

Determine if applicable policies and procedures ~~were actually~~are implemented and applied.

Determine if manufacturer rebates received were properly forwarded to applicable health plans.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebates ~~discounts, administrative fees, credits, incentives and penalties~~ are passed through to health plans ~~or covered entities as applicable to~~ if required by current statutes, rules and regulations.

Commented [A56]: Suggest combining with Standard 1 in this section as it is duplicative.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates, fees and discounts.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures ~~related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company~~health plan within scope for this examination standard to the extent needed to confirm compliance with state law.

Commented [A57]: Updates are to ensure the documents requested are limited to those relevant to compliance with this examination standard.

_____ A listing of all health plans ~~or covered entities~~ with which the PBM provides services in the state (for the applicable examination period).

_____ ~~Complete and unredacted c~~All impacted contracts or applicable material amendments thereto between the PBM and health plans ~~or covered entities~~ within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates fees and discounts received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates, fees and discounts ~~exist and whether those standards~~ comply with state requirements.

Determine if applicable policies and procedures were ~~actually~~ implemented ~~and applied~~.

Determine if manufacturer rebates, fees and discounts received were properly forwarded to applicable health plans.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 3
The PBM demonstrates pharmaceutical manufacturer rebate payments are passed through directly to ~~the~~ patients ~~as applicable to~~if required by current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ An index of all training manuals relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ Policies and procedures related to ~~rebate processing,~~ rebate crediting at the point of sale~~, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company~~ to the extent needed to confirm compliance with state law.

_____ A listing of all pharmacies that the PBM utilizes to pass rebates through to patients at the point of sale (for the applicable examination period).

_____ ~~Complete and unredacted c~~Contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent needed to confirm the PBM's compliance with applicable state law.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans or patients to monitor rebates received by the PBM and/or amounts passed through directly to patients.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates ~~exist and whether those standards~~ comply with state requirements.

Determine if applicable policies and procedures were ~~actually~~ implemented and applied.

Determine if manufacturer rebates received were ~~properly amounts~~ passed through directly to patients.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 4
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly provided to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all training manuals relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all policies and procedures relating to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the ~~Company~~PBM.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ ~~Complete and unredacted c~~Impacted contracts or material amendments thereto between the PBM and manufacturers. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ An index of internal reports, certifications, or real-time systems used by employees in the preparation of statutorily required reports.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the preparation of statutorily required reports ~~exist and whether those standards~~ comply with state requirements.

Determine if applicable policies and procedures were ~~actually~~ communicated to employees responsible for the preparation of statutorily required reports.

Determine if the statutorily required reports were complete, accurate, and timely filed.

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for all pharmacies in its network is in compliance with applicable statutes, rules, and regulations. ~~Must show its credentialling criteria from beginning to end.~~

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ Pharmacy contracts and manuals ~~for~~ relating to a PBM's language relating to credentialing.

_____ PBM to provide an index of all internal policies and procedures for the credentialing process.

_____ All policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for all pharmacies and pharmacy staff including but not limited to the pharmacist in charge (pharmacy manager), pharmacists, pharmacy technicians, and any customer service representatives. Review all exclusionary criteria such as requirements that pharmacists cannot be excluded or revoked by any licensing board.

Review any requirements for other personnel including but not limited to pharmacy owners, officers or directors. Review all exclusionary criteria that may apply.

Review all requirements for pharmacies including but not limited to application documents, insurance requirements such as professional liability coverage, any required minimum stock of drugs, and technological capabilities such as claims submission platforms.

Review policies and procedures for providing information to pharmacies about the credentialing process. Including

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how PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as via email, web portal or postal mail, any credentialing fees required.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy, how pharmacy may correct deficiencies or provide additional information.

Review contracts and manuals for details provided to pharmacies about the credentialing process. PBM should provide clear and concise information that is consistent with its own policies and procedures. Information provided to pharmacies should address all the requirements and steps for credentialing and should provide pharmacies with adequate time to provide all documentation and provide pharmacies with ability to address any questions about the process.

Request a listing of all pharmacies ~~and staff~~ that went through the credentialing process during the examination period. Request the results of each process (i.e. was the pharmacy 'approved' to be in the PBM's network or not). Request the reasoning for all approval or denials. ~~*It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*~~

Request ~~*all*~~ ~~o~~final/fully executed ~~fficial~~ correspondence between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sampling of those that went through the credentialing process. "Correspondence" may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM and any relevant and responsive emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy. Require documents to be provided in a~~n~~ ~~un~~readable format. Ensure all correspondence from the PBM is clear~~, and~~ concise and provides reasonably sufficient information to pharmacies ~~to understand~~regarding the credentialing process and any decisions made by the PBM to the extent required by law.

~~In any Summary of the PBM Network Adequacy that proceeds these standards~~,T~~t~~he PBM should ~~need to~~ describe the difference between the *PBM's network* and *pharmacy networks*. The PBM's network encompasses all pharmacies with which it contracts in the state. The PBM may have multiple pharmacy networks that may be designed based on types of drugs dispensed, how drugs are dispensed (i.e. mail order or retail), geographic location and will likely have differing reimbursement levels.

Commented [A58]: Removed "and staff" as this is seeking records not recorded during ordinary course of business

Commented [A59]: We recommend limiting to final/fully executed communications to reduce regulator and PBM burden and ensure production of a manageable volume of documents that is sufficient to complete examiner review for compliance.

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any)~~, carrier/employer contracts, or other reasonable criteria,~~ that it creates and maintains a network of pharmacies in a transparent manner.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts or material amendments thereto and manuals. This should include all network contracts and forms. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____ PBM to provide an index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, e~~E~~xaminers should request all relevant policies and procedures for areas being examined. Request documents be provided in an unredacted format, including requiring all pricing information be unredacted if needed to validate compliance with applicable state laws.

_____ PBM and~~&~~ ~~carrier or employer~~health plan contracts within scope. Request the entire contract, including any ~~amendments~~material amendments, in an unredacted format if needed to validate compliance with applicable state laws.

_____ PBM to provide a listing of all the pharmacies with which it contracts. ~~with.~~ The listing should require PBM to identify each pharmacy's location (or identify if it is a mail order pharmacy)~~, the types of business it serves (commercial, Medicaid or Medicare)~~, ~~the types of drugs it dispenses (generic, brand, specialty)~~, the unique pharmacy network each pharmacy participates in, whether the pharmacy is an affiliate pharmacy or not, whether the pharmacies' network participation changed at any time during the examination period ~~and the reason for such change (i.e. PBM changed terms, pharmacy opted out, carrier requested change)~~. ~~*It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*~~

Commented [A60]: Suggest removal of "the types of business it serves" as this is not typically recorded during the ordinary course of business.

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy.

_____ PBM to provide a description of the differences in each unique pharmacy network. For each pharmacy network, the PBM should identify the types of drugs dispensed, consumer access (such as mail order or retail), the reimbursement levels including any 'discounts' applied and dispensing fees provided, any criteria for participation and any participation limits or restrictions. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ PBM to provide a sample list of all ~~carriers and employer groups~~health plans within scope and each plan for the entity for which the PBM administers prescription drug benefits and which~~. Require the PBM to identify every~~ network is associated with each plan. ~~*It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*~~

Commented [A61]: Suggest sample list; would require case by case review

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_____ If required by state law, the PBM files with the department of insurance all required contract forms and any material changes to a contract proposed for use with its participating providers and intermediaries.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal policies and procedures regarding PBM requirements for ensuring PBM ~~has appropriate number of pharmacies in applicable geographic areas to ensure network pharmacies provide appropriate access to consumers. Ensure PBM~~ is compliant with state network adequacy law~~s and any requirements within its contracts with carriers and employer groups~~.

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure PBM has clear and concise requirements. PBM internal requirements should include but not be limited to:

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy desserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its ~~carrier/employer group~~health plan clients.
- Requirements for pharmacy network reimbursement levels in compliance with state law. ~~Ensure these are applied consistently among all pharmacies in each network.~~

Commented [A62]: Revised to align to applicable state laws.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear and concise~~, concise, and easily understandable~~. Areas to review include but are not limited to:

- Do contracts/manuals clearly describe the requirements for participation in each pharmacy network?
- How does the PBM change the terms of the pharmacy network requirements? Any changes should be made in a transparent manner and with timely notice to the pharmacies.
- Do the contracts/manuals clearly describe the reimbursement including dispensing fees for each network?

Review the pharmacy listing to assess how often the PBM made changes to the pharmacy network requirements and participation levels during the examination period. ~~Ensure the specific reasons for such changes are reasonable.~~ Request all correspondence with pharmacies impacted by any changes. Request all correspondence with ~~carriers/employer groups~~health plans within scope about the network changes. Ensure the message conveyed to ~~carriers/employer groups~~health plans within scope is consistent with the message provided to pharmacies.

Review the listing of pharmacies and description of pharmacy network differences to ensure compliance with state and federal requirements. Depending on the state's legal requirements, areas to consider include by are not limited to:

- Does PBM have networks that are comprised solely of affiliate pharmacies?
- Does PBM have networks that are comprised solely of mail order pharmacies?
- ~~Are the reimbursement rates among the differing networks reasonable? Or do the rates show differing levels for affiliate only networks? Are reimbursement rates discriminatory?~~

Commented [A63]: We recommend removal as comparing the rates for a client that selects a network of affiliate pharmacies to that of other clients with different networks does not produce relevant information.

In any Summary of the PBM Network Adequacy that proceeds these standards, consider reviewing the PBM's contracts and manuals with pharmacies as part of how to ask for specific information about "contracting."

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STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 3
The PBM demonstrates ~~compliance with state law (if any) or other reasonable criteria,~~ that it maintains a network of pharmacies that is sufficient in number and types of pharmacies to ensure that all services to covered persons will be accessible without unreasonable delay if required by state law.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM policies and procedures for providing information to covered persons about pharmacy directories.

_____ PBM policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.

_____ ~~The PBM will demonstrate how it makes its provider directory (that lists all providers who participate in its network) available to covered persons. It also makes available, on a timely and reasonable basis, updates to its directory.~~ PBM policies and procedures regarding availability of and updates to its provider network.

_____ All documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how the covered persons may contact the PBM with inquiries.

_____ PBM to provide a listing of all the pharmacies it contracts with. The listing should require PBM to identify each pharmacy's location or identify if it is a mail order pharmacy, ~~the types of business it serves (commercial, Medicaid or Medicare),~~ the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Ensure the PBM has established and will maintain adequate arrangements to ensure reasonable proximity of participating pharmacies to the business or personal residence of covered persons. In determining whether a PBM has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

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Review policies and procedures for providing information to covered persons about in-network pharmacies and emergency services.

Review all information provided to covered persons to ensure the information is provided in a clear and concise manner and updated regularly. PBMs should have clear information that describes how consumers may contact the PBM with any inquiries about pharmacy options.

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H. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that companies and their designees that provide or perform utilization review services comply with standards and criteria for the structure and operation of utilization review processes as required by state law.

The areas to be considered in this kind of review include the company's written utilization review policies and procedures, annual summary reports, timeliness in making utilization review decisions and handling appeals, communications with members about the program and oversight of delegated utilization review functions.

2. Techniques

The analysis of utilization review activities should include an overview of the pharmacy benefit manager's written utilization review policies, procedures and scripts, in addition to an overview of how utilization review activities are applied to individual cases. Utilization review issues may also surface during the examiners' inspection of claims, complaints and grievance procedures.

a. Examiners should request a written overview of the pharmacy benefit managers' utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the pharmacy benefit manager maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.

b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.

c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.

d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.

e. Obtain listings of utilization review approvals ~~or certifications~~, denials and requests for reconsideration. Use sampling techniques to review specific cases. Evaluate handling for adherence to written guidelines and standards.

Commented [A64]: This is language used in medical services

3. Tests and Standards

The utilization review assessment includes, but is not limited to, the following standards related to the performance of utilization review activities by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 1
The pharmacy benefit manager establishes and maintains a utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____Applicable statutes, rules and regulations, including those related to mandated benefits and services

_____Utilization review policies and procedures

_____Utilization review program or plan documentation

_____Medical criteria used to make utilization review determinations

_____Job description of the staff position functionally responsible for day-to-day management

_____Minutes of the Pharmacy Benefit Managers' board of directors

_____Minutes of the Pharmacy Benefit Managers' utilization review committee

_____Documentation of clinical staff credentialing maintenance and education requirements

_____Program assessment reports

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a Pharmacy Benefit Manager that requires a request for benefits under the covered person's health benefit plan to be subjected to utilization review, implements a written utilization review program that describes all review activities, both delegated and nondelegated for:

- The filing of benefit requests;
- The notification of utilization review and benefit determinations; and
- The review of adverse determinations in accordance with applicable state statutes,

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- Verify that the Pharmacy Benefit Manager's written utilization review program document describes all the following:
  - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of health care services;
  - Data sources and clinical review criteria used in decision-making;
  - Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
  - Data collection processes and analytical methods used in assessing utilization of health care services;
  - Provisions for ensuring confidentiality of clinical and proprietary information;
  - The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the health insurer's ~~carrier's~~ governing body; and
  - The staff position functionally responsible for day-to-day program management.

- Verify that the Pharmacy Benefit Manager ensures that appropriate personnel have operational responsibility for conducting the insurer's ~~carrier's~~ utilization review program.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 2
The pharmacy benefit manager ~~establishes and maintains a~~operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager utilization review program uses documented clinical review criteria that are based on sound clinical evidence-based medicine and evaluated periodically to assure ongoing efficacy.

Note: The Pharmacy Benefit Manager may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the Pharmacy Benefit Manager makes its clinical review criteria available upon request to authorized government agencies.

Verify that the Pharmacy Benefit Manager ensures that qualified health care professionals administer the utilization review program and oversee review decisions. Verify that the Pharmacy Benefit Manager has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the Pharmacy Benefit Manager issues utilization review decisions and benefit determinations in a timely and efficient manner pursuant to the requirements set forth in applicable state statutes, rules and regulations.

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Verify that the Pharmacy Benefit Manager has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the Pharmacy Benefit Manager conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the Pharmacy Benefit Manager's data systems are sufficient to support utilization review program activities and to generate management reports to enable the Pharmacy Benefit Manager to monitor and manage health care services effectively.

If a Pharmacy Benefit Manager delegates any utilization review activities to a utilization review organization, verify that the Pharmacy Benefit Manager maintains adequate oversight, to include all the following:

- A written description of the utilization review organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the utilization review organization program by the Pharmacy Benefit Manager or respective insurer~~carrier~~; and
- A process by which the Pharmacy Benefit Manager evaluates the performance of the utilization review organization.

Verify that the Pharmacy Benefit Manager coordinates its utilization review program activities with other medical management activity conducted by the health insurer~~carrier~~, such as quality assurance, credentialing, provider contracting, data reporting, grievance procedures, claims adjudication, processes for assessing member satisfaction and risk management.

Verify that the Pharmacy Benefit Manager provides covered persons, or, if applicable, the covered person's authorized representatives and participating providers with access to its utilization review staff via a toll-free number or collect call telephone line.

Verify that the Pharmacy Benefit Manager, when conducting utilization review, collects only the information necessary, including pertinent clinical information, to make the utilization review or benefit determination.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 3
The Pharmacy Benefit Manager discloses information about its utilization review and benefit determination procedures to covered persons, or, if applicable, the covered persons' authorized representative, in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Member materials

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager provides a clear and accurate summary of its utilization review and benefit determination procedures to the covered person's authorized representative.

Verify that the Pharmacy Benefit Manager provides a clear and comprehensive description of its utilization review procedures, including the procedures for obtaining adverse review determinations, and a statement of rights and responsibilities of covered persons.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 4
The Pharmacy Benefit Manager makes standard utilization review and benefit determinations in a timely manner and as required by applicable state statutes, rules and regulations, as well as the provisions of HIPAA.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the Pharmacy Benefit Manager by the covered person, or, if applicable, the covered person's authorized representative, for benefits and for notifying the covered person, and, if applicable, the covered person's authorized representative, of its determinations with respect to these requests within the specified time frames required pursuant to applicable state statutes, rules and regulations.

For prospective review determinations, verify that the Pharmacy Benefit Manager makes the determination and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether the Pharmacy Benefit Manager certifies the provision of the benefit or not, within a reasonable period of time appropriate to the covered person's medical condition, but in no event later than 15 days after the date the Pharmacy Benefit Manager receives the request.

Whenever the determination is an adverse determination, verify that the Pharmacy Benefit Manager makes the notification of the adverse determination in accordance with state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination.

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Verify that if the Pharmacy Benefit Manager extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the Pharmacy Benefit Manager has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 15-day time period, of the circumstances requiring the extension of time and the date by which the Pharmacy Benefit Manager expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Whenever the Pharmacy Benefit Manager receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the health insurer's~~carrier's~~ filing procedures, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of this failure and provides in the notice information on the proper procedures to be followed for filing a request.

Verify that the notice referenced in the previous paragraph is provided by the Pharmacy Benefit Manager as soon as possible, but in no event later than five days following the date of the failure.

