

REQUEST FOR NAIC MODEL LAW DEVELOPMENT

This form is intended to gather information to support the development of a new model law or amendment to an existing model law. Prior to development of a new or amended model law, approval of the respective Parent Committee and the NAIC's Executive Committee is required. The NAIC's Executive Committee will consider whether the request fits the criteria for model law development. Please complete all questions and provide as much detail as necessary to help in this determination.

Please check whether this is: ☒ New Model Law or ☐ Amendment to Existing Model

1. Name of group to be responsible for drafting the model:

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force

2. NAIC staff support contact information:

Jolie Matthews jmatthews@naic.org

3. Please provide a brief description of the proposed new model or the amendment(s) to the existing model. If you are proposing a new model, please also provide a proposed title. If an existing model law, please provide the title, attach a current version to this form and reference the section(s) proposed to be amended.

The Subgroup has a charge to consider developing a new NAIC model to establish a licensing or registration process for pharmacy benefit managers (PBMs).

4. Does the model law meet the Model Law Criteria? ☒ Yes or ☐ No (Check one)

(If answering no to any of these questions, please reevaluate charge and proceed accordingly to address issues).

a. Does the subject of the model law necessitate a national standard and require uniformity amongst all states? ☒ Yes or ☐ No (Check one)

If yes, please explain why

The proposed new model would provide a consistent approach among the states for providing a regulatory scheme for these entities to address, for some states, a potential regulatory gap.

b. Does Committee believe NAIC members should devote significant regulator and Association resources to educate, communicate and support this model law?

☒ Yes or ☐ No (Check one)

5. What is the likelihood that your Committee will be able to draft and adopt the model law within one year from the date of Executive Committee approval?

☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 (Check one)

High Likelihood

Low Likelihood

Explanation, if necessary:

The current subgroup would target completion of a model within one year.

6. What is the likelihood that a minimum two-thirds majority of NAIC members would ultimately vote to adopt the proposed model law?

☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 (Check one)

High Likelihood

Low Likelihood

Explanation, if necessary: Some states have already implemented laws and/or regulations establishing a regulatory scheme for these entities, which may or may not be consistent with the provisions in the proposed new model. For those states with laws or regulations not consistent with the new model's provisions, the issue will be whether these states will want to re-open those laws or regulations after adoption the new model.

7. What is the likelihood that state legislatures will adopt the model law in a uniform manner within three years of adoption by the NAIC?

☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 (Check one)

High Likelihood

Low Likelihood

Explanation, if necessary: Some states have already implemented laws and/or regulations establishing a regulatory scheme for these entities, which may or may not be consistent with the provisions in the proposed new model. For those states with laws or regulations not consistent with the new model's provisions, the issue will be whether these states will want to re-open those laws or regulations after adoption the new model.

8. Is this model law referenced in the NAIC Accreditation Standards? If so, does the standard require the model law to be adopted in a substantially similar manner?

No

9. Is this model law in response to or impacted by federal laws or regulations? If yes, please explain.

No. However, the U.S. Department of Health and Human Services (HHS) has proposed rules on rebating safe harbors. In addition, the HHS and/or other federal government agencies currently are considering proposing further federal policy guidance in the areas concerning PBMs and prescription drug pricing transparency and disclosure. In developing the new NAIC model, the Subgroup most likely will be discussing the same or similar issues.

Adopted by the Health Insurance and Managed Care (B) Committee – 6/22/21
Adopted by the Regulatory Framework (B) Task Force – 3/18/21
Adopted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup – 10/29/20

Draft: 6/22/21
A new model

[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

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Section 1. Short Title

This Act shall be known and may be cited as the Pharmacy Benefit Manager Licensure and Regulation Act.

Section 2. Purpose

- A. This Act establishes the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.
- B. The purpose of this Act is to:
 - (1) Promote, preserve, and protect the public health, safety and welfare through effective regulation and licensure of pharmacy benefit managers;
 - (2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act (15 U.S.C. §§ 1011 – 1015), as well as provide for consumer savings, and fairness in prescription drug benefits;
 - (3) Provide for powers and duties of the commissioner; and
 - (4) Prescribe penalties and fines for violations of this Act.

Section 3. Definitions

For purposes of this Act:

- A. “Claims processing services” means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:
 - (1) Receiving payments for pharmacist services;
 - (2) Making payments to pharmacists or pharmacies for pharmacist services; or
 - (3) Both paragraphs (1) and (2).
- B. “Commissioner” means the insurance commissioner of this state.

Drafting Note: Use the title of the chief insurance regulatory official wherever the term “commissioner” appears.

- C. “Covered person” means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.
- D. “Health benefit plan” means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.
- E. “Health carrier” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

- F. “Other prescription drug or device services” means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:
 - (1) Negotiating rebates, discounts or other financial incentives and arrangements with drug companies;
 - (2) Disbursing or distributing rebates;
 - (3) Managing or participating in incentive programs or arrangements for pharmacist services;
 - (4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;
 - (5) Developing and maintaining formularies;
 - (6) Designing prescription benefit programs; or
 - (7) Advertising or promoting services.
- G. “Pharmacist” means an individual licensed as a pharmacist by the [state] Board of Pharmacy.
- H. “Pharmacist services” means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.
- I. “Pharmacy” means the place licensed by the [state] Board of Pharmacy in which drugs, chemicals, medicines, prescriptions and poisons are compounded, dispensed or sold at retail.
- J.
 - (1) “Pharmacy benefit manager” means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans.
 - (2) “Pharmacy benefit manager” does not include:
 - (a) A health care facility licensed in this state;
 - (b) A health care professional licensed in this state;
 - (c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or

- (d) A health carrier to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees.

