PROJECT HISTORY - 2018

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT (#22)

1. Description of the Project, Issues Addressed, etc.

In 2013, the Regulatory Framework (B) Task Force was charged to review NAIC existing models related to health insurance to determine whether they needed to be amended in light of all the changes made by the federal Affordable Care Act (ACA). During that review process, the Task Force decided that revising the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) was a priority for state insurance regulators, carriers and consumers given the expanded role state insurance regulators were given in overseeing prescription drug formulary issues under federal regulations implementing the provisions of the ACA. In addition, in November 2015, the Health Insurance and Managed Care (B) Committee adopted a 2016 charge directing the Regulatory Framework (B) Task Force to review and, if necessary, consider revisions to Model #22 to address issues related to: 1) transparency, accuracy and disclosure regarding prescription drug formularies and formulary changes during a policy year; 2) accessibility of prescription drug benefits using a variety of pharmacy options; and 3) tiered prescription drug formularies and discriminatory benefit design.

In February 2016, the Regulatory Framework (B) Task Force established the Model #22 (B) Subgroup, with Wisconsin as chair, to begin working on revising Model #22. In April 2016, the Subgroup began meeting every other week to review and discuss the comments received on Model #22 by the Jan. 22, 2016, public comment deadline. During its conference calls, the Subgroup discussed a myriad of issues, including the model's application and scope, Pharmacy and Therapeutics (P&T) committee conflict of interest requirements, consumer disclosures, mid-year formulary changes, and nondiscrimination formulary and prescription drug benefit design. The Subgroup finished its review of the comments in September 2017 and released a second draft of proposed revisions to Model #22 with a Oct. 17, 2017, comment deadline. The Subgroup held three conference calls to discuss the comments received. The Subgroup adopted the proposed revisions to Model #22 on Nov. 7, 2017, via conference call and submitted the draft to the Regulatory Framework (B) Task Force for its consideration. The Regulatory Framework (B) Task Force adopted the proposed revisions on Dec. 2, 2017. The Health Insurance and Managed Care (B) Committee adopted the revisions on Dec. 3, 2017.

The proposed revisions to Model #22 include a number of enhancements, including more specific requirements in Section 5—Requirements for the Development and Maintenance of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures concerning P&T committee establishment and how it develops and manages a health carrier's formulary and pharmacy benefit management procedures (PBMPs). The revisions also enhance provisions concerning a P&T committee's conflict of interest policies and procedures. The proposed revisions to Model #22 also enhance and clarify requirements in Section 6—Information to Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons regarding the information consumers must be provided concerning a health carrier's formulary and other prescription drug benefit information. The revisions to this section also enhance consumer disclosure requirements whenever a health carrier makes or approves a change in a formulary or PBMP administration. Additional revisions to Model #22 include revisions to Section 7—Medical Exceptions Approval Process Requirements and Procedures adding an expedited medical exceptions process and adding a new section—Section 8—Nondiscrimination in Prescription Drug Benefit Design.

2. Name of Group Responsible for Drafting the Model and States Participating

The Model #22 (B) Subgroup of the Regulatory Framework (B) Task Force drafted the proposed revisions to Model #22. The members of the Subgroup were: Wisconsin, Chair; Alaska; California; Florida; Iowa; Missouri; Nebraska; New Mexico; Oklahoma; Oregon; Rhode Island; and Washington.

3. Project Authorized by What Charge and Date First Given to the Group

Based on the 2016 charge below from the Health Insurance and Managed Care (B) Committee, the Regulatory Framework
(B) Task Force established the Model #22 (B) Subgroup in February 2016 to consider revisions to Model #22.

