Draft Pending Adoption

Draft: 3/31/26

Market Regulation and Consumer Affairs (D) Committee
San Diego, California
March 25, 2026

The Market Regulation and Consumer Affairs (D) Committee met in San Diego, CA, March 25, 2026. The following Committee members participated: Ann Gillespie, Chair (IL); Angela L. Nelson, Vice Chair (MO); Heather Carpenter (AK); Jimmy Harris (AR); Charles Bassett (AZ); Trinidad Navarro represented by Susan Jennette (DE); Dean L. Cameron (ID); Holly W. Lambert represented by Meggan Brumbaugh (IN); Sharon P. Clark represented by Shawn Boggs (KY); D.J. Bettencourt (NH); Ned Gaines represented by Diana Branciforte (NV); Michael Humphreys and David Buono (PA); and Allan L. McVey and Joylynn Fix (WV). Also participating were: Doug Ommen (IA); Danielle Torres (MI); and Mary Block (VT).

1. Adopted its 2025 Fall National Meeting Minutes

Commissioner Humphreys made a motion, seconded by Director Nelson, to adopt the Committee's Dec. 11, 2025, minutes (*see NAIC Proceedings – Fall 2025, Market Regulation and Consumer Affairs (D) Committee*). The motion passed unanimously.

2. Appointed the Market Conduct Regulation Modernization (D) Working Group and Adopted its Charges

Director Gillespie said a new Committee priority is to consider the future of market regulation, which will be accomplished through the formation of the Market Conduct Regulation Modernization (D) Working Group. The Working Group's charges include: 1) assess with input from NAIC members and interested stakeholders the current state of the market regulatory framework and the need for changes in response to changing markets, business models, and consumer expectations; and 2) provide recommendations for the improvement and modernization of the market conduct regulatory framework.

Director Gillespie said Committee members did preliminary work during the Commissioners' Conference in February and earlier in March. She said the new Working Group will meet bi-weekly to consider: 1) the collection and analysis of market conduct data; 2) interstate collaboration; 3) the *Market Regulation Handbook* and examination approaches; 4) NAIC support and systems; 5) training; and 6) the oversight of other entities, such as third-party vendors. She said that during its first year, the Working Group will be fact-finding and gathering input from members and stakeholders. The Working Group will develop recommendations to be considered for adoption at the Fall National Meeting. The Working Group's second year will be devoted to the implementation of the recommendations. Director Gillespie stated that the Working Group's discussions will be intensive, and she is looking for full participation.

Director Cameron noted this was a very tight timeline for the new Working Group to come up with recommendations on such a big project. He said it is good to stay focused on the six areas of exploration.

Commissioner Ommen said the Life and Annuity (A) Committee is working on the topic of annuity and life illustrations and looks forward to coordinating with the new Working Group on the issues of data collection and analysis. He said he also spoke with Commissioner Clark, who is looking forward to working with the Working Group on training issues.

Lucy Culp (Blood Cancer United) said the NAIC consumer representatives look forward to assisting in the work and asked whether the Working Group's meetings would be open. She also asked how the consumer representatives

could be the most helpful. Director Gillespie said the Working Group will coordinate with the Consumer Board of Trustees. She said the Working Group's calls will be closed, but stakeholders will be invited per topic discussed.

Director Nelson made a motion, seconded by Commissioner McVey, to appoint the Market Conduct Regulation Modernization (D) Working Group and adopt its charges. The motion passed unanimously.

3. Adopted the *PBM Licensure and Regulation Guidance for Regulators*

Fix said the Pharmacy Benefit Management (D) Working Group adopted the *Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators* on Dec. 9, 2025. She said the guidelines before the Committee include additional industry and consumer representative input. Director Gillespie noted that a lot of input was received, and work based on that input has been completed since the 2025 Fall National Meeting. Director Carpenter said she appreciated the exposure process for the guidelines and agreed with the revisions. Director Cameron said the Working Group drafted a good product, took additional input, and improved the product.

Carl Schmid (HIV+Hepatitis Policy Institute) urged the Committee to adopt the guidelines. He said he appreciated the work and compromises that went into the document. He said more attention could be paid to group purchasing and rebates, but he understood this was a compromise document.

Commissioner McVey made a motion, seconded by Jennette, to adopt the *PBM Licensure and Regulation Guidance for Regulators* (Attachment ---). The motion passed unanimously.

4. Received an Update on the Development of a Cybersecurity Incident Response Framework

Torres said the Committee assigned the task of developing a cybersecurity coordination framework to the Market Conduct Examinations (D) Working Group. She said the Working Group is in the early stages of the discussions. She said a group of subject matter experts (SMEs) will draft an initial framework, which will be subject to stakeholder input via comment periods.

Torres said the framework will be a resource with extensive topical overlap to the Cybersecurity Event Response Plan (CERP). She said there is already authority that supports a state insurance regulator's role in responding to an event, but state insurance regulators lack guidance on how to respond collaboratively when appropriate. This framework will allow state departments of insurance (DOIs) to coordinate effectively.

Torres said the Working Group discussed several initial concepts during its March 12 meeting. She said the Working Group must decide: 1) the proper role of a lead state; 2) whether there is a role for any NAIC working group to support the lead state; and 3) thresholds to be met since the framework will only apply to the most significant cybersecurity events.

5. Adopted the Reports of its Task Forces and Working Groups

Director Gillespie said the Committee's working groups will continue their work, and the Committee members should ensure their work is consistent with the strategic direction to be established by the new Market Conduct Regulation (D) Modernization Working Group. Director Gillespie noted, for example, that the Market Analysis Procedures (D) Working Group plans to request the Committee's approval to retain a consultant to assist in enhancing the Market Analysis Prioritization Tool (MAPT) with new technology, such as artificial intelligence (AI). She also noted that the Market Regulation Certification (D) Working Group is continuing to receive and review states' self-certifications. The Working Group also plans to present a proposed draft of a new market analysis certification requirement for states to conduct at least 30 market analysis activities, which are recorded in the Market Analysis Review System (MARS) or Market Action Tracking System (MATS). She said Committee members

will want to explore these requests and leverage the work in conjunction with the discussion of the new Market Conduct Regulation Modernization (D) Working Group.

Buono said the Market Actions (D) Working Group is currently accepting applications for six open Working Group spots. Applications will be accepted through April 9. Buono also said that during its March 22 meeting, the Working Group heard that when several smaller states have requested follow-up examinations of a company, they have threatened to leave the market in their state. He said this is unacceptable behavior, and he has asked states to let the Market Actions (D) Working Group know if they receive this threat.

Director Nelson made a motion, seconded by Director Bassett, to adopt the reports of the following task forces and working groups: 1) Antifraud (D) Task Force; 2) Producer Licensing (D) Task Force; 3) Market Analysis Procedures (D) Working Group (Attachment ---); 4) Market Conduct Annual Statement Blanks (D) Working Group (Attachment --- and Attachment --); 5) Market Conduct Examination Guidelines (D) Working Group (Attachment ---); 6) Market Information Systems (D) Working Group; 7) Market Regulation Certification (D) Working Group; 8) Pharmacy Benefit Management (D) Working Group (Attachment – and Attachment --); and 9) Speed to Market (D) Working Group. The motion passed unanimously.

6. Received an Update from the Big Data and Artificial Intelligence (H) Working Group on the AI Systems Evaluation Tool Pilot

Block said the Big Data and Artificial Intelligence (H) Working Group is finalizing a draft of the AI systems evaluation tool through a pilot program. Block said a pilot of the tool began in March, and the pilot states are meeting weekly to share their insights and to train on using the tool. The states are deciding which companies to evaluate and engaging with the domestic states of the companies. She said there will be one to 10 companies per participating state, and there will be more property/casualty (P/C) companies and a mix of market conduct and financial analysts. As part of the pilot, the Working Group will request feedback from the companies involved.

Director Gillespie said the increasing use of AI is one of the main drivers for modernizing market conduct regulation.

Having no further business, the Market Regulation and Consumer Affairs (D) Committee adjourned.

SharePoint/Support Staff Hub/Committees/D CMTE/2026 Spring/_Final Minutes/3-D Min

Market Conduct Annual Statement Long-Term Care Stand-Alone and Hybrid Products Data Call & Definitions

Approved by the MCAS Blanks (D) Working Group on 05/21/26

Line of Business: Individual Stand-Alone Long-Term Care
Individual Long-Term Care Hybrid Products
Life-LTC Hybrid Products
Annuity-LTC Hybrid Products

Reporting Period: January 1, 2027 through December 31, 2027
Filing Deadline: April 30, 2028

Contact Information

MCAS Administrator	The person responsible for assigning who may view and input company data.
MCAS Contact	The person most knowledgeable about the submitted MCAS data. This person can be the same as the MCAS Administrator.
MCAS Attestor	The person who attests to the completeness and accuracy of the MCAS data.