Section 4. Applicability

- A. This Act shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of this Act, including any health carrier that performs claims processing or other prescription drug or device services through a third party.

Drafting Note: States may want to consider adding language to Subsection A above or Section 10 of this Act providing additional time for pharmacy benefit managers to come into compliance with the requirements of this Act.

- B. As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this state shall comply with the requirements of this Act.
- C. Nothing in this Act is intended or shall be construed to conflict with existing relevant federal law.

Section 5. Licensing Requirement

- A. A person may not establish or operate as a pharmacy benefit manager in this state for health benefit plans without first obtaining a license from the commissioner under this Act.
- B. The commissioner may adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers under this Act.

Drafting Note: States that are restricted in their rulemaking to only what is prescribed in statute may want to consider including in this section specific financial standards required for a person or organization to obtain a license to operate as a pharmacy benefit manager in this state.

- C. A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the commissioner.

Drafting Note: States may want to consider reviewing their third-party administrator statute if a state wishes to specify what documents must be provided to the commissioner to obtain a pharmacy benefit manager license in the state.

- D. A person submitting an application for a pharmacy benefit manager license shall include with the application a non-refundable application fee of \$[X].
- E. The commissioner may refuse to issue or renew a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible or of good personal and business reputation or has been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.
- F.
 - (1) Unless surrendered, suspended or revoked by the commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager continues to do business in this state and remains in compliance with the provisions of this act and any applicable rules and regulations, including the payment of an annual license renewal fee of \$[X] and completion of a renewal application on a form prescribed by the commissioner.
 - (2) Such renewal fee and application shall be received by the commissioner on or before [x] days prior to the anniversary of the effective date of the pharmacy benefit manager's initial or most recent license.

Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices

- A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding:
 - (1) The nature of treatment, risks or alternative thereto;
 - (2) The availability of alternate therapies, consultations, or tests;
 - (3) The decision of utilization reviewers or similar persons to authorize or deny services;
 - (4) The process that is used to authorize or deny healthcare services or benefits; or
 - (5) Information on financial incentives and structures used by the insurer.
- B. A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.
- C. A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials, provided that:
 - (1) The recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and
 - (2) Prior to disclosure of information designated as confidential the pharmacist or pharmacy:
 - (a) Marks as confidential any document in which the information appears; or
 - (b) Requests confidential treatment for any oral communication of the information.
- D. A pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy due to pharmacist or pharmacy:
 - (1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by state law or the commissioner; or
 - (2) Sharing any portion of the pharmacy benefit manager contract with the commissioner pursuant to a complaint or a query regarding whether the contract is in compliance with this Act.
- E.
 - (1) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.
 - (2) Any amount paid by a covered person under paragraph (1) of this subsection shall be attributable toward any deductible or, to the extent consistent with section 2707 of the Public Health Service Act, the annual out-of-pocket maximums under the covered person's health benefit plan.

Section 7. Enforcement

- A. The commissioner shall enforce compliance with the requirements of this Act.
- B.
 - (1) The commissioner may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance with this Act.

Drafting Note: States may want to consider including a reference to the cost of examinations in the *Model Law on Examinations* (#390).

Drafting Note: States may want to consider incorporating their existing market conduct examination statutes into this Act rather than relying on the examination authority provided under this section.

- (2) The information or data acquired during an examination under paragraph (1) is:
 - (a) Considered proprietary and confidential;
 - (b) Not subject to the [Freedom of Information Act] of this state;
 - (c) Not subject to subpoena; and
 - (d) Not subject to discovery or admissible in evidence in any private civil action.
- C. The commissioner may use any document or information provided pursuant to Section 6C of this Act or Section 6D of this Act in the performance of the commissioner's duties to determine compliance with this Act.
- D. The commissioner may impose a penalty on a pharmacy benefit manager or the health carrier with which it is contracted, or both, for a violation of this Act. The penalty may not exceed [insert appropriate state penalty] per entity for each violation of this Act.

Drafting Note: If an appeals process is not otherwise provided, a state should consider adding such a provision to this section.

Section 8. Regulations

The commissioner may promulgate regulations relating to pharmacy benefit managers that are not inconsistent with this Act.

Section 9. Severability

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of this Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

Section 10. Effective Date

This Act shall be effective [insert date]. A person doing business in this state as a pharmacy benefit manager on or before the effective date of this Act shall have six (6) months following [insert date that the Act is effective] to come into compliance with the requirements of this Act.