"Utilize the Regulatory Framework (B) Task Force to review and, if necessary, consider revisions to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) to address issues related to: 1) transparency, accuracy and disclosure regarding prescription drug formularies and formulary changes during a policy year; 2) accessibility of prescription drug benefits using a variety of pharmacy options; and 3) tiered prescription drug formularies and discriminatory benefit design.—*Important*" A General Description of the Drafting Process (e.g., drafted by a subgroup, interested parties, the full group, etc.; include any parties outside the members that participated)

Beginning in March 2016 and ending in November 2017, the Subgroup reviewed and discussed all of the comments received as part of the drafting process. Numerous interested parties participated in the process. The interested parties represented all stakeholder groups, including consumers, health care providers, hospitals, insurers and health care facilities. Each draft of proposed revisions was posted to the Subgroup's page on the NAIC website. All comment letters received also were posted. The Subgroup met via conference call every other week and sometimes weekly during the drafting process and also held in- person meetings at the NAIC national meetings.

4. A General Description of the Due Process (e.g., exposure periods, public hearings, or any other means by which widespread input from industry, consumers and legislators was solicited)

Beginning in March 2016 and ending in November 2017, the Subgroup reviewed and discussed all of the comments received. Numerous interested parties participated in the drafting process. The interested parties represented all stakeholder groups, including consumers, health care providers, hospitals, insurers and health care facilities. Each draft of proposed revisions with public comment deadlines was posted to the Subgroup's page on the NAIC website. All comment letters received also were posted. The Subgroup met via conference call twice weekly during the drafting process and also held in-person meetings at the NAIC national meetings.

5. A Discussion of the Significant Issues (items of some controversy raised during the due process and the group's response)

A number of significant issues were raised and addressed, including a provision on nondiscrimination requirements in formulary benefit design, prohibition on mid-year formulary changes and whether to apply certain provisions to qualified health plans (QHPs) only or to any health benefit plan providing prescription drug benefits.

With respect to the nondiscrimination in formulary benefit design provision, the Subgroup considered three options: 1) not include nondiscrimination language because it exists in other models; 2) include general nondiscrimination language that state insurance regulators may want to reference to ensure things are nondiscriminatory; or 3) include a more extensive proposal along the lines of the proposed draft language. After extension discussion, as reflected in Section 8, the Subgroup decided: 1) the model should include a nondiscrimination section containing some general language to allow state insurance regulators to look at PBMPs and formulary structural issues to make sure they are not discriminatory; 2) there should be a reference to federal nondiscrimination provisions that may apply; and 3) there should be a reference to existing NAIC models with nondiscrimination language that states may want to consider if developing implementing regulations to this model.

Another issue the Subgroup discussed extensively was whether to include language in the revisions prohibiting health carriers from making mid-year formulary changes. Interested parties advocating for such language said allowing health carriers to make mid-year formulary changes means that consumers who enrolled in a plan based on the formulary will not be getting the benefits they thought they would be receiving at the time of plan enrollment. The Subgroup acknowledged those concerns, but because the model applies to all markets—individual market, small group market and large group market— implementing such a provision would be administratively complex. The Subgroup also felt that other revisions to the model, including additional consumer disclosure requirements on this issue and enhanced medical exceptions process provisions, addressed the issue.

Another issue the Subgroup discussed was whether to apply certain provisions to QHPs only or apply to any health benefit plan providing prescription drug benefits. The Subgroup decided not to make such a distinction in the model and instead make decisions on the revisions based on policy.

6. Any Other Important Information (e.g., amending an accreditation standard).

None.

Section-by-Section Summary of Proposed Revisions

Section 1. Short Title

The proposed revisions to Model #22 make no changes to this section.

Section 2. Purpose and Intent

The proposed revisions to Model #22 make no substantive changes to this section, but add a drafting note clarifying that Model #22 is not intended to address prescription drug formularies and other PBMPs that health carriers or their designees may use for the purpose of workers' compensation.