Long-Term Care Product Types

Product Identifier	Explanation of Product Identifiers
SALTC	Stand-Alone – Long-Term Care Products
LifeLTC	Life – Long-Term Care Hybrid Products
AnnLTC	Annuity – Long-Term Care Hybrid Products

Schedule 1 - Interrogatories

ID	Description	Response
1-1	Does the company have data to report for Stand-Alone Long-Term Care?	Yes/No
1-2	Does the company have data to report for Life Long-Term Care Hybrid?	Yes/No
1-3	Does the company have data to report for Annuity Long-Term Care Hybrid?	Yes/No
1-4	Stand-Alone LTC - Has the company had a significant event or business strategy change that would affect the data for this reporting period?	Yes/No
1-5	If yes, add additional comments.	Comment

1-6	Life LTC Hybrid - Has the company had a significant event or business strategy change that would affect the data for this reporting period?	Yes/No
1-7	If yes, add additional comments.	Comment
1-8	Annuity LTC Hybrid - Has the company had a significant event or business strategy change that would affect the data for this reporting period?	Yes/No
1-9	If yes, add additional comments.	Comment
1-10	Stand-Alone LTC - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?	Yes/No
1-11	If yes, add additional comments.	Comment
1-12	Life LTC Hybrid - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?	Yes/No
1-13	If yes, add additional comments.	Comment
1-14	Annuity LTC Hybrid - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?	Yes/No
1-15	If yes, add additional comments.	Comment
1-16	Stand-Alone LTC - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?	Yes/No
1-17	If yes, add additional comments.	Comment
1-18	Life LTC Hybrid - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?	Yes/No
1-19	If yes, add additional comments.	Comment
1-20	Annuity LTC Hybrid - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?	Yes/No
1-21	If yes, add additional comments.	Comment
1-22	Stand-Alone LTC - Was the company still actively writing policies in the state at year end?	Yes/No
1-23	Life LTC Hybrid - Was the company still actively writing policies in the state at year end?	Yes/No

1-24	Annuity LTC Hybrid - Was the company still actively writing policies in the state at year end?	Yes/No
1-25	Does the company use Managing General Agents (MGAs)?	Yes/No
1-26	Does the company use Third Party Administrators (TPAs)?	Yes/No
~~1-16~~ 1-27	Additional state specific Stand-Alone Long-Term Care comments (optional).	Comment
~~1-17~~ 1-28	Additional state specific Life Long-Term Care Hybrid comments (optional).	Comment
~~1-18~~ 1-29	Additional state specific Annuity Long-Term Care Hybrid comments (optional).	Comment

Schedule 2 - General Information

ID	Description
2-30	Direct written premium during the period.
2-31	Direct earned premium during the period.
~~2-19~~ 2-32	Number of policies/contracts in-force as of the beginning of the reporting period.
~~2-20~~ 2-33	~~Number of new business policies/contracts issued during the period.~~ Number of applications approved during the period.
2-34	Number of applications pending at the beginning of the period.
2-35	Number of applications pending at the end of the period.
2-36	Number of applications received.
2-37	Number of applications denied during the period.
~~2-21~~ 2-38	Number of free look cancellations during the period.
~~2-22~~ 2-39	Number of lapses during the period.
2-40	Number of policies terminated or cancelled at the request of the insured.
2-41	Number of policies terminated or cancelled by the insurer for reasons other than non-payment or at the request of the insured.
~~2-23~~ 2-42	Number of rescissions during the period.
~~2-24~~ 2-43	Number of policies/contracts in-force as of the end of the reporting period.
~~2-25~~ 2-44	Number of internal replacements during the period.
~~2-26~~ 2-45	Number of external replacements during the period.
~~2-27~~ 2-46	Number of policies/contracts replaced where age of insured at replacement was < 65.
~~2-28~~ 2-47	Number of policies/contracts replaced where age of insured at replacement was between 65 and 80.

~~2-29~~ 2-48	Number of policies/contracts replaced where age of insured at replacement was > 80.
~~2-30~~ 2-49	Number of complaints received directly from ~~consumers~~ any person or entity other than the DOI.
2-50	Number of adverse determinations overturned upon request for internal review (Do not include additional voluntary levels of reviews).
2-51	Number of adverse determinations upheld upon request for internal review (Do not include additional voluntary levels or reviews).
2-52	Number of customer requested appeals on final adverse determinations to an external review organization.
2-53	Number of final adverse determinations overturned upon request for external review.
2-54	Number of final adverse determinations upheld upon request for external review.

Schedule 3 – Claimants and Claimant Requests Activity

ID	Description
~~3-31~~ 3-55	Number of claimants approved for benefits as of the beginning of the period.
~~3-32~~ 3-56	Number of claimants with pending claimant request determinations as of the beginning of the period.
~~3-33~~ 3-57	Number of new claimants during the period.
~~3-34~~ 3-58	Number of claimants with pending claimant request determinations as of the end of the period.
~~3-35~~ 3-59	Number of claimants approved for benefits as of the end of the period.
~~3-36~~ 3-60	Number of claimant requests denied or not paid because claimant did not pursue (inactivity or death).
~~3-37~~ 3-61	Number of claimant requests denied or not paid because of preexisting condition exclusion.
~~3-38~~ 3-62	Number of claimant requests denied or not paid because of elimination or waiting period not met.
~~3-39~~ 3-63	Number of claimant requests denied or not paid because services provided not covered under the policy.
~~3-40~~ 3-64	Number of claimant requests denied or not paid because provider or facility not qualified under the policy.
~~3-41~~ 3-65	Number of claimant requests denied or not paid because benefits eligibility criteria not met.
~~3-42~~ 3-66	All other claimant requests denied or closed without payment.

~~3-43~~ 3-67	Number of claim request determinations made within 0-30 days.
~~3-44~~ 3-68	Number of claim request determinations made within 31-60 days.
~~3-45~~ 3-69	Number of claim request determinations made within 61-90 days.
~~3-46~~ 3-70	Number of claim request determinations made beyond 90 days.

Schedule 4 - Benefit Payment Requests Activity

ID	Description
~~4-47~~ 4-71	Number of benefit payment requests pending as of the beginning of the period.
~~4-48~~ 4-72	Number of benefit payment requests received during the period.
~~4-49~~ 4-73	Number of benefit payment requests denied or not paid during the period.
~~4-50~~ 4-74	Number of benefit payment requests pending as of the end of the period.
~~4-51~~ 4-75	Number of benefit payment requests paid within 0-30 days.
~~4-52~~ 4-76	Number of benefit payment requests paid within 31-60 days.
~~4-53~~ 4-77	Number of benefit payment requests paid within 61-90 days.
~~4-54~~ 4-78	Number of benefit payment requests paid beyond 90 days.
~~4-55~~ 4-79	Number of benefit payment requests denied or not paid within 0-30 days.
~~4-56~~ 4-80	Number of benefit payment requests denied or not paid within 31-60 days.
~~4-57~~ 4-81	Number of benefit payment requests denied or not paid within 61-90 days.
~~4-58~~ 4-82	Number of benefit payment requests denied or not paid beyond 90 days.

Schedule 5 - Lawsuit Activity

ID	Description
~~5-59~~ 5-83	Number of lawsuits open as of the beginning of the period.

~~5-60~~ 5-84	Number of lawsuits opened during the period.
~~5-61~~ 5-85	Number of lawsuits closed during the period - total.
~~5-62~~ 5-86	Number of lawsuits closed during the reporting period with consideration for the consumer.
~~5-63~~ 5-87	Number of lawsuits open as of the end of the period.

In determining what business to report for a particular state, all reporting companies should follow the same methodology/definitions used to file the Financial Annual statement (FAS) and its corresponding state pages and in accordance with each applicable state's regulations.

Schedule 6 - Long-Term Care Attestation

By completing the attestation information, those named understand, agree and certify on behalf of the named company that:

1. They are authorized to submit the Market Conduct Annual Statement on behalf of the named company and to bind the company to the statements in this attestation;
2. They are knowledgeable of the information required to be provided in the Market Conduct Annual Statement filed by this company and have reviewed this filing;
3. To the best of their knowledge and belief, this filing represents a full and accurate statement of the information required to be provided in the Market Conduct Annual Statement pursuant to the applicable instructions; and
4. They are aware that the state insurance department(s) receiving the data may initiate regulatory action as authorized by law in a specific jurisdiction if the data submitted in the MCAS is inaccurate, incomplete, or found to be materially false, misleading or omissive.
5. They affirm that the company is able to accurately trace the data as reported to its source within the company and if necessary, recreate the MCAS results as reported in this filing.

NOTE: The company must provide the name for at least two individuals who are able to attest that the criteria listed above have been met and attest to the overall accuracy of the MCAS filing. Both attestors should have participated in the review and validation of the filing. We recommend that one person be the individual with operational responsibility for the source data such as a responsible individual from claims, underwriting or compliance. We recommend that the second person should be a responsible IT person that participated in the creation of the data in the filing.

ID	Description
~~6-64~~ 6-88	First Attestor Information (First Name, Middle Name, Last Name, Suffix, Title).

~~6-65~~ 6-89	Second Attestor Information (First Name, Middle Name, Last Name, Suffix, Title).
~~6-66~~ 6-90	Overall comments for the filing period.