Verify that the Pharmacy Benefit Manager provides the notice orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to meet the ~~health carrier's~~Pharmacy Benefit Manager's filing procedures apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and

- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a Pharmacy Benefit Manager has certified an ongoing course of treatment to be provided over a period of time or number of treatments, examiners need to be aware that:

- Any reduction or termination by the Pharmacy Benefit Manager during the course of treatment before the end of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and

- The Pharmacy Benefit Manager shall notify the covered person, or, applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the

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covered person's authorized representative, to file a grievance to:
- Request a review of the adverse determination pursuant to state statutes, rules and regulations; and
- Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

Verify that the health care service or treatment that is the subject of the adverse determination is continued by the Pharmacy Benefit Manager without liability to the covered person with respect to the internal review request made pursuant to state statutes, rules and regulations.

For retrospective review determinations, verify that the Pharmacy Benefit Manager makes the determination within a reasonable period of time, but in no event later than 30 working days after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination to the covered person, or, if applicable, the covered person's authorized representative, in accordance with applicable state statutes regarding procedures for standard utilization review and benefit Pharmacy Benefit Manager determination.

Verify that if the health insurer~~carrier~~ extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the health insurer~~carrier~~ has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 30-day time period, of the circumstances requiring the extension of time and the date by which the health insurer~~carrier~~ expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Verify that the Pharmacy Benefit Manager calculates the time periods, within which a prospective or retrospective determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is received by the Pharmacy Benefit Manager in accordance with the health insurer's~~carrier's~~ procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to make the determination, verify that the Pharmacy Benefit Manager calculates the time period for making the determination to begin on the date on which the Pharmacy Benefit Manager sends the notification of the extension to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:
- The date on which the covered person, or, if applicable, the covered person's authorized representative, responds to the request for additional information; or
- The date on which the specified information was to have been submitted.

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 5
The Pharmacy Benefit Manager provides written notice of an adverse determination of standard utilization review and benefit determinations in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager issues notification of an adverse determination, as required by state law. ~~in a manner calculated to be understood by the covered person, to include all the following:~~

- ~~The specific reason or reasons for the adverse determination;~~
- ~~Reference to the specific plan provisions on which the determination is based;~~
- ~~A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to perfect the benefit request, including an explanation of why the material or information is necessary to perfect the request;~~
- A description of the Pharmacy Benefit Manager's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;
- ~~If the Pharmacy Benefit Manager relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative, upon request;~~
- ~~If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;~~
- ~~A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination;~~
- ~~The written statement of the scientific or clinical rationale for the adverse determination; and~~
- ~~A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for~~

Commented [A65]: Suggesting all the bullets be removed since states will have specific requirements that PBMs must meet around notifications.

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~~assistance or, upon completion of the Pharmacy Benefit Manager's grievance procedure process as provided under state statutes, rules and regulation, to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.~~

Verify that the Pharmacy Benefit Manager ~~health carrier~~ provides the notice as required by state law if they are delegated to do so. ~~in writing or electronically.~~

Commented [A66]: Some states require verbal notices and not all are written or electronically

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 6
The Pharmacy Benefit Manager conducts expedited utilization review and benefit determinations in a timely manner and in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager has established written procedures pursuant to applicable state statutes, rules and regulations for receiving benefit requests from covered persons, or, if applicable, their authorized representatives, and for making and notifying the covered person, or, if applicable, the covered person's authorized representative, of expedited utilization review and benefit determinations with respect to urgent care requests ~~and concurrent review urgent care requests~~.

Verify that the Pharmacy Benefit Manager, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request, notifies the covered person, or, if applicable, the covered person's authorized representative, of the failure and the proper procedures to be followed for filing the request.

Verify that the Pharmacy Benefit Manager's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's as required by applicable state statues, rules, and regulations. ~~, failure to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request:~~

- ~~Is provided to the covered person, or, if applicable, the covered person's authorized representative, as appropriate, as soon as possible, but not later than 24 hours after receipt of the request; and~~
- ~~May be oral, unless the covered person, or, if applicable, the covered person's authorized representative, requests the notice in writing.~~

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request apply only in the case of a failure that:

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Commented [A67]: Concurrent review only happens in medical services

Commented [A68]: State laws have specific TAT and notification requirements for urgent request.

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- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and
- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment or provider for which approval is being requested.

For an urgent care request, unless the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the Pharmacy Benefit Manager to determine whether, or to what extent, the benefits requested are covered benefits or payable under the health insurer's~~carrier's~~ health benefit plan, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of the Pharmacy Benefit Manager's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, and within the timeline required by applicable state statues, rules and regulations. ~~but in no event later than 72 hours after the receipt of the request by the Pharmacy Benefit Manager.~~

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the health insurer~~carrier~~ to make a determination, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, as required by applicable state statues, rules, and regulations around notification and timeframe. ~~either orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing of this failure and states what specific information is needed as soon as possible, but in no event later than 24 hours after receipt of the request.~~

Verify that the Pharmacy Benefit Manager provides the covered person, or, if applicable, the covered person's authorized representative, a reasonable period of time to submit the necessary information, taking into account the circumstances, ~~but in no event less than 48 hours after notifying the covered person, or, if applicable, the covered person's authorized representative, of the failure to submit sufficient information,~~ pursuant to applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible and as required by applicable state statues, rules and regulations. ~~, but in no event more than 48 hours after the earlier of:~~

~~• The Pharmacy Benefit Manager's receipt of the requested specified information; or~~
~~• The end of the period provided for the covered person, or, if applicable, the covered person's authorized representative, to submit the requested specified information.~~

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

~~For concurrent review urgent care requests involving a request by the covered person, or, if applicable, the covered person's authorized representative, to extend the course of treatment beyond the initial period of time or the number of treatments, if the request is made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments, verify that the Pharmacy Benefit Manager makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the~~

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~~covered person's medical condition, but in no event more than 24 hours after the Pharmacy Benefit Manager's receipt of the request.~~

If the Pharmacy Benefit Manager's determination is an adverse determination, the Pharmacy Benefit Manager shall provide notice of the adverse determination or coordinate with the insurer~~carrier~~ in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

Verify that the Pharmacy Benefit Manager calculates the time period within which a determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is filed with the either the health insurer~~carrier~~ or Pharmacy Benefit Manager in accordance with the health insurer's~~carrier's~~ procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

Verify that the Pharmacy Benefit Manager's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative as required by applicable state statutes, rules, and regulations.~~, to include all the following:~~

~~• The specific reason or reasons for the adverse determination;~~
~~• Reference to the specific plan provisions on which the determination is based;~~
~~• A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to complete the request, including an explanation of why the material or information is necessary to complete the request;~~
~~• A description of the health insurer's~~carrier's internal review procedures established pursuant to applicable state statutes, rules and regulations including any time limits applicable to those procedures;
• A description of the Pharmacy Benefit Manager expedited review procedures established pursuant to applicable state statutes, rules and regulations;
~~• If the Pharmacy Benefit Manager relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative upon request;~~
~~• If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;~~
~~• If applicable, instructions for requesting:~~
~~○ A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination, as set forth in applicable state statutes, rules and regulations; or~~
~~○ The written statement of the scientific or clinical rationale for the adverse determination, as set forth in applicable state statutes, rules and regulations; and~~
~~• A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the health insurer's~~carrier's grievance procedure process as provided under applicable state statutes, rules and regulations to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.~~

Verify that the Pharmacy Benefit Manager provides the notice orally, in writing or electronically.

~~If the Pharmacy Benefit Manager provides the notice of adverse determination orally, verify that the Pharmacy Benefit Manager also provides written or electronic notice of the adverse determination within three days~~

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~~following the oral notification.~~

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STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 7
The Pharmacy Benefit Manager monitors the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and ensures that the contracting organization complies with applicable state provisions and accompanying regulations.

Apply to: PBMs contracting out utilization review services.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Contracts with organizations or entities within scope for this examination standard. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Reports of entity reviews and audits (if any) by health ~~carrier~~plan

_____Periodic reports from the organization or entity, if required by contract or state law. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's board of directors. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's utilization review committee. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

_____Policies and procedures for oversight within scope. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a Pharmacy Benefit Manager contracts to have a utilization review organization or other entity perform the utilization review functions required by the Utilization Review and Benefit or applicable state statutes, rules and regulations, the Pharmacy Benefit Manager is responsible for monitoring the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and for ensuring that the requirements of the Utilization Review and applicable state statutes, rules and regulations are met.

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Verify that the Pharmacy Benefit Manager has policies and procedures in place that ensure the utilization review programs of designees comply with all applicable state and federal laws establishing confidentiality and reporting requirements.

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The Drug Formulary, Placement and Specialty Drug review includes, but is not limited to, the following standards related to how the Formulary is managed and controlled by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 1
The pharmacy benefit manager establishes and maintains a fFormulary program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Formularies and fFormulary tTemplates used during the examination period.

All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

Commented [A71]: Revised language to permit disclosure of roles and credentials without requiring PII beyond what is necessary for compliance.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period are ~~appropriate to all~~compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period are ~~appropriate to all~~compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other cCommittees decisions and statements ~~comport~~ comply with all applicable state statutes, rules and regulations.

The identification of members of a P&C Committee shall not be publicly disclosed.

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STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 2
The pharmacy benefit manager establishes and maintains a f~~F~~ormulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and f~~F~~ormulary t~~T~~emplates used during the examination period. ~~Utilization review policies and procedures.~~

_____ All policies, procedures, and other documentation relevant to drug utilization management; including but not limited to, all fail-first policies including step-therapy protocols, prior authorization requirements, and medical necessity guidelines.

_____Any and all list(s) of medications included in and excluded from the mail order benefit.

_____Any ~~and~~ list(s) of all medications allowed for a 90-day supply~~,~~ and those only allowed for 30-day supply or less, for both mail order and retail pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to ~~comport~~ comply with all applicable state statutes, rules and regulations.

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period ~~do not restrict access to drugs to select pharmacies in violation of any required and~~ are compliant with applicable state statutes, rules or regulations.

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STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 3
The pharmacy benefit manager defines ~~and appropriately places any~~ specialty drug and executes specialty drug ~~on the~~ formulary placement ~~when a state has a specialty drug definition to comport~~ in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential if required by applicable state law

Documents to Be Reviewed

_____Applicable statutes, rules and regulations that are applicable to Pharmacy Benefit Managers

_____Formularies and f~~F~~ormulary t~~T~~emplates used during the examination period.

_____Utilization review policies and procedures

_____Specialty drug list(s)

_____All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period ~~use the applicable definition in accordance with all~~are compliant with applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period ~~have any drug that meets~~that places specialty and non-specialty drugs on formularies in compliance with all applicable ~~the~~ state statutes, rules, and regulations. ~~statute definition of specialty drug placed appropriately and further that any drug that does not meet the state statute definition of specialty drug tiered appropriately in accordance compliance with all applicable state statutes, rules and regulations.~~

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other ~~C~~committee~~s~~ decisions and statements use and apply the ~~correct~~ state statute definition of specialty drug to ~~comport~~ in compliance with all applicable state statutes, rules and regulations.

The identification of members of a P&C Committee shall not be publicly disclosed.

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Commented [A72]: This highlights that our formularies and utilization management programs are standardized and not tailored to individual state requirements, as compliance with state-specific laws rests with the plan sponsor—not the PBM

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J. Complaints, Grievances, and Appeals

1. Purpose

The purpose of complaints, grievances and appeals handling procedures is to provide a process for consumers or providers to address issues, and to evaluate how well a regulated entity complies with laws, resolves issues, and timely responds to dissatisfaction expressed by consumers or providers. This includes:

- Ensuring compliance with applicable statutes and/or regulations[1], including:
    - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
    - Establishing whether violations were committed; and
    - Monitoring future conduct for compliance;
- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers or providers; and
- Identifying problem areas that may indicate broader operational issues.

All sections emphasize the importance of reviewing how concerns-whether classified as complaints, grievances or appeals-are processed, documented, and used to improve consumer service.

2. Techniques

The examination approach for complaints, grievances, and appeals procedures include the following shared techniques:

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems.
- **Documentation Review:** Assessing written policies, procedures, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, and providers are informed of the procedures and their rights.

All procedures call for reviewing the frequency and nature of the issues raised and whether they were resolved in accordance with the applicable standards

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, resolution)
- **Procedural Adequacy:** Verifying that the regulated entity has adequate written procedures for handling and resolving the issue, and that these are disclosed to consumers
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law
- **Compliance and Fairness:** Determine that responses:

[1] The term statutes and/or regulations refers to all legally binding statutes, rules, regulations, policies or other documents promulgated by an entity with said power.

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- Fully address the issue(s) that was raised.
- Include adequate supporting documentation.
- Are compliant with policy statutes and regulations.
- Provide appropriate remedies when necessary.

Complaints, Grievances and Appeals stress maintaining records that are accessible to regulators and retaining them for appropriate time periods.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The pharmacy benefit manager maintains a detailed, accessible register documenting each complaint, grievance, or appeal, in accordance with ~~the applicable records retention schedule~~applicable statutes, rules and regulations.~~.~~

Commented [A73]: Alternative language proposal: All member, pharmacy, and/or state department of insurance complaints are documented in accordance with applicable state requirements.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Regulated entity register

_____Insurance department records

_____Direct consumer complaint, grievance, or appeal

_____Member evidence of coverage

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify accurate logging of the issue, date received, review actions, and resolution

Verify that the register includes enough detail to support regulatory review

Verify that the PBM retains the register for at least 3 years if required by state law.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The pharmacy benefit manager has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers and contracted providers.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.

_____Member evidence of coverage.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the ~~company~~ PBM maintains a complaint register.

~~Verify that the PBM included the complaint log and procedures that include the audit, credentialing, and network enrollment departments.~~

Commented [A74]: Recommend removal because this is unclear.

Verify that the PBM's procedures comply with applicable statutes and regulations.

Verify that the PBM's procedures are communicated to consumers and contracted providers.

Verify that the PBM has filed procedures with the insurance commissioner where required.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Commented [A75]: Timeframes vary by state laws.

Standard 3
The pharmacy benefit manager must resolve and respond to complaints, grievances, and appeals within prescribed timeframes required by applicable statues, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review test sample to ensure the PBM is maintaining adequate documentation.

Determine if the PBM's response is timely. The Examiner should refer to state laws and regulations for the required time frame. *Note:* Timing is measured from the date the issue is received.

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STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The pharmacy benefit manager actions taken in response to complaints, grievances, or appeals must comply with ~~insurance laws, contracts, and regulations as well as address all identified concerns~~applicable statutes, rules and regulations.

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to Be Reviewed

_____Applicable statutes and regulations

_____~~Contracts, including provider~~ Complaint, grievance, and appeal procedure manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review documentation to determine if the PBM response fully addresses the issues raised. If the PBM did not properly address/resolve the complaint, the Examiner should ask the PBM what corrective action it intends to take.

For reviewing responses:
- Was the response timely.
- Was the response complete and responds to all issues raised.
- Does the response include adequate documentation to support the respondent's position.
- Were the respondent's actions appropriate from a business standpoint.
- Were the respondent's actions compliant with applicable statutes and regulations.
- Were the appropriate remedies for the consumer identified.

Document potential violations.

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STANDARDS
PHARMACY BENEFITS MANAGERS
AUDITS

Standard 1
The PBM demonstrates that it has ~~reasonable and uniform criteria~~ documented policies and procedures for pharmacy audits and demonstrates that it ~~follows those reasonable standards~~conducts the pharmacy audit in compliance with its policies and procedures and in compliance with appliable statutes, rules, and regulations. .

Apply to: All PBMs if services are delegated by the health plan.

Priority: Essential if required by applicable state law.

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.

_____ Listing of all types of audits that may include but not be limited to, on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)

_____ From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted format to the extent needed to confirm compliance with state law.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format to the extent needed to confirm compliance with state law.)

_____ Listing of all audits initiated or that were ongoing during the examination period. (As part of this request, require a timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal. ~~*It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.)*~~

_____ A*ll correspondence* within scope between the PBM and a pharmacy as part of audits during the examination period. (Consider whether to request information from all audits or just a sampling of the audits. 'Correspondence' may include ~~but not be limited to,~~ all final and fully executed documents and communications sent by the PBM to the pharmacies and~~, all documents sent~~ by the pharmacies to the PBM ~~and any emails, notes from phone conversations, and any other communications about~~ as part of the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format to the extent needed to confirm compliance with state law.)

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_____ ~~Summary of any use of artificial intelligence (AI) that it may use as part of auditing a pharmacy~~.

_____ ~~Policies and procedures associated with the use of AI~~.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal PBM policies and procedures regarding the PBM's audit process with pharmacies. Review criteria for the different types of audits to assess whether PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit including but not limited to processes for initiating, conducting and resolving each type of audit.

Review contracts and manuals with details about the audit process to ensure the information provided to pharmacies is clear, ~~concise, and easily understood~~and concise. ~~*While the details of the audit process are important, the information must be provided in a manner that will be easily understood by pharmacies.*~~

Commented [A76]: Remove language as standard of "easily understood" is unclear (i.e. who makes this determination?)