Section 3. Definitions

The proposed revisions to Model #22 add, revise and delete definitions to reflect the substantive changes made in the other sections of the Act. In addition, some of the definitions in this section have been revised for consistency with the revisions to the same terms used in the *Health Benefit Plan Network Access and Adequacy Model Act* (#74). The proposed revisions add one new definition for the term "drug substitution" and revise several definitions, including definitions for the terms "authorized representative," "medical and scientific evidence," "pharmaceutical benefit management procedure," "Pharmacy and Therapeutics committee," "prescription drug," and "step therapy." The proposed revisions to Model #22 delete definitions for the terms "generic substitution" and "health maintenance organization."

Section 4. Applicability and Scope

The proposed revisions to Model #22 revise this section substantively for clarity as to the model's application to prescription drugs categorically or contractually excluded from coverage under a covered person's health benefit plan. The proposed revisions add a drafting note on the issue. The proposed revisions also add another drafting note clarifying that the reference to "designee" in this section is intended to be construed broadly to any person or entity a health carrier contracts with to perform, or carry out on its behalf, specified activities required under the Act or applicable regulations.

Section 5. Requirements for the Development and Maintenance of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures

The proposed revisions to Model #22 enhance the existing provisions of this section to more clearly establish the responsibilities and duties of any P&T committee a health carrier uses to develop and maintain its prescription drug formulary and implement its PBMPs. The proposed revisions also include additional P&T committee member conflict of interest requirements. The proposed revisions also include a provision requiring health carriers to allow covered persons access to prescription drug benefits at in-network retail or mail order pharmacies, except under specified circumstances.

Section 6. Information to Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons

The proposed revisions to Model #22 clarify and enhance the provisions in this section concerning disclosures, particularly consumer disclosures, related to formulary and prescription drug benefit information and changes to that information. The proposed revisions also specifically require health carriers to provide a 60-day notice or take other specific action whenever the health carrier makes or approves a change in a formulary affecting prescription drug benefit coverage or PBMP administration, including, but not limited to, co-payment amounts, co-insurance percentage level, step therapy, drug substitution and mandatory generics.

Section 7. Medical Exceptions Approval Process Requirements and Procedures

The proposed revisions to Model #22 clarify the provisions in this section related to the medical exceptions process. The proposed revisions also add an expedited medical exceptions process.

Section 8. Nondiscrimination in Prescription Drug Benefit Design

The proposed revisions to Model #22 add this section. This section prohibits a health carrier or its designee from adopting or implementing a formulary or prescription drug benefit design that is discriminatory in violation of state or federal law. The revisions also add three drafting notes to provide guidance to state insurance regulators in implementing this section. One drafting note references existing NAIC models with nondiscrimination language that states may want to consider if developing implementing regulations to this model.

Section 9. Recordkeeping and Reporting Requirements

The proposed revisions to Model #22 make one substantive revision to this section. The revisions require a health carrier to also maintain data on and, upon request, make available to the commissioner information on the changes to its formulary or prescription drug benefit information made after the state of a plan year. This revision is optional for a state to include when adopting the revisions.

Section 10. Oversight and Contracting Responsibilities

The proposed revisions to Model #22 make no changes to this section.

Section 11. Disclosure Requirements

The proposed revisions to Model #22 make a few clarifying changes to this section for consistency with the revisions made to other sections concerning the information concerning formularies and PBMPs a health carrier must disclose in a policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons.

Section 12. Regulations

The proposed revisions to Model #22 make no changes to this section.

Section 13. Penalties

The proposed revisions to Model #22 make no changes to this section.

Section 14. Separability

The proposed revisions to Model #22 make no changes to this section.

Section 15. Effective Date

The proposed revisions to Model #22 add optional language related to the effective date of model revisions.

PROJECT HISTORY - 2003

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT (#22)

1. Description of the project, issues addressed, etc.

This model law was drafted to address an issue of increasing concern to consumers—the use by health carriers of formularies and other pharmaceutical benefit management procedures to manage prescription drug utilization. The model sets out standards for the establishment, maintenance and management of prescription drug formularies and other pharmaceutical benefit management procedures to assure that covered persons have appropriate access to medically necessary prescription drugs. The model law also establishes a medical exceptions process that would permit consumers to request a nonformulary prescription drug or to request an exception to a dose restriction or step therapy requirement.