General Instructions – All LTC Products:

For the purpose of the MCAS Long-term care insurance reporting blank:

1. "Long-term care insurance" means that as defined in Section 4.A. of the NAIC Long-Term Care Insurance Model Act (#640), with the exception that long-term care insurance riders attached to a life insurance policy or an annuity contract, and group insurance plans are not included.
2. Schedule~~s~~ 3~~, 4 and 5~~ refers to claimants and claimant requests. A claimant request is the initial request for LTC benefits under the policy or contract. It is the determination by the insurer that the claimant is entitled to benefits under the policy or contract.
3. Reporting for schedule~~s~~ 3 ~~through 5~~ is to be done on a "per claimant" basis (counts each individual who makes one or a series of requests or demands for payment of benefits under a policy) [Model #641, Appendix E]
4. Schedule~~s~~ ~~6~~4 ~~and 7~~ refers to individual benefit payment requests following the initial determination by the insurer that the claimant is entitled to benefits under the policy or contract. The purpose of the schedule~~s~~ is to differentiate between initial coverage request activities (Schedule~~s~~ 3~~, 4 and 5~~) and benefit payment request activities (Schedule~~s 6 and 7~~4) once the insurer has affirmed the initial coverage requests.
5. Reporting for schedule~~s~~ ~~6 and 7~~4 is to be done on a "per transaction" basis (counts each benefit payment request pending and benefit payment made). [Model #641, Appendix E]

General Instructions – Life and Annuity Hybrid LTC

1. For purposes of the LTC Hybrid Product MCAS, "LTC Hybrid Product" means those products providing Long-Term Care insurance as defined in Section 4.A. of the NAIC Long-Term Care Insurance Model Act (#640), as part of a Life-LTC hybrid insurance policy or Annuity-LTC hybrid contract. Such LTC hybrid benefits may be built into the life policy or annuity contract, or may be attached to such policy or contract by a rider. Report experience for Life-LTC hybrid products separately from Annuity-LTC hybrid products in the schedules provided. Report experience on individual LTC hybrid policies and contracts only. Do not report experience on group policies and contracts.
2. For Schedule 2, report experience for all policies or contracts with LTC hybrid benefits. For all data elements in Schedule 2, report the number of policies or contracts with Life-LTC hybrid or Annuity-LTC hybrid benefits and which meet the definition of the specific data element. For example, for data element ~~2-19~~ 2-32 in the Life-LTC hybrid schedules, report the number of life insurance policies with LTC benefits in force at the beginning of the reporting period. For data

element ~~2-19~~ 2-32 in the Annuity-LTC hybrid schedules, report the number of annuity contracts with LTC benefits in force at the beginning of the reporting period. For data element ~~2-20~~ 2-33, report the number of new business policies or contracts with LTC hybrid benefits.

3. For Schedules 3~~ through 7~~and 4, report the experience for those policies or contracts with LTC hybrid benefits and report experience only for the LTC benefit portion of the policy or contract. For example, report experience for claimants, claimant requests denied/not paid, claimant request determination timeliness, benefit payment requests, and benefit payment request timeliness only for the LTC benefit portion of the LTC hybrid product.
4. For Schedule ~~8~~5, report experience for those policies or contracts with some form of LTC benefit. Report lawsuit experience for all lawsuits related to the LTC product, regardless of what aspect of the product, coverage or benefit the lawsuit is about.

Definitions:

Actively Writing - Refers to premium written during the reporting period.

Adverse Determination - A rescission, or a denial, reduction, termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a member's, or eligible dependent's, eligibility to participate in a plan, and including a denial, reduction, termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

Benefit Payment Request - A request for benefits after the insurer has determined the insured is entitled to benefits following the initial claimant request. (See Claimant Request and Claimant Request Determination, below.) Each request or demand for a benefit payment (after satisfaction of the waiting or elimination period, if any) is treated as a distinct benefit payment request, and continuing payments for the same service should each be treated as a distinct benefit payment request. The data elements in Schedule 4 capture the period of time between the company's receipt of a claim form, bill, invoice, or other satisfactory documentation to the date the company makes payment for an approved claimant (after satisfaction of the waiting or elimination period, if any).

Cancellations / Terminations - Includes all cancellations of the policies where the cancellation effective date is during the reporting year. The number of cancellations should be reported on a policy basis.
Report cancellations separately for:

- **Policies cancelled for non-payment of premium or non-sufficient funds**.
  - These should be reported every time a policy cancels for the above reasons. (i.e., if a policy cancels for non-pay three times in a policy period and is reinstated each time; each cancellation should be counted.)
- **Policies cancelled at the insured's request**.
- **Policies cancelled by the insurer for reasons other than non-payment or free looks.**

Exclude: Policies cancelled for 're-write' purposes where there is no lapse in coverage.

Claimant - An insured under an in-force policy or contract who the insurer has determined has met the benefit trigger of the policy or contract, or is in the process of making such determination, and such insured is, or may be, eligible to submit benefit payment requests.

Claimant Request - A request or demand for payment made by an insured, or a representative of the insured, for a loss that may be included within the terms of coverage of the LTC stand-alone or LTC hybrid policy or contract. It does not include events that were reported by the insured for "information only" or an inquiry of coverage when a claim has not actually been presented (opened) for payment.
If a claim is re-opened, report the claim as a new claim and the claim determination time period should be measured from the date the claim was re-opened to the benefit trigger determination date.

Claimant Request Determination - A determination as to whether an insured has met a contractual provision of an LTC policy or contract that conditions the payment of benefits on the insured's ability to perform activities of daily living, cognitive impairment, or other loss of functional capacity. For purposes of this blank, the term applies to the initial claimant request, and captures the period of time from notice of claim to the benefit trigger/claimant request determination date. For claimant requests that are denied/not paid, report the period of time from the date of notice of claim to the date the claimant was notified of the determination to deny or not pay the claim.

Claimant Request Denied or Not Paid because Benefit Eligibility Criteria Not Met - A determination, following the initial claimant request for coverage under the LTC benefit of the policy or contract, that a benefit trigger has not been met, or a required certification by a licensed health care practitioner has not been provided, or a plan of care has not been provided.

Claimant Request Denied or Not Paid Because Claimant Did Not Pursue - A claimant or policyholder made a request or demand for payment for the purpose of receiving a benefit trigger/claimant request determination and/or benefit payment under the LTC benefit of a policy or contract, but did not provide the necessary documentation or contact the insurer again (inactivity could be the result of death.)

Claimant Request Denied or Not Paid Because Elimination or Waiting Period Not Met - A determination, following the initial claimant request for coverage under the LTC benefit of the policy or contract that the elimination/waiting period had not yet elapsed.

Claimant Request Denied or Not Paid Because Services Provided Not Covered - Expenses incurred for services and support which are not eligible for reimbursement under the LTC benefit of a policy or contract, such as an expense incurred for home health care when the policy or contract only provides benefits for nursing home confinements.

Claimant Request Denied or Not Paid Because of Preexisting Condition Exclusion - A denial of coverage because benefits for the medical advice or treatment recommended by, or received from a provider of health care services are subject to a restriction as a pre-existing condition for a period of time following the effective date of coverage of an insured person.

Claimant Request Denied or Not Paid Because Provider or Facility Not Qualified - A long-term care provider or facility does not meet the minimum level of requirements or licensing as outlined in the policy or contract.

Complaint - Any written communication from a consumer that expresses dissatisfaction with a specific person, or entity, or product subject to regulation under the state's insurance laws. An oral communication, which is subsequently converted to a written form, will meet the definition of a complaint for this purpose.

Denied or Not Paid - A request or demand for payment that is not paid for any reason.

- Under Schedule 4, if a denial could be reported under more than one of the categories, report the denial in the category that is most specific to the circumstances surrounding the denial. If a claimant's request was denied, the denial should not be counted more than once.
- Under Schedule 5, exclude denials for failure to meet the waiting or elimination period or because of an applicable preexisting condition.

The term does not include a request or demand for payment that is in excess of the applicable contractual limits.

Direct Earned Premiums -
Collected Premiums + Change in Due Premiums – Change in Advanced Premiums – Change in Unearned Premium Reserves.

If necessary, the premium may be derived as the gross premium of the policy with the inclusion of LTC coverage less the gross premium of that policy without LTC coverage.

Direct Written Premiums - The total amount of direct written premium for all policies covered by the market conduct annual statement (new and renewal) written during the reporting period.

Calculation Clarification:

- Premium amounts should be determined in the same manner as used for the financial annual statement.
- If premium is refunded or additional premium is written during the reporting period (regardless of the applicable policy effective date), the net effect should be reported.
- If there is a difference of 20% or more between the Direct Written Premium reported for market conduct annual statement and the Direct Written Premium reported on the financial annual statement, provide an explanation for the difference when filing the market conduct annual statement in order to avoid inquiries from the regulator receiving the market conduct annual statement filing.
- Reporting shall not include premiums received from or losses paid to other carriers on account of reinsurance assumed by the reporting carrier, nor shall any deductions be made by the reporting carrier for premiums added to or for losses recovered from other carriers on account of reinsurance ceded.