Review contracts and manuals for details provided to pharmacies about the audit process. Review how PBM informs pharmacies of how audits are initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail), any fees required by the PBM that are outside the audit finding, how the pharmacy may address and rectify potential findings, PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

Assess whether the PBM's pharmacy audit requirements ~~for pharmacies are reasonable~~are compliant with state law and provide pharmacies with the following:

- The scope, frequency (including the maximum annual amount) and method of all audits.
- Detailed guidelines, including metrics and data, used during audits.
- Advanced notice of an upcoming audit.
- Sufficient time to prepare and collect required information.
- Convenient and accessible methods for corresponding with the PBM during the audit, for example does the pharmacy have a point of contact to ask questions and obtain clarification on the PBM's expectations.
- Sufficient time to review and correct any audit findings prior to the PBM's final determination.
- Sufficient input into the implementation of a corrective action plan (if applicable) and sufficient time to comply with the requirements of a corrective action plan.
- An appropriate dispute resolution process that pharmacies may use to dispute audit findings. The process for pharmacies should be convenient and accessible and should not create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute resolution process.

If the regulator feels the PBM's policies and procedures are ~~reasonable~~compliant with state law, ensure the PBM also follows and implements its own policies & procedures. Review timeframe requirements, whether the PBM provides reasonable and concise information to pharmacies in response to any questions, and whether the PBM provides appropriate justifications in the draft and final audit reports.

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Review the results of all audits to determine ~~if audits are conducted in a manner that appears reasonable for each of the individual pharmacy being audited and that~~ there are no concerning trends with how the PBM conducts audits. For example, when conducting routine audits, are pharmacies selected randomly or does the PBM only audit non-affiliated, independent pharmacies? ~~*The latter trend would be problematic.*~~

Verify that the PBM conducts pharmacy audits in compliance with applicable state laws and regulations. Ensure such methods are reasonable, utilized appropriately and consistent with any regulatory requirements (or prohibited if required by state law or regulation). For example, if use of auditing techniques such as extrapolation is prohibited by state law or regulation, the PBM should not apply the method in any audits.

Assess whether PBM has staffing models to effectively initiate, conduct and finalize audits.

~~Assess the PBM's use of AI to ensure it is reasonable and that any results or findings from the use of AI are conveyed to the pharmacy in a clear and transparent manner.~~

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Coalition Claims Data Template Recommendations

(October 2, 2025)

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October 2, 2025

Ms. Joylynn Fix
Pharmacy Benefit Management (D) Working Group
National Association of Insurance Commissioners
444 North Capital Street, NW, Suite 700
Washington, DC 20001-1512
Forwarded via email: Jolie H. Matthews (jmatthews@naic.org)

RE: Submission of PBM Market Conduct Claims Data Template Recommendations

Dear Ms. Fix:

The undersigned Coalition of Pharmacy Benefit Managers (PBMs) and health insurers[1] is committed to assisting the Pharmacy Benefit Management (D) Working Group as it develops robust and transparent standards to enable consistent market regulation by state regulators. During our Coalition call with the drafting group, we discussed the importance of establishing a standard claims data template for regulators to leverage when requesting claims data from PBMs. A common template will streamline the data collection process, improve the comparability of information across states, mitigate the risk of inaccuracies due to interpretations, and facilitate a more effective review of market regulation data.

In the context of Market Conduct Examinations (MCEs), the definition of a "standard" claims data universe or layout must be grounded in how PBMs typically store, use, maintain and report data in the ordinary course of business. This objective is best served by leveraging existing operational data structures or commonly calculated values that align with standard reporting rather than imposing artificial reporting constructs that require logic, transformation, or calculation beyond what is routinely maintained or reported.

After reviewing several templates used in recent examinations, the Tennessee template, based on National Council for Prescription Drug Program (NCPDP) standards, offers a strong starting point for standardizing claims data collection. These standards are currently used throughout the PBM industry for claims processing, data reporting and for other purposes making data retrieval efficient and accurate. Further, it deliberately avoids Personally Identifiable Information (PII) concerns and is easily adaptable across various systems, supporting seamless implementation and integration.

While we support NCPDP standards as the basis of the initial request for claims data, the Coalition notes that due to the variances among state PBM laws, not all data fields in the

[1] The Cigna Group, CVS/Aetna, Elevance, UnitedHealth Group

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Tennessee template will be applicable in every state or should be the basis of a 100% claims data set. In the context of the Tennessee template, there are instances where deviations from the template make sense.

State Specific Data Requirements: Some data elements required by the Tennessee template do not apply broadly across all states. Moreover, these data fields do not have a corresponding NCPDP field and thus are not going to be standardized across PBMs. These fields include Low Volume Pharmacy Indicators, Sponsor Administrative Fee, Sponsor Amount and Cost Spread to PBM. The Coalition suggests that these, and other state-specific data elements, not be included in the NAIC template to preserve the integrity of a standard layout. State-specific compliance testing can be effectively addressed through:

- Targeted sampling, as endorsed in the NAIC Market Regulation Handbook; or
- Supplemental requests which allow regulators to explore specific issues without burdening all PBMs with non-standard reporting.

Data Elements Needing Calculation/Logic: Some data elements require additional calculations using business rules that are not uniformly applied and, therefore, are more appropriately and efficiently requested as part of an ad-hoc or sample-size claims request. As examples, these data elements include Accumulated Deductible Amount, Remaining Deductible Amount, Remaining Benefit Amount, Amount Applied to Periodic Deductibles and Amount Exceeding Periodic Benefit Maximum. This information cannot be automated and requires manual processes which will create inefficiencies and inaccuracies if applied broadly across all claims.

For your convenience, attached is a draft template for your consideration. Our recommendation is based on Tennessee's template and modified to allow for variances in state law. The data elements noted above are highlighted in the draft and those elements would therefore be done through either a sample-size methodology or some other type of agreeable process outside of the full claims dataset. We expect that states may have to supplement this template with other NCPDP standards to enforce their specific state laws, but those state-specific elements should not be included in the NAIC adopted template. To keep data operability across the industry, we would recommend that where deviations are necessary, they should be based on NCPDP standards wherever possible.

We appreciate the opportunity to contribute to this important initiative and look forward to working collaboratively with the working group to refine the template.

Sincerely,

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Sr. Director, State Regulatory Affairs
The Cigna Group

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CVS/Aetna

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Elevance Health

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UnitedHealth Group

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List of Pharmacy Claims

File Name: ClaimsWks[week numbers].xlsx. E.g., "ClaimsWks1and2.xlsx, ClaimsWks3and4.xlsx", etc.
Data should be submitted in bi-weekly files to manage file size.

The files should be downloaded from company system(s) and contain one record for each paid claim transaction submitted by pharmacies physically located in Tennessee, mail order pharmacies that served Tennessee residents, or specialty pharmacies that served Tennessee residents that the company processed within the scope of the audit.

Characters are required in all requested fields if applicable to a claim.

PBM may exclude information if the information pertains exclusively to plans in T.C.A. § 56-7-3102(1)(8).)

Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
503_F3	A	503-F3	Authorization Number	Number assigned by the processor to identify an authorized transaction.	
283	D	283	Original Claim Received Date	The date the pharmacy submitted the claim electronically for a paper claim- matching program.	MM/DD/YYYY
578	D	578	Adjudication Date	Date the claim or adjustment is processed.	MM/DD/YYYY
101_A1	A	101-A1	BIN Number	Card Issuer ID or Bank ID Number used for network routing.	
103_A3	A	103-A3	Transaction Code	Code identifying the type of transaction.	
104_A4	A	104-A4	Processor Control Number	Number assigned by the processor.	
201_B1	A	201-B1	Service Provider ID	NPI	The Service Provider ID should correspond to a NPI found on the Pharmacies Table
PhrmNme	A		Pharmacy Name		
Address1	A		Pharmacy Address Line 1		
Address2	A		Pharmacy Address Line 2 (if necessary)		
City	A		Pharmacy City		
State	A		Pharmacy State Abbreviation		
ZIPCode	A		Pharmacy Zip Code		
LwVolCrt	A		Low-Volume Pharmacy Indicator	Whether the pharmacy certified as a low-volume pharmacy with the PBM pursuant to Rule 0780-01-95-.10 for any portion of the calendar year	"Y"=Low Volume Pharmacy, "N"=Not a Low Volume Pharmacy
401_D1	D	401-D1	Date of Service	Identifies date the prescription was filled or professional service rendered or subsequent payer began coverage following Part A expiration in a long-term care setting only.	MM/DD/YYYY
332_CY	A	332-CY	Patient ID	ID assigned to the patient.	
302_C2	A	302-C2	Cardholder ID	Insurance ID assigned to the cardholder or identification number used by the plan.	
301_C1	A	301-C1	Group ID	ID assigned to the cardholder group or employer group.	
524_FO	A	524-FO	Plan ID	Assigned by the processor to identify a set of parameters, benefit, or coverage criteria used to adjudicate a claim.	
455_EM	A	455-EM	Prescription/Service Reference Number Qualifier	Indicates the type of billing submitted.	
402_D2	A	402-D2	Prescription/Service Reference Number	Reference number assigned by the provider for the dispensed drug/product and/or service provided.	
436_E1	A	436-E1	Product/Service ID Qualifier	Code qualifying the value in 'Product/Service ID' (407-D7).	
407_D7	A	407-D7	Product/Service ID	ID of the product dispensed or service provided.	
442_E7	N	442-E7	Quanity Dispensed	Quantity dispensed expressed in metric decimal units.	
403_D3	N	403-D3	Fill Number	The code indicating whether the prescription is an original or a refill.	
405_D5	N	405-D5	Days Supply	Estimated number of days the prescription will last.	
406_D6	A	406-D6	Compound Code	Code indicating whether or not the prescription is a compound.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
408_D8	A	408-D8	Dispense As Written (DAW)/Product Selection Code	Code indicating whether or not the prescriber's instructions regarding generic substitution were followed.	
414_DE	D	414-DE	Date Prescription Written	Date prescription was written.	MM/DD/YYYY
415_DF	N	415-DF	Number of Refills Authorized	Number of refills authorized by the prescriber.	
460_ET	N	460-ET	Quanity Prescribed	Amount expressed in metric decimal units.	
429_DT	A	429-DT	Unit Dose Indicator/Special Packaging Indicator	Code indicating the type of dispensing dose.	
600_28	A	600-28	Unit Of Measure	NCPDP standard product billing codes.	
461_EU	A	461-EU	Prior Authorization Type Code	Code clarifying the 'Prior Authorization Number Submitted' (462-EV) or benefit/plan exemption.	
462_EV	A	462-EV	Prior Authorization Number Submitted	Number submitted by the provider to identify the prior authorization.	
337_4C	A	337-4C	Coordination of Benefits/Other Payments Count	Count of other payment occurrences.	
338_5C	A	338-5C	Other Payer Coverage Type	Code identifying the type of 'Other Payer ID' (340-7C).	
339_6C	A	339-6C	Other Payer ID Qualifier	Code qualifying the 'Other Payer ID' (340-7C).	
340_7C	A	340-7C	Other Payer ID	ID assigned to the payer.	
443_E8	D	443-E8	Other Payer Date	Payment or denial date of the claim submitted to the other payer. Used for coordination of benefits.	MM/DD/YYYY
341_HB	N	341-HB	Other Payer Amount Paid Count	Count of the payer amount paid occurrences.	
342_HC	A	342-HC	Other Payer Amount Paid Qualifier	Code qualifying the 'Other Payer Amount Paid' (431-DV).	
431_DV	N	431-DV	Other Payer Amount Paid	Amount of any payment known by the pharmacy from other sources.	
409_D9	N	409-D9	Ingredient Cost Submitted	Submitted product component cost of the dispensed prescription. This amount is included in the 'Gross Amount Due' (430-DU).	
412_DC	N	412-DC	Dispensing Fee Submitted	Dispensing fee submitted by the pharmacy. This amount is included in the 'Gross Amount Due' (430-DU).	
477_BE	N	477-BE	Professional Service Fee Submitted	Amount submitted by the provider for professional services rendered.	
433_DX	N	433-DX	Patient Paid Amount Submitted	Amount the pharmacy received from the patient for the prescription dispensed.	
438_E3	N	438-E3	Incentive Amount Submitted	Amount represents a fee that is submitted by the pharmacy for contractually agreed upon services. This amount is included in the 'Gross Amount Due' (430-DU).	
478_H7	N	478-H7	Other Amount Claimed Submitted Count	Count of other amount claimed submitted occurrences.	
479_H8	A	479-H8	Other Amount Claimed Submitted Qualifier	Code identifying the additional incurred cost claimed in 'Other Amount Claimed Submitted' (480-H9).	
480_H9	N	480-H9	Other Amount Claimed Submitted	Amount representing the additional incurred costs for a dispensed prescription or service.	
426_DQ	N	426-DQ	Usual and Customary Charge	Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed.	
430_DU	N	430-DU	Gross Amount Due	Total price claimed from all sources. For prescription claim request, field represents a sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9). For service claim request, field represents a sum of 'Professional Services Fee Submitted' (477-BE), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Other Amount Claimed' (480-H9).	
423_DN	A	423-DN	Basis of Cost Determination	Code indicating the method by which 'Ingredient Cost Submitted' (Field 409-D9) was calculated.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
450_EF	A	450-EF	Compound Dosage Form Description Code	Dosage form of the complete compound mixture.	
451_EG	A	451-EG	Compound Dispensing Unit Form Indicator	NCPDP standard product billing codes.	
452_EH	A	452-EH	Compound Route of Administration	Code for the route of administration of the complete compound mixture.	
447_EC	N	447-EC	Compound Ingredient Component Count	Count of compound product IDs (both active and inactive) in the compound mixture submitted.	
488_RE	A	488-RE	Compound Product ID Qualifier	Code qualifying the type of product dispensed.	
489_TE	A	489-TE	Compound Product ID	Product identification of an ingredient used in a compound.	
448_ED	N	448-ED	Compound Ingredient Quantity	Amount expressed in metric decimal units of the product included in the compound mixture.	
449_EE	N	449-EE	Compound Ingredient Drug Cost	Ingredient cost for the metric decimal quantity of the product included in the compound mixture indicated in 'Compound Ingredient Quantity' (Field 448-ED).	
490_UE	A	490-UE	Compound Ingredient Basis of Cost Determination	Code indicating the method by which the drug cost of an ingredient used in a compound was calculated.	
545_2F	A	545-2F	Network Reimbursement ID	Field defined by the processor. It identifies the network, for the covered member, used to calculate the reimbursement to the pharmacy.	The Network Reimbursement ID should correspond to a NwkID found on the Network Table
568_J7	A	568-J7	Payer ID Qualifier	Code indicating the type of payer ID.	
569_J8	A	569-J8	Payer ID	ID of the payer.	
505_F5	N	505-F5	Patient Pay Amount	Amount that is calculated by the processor and returned to the pharmacy as the TOTAL amount to be paid by the patient to the pharmacy; the patient's total cost share, including copayments, amounts applied to deductible, over maximum amounts, penalties, etc.	
506_F6	N	506-F6	Ingredient Cost Paid	Drug ingredient cost paid included in the 'Total Amount Paid' (509-F9).	
507_F7	N	507-F7	Dispensing Fee Paid	Dispensing fee paid included in the 'Total Amount Paid' (509-F9).	
521_FL	N	521-FL	Incentive Amount Paid	Amount represents the contractually agreed upon incentive fee paid for specific services rendered. Amount is included in the 'Total Amount Paid' (509-F9).	
509_F9	N	509-F9	Total Amount Paid	Total amount to be paid by the claims processor (i.e. pharmacy receivable). Represents a sum of 'Ingredient Cost Paid' (506-F6), 'Dispensing Fee Paid' (507-F7), 'Flat Sales Tax Amount Paid' (558-AW), 'Percentage Sales Tax Amount Paid' (559-AX), 'Incentive Amount Paid' (521-FL), 'Professional Service Fee Paid' (562-J1), 'Other Amount Paid' (565-J4), less 'Patient Pay Amount' (505-F5) and 'Other Payer Amount Recognized' (566-J5).	
693	N	693	Total Gross Amount Due	Total sum of the gross amount due fields on the claim level.	
522_FM	A	522-FM	Basis of Reimbursement Determination	Code identifying how the reimbursement amount was calculated for 'Ingredient Cost Paid' (506-F6).	
512_FC	N	512-FC	Accumulated Deductible Amount	Amount in dollars met by the patient/family in a deductible plan.	
513_FD	N	513-FD	Remaining Deductible Amount	Amount not met by the patient/family in the deductible plan.	
514_FE	N	514-FE	Remaining Benefit Amount	Amount remaining in a patient/family plan with a periodic maximum benefit.	
517_FH	N	517-FH	Amount Applied to Periodic Deductible	Amount to be collected from a patient that is included in 'Patient Pay Amount' (505-F5) that is applied to a periodic deductible.	