2. Name of group responsible for draft the model:

Pharmaceutical Issues Working Group of the Regulatory Framework (B) Task Force.

States Participating:

North Carolina, Chair
Colorado
Delaware
District of Columbia
Illinois
Indiana
Kansas
Kentucky
Louisiana
Maine
Maryland
New Hampshire
Ohio
Texas
Vermont
Washington
Wisconsin

3. Project authorized by what charge and date first given to the group:

The following charge given in February 2000: Study the issue of formulary regulation and pharmacy benefit managers, and how they are currently handled at the state level; determine if a more formal regulatory framework is warranted. Report by Winter 2000 Meeting.

After the working group held public hearings in June 2000, the following revised charge was given in February 2001:

Study the issue of formulary regulation and pharmacy benefit managers, and how they are currently handled at the state level and develop a new model or amend an existing model or models, as appropriate. Report by Winter 2001 Meeting.

4. A general description of the drafting process (e.g., drafted by a subgroup, interested parties, the full group, etc). Include any parties outside the members that participated.

The model was drafted by the working group. Numerous interested parties participated, including industry representatives, such as the American Association of Health Plans (AAHP), the Health Insurance Association of America (HIAA), the Blue Cross and Blue Shield Association (BCBSA), the National Association of Health Underwriters (NAHU), the Academy of Managed Care Pharmacy (AMCP), the Pharmaceutical Care Management Association (PCMA), AdvancePCS, Express Scripts, Inc., Kaiser Permanente, and the American Republic Insurance Company; prescription drug manufacturer representatives, such as Pfizer Pharmaceuticals, Inc., the Pharmaceutical Research and Manufacturers of America (PhRMA), GlaxoSmithKline and Schering-Plough Corporation; provider representatives, such as the American Medical Association (AMA), the American Psychiatric Association (APA), the American Society of Health-System Pharmacists (ASHP), and the National Association of Chain Drug Stores (NACDS); consumer representatives, such as AARP, the National Mental Health Association (NMHA), Leukemia & Lymphoma Society (LLS), Epilepsy Foundation of Colorado, National Partnership for Women and Families; and other interested parties, such as the National Pharmaceutical Council (NPC), the National Health Council and the National Committee for Quality Assurance (NCQA).

5. A general description of the due process (e.g., exposure periods, public hearings, or any other means by which widespread input from industry, consumers and legislators was solicited.

There have been five drafts of the proposed new model. Each draft was circulated for comment to interested parties prior to discuss at NAIC quarterly meetings. In addition, all drafts of the proposed model were posted on the NAIC web site. Throughout the drafting process comments from various interest groups and organizations were received and discussed by the working group.

6. A discussion of the significant issues (items of some controversy) raised during the due process and the group's response.

The most significant issue that arose during the drafting of this proposed model concerned its scope. Industry wanted to limit the scope of the model such that it applied only to prescription drug formulary development and maintenance. The working group, however, determined that because health carriers use other pharmaceutical benefit management procedures in addition to formularies to manage prescription drug utilization, these other procedures, such as prior authorization requirements, dose restrictions and step therapy protocols, should be included in the model and should be subject to the same requirements as prescription drug formularies.

Another significant issue of controversy that arose during the drafting of the proposed model concerned whether covered persons should be able to use the medical exceptions process to request a medical exception to having to pay a higher co- payment for a higher tier prescription drug when the lower tier drug (with a lower co-payment amount) was determined not to be effective or appropriate for treating the covered person's medical condition. The working group decided not to permit such requests under the medical exceptions process because they believed that this was a plan design issue and, in addition, this was an issue that could not be easily addressed in a model law due to a myriad of other issues, including cost and the ability for one covered person versus another covered person to pay that cost.