Elimination Period - A period of time, as specified in the policy or contract, during which the insured incurs qualified long-term care services and support for which benefits are not payable until the end of such period.

Free Look - A set number of days provided in an insurance policy or contract that allows time for the owner/purchaser to review the policy or contract provisions with the right to return the policy or contract for a full refund of all monies paid. Report the number of policies that were returned by the owner under the free look provision.

Lapse - The termination of the entire policy or contract or the termination of the LTC benefit of the policy or contract due to nonpayment of premium.

Lawsuit - An action brought in a court of law in which one party, the plaintiff, claims to have incurred a loss as a result of the action of another party, the defendant.
For purposes of reporting lawsuits for LTC hybrid products:

- Include only lawsuits brought by an applicant for insurance, a policyholder or a beneficiary as a plaintiff against the reporting insurer or its agent as a defendant;
- Include all lawsuits, whether or not a hearing or proceeding before the court occurred;
- Do not include arbitrations of any sort;
- If one lawsuit has two or more complainants, report the number of complainants as the number of lawsuits. For example, if one lawsuit has two complainants, report two lawsuits. If the lawsuit is a class action, see instructions for treatment of class action lawsuits;
- Report a lawsuit in the jurisdiction in which the policy or contract was issued with the exception of class action lawsuits;
- Treatment of class action lawsuits: Report the opening and closing of a class action lawsuit once in each state in which a potential class member resides. Include an explanatory note with your submission stating the number of class action lawsuits included in the data and the general cause of action.

Lawsuits Closed During the Period with Consideration for the Consumer - A lawsuit closed during the reporting period in which a court order, jury verdict, or settlement resulted in payment, benefits, or other thing of value, i.e., consideration, to the applicant, policyholder, or beneficiary in an amount greater than offered by the reporting insurer before the lawsuit was brought.

Managing General Agent (MGA) - An insurance producer authorized by an insurance company to manage all or part of the insurer's business. Activities on behalf of the insurer may include marketing, underwriting, issuing policies, collecting premiums, appointing and supervising other agents, paying claims, and negotiating reinsurance. Many states regulate the activities and contracts of MGAs.

New Business Policy or Contract - A newly written agreement that puts insurance coverage into effect under a policy or contract during the reporting period.

Number of policy terminations and cancellations initiated by the policyholder - Number of policies terminated at the insured's request.

Number of policy terminations and cancellations due to non-payment of premium - Number of policies terminated because the insured never paid, or stopped paying, the required premium for coverage.

Overturned Decision - A reversal of a denial of an adverse determination by a health carrier or its designee utilization review organization.

Pending Claim - A claim that has not yet been paid or denied.

Replacement - Replacement of any life policy, annuity contract or LTC policy already in force with a new policy or contract with LTC insurance coverage.

- External Replacement—If the policy or contract to be replaced was issued by another insurer.
- Internal Replacement—If the policy or contract to be replaced was issued by your company.

For Data Elements 2-~~2544~~ (Number of Internal Replacements) and 2-~~2645~~ (Number of External Replacements), report the number of policies included in data element 2-~~20~~33 (Number of new ~~business policies~~ applications approved during the period) which are replacements of any type of life, annuity or long-term care policies.

Rescission - Invalidation of a policy or contract or invalidation of the LTC coverage portion of a policy or contract by an insurer, in accordance with the guidelines provided in the NAIC Long-Term Care Insurance Model Act (#640).

Third Party Administrator (TPA) - From the MCAS FAQs: For MCAS purposes, the definition of third-party administrators (TPAs) should be used broadly for any purpose for which a company uses a TPA. This may include, but is not limited to, marketing, claims, underwriting, or other administrative functions.

Upheld Decision - A denial of an adverse determination that has been found to be supported by a health carrier or its designee utilization review organization.

Waiting Period - See definition of Elimination Period.

MCAS Market Conduct Annual Statement

Long-Term Care (2027)

Approved by MCAS Blanks (D) Working Group on 05/21/26

Long-Term Care Interrogatories

		Yes/No Response	Explanation
01	Does the company have data to report for Stand-Alone Long-Term Care?		--
02	Does the company have data to report for Life Long-Term Care Hybrid?		--
03	Does the company have data to report for Annuity Long-Term Care Hybrid?		--
04	Stand-Alone LTC - Has the company had a significant event or business strategy change that would affect the data for this reporting period?		--
05	If yes, add additional comments.	--	
06	Life LTC Hybrid - Has the company had a significant event or business strategy change that would affect the data for this reporting period?		--
07	If yes, add additional comments.	--	
08	Annuity LTC Hybrid - Has the company had a significant event or business strategy change that would affect the data for this reporting period?		--
09	If yes, add additional comments.	--	
10	Stand-Alone LTC - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?		--
11	If yes, add additional comments.	--	
12	Life LTC Hybrid - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?		--
13	If yes, add additional comments.	--	
14	Annuity LTC Hybrid - Has all or part of this block of business been sold, closed or moved to another company during the reporting period?		--
15	If yes, add additional comments.	--	
16	Stand-Alone LTC - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?		--
17	If yes, add additional comments.	--	
18	Life LTC Hybrid - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?		--
19	If yes, add additional comments.	--	
20	Annuity LTC Hybrid - Is there a reason that the reported LTC information may identify the company as an outlier or be substantially different from previously reported data (such as assuming, selling or closing blocks of business; shifting market strategies; underwriting changes, etc.)?		--
21	If yes, add additional comments.	--	
22	Stand-Alone LTC - Was the company still actively writing policies in the state at year end?		--
23	Life LTC Hybrid - Was the company still actively writing policies in the state at year end?		--
24	Annuity LTC Hybrid - Was the company still actively writing policies in the state at year end?		--
25	Does the company use Managing General Agents (MGAs)?		--
26	Does the company use Third Party Administrators (TPAs)?		--
~~16~~ 27	Additional state specific Stand-Alone Long-Term Care comments (optional).	--	
~~17~~ 28	Additional state specific Life Long-Term Care Hybrid comments (optional).	--	
~~18~~ 29	Additional state specific Annuity Long-Term Care Hybrid comments (optional).	--	

Long-Term Care General Information

		Stand-Alone LTC	Life LTC Hybrid	Annuity LTC Hybrid
30	Direct written premium during the period.			
31	Direct earned premium during the period.			
~~19~~ 32	Number of policies/contracts in-force as of the beginning of the reporting period.			
~~20~~ 33	Number of applications approved during the period.			
34	Number of applications pending at the beginning of the period.			
35	Number of applications pending at the end of the period.			
36	Number of applications received.			
37	Number of applications denied during the period.			
~~21~~ 38	Number of free look cancellations during the period.			
~~22~~ 39	Number of lapses during the period.			

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Long-Term Care General Information Continued

		Stand-Alone LTC	Life LTC Hybrid	Annuity LTC Hybrid
40	Number of policies terminated or cancelled at the request of the insured.			
41	Number of policies terminated or cancelled by the insurer for reasons other than non-payment or at the request of the insured.			
~~23~~ 42	Number of rescissions during the period.			
~~24~~ 43	Number of policies/contracts in-force as of the end of the reporting period.			
~~25~~ 44	Number of internal replacements during the period.			
~~26~~ 45	Number of external replacements during the period.	--		
~~27~~ 46	Number of policies/contracts replaced where age of insured at replacement was < 65.	--		
~~28~~ 47	Number of policies/contracts replaced where age of insured at replacement was between 65 and 80.	--		
~~29~~ 48	Number of policies/contracts replaced where age of insured at replacement was > 80.			
~~30~~ 49	Number of complaints received directly from ~~consumers~~ any person or entity other than the DOI.			
50	Number of adverse determinations overturned upon request for internal review (Do not include additional voluntary levels of reviews).			
51	Number of adverse determinations upheld upon request for internal review (Do not include additional voluntary levels or reviews).			
52	Number of customer requested appeals on final adverse determinations to an external review organization.			
53	Number of final adverse determinations overturned upon request for external review.			
54	Number of final adverse determinations upheld upon request for external review.			

Long-Term Care Claimants and Claimant Requests Activity

		Stand-Alone LTC	Life LTC Hybrid	Annuity LTC Hybrid
~~31~~ 55	Number of claimants approved for benefits as of the beginning of the period.			
~~32~~ 56	Number of claimants with pending claimant request determinations as of the beginning of the period.			
~~33~~ 57	Number of new claimants during the period.			
~~34~~ 58	Number of claimants with pending claimant request determinations as of the end of the period.			
~~35~~ 59	Number of claimants approved for benefits as of the end of the period.			
~~36~~ 60	Number of claimant requests denied or not paid because claimant did not pursue (inactivity or death).			
~~37~~ 61	Number of claimant requests denied or not paid because of preexisting condition exclusion.			
~~38~~ 62	Number of claimant requests denied or not paid because of elimination or waiting period not met.			
~~39~~ 63	Number of claimant requests denied or not paid because services provided not covered under the policy.			
~~40~~ 64	Number of claimant requests denied or not paid because provider or facility not qualified under the policy.			
~~41~~ 65	Number of claimant requests denied or not paid because benefits eligibility criteria not met.			
~~42~~ 66	All other claimant requests denied or closed without payment.			
~~43~~ 67	Number of claim request determinations made within 0-30 days.			
~~44~~ 68	Number of claim request determinations made within 31-60 days.			
~~45~~ 69	Number of claim request determinations made within 61-90 days.			
~~46~~ 70	Number of claim request determinations made beyond 90 days.			