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Table Field	Type	NCPDP Field	Long Field Name	Definition	Notes
518_FI	N	518-FI	Amount of Copay	Amount to be collected from the patient that is included in 'Patient Pay Amount' (505-F5) that is due to a per prescription copay.	
520_FK	N	520-FK	Amount Exceeding Periodic Benefit Maximum	Amount to be collected from the patient that is included in 'Patient Pay Amount' (505-F5) that is due to the patient exceeding a periodic benefit maximum.	
346_HH	A	346-HH	Basis of Calculation-Dispensing Fee	Code indicating how the reimbursement amount was calculated for 'Dispensing Fee Paid' (507-F7).	
347_HJ	A	347-HJ	Basis of Calculation-Copay	Code indicating how the Copay reimbursement amount was calculated for 'Patient Pay Amount' (505-F5).	
571_NZ	N	571-NZ	Amount Attributed to Processor Fee	Amount to be collected from the patient that is included in Patient Pay Amount (505-F5) that is due to the processing fee imposed by the processor.	
148_U8	N	148-U8	Ingredient Cost Contracted/Reimbursable Amount	Informational field used when Other Payer-Patient Responsibility Amount (352-NQ) or Patient Pay Amount (505-F5) is used for reimbursement. Amount is equal to contracted or reimbursable amount for product being dispensed.	
149_U9	N	149-U9	Dispensing Fee Contracted/Reimbursable Amount	Informational field used when Other Payer-Patient Responsibility Amount (352-NQ) or Patient Pay Amount (505-F5) is used for reimbursement. Amount is equal to contracted or reimbursable dispensing fee for product being dispensed.	
355_NT	N	355-NT	Other Payer ID Count	Count of other payers with payment responsibility.	
991_MH	A	991-MH	Other Payer Processor Control Number	A number that uniquely identifies the secondary, tertiary, etc. payer to the processor.	
356_NU	A	356-NU	Other Payer Cardholder ID	Cardholder ID for this member that is associated with the Payer noted.	
992_MJ	A	992-MJ	Other Payer Group ID	ID assigned to the cardholder group or employer group by the secondary, tertiary, etc. payer.	
142_UV	A	142-UV	Other Payer Person Code	Code assigned by the other payer to a specific person within a family.	
DrgNmS	A		Drug Name and Strength	Drug Name-The name under which the drug is marketed. I.e., the brand name if applicable or the generic name if the drug was not a brand name drug. Strength-How much of the active ingredient is present in each dosage.	
SpnsrFee	N		Sponsor Administrative Fee	Administrative fee charged to the plan sponsor	
SpnsrAmt	N		Sponsor Amount	Amount charged to the plan sponsor by the PBM for the cost of the drug or device	
SprdCst	N		Cost spread to the PBM	Amount charged to the plan sponsor by the PBM for the cost of the drug or device less the amount paid by the PBM.	

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September 17, 2026

Mr. Brett Bache, Chair; Ms. Danielle Torres; Vice Chair and Ms. Petra Wallace
Market Conduct Examination Guidelines (D) Working Group
National Association of Insurance Commissioners
444 North Capital Street, NW, Suite 700
Washington, DC 20001
EMAIL: Brett.Bache@dbr.ri.gov

Re: Coalition Comments on the PBM Exam Standards DRAFT

Dear Mr. Bache, Ms. Torres, and Ms. Wallace:

EXECUTIVE SUMMARY

Thank you for the opportunity to comment on the draft Pharmacy Benefit Manager (PBM) Examination Standards chapter for the Market Regulation Handbook (Handbook).

As background, when PBMs first became subject to market conduct examinations, examiners, consultants, and PBMs were navigating a new regulatory process. Examiners and consultants often approached these examinations using frameworks developed for health insurers, even though PBM operations, business models, and compliance processes are distinct. At the same time, PBMs had limited experience with market conduct oversight and were adapting to new regulatory expectations. These dynamics led to inconsistent examination approaches, confusion regarding expectations for the exam, and inefficiencies for both regulators and regulated entities. To address these challenges, PBMs proactively sought the development of dedicated examination standards and began working with regulators to develop the PBM Examination Standards with the goal of improving transparency, fostering a shared understanding of PBM operations, and creating a more consistent and efficient examination process.

Our Coalition, which includes The Cigna Group, CVS Health, Elevance Health, and UnitedHealth Group, appreciates the significant time, effort, and collaboration that the Market Regulation and Consumer Affairs (D) Committee has devoted to the development of these examination standards. We continue to strongly support the D Committee's objective of creating consistent, transparent, and practical examination standards that promote regulatory clarity, improve examination efficiency, and foster a more uniform approach across jurisdictions.

Since the inception of this initiative, Coalition members have been actively engaged with the PBM (D) Working Group. We recognize the value of establishing well-defined standards and examination expectations. Thoughtful and consistent

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standards benefit regulators, regulated entities, and consumers alike by promoting predictability, reducing unnecessary variation among states, and enabling examinations to focus on meaningful compliance objectives.

Throughout the development process, the Coalition has submitted multiple comment letters and participated extensively in discussions with the PBM (D) Working Group (Working Group). We appreciate the Working Group's willingness to consider stakeholder feedback and the revisions that have been made thus far. For ease of reference, this comment submission includes copies of the Coalition's prior comment letters provided during the development of the standards along with redlined versions of our suggested revisions to the PBM exam chapter.

While the Coalition remains supportive of the overall effort to develop PBM exam standards, our comments have consistently focused on several key areas that we believe are critical to ensuring the final standards are effective, operationally feasible, and aligned with existing legal and regulatory frameworks.

- **Clarify examination scope up front**: The final PBM exam chapter should establish pre-examination processes to ensure that PBM examinations are appropriately tied to the applicable statutory and regulatory requirements of the examining jurisdiction and do not create new obligations PBMs beyond those established by law. Establishing these parameters – and facilitating dialogue regarding expectations before information requests begin – will provide a clear foundation for a focused, efficient, and collaborative examination process.
- **Obtain only essential information**: To support effective and efficient exams, the chapter should direct examiners to limit requests to material, in-scope information and establish clear parameters for when unredacted documentation is necessary and how the documentation request should be handled.
- **Right-size document production expectations**: Consistent with other examination chapters, requests should be limited to final, fully executed documents, coupled with related processes and procedures as appropriate to determine compliance with applicable law.
- **Leverage sampling first**: Consistent with the Handbook’s longstanding treatment of sampling as a foundational examination methodology, examiners should initially request samples and then expand upon them when warranted based on the findings, applicable risks, and a reasonable assessment of costs and benefits.

Attached is a redline version of the draft chapter to reflect the above. Notably, it includes an updated recommendation to address examination scope and redactions which we believe should provide regulators with the information necessary to determine compliance while addressing our concerns around early identification of the examination scope and treatment of out of scope or otherwise highly sensitive information. The second attachment for your reference is what we have previously provided to the PBM (D) Working Group.

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Similar to our commitment to the PBM (D) Working Group, the Coalition remains committed to working constructively with the Market Conduct Examination Guidelines (D) Working Group and state regulators to support the development of examination standards that are clear, consistent, effective, and capable of achieving the shared goal of promoting compliance and protecting consumers. We appreciate the opportunity to provide feedback and look forward to continued engagement as this important work progresses.

Sincerely,

Franca D'Agostino
Director, National Regulatory Affairs
The Cigna Group

Leanne D. Gassaway
VP State Government Affairs
CVS Health

Christine Cappiello
Sr. Director, State Affairs and NAIC
Elevance Health

Mollie Zito
Deputy General Counsel, Reg. Affairs
UnitedHealth Group

Attachments:

1. Coalition Redlines for the MCES(D) WG of the draft Pharmacy Benefit Management Chapter (September 17, 2026)
2. Coalition Comments and Redlines of the Draft "Conduct the Pharmacy Benefit Manager Examination" Chapter, as submitted to the PBM (D) Working Group (October 2, 2025 through April 3, 2026)

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Coalition Redlines for the MCEG (D) WG

of the

Draft "Conducting the Pharmacy Benefit Manager Examination" Chapter

Coalition Members:

The Cigna Group, CVS Health, Elevance Health, and UnitedHealth Group

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Draft 4/7/26

Any comments on this draft should be sent by email only to Jolie Matthews at jmatthews@naic.org.

Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:
The standards set forth in this chapter are based on state procedures, not on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination process. Since there are limits to state procedures and state laws vary, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in Chapter 1—Introduction.

This chapter provides a suggested format for conducting pharmacy benefit manager (PBM) examinations and reviews. In addition to this chapter, the examiner should be familiar with the NAIC white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (NAIC White Paper) *and the NAIC's Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation and Guidance Document – ERISA Preemption and State PBM Laws (once finalized and adopted).*

Background, Scope and Types of Examinations

"Pharmacy Benefit Manager" is defined in the NAIC White Paper as entities that negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. Insurers, employers, other payors, and even other PBMs contract with PBMs to design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols). PBMs engage in negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

PBM examinations can be either comprehensive or targeted. A PBM examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the PBM's systems and procedures are similar, if not identical, for every state, the examination and resulting report should be acceptable in all states, regardless of which jurisdiction conducts the examination.

Unlike insurance company examinations, currently there are generally little, if any, "market analysis" procedures or tools developed to assist in the conduct of PBM examinations. Similarly, PBMs are not regulated for solvency. Rather, PBMs negotiate on behalf of insurers and other PBMs and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related items. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. In addition, PBMs contract directly with Pharmacy Services Administrative Organizations (PSAOs), who provide administrative services to independent pharmacies, including, but not limited to, contract negotiations with PBMs.

For additional information on background and scope, please refer to Chapter 12, ~~and~~ Chapter 13, and Chapter 16 of this handbook.
Key Terms:

Commented [A1]: This document includes recommended redlines and comments from the Coalition that includes The Cigna Group, CVS Health, Elevance Health, and UnitedHealth Group. For additional details and rationale regarding these requested changes, please refer to the Coalition's April 3, 2026, January 30, 2026, and October 2, 2025 comment letters to the PBM (D) WG.

Commented [A2]: In addition to the noted documents, we believe examiners should be familiar with the NAIC's guidance documents on ERISA as the scope of the PBM contracts and data that are subject to examination must be consistent with applicable state statutes, rule, and regulations, and federal preemption may also apply.

Commented [A3]: Chapter 16, Scheduling, Coordinating and Communicating, details scope considerations for examiners, so we believe it should also be included in this list.

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Regulators must consider state specific definitions when conducting a PBM Examination.

340B Pharmacy – a pharmacy that dispenses outpatient drugs purchased at significant discounts by eligible "covered entities" such as safety-net hospitals, clinics, and health centers under the federal 340B Drug Pricing Program. These pharmacies are often excluded from additional drug manufacturer rebates for certain drug claims.

Note: The term "340B" is derived from the section of the Public Health Service Act (PHSA), 42 U.S.C. 256b, from which the 340B Program is defined.

Affiliated Pharmacies – refers generally to pharmacies that are formally connected to or associated with a larger organization, such as a health system, hospital, or a PBM, through ownership, partnership, or contracted arrangement.

Biologic Drugs - are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, certain vaccines, and cell and gene therapies. Biologics are sometimes referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the U.S. Food & Drug Administration (FDA) to sell their products through a separate application process. Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.

Biosimilar Drugs - are FDA approved as having no clinically meaningful difference from the referenced product and may be produced following the expiration of the biologic's patent and exclusivity period. Biosimilar drugs are listed in the FDA Purple Book and are not considered "generic" of their brand referenced biologic product.

Brand Name Drugs - are medications discovered, developed, and marketed by a pharmaceutical company under a specific, patented, and trademarked name. These original, FDA-approved, or regulatory-approved drugs have exclusive marketing rights for a set period to recoup research costs, often making them more expensive than generic alternatives. Brand name drugs are often designated as the "Reference Listed Drug" in the FDA Orange Book.

Chain Pharmacy – Unless otherwise defined in the state, a chain pharmacy is owned, operated, or controlled by a corporate-owned entity, generally defined as four or more locations, often operating under a shared corporate banner and utilizing centralized management.

Covered Entity – means, as defined in 45 CFR 160.103, a health plan, a healthcare clearinghouse, or a health care provider who transmits health information electronically in connection with covered transactions.

Generic Drugs - are small molecule drugs that are therapeutically equivalent to their reference brand name drug. Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Like brand-name drugs, the FDA must approve a generic drug application called an Abbreviated New Drug Application to ensure its bioequivalence to the brand-name drug before it can be produced. Generic drugs comprise the largest portion of the pharmaceutical market.

Independent Pharmacy – unless otherwise defined in the state, a pharmacy that is privately and independently owned and operated by one or more pharmacists or under common ownership with not more than three pharmacies and whose primary function is to provide direct pharmaceutical care to patients. These services can include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling in a community setting.

Insurers – entities that contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees. Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management. In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including, but not limited to, utilization management,

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prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks. Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

Long-Term Care (LTC) Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses medications and delivers them directly to a licensed long-term care facility, such as a nursing home, group home, or specialized health care facility, and generally does not provide medications to inpatient hospitals.

Mail-Order Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses prescription medications and delivers them directly to a patient's home, workplace, or preferred location through the mail or courier service.

Payors - include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (individual, small group, large group, government programs) and the arrangement that the payor chooses. In this chapter, when PBM functions are referenced, payors may choose to do those tasks internally.

Pharmaceutical Manufacturers or Manufacturers - research, develop, produce, market, and sell prescription drugs to treat medical conditions. The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition. Pharmaceutical manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Pharmaceutical manufacturers may also purchase prescription drugs developed by other manufacturing companies to market as their own. Pharmaceutical manufacturers may also offer patient assistance programs and direct-to-consumer programs for some of the drugs they market.

Pharmacies - a place licensed by a state Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed. A pharmacy may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling, and other health care related functions, as permitted by the state in which the pharmacy is licensed.

Pharmacists - are licensed and trained health care providers that assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a medication to a patient to ensure patients do not receive the wrong drug or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals. Pharmacists are licensed by a State Board of Pharmacy and are permitted to conduct various levels of health care services in different states, depending on state licensure requirements.

Pharmacy and Therapeutics (P&T) Committee – are expert, multidisciplinary groups, which are usually comprised of physicians, pharmacists, and other health care professionals, that evaluate clinical, safety, and economic evidence for prescription drugs. P&T Committees determine which medications are covered, create formularies, and manage utilization policies, such as prior authorization.

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Pharmacy Benefit Managers (PBMs) - provide claims processing services or other prescription drug services on behalf of insurers or administer an insurer's prescription drug coverage pursuant to its contract or under an employment relationship with an insurer or health plan that directly manages the prescription drug coverage provided by the insurer or health plan. Insurers determine through contractual delegation which activities a PBM may perform on their behalf, which may include negotiating and contracting with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs may also develop, negotiate, implement, or administer clinical, formulary, or other preferred lists for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers and other entities. PBMs may be delegated the responsibility of the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example ,drug coverage tiers, and utilization management protocols). PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies. PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews (DURs).

Pharmacy Benefit Manager Network –is a contracted, organized group of retail, mail-order, specialty, and other pharmacies established by a PBM to provide covered prescription drug services to health plan members. Pharmacies within the network have specific reimbursement rates, terms, and, in some cases, performance-based quality measures.

Pharmacy Services Administrative Organizations (PSAOs) - are organizations that provide administrative services to independent pharmacies. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly. The PSAO's overall administrative function is to assist with contract evaluation and execution with the PBM or wholesaler, customer service, central payment and reconciliation, and patient data evaluation. In many instances a PSAO is owned by a wholesaler.

Rebates or Manufacturer Rebates – are a post-purchase discount or price concession paid by pharmaceutical manufacturers directly or indirectly to rebate aggregators, group purchasing organizations (GPOs), PBMs, covered entities, or health insurers. These payments are typically negotiated in exchange for favorable placement of a drug on a health plans' formulary and may be described as reducing the overall cost of drugs for covered entities or payors.

Note: Rebates may also apply when speaking of wholesaler or pharmacy rebates, which are contractual incentives paid to pharmacies based on specific performance metrics. For purposes of this chapter unless otherwise specified, the term "rebates" includes "manufacturer rebates."

Specialty Drugs - is a term that generally refers to drugs and biologics that are typically high-cost, and can be complex to ship, or store, require specialized administration, subject to limited or exclusive distribution, or may require specialized clinical care, such as frequent dosage adjustments, intensive patient monitoring or counseling, or ongoing clinical support (i.e. high-touch).It often references medications used to treat rare, complex, life threatening, or chronic conditions. Because of this, these drugs often dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

Note: There is no unified regulatory definition of the term "specialty drug." Examiners should consult applicable state law and impacted health plan formulary definitions.

Specialty Pharmacy – is a type of pharmacy that dispenses specialty medications. Specialty pharmacies often hold limited-distribution contracts with a pharmaceutical manufacturer to be one of just a few pharmacies authorized to dispense a particular specialty medication. Specialty pharmacies may offer in-depth patient support such as clinical patient management.

Utilization Review – which is also known as utilization management or DUR, includes using predetermined criteria for appropriate drug therapy, utilizing patient-specific information to ensure safe and effective use of drug therapy to potentially lower the overall cost of health care. Types of utilization review include prospective, concurrent, and

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respective utilization review. PBMs and/or payors may develop utilization review standards to evaluate and approve or deny services when compared to clinical need, cost, and established national guidelines.

Wholesalers/Distributors - Wholesalers purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. Wholesalers own several of the largest PSAOs used by independent pharmacies.