Long-Term Care Benefit Payment Requests Activity

		Stand-Alone LTC	Life LTC Hybrid	Annuity LTC Hybrid
~~47~~ 71	Number of benefit payment requests pending as of the beginning of the period.			
~~48~~ 72	Number of benefit payment requests received during the period.			
~~49~~ 73	Number of benefit payment requests denied or not paid during the period.			
~~50~~ 74	Number of benefit payment requests pending as of the end of the period.			
~~51~~ 75	Number of benefit payment requests paid within 0-30 days.			
~~52~~ 76	Number of benefit payment requests paid within 31-60 days.			
~~53~~ 77	Number of benefit payment requests paid within 61-90 days.			
~~54~~ 78	Number of benefit payment requests paid beyond 90 days.			
~~55~~ 79	Number of benefit payment requests denied or not paid within 0-30 days.			
~~56~~ 80	Number of benefit payment requests denied or not paid within 31-60 days.			
~~57~~ 81	Number of benefit payment requests denied or not paid within 61-90 days.			
~~58~~ 82	Number of benefit payment requests denied or not paid beyond 90 days.			

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Long-Term Care Lawsuit Activity

		Stand-Alone LTC	Life LTC Hybrid	Annuity LTC Hybrid
~~59~~ 83	Number of lawsuits open as of the beginning of the period.			
~~60~~ 84	Number of lawsuits opened during the period.			
~~61~~ 85	Number of lawsuits closed during the period - total.			
~~62~~ 86	Number of lawsuits closed during the reporting period with consideration for the consumer.			
~~63~~ 87	Number of lawsuits open as of the end of the period.			

Long-Term Care Attestation

		First Name	Middle Name	Last Name	Suffix	Title	Comments
~~64~~ 88	First Attestor Information.						--
~~65~~ 89	Second Attestor Information.						--
~~66~~ 90	Overall comments for the filing period.	--	--	--	--	--	

Chapter 21B—Conducting the Pet 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 pet 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 pet 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 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.

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

1. Purpose

The marketing and sales portion of the examination is designed to evaluate the representations made by the pet insurer about its product(s). It is not typically based on sampling techniques, but it can be. The areas to be considered in this kind of review include all 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 pet insurer 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 and authorized by the pet insurer are the responsibility of the pet insurer.

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 in mind, when the examiner is reviewing a pet insurer's Internet advertisements, it is important to also review the safeguards implemented by the pet insurer.

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.

The *Pet Insurance Model Act* (#633) was adopted by the Property and Casualty Insurance (C) Committee on August 1, 2022. Model #633 addresses required disclosures, definitions, policy conditions, sales practices for wellness programs and producer training requirements.

3. Tests and Standards

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

STANDARDS
MARKETING AND SALES

Standard 1
The pet insurer's disclosures are in compliance with applicable statutes, rules and regulations.

Apply to: All pet insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pet insurer policy forms and endorsements, policy certificates, policy riders, fulfillment materials, advertising/marketing and sales materials and disclosures

_____ Pet insurer's website and pet insurance program administrator's website

_____ Policy/Underwriting file

_____ Pet insurer correspondence file/Agency bulletins

_____ Pet insurer procedural manual

_____ Pet insurer sales/lapse records

_____ Pet insurer systems manual

_____ Pet insurer producer training materials

_____ Pet insurer contracts with third-party vendors with compliance responsibilities

_____ Pet insurer complaint register/logs/files

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Pet Insurance Model Act (#633)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Review pet insurance policies to verify that the following information has been disclosed:

- If the policy excludes coverage due to any of the following:
  - A preexisting condition;
  - A hereditary disorder;
  - A congenital anomaly or disorder; or
  - A chronic condition;

- If the policy includes any other exclusions, the following statement "Other exclusions may apply. Please refer to the exclusions section of the policy for more information.";
- Any policy provision that limits coverage through a waiting or affiliation period, a deductible, coinsurance, or an annual or lifetime policy limit;
- Whether the pet insurer reduces coverage or increases premiums based on the insured's claim history, the age of the covered pet or a change in the geographic location of the insured; and
- If the underwriting company differs from the brand name used to market and sell the product.

Verify that unless the insured has filed a claim under the pet insurance policy, pet insurance applicants have the right to:

- Examine and return the policy, certificate or rider to the pet insurer or an agent/insurance producer of the pet insurer within 15 days of policy receipt; and
- Have the premium refunded if, after examination of the policy, certificate or rider, the applicant is not satisfied for any reason.

Review pet insurance policies, certificates and riders to verify they have a notice prominently printed on the first page or attached thereto including specific instructions to accomplish a return. Verify the following free look statement or language substantially similar is included:

> "You have 15 days from the day you receive this policy, certificate or rider to review it and return it to the company if you decide not to keep it. You do not have to tell the company why you are returning it. If you decide not to keep it, simply return it to the company at its administrative office or you may return it to the agent/insurance producer that you bought it from as long as you have not filed a claim. You must return it within 15 days of the day you first received it. The company will refund the full amount of any premium paid within 30 days after it receives the returned policy, certificate, or rider. The premium refund will be sent directly to the person who paid it. The policy, certificate or rider will be void as if it had never been issued."

Review the pet insurer's policy and the program administrator's website to verify the pet insurer clearly discloses a summary description of the basis or formula on which the pet insurer determines claim payments under a pet insurance policy within the policy, prior to policy issuance and through a clear and conspicuous link on the main page of the pet insurer or the pet insurer's program administrator's website.

For pet insurers that use a benefit schedule to determine claim payment under a pet insurance policy, review the pet insurer's policy and the program administrator's website to verify that the benefit schedule:

- Clearly discloses the applicable benefit schedule in the policy; and
- Discloses all benefit schedules used by the pet insurer under its pet insurance policies through a clear and conspicuous link on the main page of the pet insurer or the pet insurer's program administrator's website.

Review the pet insurer's policy and the program administrator's website to verify that a pet insurer that determines claim payments under a pet insurance policy based on usual and customary fees, or any other reimbursement limitation based on prevailing veterinary service provider charges, performs <u>both</u> of the following:

- Includes a usual and customary fee limitation provision in the policy that clearly describes the pet insurer's basis for determining usual and customary fees and how that basis is applied in calculating claim payments; and
- Discloses the pet insurer's basis for determining usual and customary fees through a clear and conspicuous link on the main page of the pet insurer or the pet insurer's program administrator's website.

If any medical examination by a licensed veterinarian is required to effectuate coverage, review advertising/marketing and sales materials and the disclosures to verify:

- The pet insurer clearly and conspicuously discloses the required aspects of the examination prior to policy purchase; and
- The pet insurer discloses that examination documentation may result in a preexisting condition exclusion.

Review advertising/marketing and sales materials and the disclosures to verify the pet insurer clearly and prominently discloses to consumers, waiting periods and the requirements applicable to them, prior to policy purchase.

Review the pet insurer's "Insurer Disclosure of Important Policy Provisions" document and the program administrator's website to ensure the pet insurer includes a summary of all policy provisions required in applicable state statutes, rules and regulations relating to Subsections (A) through (G) of Model #633, inclusive, in a separate document titled "Insurer Disclosure of Important Policy Provisions."

Verify the pet insurer posts the "Insurer Disclosure of Important Policy Provisions" document required by applicable state statutes, rules and regulations relating to Subsection H of Model #633, through a clear and conspicuous link on the main page of the pet insurer or the pet insurer's program administrator's website.

Verify the pet insurer, in connection with the issuance of a new pet insurance policy, provides the consumer with a copy of the "Insurer Disclosure of Important Policy Provisions" document required pursuant to applicable state statutes, rules and regulations relating to Subsection H of Model #633 in at least 12-point type when the policy is delivered.

Verify the pet insurer, at the time a pet insurance policy is issued or delivered to a policyholder, includes a written disclosure with the following information, printed in 12-point boldface type:

- The [insert applicable state insurance department]'s mailing address, toll-free telephone number and website address;
- The address and customer service telephone number of the pet insurer or the agent or broker of record; and
- If the policy was issued or delivered by an agent or broker, a statement advising the policyholder to contact the broker or agent for assistance.

Verify the pet insurer complies with any other disclosure requirements required by applicable state statutes, rules and regulations.

Review pet insurer complaint register/logs/files for any complaints relating to disclosures.

STANDARDS
MARKETING AND SALES

Standard 2
The pet insurer's marketing of pet insurance is in compliance with applicable statutes, rules and regulations.

Apply to: All pet insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pet insurer advertising/marketing and sales materials including radio and audiovisual items, such as television commercials, telemarketing scripts and pictorial materials

_____ Pet insurer policy forms and endorsements, policy certificates, policy riders, as they coincide with advertising/marketing and sales materials

_____ Pet insurer producers' own advertising/marketing and sales materials

_____ Pet insurer complaint register/logs/files

_____ Pet insurer underwriting guidelines

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Pet Insurance Model Act (#633)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Evaluate the pet insurer's system for controlling advertisements. Every pet 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 pet insurer.

Ensure the pet 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 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 time as set forth by applicable state statutes, rules and regulations.

Review pet insurer advertising materials in conjunction with the appropriate policy forms and endorsements.

Review pet insurer marketing procedures for noncompliance with applicable state-specific rates, rules, regulations and procedures regarding rebating. Determine if the pet insurer approves producer sales materials and advertising.

Review pet insurer complaint register/logs/files for any complaints relating to marketing of pet insurance.

Review underwriting guidelines, new business policy files, advertising materials, disclosure materials and complaints to verify that disclosures are provided, as required.

STANDARDS
MARKETING AND SALES

Standard 3
The pet insurer's wellness program sales practices are in compliance with applicable statutes, rules and regulations.

Apply to: All pet insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pet insurer procedural manual

_____ Pet insurer producer training materials

_____ Pet insurer policy forms and endorsements, policy certificates, policy riders, fulfillment materials, advertising/marketing and sales materials and disclosures

_____ Pet insurer's website and pet insurance program administrator's website

_____ Pet insurer advertising/marketing and sales materials including radio and audiovisual items, such as television commercials, telemarketing scripts and pictorial materials

_____ Pet insurer policy forms and endorsements, policy certificates, policy riders, as they coincide with advertising/marketing and sales materials

_____ Pet insurer producers' own advertising/marketing and sales materials

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Pet Insurance Model Act (#633)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Review the pet insurer's wellness program sales practices to verify that the pet insurer and/or producer does not do the following:

- Market a wellness program as pet insurance; and
- Market a wellness program during the sale, solicitation or negotiation of pet insurance.

If a wellness program is sold by a pet insurer and/or producer, review the pet insurer's wellness program sales practices to verify that:

- The purchase of the wellness program is not a requirement for the purchase of pet insurance.
- The cost of the wellness program is separate and identifiable from any pet insurance policy sold by a pet insurer and/or producer;
- The terms and conditions for the wellness program are separate from any pet insurance policy sold by a pet insurer and/or producer;
- The products or coverages available through the wellness program do not duplicate products or coverages available through the pet insurance policy;
- The advertising of the wellness program is not misleading and is in accordance with applicable state statutes, rules and regulations relating to Subsection 6B of Model #633; and
- The pet insurer and/or producer clearly discloses the following to consumers, printed in 12-point boldface type:
    - That wellness programs are not insurance;
    - The address and customer service telephone number of the pet insurer or producer or broker of record; and
    - The [insert applicable state insurance department]'s mailing address, toll-free telephone number and website address.

Note: Coverages included in a pet insurance policy described as "wellness" benefits are insurance.

D. Producer Licensing

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

STANDARDS
PRODUCER LICENSING

Standard 1
The pet insurer's producer training is in compliance with applicable statutes, rules and regulations.

Apply to: All pet insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pet insurer producer training materials

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

_____ Pet insurer listing of currently licensed and/or appointed producers and, if applicable, adjusters

_____ Pet insurer listing of commissions

_____ New business application

_____ Pet insurer procedures for appointing a producer

_____ MGA licensure, where applicable

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Pet Insurance Model Act (#633)
Unfair Trade Practices Model Act (#880)
Producer Licensing Model Act (#218)
Managing General Agents Act (#225)

Review Procedures and Criteria

Review the producer's license and appointment records to verify that insurance producers do not sell, solicit or negotiate a pet insurance product until after the producer is appropriately licensed and has completed the required training set forth in applicable state statutes, rules and regulations relating to Subsection 7C of Model #633.

Review the pet insurer's producer training materials to verify that pet insurers ensure that its producers are trained under the requirements set forth in applicable state statutes, rules and regulations relating to Subsection 7C of Model #633 and that its producers have been appropriately trained on the coverages and conditions of its pet insurance products.

Review the pet insurer's producer training materials to verify that the aforementioned training includes information on the following topics:

- Preexisting conditions and waiting periods;
- The differences between pet insurance and noninsurance wellness programs;
- Hereditary disorders, congenital anomalies or disorders and chronic conditions and how pet insurance policies interact with those conditions or disorders; and
- Rating, underwriting, renewal and other related administrative topics.

Note: The satisfaction of the training requirements of another jurisdiction that are substantially similar to the provisions of applicable state statutes, rules and regulations relating to Subsection 7C of Model #633 shall be deemed to satisfy the training requirements in [insert applicable jurisdiction].

E. Policyholder Service

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

F. Underwriting and Rating

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

STANDARDS
UNDERWRITING AND RATING

Standard 1
The pet insurer's insurance policy conditions are in compliance with applicable statutes, rules and regulations.

Apply to: All pet insurance products

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pet insurer policy forms and endorsements

_____ Pet insurer complaint register/logs/files concerning waiting periods (supporting documentation, including, but not limited to: written and phone records of inquiries, complaints, complaints, complainant correspondence and pet insurer response)

Others Reviewed

_____ _____

_____ _____

NAIC Model References

Pet Insurance Model Act (#633)
Unfair Trade Practices Model Act (#880)

Review Procedures and Criteria

Note: A pet insurer may issue policies that exclude coverage on the basis of one or more preexisting conditions with appropriate disclosure to the consumer. The pet insurer has the burden of proving that any preexisting condition exclusion applies to the condition for which a claim is being made.

Review pet insurance policies to verify that the pet insurer issues policies that impose waiting periods upon effectuation of the policy that do not exceed 30 days for illnesses or orthopedic conditions not resulting from an accident. Review pet insurance policies to verify that the pet insurer does not impose waiting periods for accidents.

- Review pet insurance policies to verify that a pet insurer utilizing a waiting period permitted in the above bulleted item by applicable state statutes, rules and regulations includes a provision in the insurance policy that allows waiting periods to be waived upon completion of a medical examination. A pet insurer may require the examination to be conducted by a licensed veterinarian after the purchase of the policy.
    - Review pet insurance policies to verify that the pet insurer includes a provision where the policyholder pays for the aforementioned medical examination conducted by a licensed veterinarian, unless the policy otherwise specifies that the pet insurer will pay for the examination.
    - Review pet insurance policies to verify that while a pet insurer can specify elements to be included as part of the medical examination and require documentation thereof, these specifications set forth by the pet insurer do not unreasonably restrict a policyholder's ability to waive any applicable waiting periods set forth in the policy.

- Review pet insurance policies to verify that the pet insurer clearly and prominently discloses waiting periods and all requirements applicable to waiting periods prior to policy purchase.

Review pet insurance policies to verify that the pet insurer does not require a veterinary examination of the covered pet for the purpose of policy renewal.

Review pet insurance policies to verify that a pet insurer which includes any prescriptive, wellness, or non-insurance benefits in the policy form makes these benefits part of the policy. Verify that these benefits comply with all applicable state statutes, rules and regulations.

Review pet insurance policies to verify that an applicant's eligibility to purchase a pet insurance policy is not contingent upon the covered pet's participation or lack of participation in a separate wellness program.

G. Claims

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

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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 ~~are responsible for~~ 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.

~~Examinations of Pharmacy Benefit Manager~~PBM examinations can be either comprehensive or targeted. A ~~Pharmacy Benefit Manager~~PBM examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the ~~Pharmacy Benefit Manager's~~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 ~~is~~ little, if any, "market analysis" procedures or tools developed to assist in the conduct of ~~for Pharmacy Benefit Manager~~PBM examinations. Similarly, ~~Pharmacy Benefit Managers~~PBMs 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.~~ 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&13~~Chapter 12 and Chapter 13 of ~~the Market Regulation Handbook~~this handbook.

~~Definitions~~Key Terms:

Regulators ~~may want to~~must consider state specific definitions when conducting a PBM Examination.

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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.

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Biologic Drugs - ~~Biologic drugs~~ are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, ~~and~~ 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.

~~A biosimilar~~**Biosimilar Drugs** ~~drug product~~ - 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 - ~~Manufacturers who produce brand name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name drugs receive patents and exclusivities from the FDA. 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.~~ 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.

~~**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, but sometimes hires an insurance company, PBM, or other benefit manager to administer the benefits. Employers choose how much of the benefits they will allow a contracted insurance provider or PBM to design and may choose to "carve out" the pharmacy administration and have external entities perform different functions.~~

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.

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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~~, approximately 90 percent of all drugs dispensed to consumers~~.

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 – ~~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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~~**Manufacturers** - Pharmaceutical 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.~~

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.

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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 (individual, small group, large group, government programs) and the arrangement that the payor chooses. In this ~~paper~~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 pharmacy chain refers to a third party entity that engages in a retail business and that owns or operates multiple retail outlets at which an individual consumer may have a prescription drug order filled. Retail outlets~~ 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.