Qualifications of Examiners

Information on qualifications, please refer to Chapter 14 of this handbook**.** In addition, states might want to include a pharmacist or other PBM-specific qualifications to the examination team.

Types of Examinations

When planning the examination, it is helpful to first identify which services and products are regulated and the impact on regulated entities. A PBM examination can take the form of a comprehensive examination, a targeted examination, a risk-focused examination, a re-examination, a multistate cooperative examination or a desk examination. Most of the elements found in Chapter 13—Types of Examinations will apply to the PBM examination. Because most operations for these entities remain consistent in all states, it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Scheduling, Coordination and Planning Scope

The procedures discussed in this section are to assist the regulator in determining if an examination or other type of regulatory action needs to be scheduled. It will also assist in developing a plan for conducting examinations, investigations, desk audits, interrogatories, letters or interviews when deemed necessary.

1. Determine the jurisdiction's requirements for licensing and examining the PBM and determine if the jurisdiction is permitted to accept the examination report of another state;
2. Survey appropriate divisions within the insurance department to identify potential areas of concern or interest relating to PBMs operating in the jurisdiction.
3. For those PBMs for which a recent and current examination report has been made public and no unaddressed regulatory concerns exist, no additional analysis should be necessary. If analysis indicates that a market regulation action—such as a desk audit, letter, interrogatory, interview, investigation or examination—is appropriate, consider the possibility of coordinating with other jurisdictions with similar requirements or market regulation issues. Consider use of NAIC tools such as the Market Action Tracking System (MATS) for recording continuum types of regulatory responses and communicating with members of the Pharmacy Benefit Manager Examination Oversight (D) Working Group for multistate coordination of regulatory responses.
4. Survey the NAIC Research Division for relevant information to identify potential areas of concern in the evaluation process; and
5. Determine what specialists may be necessary to assist with the examination, such as a licensed pharmacist (ideally one with experience with the functions of a PBM or pharmacy operations).
6. Due to the complexity of pharmacy claims data, a comprehensive data dictionary shall be developed for all requested datasets. The data dictionary must clearly define all data fields, formats, and required inputs and shall be reviewed and finalized to ensure mutual understanding and agreement among all parties before data collection begins. The regulator may develop the data dictionary or may work with the PBM to develop the dictionary. The final regulator-approved data dictionary shall be used by the PBM. Any questions, clarifications, or necessary revisions must be addressed and resolved before data extraction occurs in order to minimize discrepancies, ensure data integrity, and prevent delays during the examination process.

For very narrow or specific regulatory issues, or for situations in which an examination is not required by statute, consider use of regulatory options other than an examination. For example, certain issues can be handled by a telephone call, letter or email; a data request; policy and procedure review; interrogatories; or desk audits. The

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remainder of this chapter is primarily written to facilitate examinations; however, certain information may be adaptable for the above-mentioned "continuum" type responses. An additional discussion of continuum of market actions is in Chapter 2 of this handbook.

Procedural Considerations

Although not an insurance company examination, the basic procedures for a market conduct examination in Chapter 17 and 20 of this handbook should be followed in a PBM examination:

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;
- Notification of the examination;
- Preexamination procedures;
- On-site coordination, if applicable;
- Data calls;
- Sampling;
- Test procedures;
- Communication management;
- Post-examination procedures; and
- The examination report.

Where possible, each state's defined examination protocols applicable to the examination of insurers—such as time frames and report submissions—should be applied to PBM examinations, as well. Examiners may consider rolling production timelines and good faith extensions for complex or comprehensive data and document production requests.

When determining the scope of the examination, examiners should clearly outline which PBM contracts and lines of business are subject to the state's insurance regulatory oversight and included in the examination. Examiners should consult applicable state law, federal law, and legal rulings relevant to federal preemption as part of that determination. Examiners should also consult the NAIC's *ERISA Preemption and State PBM Laws* guidance document and the NAIC *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation.*

Additionally, examiners should determine how to handle information requests that may capture documents or materials outside the examination's scope or the state's jurisdiction. This may include permitting redactions of out-of-scope information, such as contract language or claims data for out-of-scope clients, as well as PHI, PII, or proprietary or confidential information unrelated to the examination's scope. Where responsive documents contain both in-scope and out-of-scope information, the PBM should be permitted to redact or otherwise segregate information that is not reasonably necessary to the examination, subject to an appropriate process for the examiner to raise questions regarding particular redactions.

These determinations are an essential component of the pre-examination process. Limiting the collection, retention, and sharing of PHI, PII, proprietary business information, and other confidential materials to information that is necessary, relevant, and material to the examination's scope reduces avoidable regulator cybersecurity and privacy risks, protects affected individuals and businesses, and reinforces confidence in the integrity of the examination process.

Once examiners have determined the applicable scope and redaction parameters and communicated those expectations to the PBM, the PBM should have an opportunity to raise concerns as part of the preliminary examination process and before the estimated commencement of the examination. The examiner and PBM should make reasonable efforts to resolve such issues before large-scale production of sensitive information begins.

Commented [A4]: We recommend adding a reference to Chapter 17, Sampling, which details variations in sample sizes to reach statistically valid conclusions, cautioning that regulators should carefully weigh the costs and benefits when making sampling decisions, such as whether gains in precision or higher confidence are merited by the cost of producing and investigating a larger sample of files.

Commented [A5]: We believe this approach will better result in response deadlines that appropriately reflect the scope and operational complexity of the request, increasing PBMs' responsiveness and improving overall efficiency.

Commented [A6]: Because market conduct examinations are intended to ensure compliance with a state's laws, establishing the scope at the onset is critical. Importantly, examiners should also address issues relating to redactions of out-of-scope information, PHI, PII, and proprietary or confidential information unrelated to the examination's scope. The language below provides guidance for examiners on this crucial step, which will improve the examination process for regulators and regulated entities and reduce the unnecessary disclosure of sensitive information that is not relevant to the examination.

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If the examiner determines that unredacted production of data or documents is necessary, the examiner should document the specific examination objective and explain why the unredacted information is relevant and material to determining compliance with the state law(s) being examined and why reasonable alternatives (e.g., sampling, summaries or walk throughs, targeted provisions, or redacted production) are insufficient.

To protect sensitive information while allowing examiner review, examiners should permit PBMs to make unredacted information available on-site or through a secure video conference, walk through proposed redactions, and then submit redacted materials with a redaction log.

The examiner must ensure the state's confidentiality laws provide that "*documents, materials or other information, including, but not limited to, all working papers, and copies thereof, created, produced or obtained by or disclosed to the commissioner, or in the possession or control of the National Association of Insurance Commissioners and its affiliates and subsidiaries, or any other person in the course of an examination, or in the course of analysis by the commissioner of the financial condition or market conduct of a company, shall be confidential by law and privileged, shall not be subject to [insert open records, freedom of information, sunshine or other appropriate phrase], shall not be subject to subpoena, and shall not be subject to discovery or admissible in evidence in any private civil action. The commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the commissioner's official duties*."

Before requesting production of highly sensitive or unredacted information, the examiner should confirm that these protections apply to the information throughout the examination process, including information maintained by or shared with contract examiners, consultants, vendors, or other third parties acting on behalf of the department.

If the state's confidentiality laws do not provide substantially the same protections for market conduct examinations, the examiner must coordinate with the PBM to access highly sensitive data relevant to the examination in a manner that appropriately safeguards the information. These confidentiality expectations apply not only to the department, but also to any contract examiners and vendors, and reasonable steps must be taken to prevent unauthorized access, reproduction, disclosure, or distribution of confidential information.

Commented [A7]: Requests should be reasonably tailored to avoid the unnecessary collection or disclosure of information outside the state's jurisdiction or the established scope of the examination. We offer language to instruct examiners to (1) review and confirm state and federal confidentiality protections before requesting highly sensitive information; and (2) when requesting unredacted information, identify (and document) why the unredacted information is necessary, material and relevant to the examination's scope and objectives and why less sensitive alternatives (e.g., sampling, summaries or walk throughs, targeted provisions, or redacted versions) are insufficient. For additional details, please refer to the Coalition's April 3, 2026 letter to the PBM (D) WG.

Writing the Examination Report
The report preparation elements as outlined in Chapter 19 of this handbook are generally applicable to PBM examinations. However, the following special considerations also apply:

- In addition to safeguarding the confidentiality of individual policyholder information, care should be taken to not disclose trade secret information of the examinees or insurers that are customers of the examinees (e.g., individual insurer information in class or territory detail, or the processes and procedures of the examinee). The PBM should be given the opportunity to mark exhibits and/or portions of the report as "confidential and proprietary," if such is allowed under state law and these are not subject to otherwise applicable public release laws outside the regulatory community; and
- The PBM should be given the opportunity to review the examination findings prior to issuing a final report, if such practice is consistent with the state's insurers' examination act or other applicable statute.

Use of Examination Standards
Each of the following examination standards may be applicable to specific functions performed by a PBM. The examination plan should indicate which standards for review will be used for each specific examination.

A. PBM Operations/Management
B. PBM Pricing and Methodologies
C. Contracts
D. Pharmacy Claims
E. Pharmaceutical Manufacturer Rebates

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F. Pharmacy Network Adequacy
G. Utilization Review
H. Drug Formulary, Placement and Specialty Drug
I. Complaints, Grievances, and Appeals
J. Pharmacy Audits

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A. PBM Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

The following standards would be the most applicable to a PBM examination.

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.
Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.
Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.
Standard 4 - The PBM has a valid disaster recovery plan.
Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.
Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.
Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.
Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.
Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.
Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.
Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.
Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.
Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

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B. PBM Pricing and Methodologies

STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 1
The PBM demonstrates it does not charge a covered entity, payor, or health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and health plan.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and pharmacy.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges.

_____ A schedule of claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to the covered entity, payor, or health plan for each prescription drug claim.

_____ Documentation of health plan billings during the exam period including a itemized breakdowns.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Commented [A8]: References were added to clarify that documents should be unredacted to the extent necessary to confirm compliance, which we believe more appropriately balances regulator access to relevant information needed to assess compliance with applicable law that protects the trade secrets, proprietary business information, and other nonpublic information of the regulated entity, its clients, customers, and patients.

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Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 2
The PBM demonstrates the difference in its payment rates received by a covered entity, payor, or health plan compared to the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ An index of all policies and procedures relating to the PBM's payment to pharmacies.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and health plan.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and pharmacies.

_____ Request ~~all claims data~~claim files for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to the covered entity, payor, or health plan for each prescription drug claim.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent with state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

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Commented [A9]: Throughout the standards we have removed references to "all" files or documents to align with other chapters in the Handbook and permit examiner discretion, consistent with core Market Regulation principles. Notably, this approach does not preclude an examiner from requesting more information when there is a clear risk for consumer harm.

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STANDARDS
PHARMACY BENEFIT MANANGERS
PBM PRICING METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent payment methodologies for reimbursement of all drugs that enable a pharmacy to understand the reimbursement amount for each claim prior to the pharmacy submitting the claim for reimbursement.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM to provide an index of all policies and procedures relating to pharmacy reimbursement.

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to the pharmacy reimbursement method being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM contracts with pharmacies in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's pricing methods that it sends to pharmacies.

_____ All documents provided to pharmacies that support or describe the PBM's reimbursement amounts to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.

____ ~~All c~~Contracts between the PBM and any third-party entities that may process prescriptions on behalf of the PBM or the PBM's clients, including but not limited to, any drug discount coupons or programs from manufacturers or drug discount entities.

_____ Contracts with the PBM and the insurer or employer group that include any references to the requirements for PBM's reimbursement to pharmacies and that describe the insurer's or employer group's oversight of the processes. Request the entire contract in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Request ~~all claims data~~claim files for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing

Commented [A10]: We recommend updating this list to correspond to the TN template as reflected in our October 2, 2025 and April 3, 2026 comment letters as it does not align to standard NCPDP data fields.

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source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.

- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed~~, for example, commercial vs. Medicare and self-funded vs. fully insured~~.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

Others Reviewed

Commented [A11]: This and related references have been removed to better reflect scope limitations, which are grounded in state and federal laws.

Review Procedures and Criteria

Review ~~all~~ in-scope contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, drug discount or manufacturer coupon contracts. Ensure ~~all~~ contractual language is transparent and sufficiently clear to enable the pharmacy to understand the payment rate prior to the pharmacy being paid.

- Assess how the PBM determines the drug pricing source it uses to reimburse each drug type including generic, brand and specialty drugs. Confirm the selection of the drug pricing source is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language.
- Assess the PBM's ability to change the drug pricing source selection, for example through application of the "lessor of logic" method. Confirm the "change" process is transparent and communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. If the PBM contract language gives the PBM authority to change this drug pricing source, assess how that change occurs, how often it occurs, how it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.
- Assess whether the PBM applies any "discounts" or other methods of reducing the amount of the selected drug pricing source. If the PBM does reduce the amount of the drug prior to paying the pharmacy, ensure that the "discount" reduction amount is transparent and communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.
- If the PBM does apply does apply "discounts" or otherwise reduce the amount of the drug pricing source, ensure the contract language describes the extent of the PBM's ability to change this "discount," how that change occurs, how often it occurs, how and when it is communicated to the pharmacy, and whether the change can be done with or without the pharmacy's consent.

Review contracts between the PBM and the insurer or employer group to determine whether the pricing methodologies described to pharmacies are consistent with the PBM's requirements described in the insurer's or employer group's contract with the PBM.

Review a sample of (or all) in-scope claims to ensure the PBM follows its own policies and procedures

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regarding reimbursement of pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, LTC, 340B, specialty or affiliate. Review "discount" amounts applied for claims to assess whether the PBM's description of the "discounts" to pharmacies is consistent with the actual reimbursement amounts. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment should be consistent across pharmacies within the same network.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 4
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies or all brand effective rate (BER) policies. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM template contracts and amendments and final executed contracts with pharmacies or PSAOs in an unredacted (to the extent necessary to confirm compliance with state law) format.

Commented [A12]: This and related changes more clearly align requests with relevant documents to ensure compliance. Additional details are noted in the Coalition's April 3, 2026 comment letter.

_____ All notices, amendments, updates, or other communications describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.

_____ All documents provided to pharmacies that support or describe the PBM's effective rate reconciliation process and calculation to specific pharmacies, including but not limited to retail, mail order, specialty, or affiliate pharmacies.

_____ All reports or accounting documents provided to pharmacies or PSAOs showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and claims data.

_____ Request ~~all claims data~~claim files for a specified pharmacy and time period in a standardized template showing how each claim was "reconciled" by the PBM. Claims detail may include but not be limited to:

Commented [A13]: We recommend updating this list to correspond to the TN template as reflected in our October 2, 2025 and April 3, 2026 comment letters as it does not align to standard NCPDP data fields.

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category;
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its initial payment to the pharmacy when

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the pharmacy submitted the claim.

- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid the pharmacy when it submitted the claim; the amount should not include the dispensing fee).
- The total initial reimbursement of any dispensing fee.
- The reconciled percentage of "discount" applied to each claim or batch of claims.
- The total final reimbursement amount for each drug claim or batch of claims after reconciliation. This should not include the dispensing fee amount.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each drug. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO.
- The type of health coverage being reimbursed. ~~For example, commercial vs. Medicare and self-funded vs. fully insured.~~
- The status of the claim. For example, paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.

The PBM should indicate whether its ~~C~~contracts with ~~the PBM and~~ the insurer or employer group ~~that~~ include any references to the requirements for PBM's effective rate reconciliation process with pharmacies and that describe the carrier or employer group's oversight of the processes. If affirmatively indicated, ~~so,~~ request a list of contracts containing these references; ~~.~~ ~~R~~requesting a sampling of these ~~entire~~ contracts or the applicable contract language in an unredacted (to the extent necessary to confirm compliance with state law) format.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review ~~all~~ standard contract templates and amendments ~~-~~between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, provider updates or manual amendments. Ensure ~~all~~ contractual language is transparent and sufficiently clear to enable the pharmacy to understand how the effective rate reconciliation process will be implemented prior to the PBM beginning the annual (or quarterly) reconciliation.

Request a listing of ~~all~~ in-scope network pharmacies or PSAOs that have an effective rate contract and ~~all~~ in-scope pharmacies or PSAOs that do not have one. Ensure the PBM is offering contracts to ~~all~~ similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer an effective rate contract to any specific pharmacies or pharmacy types, such as independent pharmacies. Understanding which pharmacies have an effective rate contract will assist the regulator in ensuring the PBM is compliant with state laws. For example, if a state requires NADAC payment for each drug, the regulator will not expect to see any effective rate contracts in that state.

Assess how the PBM determines which claims will be part of the reconciliation process, including categories of claims that are included and excluded in accordance with contract language. Confirm the selection of the claims is communicated to the pharmacies in clear and concise language.

Review ~~all~~ documents and communications sent from the PBM to the pharmacy as part of the reconciliation process. This should include but not be limited to ~~any~~ reconciliation reports, ~~any~~ claims data that is provided or can be requested by the pharmacy, ~~any emails or other~~ and formal correspondence between the PBM and the

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pharmacy. Ensure ~~all~~ communications from the PBM provide sufficient detail to enable the pharmacy to understand the process and that ~~all~~ questions are appropriately addressed.