~~**Independent** – Independent pharmacies refer to pharmacies that are privately and independently owned and operated by one or more pharmacists, 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.~~

Pharmacists - ~~The basic duty of a community pharmacist is to~~are licensed and trained health care providers that assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing ~~the~~a medication to ~~the~~a 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 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) - ~~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 negotiat~~e~~ing 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 ~~design~~develop, negotiate, implement, ~~and~~or administer clinical, ~~manage~~ formulary, or other preferred lists ~~designs~~ for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers and other entities. PBMs ~~are responsible for~~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, ~~out-of-pocket responsibilities for patients~~ 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~~s~~ Manager Network ~~– means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacy goods or services~~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) - ~~Pharmacy Services Administrative Organizations (PSAOs)~~ are organizations that provide administrative services to independent pharmacies ~~to support the evaluation and execution of a contract with PBMs or wholesalers~~. 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 – ~~means a discount or other price concession, or payment that is both of the following: 1. Based on utilization of a prescription drug. 2. 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 a pharmacy benefits manager~~ 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."

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Specialty ~~drug~~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)~~, or high-touch~~It often references medications used to treat rare, complex, life threatening, or chronic conditions. Because of this, ~~These~~these drugs often ~~require specialized handling, administration, and~~ 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.

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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.

Qualifications of Examiners

Information on qualifications, please refer to ~~c~~Chapter 14 of ~~the Market Regulation Handbook~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Managers~~PBMs operating in the jurisdiction.
3. For those ~~Pharmacy Benefit Manager~~PBMs ~~that have provided a current examination report~~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 ~~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~~a licensed pharmacist (ideally one with experience with the functions of a ~~Pharmacy Benefit Manager~~PBM or pharmacy operations).
~~5.~~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 ~~Pharmacy Benefit Manager~~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.

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~~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 ~~Pharmacy Benefit Manager~~PBM. The examination plan should indicate which standards for review will be used for each specific examination.

A. ~~Pharmacy Benefit Manager~~PBM Operations/Management
B. PBM Pricing and Methodologies
C. ~~Provider/Pharmacy Relations~~Contracts
D. Pharmacy Claims
~~E. PBM Pricing Methodologies~~
~~F~~E. Pharmaceutical Manufacturer Rebates
~~G~~F. Pharmacy Network Adequacy
~~H~~G. Utilization Review
~~I~~H. Drug Formulary, Placement, and Specialty Drug
~~J~~I. Complaints, Grievances, and Appeals
~~K~~J. Pharmacy Audits

A. ~~Pharmacy Benefit Manager~~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.

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. ~~AKA SPREAD PRICING.~~

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 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

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.

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.

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.*

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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 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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard ~~3~~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 ~~informative documents~~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 ~~and~~ 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, ~~Retail,~~ 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 ~~when~~.
- 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.

- 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 ~~carrier~~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 ~~that is easily understandable and cannot be misinterpreted to mean more than the plane 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 ~~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

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 ~~sampling~~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?

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard ~~4~~5
The PBM demonstrates it has transparent payment methodologies for the dispensing fees of all drugs that enable a pharmacy to ~~understand~~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.

_____ ~~PBM to provide an~~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 ~~carrier~~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, ~~Retail,~~ 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~~;~~.

- 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)~~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. ~~But~~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 ~~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 & 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 ~~sampling~~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.

C. Contracts

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STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND ~~PHARMACY~~PHARMACIES ~~(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

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ ~~PBM to provide an~~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. ~~The Examiner should 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.~~

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~~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.

Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. ~~Including~~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.

~~*We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)~~

STANDARDS
PHARMACY BENEFIT~~S~~ 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.

_____ ~~PBM to provide an~~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 ~~including~~include a description of ~~those~~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, ~~retail~~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 affiliate pharmacies over non-affiliated pharmacies.

~~*We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*~~

STANDARDS
PHARMACY BENEFIT~~S~~ 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.

_____ ~~PBM to provide a~~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.

_____ ~~PBM to provide an~~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 ~~of~~ 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. 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.

D. Pharmacy Claims

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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

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format

_____ PBM to provide anAn index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ PBM to provide anAn 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, NPNNPI, and address.
- Pharmacy network name associated with each claim.
- RetailChain, 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.
- 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 ~~for pharmacy requirements to be able~~ 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 ~~price~~ 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 ~~denial/~~rejection of the claim.
- The PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is ~~denied or~~ 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 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, 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 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? DoesCan the pharmacy have the ability to "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 situsted in the state, or some other criteria). *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 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 carriersplans.

Review all, or a samplingsample 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 carrierinsurer contract, is that consistent with the payment method (and applicable description) to pharmacies?

E. Pharmaceutical Manufacturer Rebates

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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 ~~A~~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~~s~~ administration, accounting, and reporting processes.

_____ All p~~P~~olicies 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 ~~Company~~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.

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_____ 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:

- 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).

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Others Reviewed

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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.

~~Determine if applicable policies and procedures were actually implemented and applied.~~

~~Determine if manufacturer rebates received were properly forwarded to applicable health plans.~~

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
- Whether spread pricing or other pricing methodologies are authorized under the contract.

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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.

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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.

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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.

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebate discounts, administrative fees, credits, incentives and penalties are passed through to health plans 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, 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.

_____ 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 contracts between the PBM and health plans or covered entities.

_____ 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.

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 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 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.

_____ 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 contracts between the PBM and pharmacies.

_____ 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.

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 42
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly ~~provided~~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;

- 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.

~~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.~~

~~A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).~~

~~Complete and unredacted contracts between the PBM and manufacturers.~~

~~An index of internal reports, certifications, or real-time systems used by employees in the preparation of statutorily required reports.~~

Others Reviewed

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____ _____

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.

F. Pharmacy Network Adequacy

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STANDARDS
PHARMACY BENEFITS 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. Must show its credentialling criteria from beginning to 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 forwith the PBM's language relating to credentialing.

_____ PBM to provide anAn 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 pPharmacy Mmanager, 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.

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~~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. ~~It may be helpful to~~Consider ~~create~~creating 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 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~~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, ~~and~~ 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 ~~unreadable~~unredacted 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.

In any Summary of the PBM Network Adequacy that proceeds these standards, ~~need to describe~~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 ~~retail~~chain/independent), or geographic location and will likely have differing reimbursement levels.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any), ~~carrier~~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.

_____ ~~PBM to provide an~~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 ~~& carrier~~and insurer or employer plan contracts. Request the entire contract, including any amendments, in an unredacted format.

_____ ~~PBM to provide a~~A listing of all the pharmacies ~~it contracts with~~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 ~~(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.*~~Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ ~~PBM to provide a~~A state map or geo-maps identifying the location of each pharmacy.

_____ ~~PBM to provide a~~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~~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.

_____ ~~PBM to provide a~~A list of all ~~carriers~~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. ~~*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.*~~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.

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Others Reviewed

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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 ~~carriers~~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 ~~desserts~~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 ~~carriers~~insurers ~~/~~and employer groups about the network changes. Ensure the message conveyed to ~~carriers~~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~~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.”

STANDARDS
PHARMACY BENEFITS 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

_____ ~~P BM policies~~Policies and procedures for providing information to covered persons about pharmacy directories.

_____ ~~PBM policies~~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~~Documentation regarding how ~~it~~the PBM makes its provider directory (that lists all providers who participate in its network) available to covered persons~~. It also~~ and how it makes available, on a timely and reasonable basis, updates to its directory.

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_____ 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.

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_____ ~~PBM to provide a~~A listing of all the pharmacies with which the PBM ~~it~~ contracts ~~with~~. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, LTC, or 340B pharmacy ~~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 name, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ ~~PBM to provide a~~A state map or geo-maps identifying the location of each pharmacy in relation to consumers.

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Others Reviewed

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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 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.

~~H~~G. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that ~~companies~~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 ~~company~~insurer's ~~written~~ 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 ~~pharmacy benefit manager's~~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 ~~pharmacy benefit managers~~'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 ~~pharmacy benefit manager~~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 approvals or certifications, denials and requests for reconsideration. Use~~

~~sampling techniques to review specific cases. Evaluate handling for adherence to written guidelines and standards.~~Obtain listings of utilization review determinations, including approvals or certifications, denials, and requests for 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.
- ~~e.~~ Whether or not each of the above was derived from AI, clinical staff, or non-clinical staff.

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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~~PBM. ~~The sequence of the standards listed here does not indicate priority of the standard.~~

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 1
The ~~pharmacy benefit manager~~PBM ~~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 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 ~~Pharmacy Benefit Managers'~~PBM's board of directors.

_____Minutes of the ~~Pharmacy Benefit Managers'~~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 ~~Pharmacy Benefit Manager~~PBM implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Managers'~~PBM's written utilization review program document describes all the following:
  - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of ~~health care~~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 ~~health care~~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 ~~health carrier~~insurer's or payor's governing body; and
  - The staff position functionally responsible for day-to-day program management.