- If PBM provides any reports or charts to the pharmacy, ensure the document explains all use of acronyms and claims categories through use of a key.
- Review ~~all~~ documents describing the final reconciliation amount that may be owed to or from pharmacies or PSAOs. Does the PBM provide reasonably sufficient detail to ensure that pharmacies understand how and when they will receive payment or make payments, if applicable.
- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that it enables pharmacies to provide information to the PBM that may change the outcome of the reconciliation amount? Consider requesting specific examples of correspondence to review.

Review a sample of (or all) in-scope claims to ensure the PBM follows its own policies and procedures regarding reconciliation process. Compare the original "discount" and price paid to the pharmacy to the reconciled "discount" and price to determine if the reconciled "discount" applied to each claim or batch of claims is within the contractually stated "discount" amounts. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.

Review contracts between the PBM and the carrier or employer group to determine whether the reconciliation process as described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Consider verifying the accuracy of all the data and reports sent from the PBM with the pharmacy or pharmacy group. For example, if the PBM provides an annual report of all reconciled claims, did the pharmacy receive the same version?

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STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 5
The PBM demonstrates it has transparent payment methodologies for the dispensing fees of all drugs that enable a pharmacy to determine the dispensing fee amount paid for each claim.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ An index of all policies and procedures relating to pharmacy dispensing fees.

_____ All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM contracts with pharmacies in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.

_____ All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to retail, mail order, specialty, or affiliate pharmacies.

_____ Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the insurer or employer group's oversight of the processes. Request the entire contract in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Request ~~all claims data~~claim files for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category.
- The drug pricing source used for reimbursement of each claim at the time of adjudication.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source drug copay copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final ingredient cost reimbursement amount of each claim for the drug.

Commented [A14]: We recommend updating this list to correspond to the TN template as reflected in our October 2, 2025 and April 3, 2026 comment letters as it does not align to standard NCPDP data fields.

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- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed~~, for example, commercial vs. Medicare and self-funded vs. fully insured~~.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when the PBM reimbursed the pharmacy, to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons, including applicable rejection codes. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

**This information may be pared down if the regulator is only looking at dispensing fees and not ~~all~~ claims data. However, pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review ~~all~~ contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost lists, drug discount or manufacturer coupon contracts. Ensure ~~all~~ contractual language is transparent and sufficiently clear to enable the pharmacy to understand the dispensing fee payment prior to the pharmacy being paid.

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language.

Assess the PBM's ability to change the dispensing fee amount. Confirm the 'change' process is transparent & communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

Review contracts between the PBM and the carrier or employer group to determine whether the payment of dispensing fees described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Review a sample of (or all) in-scope claims to ensure the PBM follows its own policies and procedures regarding dispensing fees paid to pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, LTC, 340B, specialty or, if the pharmacy is affiliated or not affiliated with the PBM. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment of dispensing fees should be consistent across pharmacies within the same network.

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C. Contracts

STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACIES)

Standard 1
The PBM demonstrates that it exercises good faith and fair dealing in its contracting and contract negotiation processes with pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ An index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

_____ From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ A listing of ~~all~~ pharmacies in the PBM's network. The listing should also require the PBM to provide ~~a listing of all~~ template contracts (including provider manuals) and contract amendments offered to ~~the PBM has in place with each~~ pharmac~~y~~ies. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document. Final executed contracts for a sample of pharmacies may also be requested.

_____ ~~All d~~An explanation or walkthrough of the contracting and credentialing process, including timelines, standard documents and types of communications that are used. If specific concerns are identified which indicate a potential violation of state law, request additional materials, such as ~~Documentation and correspondence, including but not limited to emails and red-lined documents, between pharmacies and the PBM that pertain to the contact and contact amendments. The documentation should provide~~ examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, independent, mail order, LTC, 340B, specialty, or affiliate. Review ~~all~~ exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location. Standards should be applied

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Commented [A15]: This and related changes that follow address the unintended consequences of the current proposal, which could unintentionally discourage and prevent efficient, information communications with pharmacies.

in a non-discriminatory manner such that the PBM does not favor affiliate over non-affiliate pharmacies, for example.

Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Examples include how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as who can submit the information and how i.e. via email, web portal or postal mail, any fees required. Ensure the PBM's contracting process is described to pharmacies in clear and concise language such that the pharmacies understand how to request changes to the contract terms.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for the PBM's review, how the PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review the documentation to assess whether the PBM is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with pharmacies.

Review the PBM's ~~communications to pharmacies~~contracting and credentialing process and standard documents to assess the PBM's responses to pharmacy negotiation requests. Ensure the PBM provides sufficient information to support or deny the pharmacy's requests. Ensure PBM contracting process is not unilateral or one-sided to prevent pharmacies from negotiating.

Review the PBM's communications to pharmacies to assess if the PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether the PBM appears to contract with certain pharmacy types and not others. For example, does the PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM to provide an explanation for such outcomes.

Assess how the PBM responds to pharmacy inquiries about the PBM's or the pharmacy's contractual obligations. For example, does the PBM have processes for pharmacies to initiate inquiries or obtain assistance from the PBM? Assess the PBM's responses to pharmacies during the inquiry process. Assess whether the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's response or final determination. Review specific examples of inquiries and follow-up from the PBM.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 2
The PBM demonstrates that it exercises good faith and fair dealing in implementing its contractual obligations with its vendors that work with its network pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ An index of all contracts with vendors that provide pharmacy benefits management services on behalf of the PBM and that interact with the pharmacy. The index should include a description of the services provided by each vendor and how the services impact pharmacies.

_____ From the index provided, review all policies and procedures that are applicable to the practices with the pharmacies being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Unredacted (to the extent necessary to confirm compliance with state law) PBM contracts from vendors that provide pharmacy benefit management services on behalf of the PBM.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, independent, mail order, LTC, 340B, specialty, or affiliate. Standards should be applied in a non-discriminatory manner such that the PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example.

Review policies and procedures for providing information to pharmacies about vendors with whom the PBM contracts to perform certain functions. Review ~~all~~ documentation to assess if the PBM provides reasonably sufficient information to pharmacies such that they would understand the exact function of the vendor and how the pharmacy is to interact with the vendor.

Review contracts between the PBM and its vendors to ensure the PBM does not permit its vendors to engage in activities that are prohibited under state law. For example, if state law prohibits a PBM from charging fees to a pharmacy, the PBM should not have a contract with a vendor that allows the vendor to charge the prohibited fees.

Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies

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that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its affiliate pharmacies over non-affiliated pharmacies.

Examiners may request an explanation or a walkthrough of the contracting process used by the PBM that would outline timelines, standard documents and types of communications that are used in the process and require PBMs to provide policies and procedures relating to contracting, template contracts and amendments offered, final executed contracts, and provider manuals.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 3
The PBM demonstrates that it has a reasonable and easily accessible dispute resolution process for pharmacies to address matters of conflict with the PBM.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ A data dictionary or list (and definitions) of all types of disputes that it considers "disputes." This may include but not be limited to complaints, independent third-party reviews, and arbitration.

_____ An index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.

_____ From the index provided, request all policies and procedures that are applicable to dispute resolution process being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ PBM documentation showing how disputes are addressed and finalized. The PBM should provide examples of actual disputes and provide ~~all~~ documentation sent to or received by a pharmacy showing how the dispute was initiated, the correspondence between the PBM and pharmacy, any documentation that is exchanged, and documentation showing how the dispute is resolved.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding the PBM's dispute resolution process with pharmacies. Review criteria for the different types of disputes to assess whether the PBM has clear protocols, timeframes, and documentation requirements for addressing and resolving each type of dispute.

Review contracts and manuals for details provided to pharmacies about the dispute resolution process. Review how the PBM informs pharmacies of how disputes may be initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail, any fees required), the PBM's obligation to provide a justification for the final determination and timeframes for PBM response and resolution of the dispute.

Review contracts and manuals with details about the dispute resolution process to ensure the information provided to pharmacies is clear, concise, and easily understood.

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Assess whether the PBM's requirements for pharmacies are convenient and accessible or whether the requirements create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute. Examples of requirements that may dissuade a pharmacy from initiating a dispute may include but are not limited to, requiring pharmacies to initiate disputes and send supporting documentation solely through postal mail or requiring exorbitant fee amounts to request or initiate a dispute resolution process.

Assess the PBM's responses to pharmacies during the dispute resolution process. Ensure the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's final determination.

Ensure the PBM's policies and procedures and implementation of those policies and procedures are consistent with state law.

Assess whether the PBM has staffing models to effectively resolve disputes.

Examiners may request an explanation or a walkthrough of the contracting and credentialing process used by the PBM that would outline timelines, standard documents and types of communications that are used in the process and require PBMs to provide policies and procedures relating to contracting, template contracts and amendments offered, final executed contracts, and provider manuals.

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D. Pharmacy Claims

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY CLAIMS

Standard 1
The PBM demonstrates that it has timely and transparent claims submission and adjudication processes for pharmacy claims that enable pharmacies to understand the payment rate prior to claims submission.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format

_____ An index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ An index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.

_____ Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Other than contracts and manuals, request ~~all~~ documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ ~~All~~ Internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ ~~All~~ Pharmacy contacts with carriers or employer groups in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Request ~~all claims data~~claim files for a specified time period ~~and~~ in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.

Commented [A16]: We recommend updating this list to correspond to the TN template as reflected in our October 2, 2025 and April 3, 2026 comment letters as it does not align to standard NCPDP data fields.

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- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed~~, for example, commercial vs. Medicare and self-funded vs. fully insured~~.
- The status of the claim for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

_____ Regulatory actions

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures related to the requirements for pharmacies to submit claims that may include but are not limited to the following:

- Claims processing software requirements.
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.
- Any applicable NCPDP standards.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:

- Dispensed as written codes
- Over-the-counter products
- Multi-ingredient compound processing
- Override
- Coordination of benefits
- Reversals
- Submission timeframes

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:

- The PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any "discount" the PBM may apply to reduce the reimbursement amount paid to the pharmacy
- The PBM should have clear criteria for claims approvals, denials or rejections at the point of sale.
- The PBM should have clear timeframes for claims adjudication either through payment or rejection of the claim.
- The PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is rejected, which may include providing reject codes that can be reviewed by the pharmacy.
- The PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or appeals for example, about any claims that are rejected or denied. *This would not include coverage appeals initiated by a consumer.*

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Review ~~all~~ PBM policies and procedures to assess whether the PBM applies different standards to different types of claims such as self-funded, specialty drug, mail order, nonresident or discount card claims. Verify that any differing standards are consistent with state law.

Review ~~all~~ pharmacy contracts, including any Provider Manuals, to ensure the claims submission and adjudication processes are clearly and concisely described to pharmacies. The PBM should provide pharmacies with detailed information about:

- Each step necessary to submit a claim.
- The process and timeframe for the PBM to review and make a determination about whether a claim will be paid.
- How a pharmacy may submit an inquiry, appeal, or otherwise contest the PBM's response to a pharmacy's claim. Information should include timeframes for each step in the process and should describe an easily accessible process for the pharmacy.
- Ensure information describes how pharmacies are reimbursed in accordance with applicable laws that may dictate payment amount and applicable dispensing fees.

Review ~~all~~ documentation to assess whether the PBM provides reasonably sufficient information about its claims payment methodology to ensure that pharmacies understand what they will be paid prior to submitting claims. This should include but not be limited to:

- If the PBM publishes a Maximum Allowable Cost (MAC) list, the list is readily available and useful to pharmacies. Does the listing provide a "search" function to find a specific drug or is the list formatted in a way that requires the pharmacy to scroll through thousands of drugs to find a specific drug? The latter would not be reasonable.
- If the PBM applies a "discount" or other type of reimbursement reduction to the drug pricing source it uses to pay pharmacies, is that discount reasonably described in documentation to pharmacies such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a "discount" and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, is that process clearly described to pharmacies? Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Can the pharmacy "opt-in" or "opt-out" of any such programs? Does the PBM provide reasonably sufficient information such that the pharmacy will know its reimbursement level prior to submitting the claim?

When requesting claims data, require the PBM to submit ~~*all*~~ in-scope claims being examined, including a specific description of the claims being requested, including distribution channels (chain, independent, mail-order, LTC, 340B, or specialty), as well as lines of business (e.g. fully insured, ~~Medicare,~~ Medicaid (if subject to state department of insurance regulation), self-insured—ERISA, self-insured non-ERISA, etc.) subject to the state's regulatory authority. In addition, consider including the scope of claims in the description (e.g. ~~all~~ pharmacies with physical locations in the state, member claims filled in the state, claims filled for members covered by health plans situsted in the state, or some other criteria). Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of a dispensing fee. Ensure the PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

Consider requesting the PBM provide a live demonstration of its claims adjudication process for a sample of each type of claim being examined which may include but not be limited to: claims that are approved, claims that are denied, claims that are rejected, claims that are mail order only, claims that are for self-funded employer groups, or claims that are for fully insured plans.

Review ~~all, or~~ a sample of PBM contracts with carriers/employer group to assess if the PBM is compliant with the claims payment requirements in those contracts and that those terms are consistent with ~~in all~~ messaging to pharmacies. For example, if pass-through pricing is required by the insurer contract, is that consistent with the

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payment method (and applicable description) to pharmacies?

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E. Pharmaceutical Manufacturer Rebates

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to aggregators, group purchasing organizations, or affiliated entities), administrative fees, credits, incentives and penalties are passed through to health plans, payors, patients, or covered entities as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ ~~All p~~Policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans, payors, or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request document in unredacted (to the extent necessary to confirm compliance with state law) format.

_____ A listing of ~~all~~ manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ A listing of ~~all~~ health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and ~~all~~ applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates, fees, and discounts received by the PBM and/or amounts remitted to health plans.

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_____ ~~All s~~Standard rebate reports provided to health plans during the examination period, including data dictionaries and field definitions.

_____ ~~All c~~Claims data and rebate data for a specified time period in a standardized template sufficient to link:

- Pharmacy information including, but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims.
- The drug pricing source used for reimbursement of each claim.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed~~, for example, commercial vs. Medicare and self-funded vs. fully insured~~.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The NDC and units are integral parts of the rebate transaction and must be included in the data dictionary.
- The rebate eligibility of the claim/drug.
- The rebate amount invoiced of the drug/claim.
- The rebate amount collected of the drug/claim.
- The rebate amount retained by the PBM.
- The rebate amount remitted to the health plan.
- The timing of each rebate transaction (claim versus rebate invoicing versus collection).

Commented [A17]: We recommend updating this list to correspond to the TN template as reflected in our October 2, 2025 and April 3, 2026 comment letters as it does not align to standard NCPDP data fields.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates exist governing the identification, invoicing, collection, accounting, allocation, and remittance of manufacturer rebates, fees, and discounts, and whether those standards comply with state requirements.

Review contracts between the PBM and health plans, carriers, or employer groups to determine:

- Whether rebates are required to be passed through in full, in part, or retained by the PBM;

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- If rebates are to be passed through in full or in part, are they allocated to the health plan, payor, and/or patient as authorized by law or contract;
- Whether administrative fees or other retained amounts are expressly permitted; and
- Whether spread pricing or other pricing methodologies are authorized under the contract.

Review contracts between the PBM and pharmaceutical manufacturers or rebate aggregators to determine the types of remuneration received, the methodology used to calculate rebate amounts, and the timing of rebate payments.

Assess whether the PBM's descriptions of rebate practices in its contracts with health plans are consistent with its contractual arrangements with pharmaceutical manufacturers and affiliated rebate entities.

Determine whether the PBM has established processes to ensure that all rebate-eligible claims are accurately identified and included in manufacturer rebate submissions. Evaluate whether the PBM maintains controls to prevent the omission or misclassification of rebate-eligible claims.

Review ~~all~~ rebate transactions and associated pharmacy claims to verify that:

- The units for each NDC is applied appropriately and rebates are invoiced timely and appropriately in accordance with contractual and statutory requirements;
- Rebate amounts invoiced to manufacturers are supported by underlying claims data;
- Rebate amounts collected from manufacturers are consistent with contractual terms; and
- Rebate amounts remitted to health plans are calculated and transmitted in accordance with contractual and statutory requirements.

Assess whether rebates are remitted to health plans within required contractual or statutory timeframes and whether any delays are supported by documented reconciliation or dispute processes.

Where spread pricing is permitted under the contract between the PBM and the health plan, review claims and rebate data to determine whether the PBM's retention of spread or rebate amounts is consistent with the express terms of the contract and is accurately disclosed in required reporting to the health plan.

Review claims payment, pharmacy reimbursement, and rebate data collectively to ensure that drug ingredient cost, dispensing fees, administrative fees, alternative payment programs, discounts, accumulators, maximizers, spread pricing (if applicable), and manufacturer rebates are applied and reported in a consistent and transparent manner across ~~all~~ PBM financial transactions associated with a claim.

Assess whether the PBM provides health plans with reasonably sufficient detail in its reporting to enable the health plan to independently verify rebate calculations, collections, and remittances. Reports should allow reconciliation from manufacturer payment to claim-level utilization.

Determine whether the PBM applies differing rebate allocation methodologies across lines of business (e.g., fully insured, self-funded, independent, chain, LTC, specialty pharmacy) and verify that any such differences are permitted under applicable contracts and law.

Evaluate whether 340B pharmacies are included in rebate allocation and determine if permitted under applicable contracts and law.

Evaluate whether any affiliated pharmacies, specialty pharmacies, or PBM-owned entities are treated differently in rebate attribution or allocation and verify that such practices are disclosed and permitted under contract.

Where point-of-sale rebate crediting is used, review system logic, claims adjudication rules, and financial settlement processes to verify that rebate amounts applied at the point of sale are accurately calculated and reflected in both member cost sharing and health plan financial reporting.

Determine whether the PBM maintains adequate internal controls, audit trails, and reconciliation processes to ensure

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completeness and accuracy of rebate invoicing, collection, and remittance.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly reported to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ ~~All p~~Policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request documents in unredacted (to the extent necessary to confirm compliance with state law) format.

_____ A listing of ~~all~~ manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ A listing of ~~all~~ health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____ Complete and unredacted (to the extent necessary to confirm compliance with state law) contracts between the PBM and ~~all~~ applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates, fees, and discounts received by the PBM and/or amounts remitted to health plans.

_____ ~~All s~~Standard rebate reports provided to health plans during the examination period, including data dictionaries and field definitions.

_____ ~~All c~~Claims data and rebate data for a specified time period in a standardized template sufficient to link:

- National Drug Code (NDC);
- Claim identifier;
- Dispensing date;

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- Rebate eligibility;
- Rebate amount invoiced;
- Rebate amount collected;
- Rebate amount retained by the PBM;
- Rebate amount remitted to the health plan; and
- Timing of each rebate transaction.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the preparation of statutorily required reports exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the preparation of statutorily required reports.

Determine if the statutorily required reports to the regulator were complete, accurate, and timely filed.

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F. Pharmacy Network Adequacy

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for ~~all~~ pharmacies in its network and is able to demonstrate its credential~~l~~ying criteria from the beginning of the process to the end.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Pharmacy contracts and manuals with the PBM's language relating to credentialing.

_____ An index of all internal policies and procedures for the credentialing process.

_____ ~~All p~~Policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for ~~all~~ pharmacies and pharmacy staff including but not limited to the pharmacist in charge (designated in different states as Supervising Pharmacist or Pharmacy Manager, etc), staff pharmacists, nationally certified and non-certified pharmacy technicians, and any customer service representatives/pharmacy clerks. Scope of practice and licensure are governed by the laws and regulations of each State Board of Pharmacy and should be reviewed as it pertains to that particular state. Review ~~all~~ exclusionary criteria such as requirements that pharmacists cannot be excluded or revoked by any licensing board.

Review any requirements for other personnel including but not limited to pharmacy owners, officers or directors. Review all exclusionary criteria that may apply.

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Review ~~all~~ requirements for pharmacies including but not limited to application documents, insurance requirements such as professional liability coverage, any required minimum stock of drugs, and technological capabilities such as claims submission platforms.

Review policies and procedures for providing information to pharmacies about the credentialing process, including how the PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as via email, web portal or postal mail, and any credentialing fees required.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for the PBM's review, how the PBM provides feedback to a pharmacy, how a pharmacy may correct deficiencies or provide additional information.

Review contracts and manuals for details provided to pharmacies about the credentialing process. The PBM should provide clear and concise information that is consistent with its own policies and procedures and should follow any applicable state or federal law for credentialing and recredentialing. Information provided to pharmacies should address all the requirements and steps for credentialing and should provide pharmacies with adequate time to provide ~~all~~ documentation and provide pharmacies with the ability to address any questions about the process.

Request a listing of all pharmacies and staff that went through the credentialing process during the examination period. Request the results of each process (i.e. was the pharmacy "approved" to be in the PBM's network or not). Request the reasoning for all approval or denials. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

Request an explanation or a walkthrough of the credentialing process used by the PBM that would outline timelines, standard documents and types of communications that are used in the process and require PBMs to provide policies and procedures relating to contracting, template contracts and amendments offered, final executed contracts, and provider manuals.~~Request all correspondence between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sample of those that went through the credentialing process. "Correspondence" may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM, any emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy~~. Require documents to be provided in an unredacted (to the extent necessary to confirm compliance with state law) format. Ensure ~~all~~ correspondence from the PBM is clear and concise and provides reasonably sufficient information to pharmacies regarding the credentialing process and any decisions made by the PBM.

In any Summary of the PBM Network Adequacy that proceeds these standards, consider describing the difference between the *PBM's network* and *pharmacy networks*. The PBM's network encompasses all pharmacies with which it contracts in the state. The PBM may have multiple pharmacy networks that may be designed based on types of drugs dispensed, how drugs are dispensed (i.e. mail order or chain/independent), or geographic location and will likely have differing reimbursement levels.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any), insurer or employer contracts, or other reasonable criteria, that it creates and maintains a network of pharmacies in a transparent manner.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts and manuals. This should include ~~all~~ network contracts and forms. Request documents be provided in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ An index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, Examiners should request ~~all~~ relevant policies and procedures for areas being examined. Request documents be provided in an unredacted (to the extent necessary to confirm compliance with state law) format, including ~~requiring all~~ pricing information ~~be unredacted~~.

_____ PBM and insurer or employer plan contracts. Request the entire contract, including any amendments, in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ A listing of all the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, specialty, LTC, or 340B pharmacy), the types of business it serves (commercial, Medicaid (if subject to state department of insurance regulation) ~~or Medicare~~), the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, whether the pharmacy is an affiliate pharmacy or not, whether the pharmacies' network participation changed at any time during the examination period and the reason for such change (i.e. PBM changed terms, pharmacy opted out, carrier requested change). Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ A state map or geo-maps identifying the location of each pharmacy.

_____ A description of the differences in each unique pharmacy network. For each pharmacy network, the PBM should identify the types of drugs dispensed, consumer access (such as mail order or chain/independent), the reimbursement levels including any "discounts" applied and dispensing fees provided, any criteria for participation and any participation limits or restrictions. Standards should be applied in a non-discriminatory manner such that the PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ A list of ~~all~~ insurers and employer groups and each plan for the entity for which the PBM administers prescription drug benefits. Require the PBM to identify every network associated with each plan. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

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_____ If required by state law, the PBM files with the department of insurance all required contract forms and any material changes to a contract proposed for use with its participating providers and intermediaries.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal policies and procedures regarding PBM requirements for ensuring the PBM has appropriate number of pharmacies in applicable geographic areas to ensure network pharmacies provide appropriate access to consumers. Ensure the PBM is compliant with state law and any requirements within its contracts with insurers and employer groups.

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure the PBM has clear and concise requirements. The PBM internal requirements should include but not be limited to:

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy deserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its carrier/employer group clients.
- Requirements for pharmacy network reimbursement levels. Ensure these are applied consistently among ~~all~~ pharmacies in each network.
- Conditions under which a pharmacy may be terminated, including requirements on how the pharmacy is notified of the termination and payment for all unpaid claims at the time of the termination.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear, concise, and easily understandable. Areas to review include but are not limited to:

- Do contracts/manuals clearly describe the requirements for participation in each pharmacy network?
- How does the PBM change the terms of the pharmacy network requirements? Any changes should be made in a transparent manner and with timely notice to the pharmacies.
- Do the contracts/manuals clearly describe the reimbursement including dispensing fees for each network?

Review the pharmacy listing to assess how often the PBM made changes to the pharmacy network requirements and participation levels during the examination period. Ensure the specific reasons for such changes are reasonable. Request ~~all~~ correspondence with pharmacies impacted by any changes. Request ~~all~~ correspondence with insurers and employer groups about the network changes. Ensure the message conveyed to insurers and employer groups is consistent with the message provided to pharmacies.

Review the listing of pharmacies and description of pharmacy network differences to ensure compliance with state and federal requirements. Depending on the state's legal requirements, areas to consider include by are not limited to:

- Does the PBM have networks that are comprised solely of affiliate pharmacies?
- Does the PBM have networks that are comprised solely of mail order pharmacies?
- Are the reimbursement rates among the differing networks reasonable or do the rates show differing levels for affiliate only networks when compared to networks without affiliates?

In any Summary of the PBM Network Adequacy that proceeds these standards, consider reviewing the PBM's

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contracts and manuals with pharmacies as part of how to ask for specific information about “contracting.”

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 3
The PBM demonstrates compliance with state law (if any) or other reasonable criteria, that it maintains a network of pharmacies that is sufficient in number and types of pharmacies to ensure that all services to covered persons will be accessible without unreasonable delay.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Policies and procedures for providing information to covered persons about pharmacy directories.

_____ Policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.

_____ Documentation regarding how the PBM makes its provider directory (that lists all providers who participate in its network) available to covered persons and how it makes available, on a timely and reasonable basis, updates to its directory.

_____ ~~All d~~Documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how covered persons may contact the PBM with inquiries.

_____ A listing of ~~all~~ the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, LTC, or 340B pharmacy), the types of business it serves (commercial, Medicaid (if subject to state department of insurance regulation) ~~or Medicare~~), the types of drugs it dispenses (generic, brand name, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ A state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Ensure the PBM has established and will maintain adequate arrangements to ensure reasonable proximity of participating pharmacies to the business or personal residence of covered persons. In determining whether a PBM has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

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Review policies and procedures for providing information to covered persons about in-network pharmacies and emergency services.

Review ~~all~~ information provided to covered persons to ensure the information is provided in a clear and concise manner and updated regularly. PBMs should have clear information that describes how consumers may contact the PBM with any inquiries about pharmacy options.

Review ~~all~~ consumer complaints submitted to the PBM and the regulator to assess whether consumers have issues with pharmacy access.

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G. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that insurers or payors and their designees, including PBMs, that provide or perform utilization review services comply with standards and criteria for the structure and operation of utilization review processes.

The areas to be considered in this kind of review include the insurer's or payor's utilization review policies and procedures, annual summary reports, timeliness in making utilization review decisions and handling appeals, communications with members about the program and oversight of delegated utilization review functions.

DUR is conducted in three primary forms: prospective, concurrent, and retrospective. Prospective DUR occurs prior to dispensing and is designed to identify potential issues such as drug–drug interactions, therapeutic duplication, or inappropriate dosing before the medication is provided to the patient. Concurrent DUR takes place during the course of treatment and is used to monitor ongoing therapy, such as reviewing refill patterns or emerging safety concerns while a patient is actively receiving a medication. Retrospective DUR is performed after dispensing and involves analyzing historical claims data to identify patterns of inappropriate prescribing, potential overutilization, or opportunities for provider or patient education.

2. Techniques

The analysis of utilization review activities should include an overview of the PBM's written utilization review policies, procedures and scripts, in addition to an overview of how utilization review activities are applied to individual cases. Utilization review issues may also surface during the examiners' inspection of claims, complaints and grievance procedures.

a. Examiners should request a written overview of the PBM's utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. The overview should also include if the PBM utilizes artificial intelligence (AI) in its utilization review, and if so, the extent of what is being reviewed by AI and what criteria determines that it moves from AI to PBM staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the PBM maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.

b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.

c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.

d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.

e. Obtain listings of utilization review determinations, including approvals or certifications, denials, and requests for

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reconsideration. Using appropriate sampling methodology, select a representative sample of cases for detailed review. For each sampled case, obtain the clinical criteria and review guidelines applied in the determination and evaluate whether the PBM's actions were consistent with its written policies, clinical standards, and established review procedures. Ensure that the examiner assigned to this review possesses sufficient clinical expertise to interpret the applicable criteria, understand the clinical context of the request, and assess whether determinations were made in accordance with the PBM's documented guidelines and utilization review protocols.

f. Obtain annual reporting by the PBM of its utilization review. Minimum standards should include:
- Number of requests by type (prior authorization, maximum unit, appeal, etc.).
- Number approved of each type.
- Number denied of each type.
- Number appealed of each type.
- Number approved after appeal of each type.
- Timeframe of each response of each type.
- Whether or not each of the above was derived from AI, clinical staff, or non-clinical staff.

3. Tests and Standards

The utilization review assessment includes, but is not limited to, the following standards related to the performance of utilization review activities by the PBM.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 1
The PBM operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations, including those related to mandated benefits and services.

_____Utilization review policies and procedures.

_____Utilization review program or plan documentation.

_____Medical criteria used to make utilization review determinations.

_____Job description of the staff position functionally responsible for day-to-day management.

_____Minutes of the PBM's board of directors.

_____Minutes of the PBM's utilization review committee.

_____Documentation of clinical staff credentialing maintenance and education requirements.

_____Program assessment reports.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a PBM that requires a request for benefits under the covered person's health benefit plan to be subjected to utilization review, implements a written utilization review program that describes all review activities, both delegated and nondelegated for:

- The filing of benefit requests;

- The notification of utilization review and benefit determinations; and

- The review of adverse determinations in accordance with applicable state statutes,
- Verify that the PBM's written utilization review program document describes all the following:

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- Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of pharmacy services;
- Data sources and clinical review criteria used in decision-making;
- Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
- Data collection processes and analytical methods used in assessing utilization of pharmacy services;
- Provisions for ensuring confidentiality of clinical and proprietary information;
- If AI is used and in what capacity;
- The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the insurer's or payor's governing body; and
- The staff position functionally responsible for day-to-day program management.

- Verify that the PBM ensures that appropriate personnel have operational responsibility for conducting the insurer's or payor's utilization review program.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 2
The PBM operates its utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed).

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM utilization review program uses documented clinical review criteria that are based generally accepted, independently-developed clinical standards published by the federal government or professional organizations and evaluated periodically to assure ongoing efficacy.

Note: The PBM may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the PBM makes its clinical review criteria available upon request to authorized government agencies.

Verify that the PBM ensures that qualified pharmaceutical professionals administer the utilization review program and oversee review decisions. Verify that the PBM has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the PBM issues utilization review decisions and benefit determinations in a timely and efficient manner pursuant to the requirements set forth in applicable state statutes, rules and regulations.

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Verify that the PBM has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the PBM conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the PBM's data systems are sufficient to support utilization review program activities and to generate management reports to enable the PBM to monitor and manage pharmacy services effectively.

If a PBM delegates any utilization review activities to a utilization review organization, verify that the PBM maintains adequate oversight, to include all the following:

- A written description of the utilization review organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the utilization review organization program by the PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the utilization review organization.

If a PBM delegates any utilization review activities to AI, a AI program, or a AI vendor, verify that the PBM maintains adequate oversight, to include all the following:

- A written description of the AI/AI organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the AI program by the PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the AI functionality.

Verify that the PBM coordinates its utilization review program activities with other medical management activity conducted by the insurer or payor, such as quality assurance, credentialing, provider contracting, data reporting, grievance procedures, claims adjudication, processes for assessing member satisfaction and risk management.

Verify that the PBM provides covered persons, or, if applicable, the covered person's authorized representatives and participating providers with access to its utilization review staff via a toll-free number or collect call telephone line.

Verify that the PBM, when conducting utilization review, collects only the information necessary, including pertinent clinical information, to make the utilization review or benefit determination.

Verify that PBM staff conducting each type of utilization review are qualified to make clinical determinations, i.e. non-clinical staff should not be making determinations on drug coverage based on detailed clinical criteria from information based on patient-specific laboratory or clinical findings when compared to national guidelines or predetermined criteria.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 3
The PBM discloses information about its utilization review and benefit determination procedures to covered persons, or, if applicable, the covered persons' authorized representative, in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Member materials.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM provides a clear and accurate summary of its utilization review and benefit determination procedures to the covered person's authorized representative.

Determine whether the PBM makes its utilization review criteria publicly available, including whether such criteria are posted on a website or otherwise maintained in a manner that allows covered persons and providers to easily access and obtain them upon request.

Verify that the PBM provides a clear and comprehensive description of its utilization review procedures, including the procedures for obtaining adverse review determinations, and a statement of rights and responsibilities of covered persons.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 4
The PBM makes standard utilization review and benefit determinations in a timely manner and as required by applicable state statutes, rules and regulations, as well as the provisions of HIPAA.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed).

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the PBM by the covered person, or, if applicable, the covered person's authorized representative, for benefits and for notifying the covered person, and, if applicable, the covered person's authorized representative, of its determinations with respect to these requests within the specified time frames required pursuant to applicable state statutes, rules and regulations.

State and federal law may contain specific criteria outlining mandates related to communication from the PBM to the patient or prescriber, such as time limitations of response, manner of communication (written notice, portal, etc.), and may contain different criteria related to different types of insurers/payors. The evaluation should take all state and federal guidelines for any/all types of insurers/payors.

For prospective review determinations, verify that the PBM makes the determination and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether the PBM certifies the provision of the benefit or not, within a reasonable period of time appropriate to the covered person's medical condition, but in no event later than the time as required by state or federal law after the date the PBM receives the request.

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Whenever the determination is an adverse determination, verify that the PBM makes the notification of the adverse determination in accordance with state or federal statutes, rules and regulations regarding procedures for standard utilization review and benefit determination.