- Verify that the ~~Pharmacy Benefit Manager~~PBM ensures that appropriate personnel have operational responsibility for conducting the ~~carrier~~insurer's or payor's utilization review program.

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STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 2
The ~~pharmacy benefit manager~~PBM ~~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 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 ~~Pharmacy Benefit Manager~~PBM utilization review program uses documented clinical review criteria that are based ~~on sound clinical evidence based medicine~~generally accepted, independently-developed clinical standards published by the federal government or professional organizations and evaluated periodically to assure ongoing efficacy.

Note: The ~~Pharmacy Benefit Manager~~PBM may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the ~~Pharmacy Benefit Manager~~PBM makes its clinical review criteria available upon request to authorized government agencies.

Verify that the ~~Pharmacy Benefit Manager~~PBM ensures that qualified ~~health care~~pharmaceutical professionals administer the utilization review program and oversee review decisions. Verify that the ~~Pharmacy Benefit Manager~~PBM has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the ~~Pharmacy Benefit Manager~~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.

Verify that the ~~Pharmacy Benefit Manager~~PBM has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the ~~Pharmacy Benefit Manager~~PBM conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the ~~Pharmacy Benefit Manager~~PBM's data systems are sufficient to support utilization review program activities and to generate management reports to enable the ~~Pharmacy Benefit Manager~~PBM to monitor and manage ~~health care~~pharmacy services effectively.

If a ~~Pharmacy Benefit Manager~~PBM delegates any utilization review activities to a utilization review organization, verify that the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM or respective ~~carrier~~insurer; and
- A process by which the ~~Pharmacy Benefit Manager~~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.

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Verify that the ~~Pharmacy Benefit Manager~~PBM coordinates its utilization review program activities with other medical management activity conducted by the ~~health carrier~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 3
The ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 4
The ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~ 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 ~~Pharmacy Benefit Manager~~ 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 ~~Pharmacy Benefit Manager~~ PBM 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~~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 ~~15 days~~ the time as required by state or federal law after the date the ~~Pharmacy Benefit Manager~~ PBM receives the request.

Whenever the determination is an adverse determination, verify that the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~15 days~~the time required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the ~~Pharmacy Benefit Manager~~PBM has:

- Determined that the extension was necessary due to matters beyond the ~~Pharmacy Benefit Manager's~~ PBM'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 as required by state or federal law, of the circumstances requiring the extension of time and the date by which the ~~Pharmacy Benefit Manager~~ 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 ~~Pharmacy Benefit Manager~~ 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 ~~45 days~~ 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 ~~Pharmacy Benefit Manager~~PBM receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the ~~health carrier~~insurer's or payor's filing procedures, verify that the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM as soon as possible, but in no event later than ~~five days~~the time required by state or federal law following the date of the failure.

Verify that the ~~Pharmacy Benefit Manager~~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 ~~health carrier~~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 ~~Pharmacy Benefit Manager~~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 ~~health care~~pharmaceutical service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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:
  - 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 ~~health care~~pharmaceutical service or treatment that is the subject of the adverse determination is continued by the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM makes the determination within a reasonable period of time, but in no event later than ~~30 working days~~ 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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM determination.

Verify that if the ~~health carrier~~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~~ the time as required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the ~~health carrier~~insurer has:

- Determined that the extension was necessary due to matters beyond the ~~Pharmacy Benefit Manager~~PBM'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 as required by state or federal law, of the circumstances requiring the extension of time and the date by which the ~~health carrier~~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~~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 ~~45 days~~ 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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM in accordance with the ~~health carrier~~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 ~~Pharmacy Benefit Manager~~PBM calculates the time period for making the determination to begin on the date on which the ~~Pharmacy Benefit Manager~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 5
The ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM'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~~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 ~~Pharmacy Benefit Manager~~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 ~~health carrier~~PBM provides the notice in writing or electronically, when required by state or federal law.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 6
The ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~and concurrent review urgent care requests~~.

Verify that the ~~Pharmacy Benefit Manager~~PBM, 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~~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 ~~Pharmacy Benefit Manager~~PBM's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the ~~Pharmacy Benefit Manager~~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 ~~24 hours~~ 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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~health care~~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 ~~Pharmacy Benefit Manager~~PBM to determine whether, or to what extent, the benefits requested are covered benefits or payable under the ~~health carrier's~~insurer's or payor's health benefit plan, verify that the ~~Pharmacy Benefit Manager~~PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of the ~~Pharmacy Benefit Manager~~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 ~~72 hours~~ the time as required by state or federal law after the receipt of the request by the ~~Pharmacy Benefit Manager~~PBM.

If the ~~Pharmacy Benefit Manager~~PBM's determination is an adverse determination, verify that the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~24 hours~~ the time as required by state law after receipt of the request.

Verify that the ~~Pharmacy Benefit Manager~~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 ~~48 hours~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM's determination is an adverse determination, verify that the ~~Pharmacy Benefit Manager~~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 ~~24 hours~~ 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 ~~Pharmacy Benefit Manager~~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 ~~24 hours~~ the time as required by state or federal law after the ~~Pharmacy Benefit Manager~~PBM's receipt of the request.

If the ~~Pharmacy Benefit Manager~~PBM's determination is an adverse determination, the ~~Pharmacy Benefit Manager~~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.

Verify that the ~~Pharmacy Benefit Manager~~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 ~~health carrier~~insurer or ~~Pharmacy Benefit Manager~~PBM in accordance with the ~~health carrier~~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 ~~Pharmacy Benefit Manager~~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) ~~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 carrier~~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 ~~Pharmacy Benefit Manager~~PBM expedited review procedures established pursuant to applicable state statutes, rules and regulations;
- If the ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM provides the notice orally, in writing or electronically.

If the ~~Pharmacy Benefit Manager~~PBM provides the notice of adverse determination orally, verify that the ~~Pharmacy Benefit Manager~~PBM also provides written or electronic notice of the adverse determination within ~~three days~~the time as required by state or federal law following the oral notification when required by state or federal law.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
UTILIZATION REVIEW

Standard 7
The ~~Pharmacy Benefit Manager~~PBM monitors the activities of the utilization review organization or entity with which the ~~Pharmacy Benefit Manager~~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) ~~by health carrier~~.

_____Periodic reports from the organization or entity.

_____Minutes of the ~~Pharmacy Benefit Manager~~PBM's board of directors

_____Minutes of the ~~Pharmacy Benefit Manager~~PBM's utilization review committee

_____Policies and procedures for oversight

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM is responsible for monitoring the activities of the utilization review organization or entity with which the ~~Pharmacy Benefit Manager~~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.

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Verify that the ~~Pharmacy Benefit Manager~~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.

H. Drug Formulary, Placement, and Specialty Drug

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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~~PBM. ~~The sequence of the standards listed here does not indicate priority of the standard.~~

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 1
The ~~pharmacy benefit manager~~PBM establishes and maintains a ~~F~~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 ~~F~~formulary ~~T~~templates used during the examination period.

_____All ~~Pharmacy and Therapeutics (~~P&T~~)~~ Committee meeting minutes ~~and identify all~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM formularies utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the ~~Pharmacy Benefit Manager~~PBM ~~Pharmacy and Therapeutics (~~P&T~~)~~ Committee or other committee(s) decisions and statements ~~comport~~are in compliance with all applicable state and federal statutes, rules and regulations.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 2
The ~~pharmacy benefit manager~~PBM establishes and maintains a ~~F~~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 ~~F~~formulary ~~T~~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 ~~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~~PBM's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to ~~comport~~comply with all applicable state and federal statutes, rules and regulations.

Verify that all the ~~Pharmacy Benefit Manager~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 3
The ~~pharmacy benefit manager~~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 ~~F~~formulary ~~T~~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~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~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 ~~Pharmacy Benefit Manager~~PBM ~~Pharmacy and Therapeutics (~~P&T~~)~~ Committee or other Committees decisions and statements use and apply the correct definition of specialty drug ~~to comport~~in compliance with all applicable state statutes, rules and regulations.

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~~II~~. Complaints, Grievances, and Appeals

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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, 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, ~~and~~ 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.

[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.

- 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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The ~~pharmacy benefit manager~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The ~~pharmacy benefit manager~~PBM has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers, ~~and~~ 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.

STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 3
The ~~pharmacy benefit manager~~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).

~~_____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 in accordance with state and/or federal law. ~~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.

STANDARDS
PHARMACY BENEFIT~~S~~ MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The ~~pharmacy benefit manager~~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).

~~_____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.

J. Pharmacy Audits

STANDARDS
PHARMACY BENEFITS 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 reasonable 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 Llisting of all types of audits that may include but not be limited to,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 Listinglisting of all audits initiated or that were ongoing during the examination period. (As part of this request, require athe 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. It may be helpful to createConsider creating 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.)

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_____ 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,to all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM, and 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 ~~easily~~ understood by pharmacies.

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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.

Review the results of all audits to determine if audits are conducted in a manner that appears reasonable for each of the individual ~~pharmacy~~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.

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.	

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.	

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.	

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.	