Verify that if the PBM extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to the time required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the PBM has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the PBM expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the PBM issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Whenever the PBM receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the insurer's or payor's filing procedures, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of this failure and provides in the notice information on the proper procedures to be followed for filing a request.

Verify that the notice referenced in the previous paragraph is provided by the PBM as soon as possible, but in no event later than the time required by state or federal law following the date of the failure.

Verify that the PBM provides the notice orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to meet the insurer's filing procedures apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the PBM responsible for handling benefit matters; and

- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific pharmaceutical service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a PBM has certified an ongoing course of treatment to be provided over a period of time or number of treatments, examiners need to be aware that:

- Any reduction or termination by the PBM during the course of treatment before the end of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and

- The PBM shall notify the covered person, or, if applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state or federal statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the covered person's authorized representative, to file a grievance to:

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- Request a review of the adverse determination pursuant to state or federal statutes, rules and regulations; and
- Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

Verify that the pharmaceutical service or treatment that is the subject of the adverse determination is continued by the PBM without liability to the covered person with respect to the internal review request made pursuant to state statutes, rules and regulations.

For retrospective review determinations, verify that the PBM makes the determination within a reasonable period of time, but in no event later than the time as required by state or federal law after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the PBM provides notice of the adverse determination to the covered person, or, if applicable, the covered person's authorized representative, in accordance with applicable state statutes regarding procedures for standard utilization review and benefit PBM determination.

Verify that if the insurer extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to the time as required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the insurer has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the insurer expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the PBM issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Verify that the PBM calculates the time periods, within which a prospective or retrospective determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is received by the PBM in accordance with the insurer's procedures established pursuant to applicable state or federal statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to make the determination, verify that the PBM calculates the time period for making the determination to begin on the date on which the PBM sends the notification of the extension to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:

- The date on which the covered person, or, if applicable, the covered person's authorized representative, responds to the request for additional information; or
- The date on which the specified information was to have been submitted.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 5
The PBM provides written notice of an adverse determination of standard utilization review and benefit determinations in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM issues notification of an adverse determination, in a manner calculated to be understood by the covered person, to include all the following:

- The specific reason or reasons for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to perfect the benefit request, including an explanation of why the material or information is necessary to perfect the request;
- A description of the PBM's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;
- If the PBM relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative, upon request;
- The PBM's policy on level of professional clinical license that is appropriate to conduct the adverse determination and if any secondary clinical staff was consulted prior to making an adverse determination;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination;
- The written statement of the scientific or clinical rationale for the adverse determination; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered

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person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the PBM's grievance procedure process as provided under state statutes, rules and regulation, to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the PBM provides the notice in writing or electronically, when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 6
The PBM conducts expedited utilization review and benefit determinations in a timely manner and in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM has established written procedures pursuant to applicable state statutes, rules and regulations for receiving benefit requests from covered persons, or, if applicable, their authorized representatives, and for making and notifying the covered person, or, if applicable, the covered person's authorized representative, of expedited utilization review and benefit determinations with respect to urgent care requests.

Verify that the PBM, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the PBM's procedures for filing an urgent care request, notifies the covered person, or, if applicable, the covered person's authorized representative, of the failure and the proper procedures to be followed for filing the request.

Verify that the PBM's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the PBM's procedures for filing an urgent care request:

- Is provided to the covered person, or, if applicable, the covered person's authorized representative, as appropriate, as soon as possible, but not later than the time as required by state law after receipt of the request; and
- May be oral, unless the covered person, or, if applicable, the covered person's authorized representative, requests the notice in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the PBM's procedures for filing an urgent care request apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that

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is received by a person or organizational unit of the PBM responsible for handling benefit matters; and
- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific pharmaceutical service, treatment or provider for which approval is being requested.

For an urgent care request, unless the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the PBM to determine whether, or to what extent, the benefits requested are covered benefits or payable under the insurer's or payor's health benefit plan, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of the PBM's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, but in no event later than the time as required by state or federal law after the receipt of the request by the PBM.

If the PBM's determination is an adverse determination, verify that the PBM provides notice of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the health carrier to make a determination, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, either orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing of this failure and states what specific information is needed as soon as possible, but in no event later than the time as required by state law after receipt of the request.

Verify that the PBM provides the covered person, or, if applicable, the covered person's authorized representative, a reasonable period of time to submit the necessary information, taking into account the circumstances, but in no event less than the time as required by state or federal law after notifying the covered person, or, if applicable, the covered person's authorized representative, of the failure to submit sufficient information, pursuant to applicable state statutes, rules and regulations.

Verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible, but in no event more than 48 hours after the earlier of:

- The PBM's receipt of the requested specified information; or
- The end of the period provided for the covered person, or, if applicable, the covered person's authorized representative, to submit the requested specified information.

If the PBM's determination is an adverse determination, verify that the PBM provides notice of the adverse determination accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

For concurrent review urgent care requests involving a request by the covered person, or, if applicable, the covered person's authorized representative, to extend the course of treatment beyond the initial period of time or the number of treatments, if the request is made at least by the time as required by state law prior to the expiration of the prescribed period of time or number of treatments, verify that the PBM makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the covered person's medical condition, but in no event more than the time as required by state or federal law after the PBM's receipt of the request.

If the PBM's determination is an adverse determination, the PBM shall provide notice of the adverse determination or coordinate with the carrier in accordance with applicable state or federal statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

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Verify that the PBM calculates the time period within which a determination is required to be made pursuant to applicable state or federal statutes, rules and regulations, to begin on the date the request is filed with the either the insurer or PBM in accordance with the insurer's procedures established pursuant to applicable state or federal statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

Verify that the PBM's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative, to include all the following:

- The specific reason(s) for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to complete the request, including an explanation of why the material or information is necessary to complete the request;
- A description of the insurer's internal review procedures established pursuant to applicable state or federal statutes, rules and regulations including any time limits applicable to those procedures;
- A description of the PBM expedited review procedures established pursuant to applicable state statutes, rules and regulations;
- If the PBM relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative upon request;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- If applicable, instructions for requesting:
  - A copy of the rule, guideline, protocol, or other similar criterion relied upon in making the adverse determination, as set forth in applicable state statutes, rules and regulations; or
  - The written statement of the scientific or clinical rationale for the adverse determination, as set forth in applicable state or federal statutes, rules and regulations; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the health carrier's grievance procedure process as provided under applicable state or federal statutes, rules and regulations to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the PBM provides the notice orally, in writing or electronically.

If the PBM provides the notice of adverse determination orally, verify that the PBM also provides written or electronic notice of the adverse determination within the time as required by state or federal law following the oral notification when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 7
The PBM monitors the activities of the utilization review organization or entity with which the PBM contracts and ensures that the contracting organization complies with applicable state and federal provisions and accompanying regulations.

Apply to: PBMs contracting out utilization review services.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Contracts with organizations or entities.

_____Reports of entity reviews and audits (if any).

_____Periodic reports from the organization or entity.

_____Minutes of the PBM's board of directors

_____Minutes of the PBM's utilization review committee

_____Policies and procedures for oversight

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a PBM contracts to have a utilization review organization or other entity perform the utilization review functions required by the *Utilization Review and Benefit Determination Model Act (#73)* or applicable state statutes, rules and regulations, the PBM is responsible for monitoring the activities of the utilization review organization or entity with which the PBM contracts and for ensuring that the requirements of the *Utilization Review and Benefit Determination Model Act (#73)* and applicable state statutes, rules and regulations are met.

Verify that the PBM has policies and procedures in place that ensure the utilization review programs of designees comply with all applicable state and federal laws establishing confidentiality and reporting requirements.

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H. Drug Formulary, Placement, and Specialty Drug

The Drug Formulary, Placement and Specialty Drug review includes, but is not limited to, the following standards related to how the Formulary is managed and controlled by the PBM.

STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 1
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period.

_____~~All (~~P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formulary and drug placement-related systems utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the PBM formularies utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the PBM P&T Committee or other committee(s) decisions and statements are in compliance with all applicable state and federal statutes, rules and regulations.

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 2
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

_____ ~~All p~~Policies, procedures, and other documentation relevant to drug utilization management, including but not limited to, ~~all~~ fail-first policies including step-therapy protocols, prior authorization requirements, and medical necessity guidelines.

_____~~Any and all l~~List(s) of medications included in and excluded from the mail order benefit.

_____~~Any and all l~~List(s) of medications allowed for a 90-day supply, and those only allowed for 30-day supply or less, for both mail order and retail pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to comply with all applicable state and federal statutes, rules and regulations.

Verify that all the PBM's formularies utilized during the examination period do not restrict access to drugs to select pharmacies in violation of any required and applicable state and federal statutes, rules or regulations.

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 3
The PBM defines and appropriately places any specialty drug on the formulary when a state has a specialty drug definition to comport with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

_____Specialty drug list(s)

_____~~All~~ P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the PBM's formulary and drug placement-related systems utilized during the examination period use the applicable definition in accordance with all applicable state and federal statutes, rules and regulations.

Verify that the PBM formularies utilized during the examination period have any drug that meets the definition of specialty placed appropriately and further that any drug that does not meet the definition tiered appropriately in accordance with all applicable state statutes, rules and regulations.

Verify that the PBM P&T Committee or other Committees decisions and statements use and apply the correct definition of specialty drug in compliance with all applicable state statutes, rules and regulations.

I. **Complaints, Grievances, and Appeals**

1. Purpose

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The purpose of complaints, grievances and appeals handling procedures is to provide a process for consumers or providers to address issues, and to evaluate how well a regulated entity complies with laws, resolves issues, and timely responds to dissatisfaction expressed by consumers or providers. This includes:

- Ensuring compliance with applicable statutes and/or regulations[1], including:
  - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
  - Establishing whether violations were committed; and
  - Monitoring future conduct for compliance;

- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers, providers, or pharmacies; and

- Identifying problem areas that may indicate broader operational issues.

All sections emphasize the importance of reviewing how concerns, whether classified as complaints, grievances, or appeals, are processed, documented, and used to improve consumer service.

2. Techniques

The examination approach for complaints, grievances, and appeals procedures include the following shared techniques:

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances, or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems.
- **Documentation Review:** Assessing written policies, procedures, contracts, provider manuals, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, providers, and pharmacies are informed of the procedures and their rights.

All procedures call for reviewing the frequency and nature of the issues raised and whether they were resolved in accordance with the applicable standards.

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, resolution).
- **Procedural Adequacy:** Verifying that the regulated entity has adequate written procedures for handling and resolving the issue, and that these are disclosed to consumers, providers, and pharmacies.
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law.
- **Compliance and Fairness:** Determine that responses:
  - Fully address the issue(s) that was raised.
  - Include adequate supporting documentation.
  - Are compliant with policy statutes and regulations.
  - Provide appropriate remedies when necessary.

Complaints, Grievances, and Appeals stress maintaining records that are accessible to regulators and retaining them

[1] The term statutes and/or regulations refers to all legally binding statutes, rules, regulations, policies or other documents promulgated by an entity with said power.

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for appropriate time periods.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The PBM maintains a detailed, accessible register documenting each complaint, grievance, or appeal, in accordance with the applicable records retention schedule.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Regulated entity register.

_____Insurance department records.

_____Direct consumer or pharmacy complaint, grievance, or appeal.

_____Member evidence of coverage.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify accurate logging of the issue, date received, review actions, and resolution.

Verify that the register includes enough detail to support regulatory review.

Verify that the PBM retains the register for at least 3 years, or in accordance with applicable state or federal law, whichever is longer.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The PBM has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers, contracted providers, and contracted pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.

_____Member evidence of coverage.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the company maintains a complaint register.

Verify that the PBM included the complaint log and procedures that include the audit, credentialing, and network enrollment departments.

Verify that the PBM's procedures comply with applicable statutes and regulations.

Verify that the PBM's procedures are communicated to consumers and contracted providers

Verify that the PBM has filed procedures with the insurance commissioner where required.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 3
The PBM must resolve and respond to complaints, grievances, and appeals within prescribed timeframes.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____PBM register.

_____Test Sample.

_____Complaint, grievance, or appeal letter or email and PBM response.

_____Supporting documentation (claim files, extension requests, etc).

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review test sample to ensure the PBM is maintaining adequate documentation.

Determine if the PBM's response is timely in accordance with state and/or federal law. *Note:* Timing is measured from the date the issue is received.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The PBM actions taken in response to complaints, grievances, or appeals must comply with insurance laws, contracts, and regulations as well as address all identified concerns.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Contracts, including provider manuals.

_____PBM register.

_____Test Sample.

_____Complaint, grievance, or appeal letter or email and PBM response.

_____Supporting documentation (claim files, extension requests, etc).

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review documentation to determine if the PBM response fully addresses the issues raised. If the PBM did not properly address/resolve the complaint, the Examiner should ask the PBM what corrective action it intends to take.

For reviewing responses:
- Was the response timely.
- Was the response complete and responds to all issues raised.
- Does the response include adequate documentation to support the respondent's position.
- Were the respondent's actions appropriate from a business standpoint.
- Were the respondent's actions compliant with applicable statutes and regulations.
- Were the appropriate remedies for the consumer identified.

Document potential violations.

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J. Pharmacy Audits

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY AUDITS

Standard 1
The PBM demonstrates that it has reasonable and uniform criteria and procedures for pharmacy audits and demonstrates that it follows those standards.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted (to the extent necessary to confirm compliance with state law) format.

_____ Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.

_____ A listing of all types of audits that may include but not be limited to on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)

_____ From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted (to the extent necessary to confirm compliance with state law) format.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted (to the extent necessary to confirm compliance with state law) format.)

_____ A listing of parties who perform pharmacy audits on behalf of the PBM, including third-party vendors and credentials of auditor staff.

_____ A listing of all audits initiated or that were ongoing during the examination period. (As part of this request, the timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification and supporting documentation of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ Request an explanation or a walkthrough of the audit process used by the PBM that would outline timelines, standard documents and types of communications that are used in the process and require PBMs to provide policies and procedures relating to the audit process. ~~All correspondence between the PBM and a pharmacy as part of audits during the examination period. (Consider whether to request~~

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~~information from all audits or just a sampling of the audits.)~~ ~~'Correspondence' may include but not be limited to all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM, any emails, notes from phone conversations, and any other communications about the audit that occurred between the PBM and the pharmacy.~~ Require documents to be provided in an unredacted (to the extent necessary to confirm compliance with state law) format.)

_____ Summary of any use of artificial intelligence (AI) that it may use as part of auditing a pharmacy.

_____Policies and procedures associated with the use of AI.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review applicable state and federal law to ensure PBM policies and audits are compliant.

Review internal PBM policies and procedures regarding the PBM's audit process with pharmacies. Review criteria for the different types of audits to assess whether the PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit, including but not limited to processes for initiating, conducting, and resolving each type of audit.

Review contracts and manuals with details about the audit process to ensure the information provided to pharmacies is clear, concise, and easily understood. While the details of the audit process are important, the information must be provided in a clear and concise manner that will be understood by pharmacies.

Review contracts and manuals for details provided to pharmacies about the audit process. Review how the PBM informs pharmacies of how audits are initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail), any fees required by the PBM that are outside the audit finding, how the pharmacy may address and rectify potential findings, the PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

Assess whether the PBM's requirements for pharmacies are reasonable and provide pharmacies with the following:

- The scope, frequency (including the maximum annual amount) and method of all audits.
- Detailed guidelines, including metrics and data, used during audits.
- Advanced notice of an upcoming audit, and the day of the month the audit began.
- Sufficient time to prepare and collect required information.
- Convenient and accessible methods for corresponding with the PBM during the audit, for example does the pharmacy have a point of contact to ask questions and obtain clarification on the PBM's expectations.
- Sufficient time to review and correct any audit findings prior to the PBM's final determination.
- Sufficient input into the implementation of a corrective action plan (if applicable) and sufficient time to comply with the requirements of a corrective action plan.
- An appropriate dispute resolution process that pharmacies may use to dispute audit findings. The process for pharmacies should be convenient and accessible and should not create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute resolution process.

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If the regulator feels the PBM's policies and procedures are reasonable, ensure the PBM also follows and implements its own policies and procedures. Review timeframe requirements, whether the PBM provides reasonable and concise information to pharmacies in response to any questions, and whether the PBM provides appropriate justifications in the draft and final audit reports.

Review the results of ~~all~~ in-scope audits to determine if audits are conducted in a manner that appears reasonable for each of the individual pharmacies being audited and that there are no concerning trends with how the PBM conducts audits. For example, when conducting routine audits, are pharmacies selected randomly or does the PBM only audit non-affiliated, independent pharmacies? *The latter trend would be problematic.*

Verify that the PBM conducts pharmacy audits in compliance with applicable state laws and regulations. Ensure such methods are reasonable, utilized appropriately and consistent with any regulatory requirements (or prohibited if required by state law or regulation). For example, if use of auditing techniques such as extrapolation is prohibited by state law or regulation, the PBM should not apply the method in any audits.

Assess whether the PBM has staffing models to effectively initiate, conduct and finalize audits.

Assess the PBM's use of AI to ensure it is reasonable and that any results or findings from the use of AI are conveyed to the pharmacy in a clear and transparent manner.

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