PROJECT HISTORY-2021

[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

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

In 2018, after the full NAIC membership adopted the revisions to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22), there was consensus for the NAIC to explore whether to develop a new model regulating pharmacy benefit managers (PBMs). The Regulatory Framework (B) Task Force established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup to discuss the issue. In 2019, the Subgroup decided to move forward with a 2019 charge to “[c]onsider developing a new NAIC model to establish a licensing or registration process for pharmacy benefit managers.” The charge also states, “[t]he Subgroup may consider including in the new NAIC model provisions on PBM prescription drug pricing and cost transparency.”

In March 2019, the Subgroup adopted a Request for NAIC Model Law Development to work on the proposed new PBM model. The Task Force and the Health Insurance and Managed Care (B) Committee both adopted the Request for NAIC Model Law Development at the 2019 Spring National Meeting. The Executive (EX) Committee adopted the request at the 2019 Summer National Meeting. Based on its work plan, the Subgroup met 12 times throughout the summer and early fall of 2019 to hear from various stakeholders on the issues the Subgroup wanted to hear more about, such as rebating, discounts, prescription drug pricing, and how PBMs are currently regulated. The Subgroup’s goal was to have its members all equally educated on these issues before it started drafting a model.

Following these informational meetings, the Subgroup determined that it had received sufficient information to move forward with drafting the proposed model. In November 2019, the Subgroup established an ad hoc technical drafting group to develop an initial draft for the full Subgroup’s review. The ad hoc technical drafting group met in December 2019 and January 2020. Due to the COVID-19 pandemic, the Subgroup was unable to meet to discuss the ad hoc technical drafting group’s draft until July 2020. During that meeting, the Subgroup discussed the initial draft and formally exposed the draft for public comment until Sept. 1, 2020. Following the end of the public comment deadline, the Subgroup met Oct. 22, 2020; Oct. 8, 2020; Oct. 1, 2020; Sept. 24, 2020; and Sept. 14, 2020, to discuss the Sept. 1, 2020, comments received on the proposed new model. During its Oct. 29, 2020, meeting, the Subgroup adopted the new model and forwarded it to the Task Force for its consideration.

As adopted by the Subgroup, at its core, the PBM model is a PBM licensing model. Sections 1–4 of the proposed PBM model set out the model’s purpose, scope, and definitions. Section 5 provides the PBM licensing provisions, including provisions related to approving initial PBM licenses and renewals. Section 6—Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices includes language related to gag clauses and information-sharing for the purposes of enforcement. Section 7 of the proposed PBM model provides enforcement language and penalties for any violations of the model act. Section 8—Regulations provides that the commissioner may promulgate regulations relating to PBMs that are not inconsistent with the model act. Section 8 also includes a drafting note to Section 8 to providing state statutory citations for 15 topic areas that some states might want to consider when developing their state legislation regulating PBMs. Section 9 and Section 10 provide, respectively, for the severability of the model act’s provisions and an effective date.

The Task Force met during the 2020 Fall National Meeting to consider the new PBM model. Given some issues with the proposed PBM model, particularly issues concerning a proposed drafting note for Section 8, the Task Force deferred acting on the PBM model and exposed it for an additional 30-day public comment period. Following the end of the public comment period, the Task Force met March 1 to discuss the comments received. During this meeting, the Task Force extensively discussed the comments received on the Section 8 drafting note and the potential impact of the U.S. Supreme Court’s decision in *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* on the draft PBM model. The Task Force adopted the PBM model March 18 and forwarded it to the Health Insurance and Managed Care (B) Committee for its consideration. The Committee deferred acting on the proposed PBM model during its meeting at the Spring National Meeting. The Committee extensively discussed the proposed Section 8 drafting note during a meeting June 22. Following that discussion, the Committee adopted the PBM model without the Section 8 drafting note to address concerns about the precedent of including optional sections the states could consider in adopting an NAIC model. In addition, in making this decision, the Committee considered that the Task Force had adopted a new charge for the Subgroup to develop a white paper that would explore the PBM business practices highlighted in the drafting note, including current and emerging state laws on these practices.

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

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force drafted the proposed new model. The members of the Subgroup were: Alabama, Alaska, Arkansas, California, District of Columbia, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Tennessee, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Oregon chaired the Subgroup. Nebraska was vice chair of the Subgroup.

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

The Regulatory Framework (B) Task Force established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup in 2018. In 2019, the Task Force adopted a charge for the Subgroup to, “[c]onsider developing a new NAIC model to establish a licensing or registration process for pharmacy benefit managers (PBMs). The Subgroup may consider including in the new NAIC model provisions on PBM prescription drug pricing and cost transparency.”

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)

Beginning in March 2019 and ending in October 2020, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup reviewed and discussed all the comments received. Numerous interested parties participated in the drafting process. The interested parties represented all stakeholder groups, including consumers, insurers, providers, and PBM representatives. Each draft of proposed revisions was posted to the Subgroup’s web page on the NAIC website. All comment letters received were also posted. The Subgroup met in open meetings throughout the drafting process. In addition to the Subgroup’s drafting process, during its discussions of the PBM model, the Regulatory Framework (B) Task Force also held open meetings and posted all comment letters on its website.

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)

Beginning in March 2019 and ending in October 2020, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup reviewed and discussed all the comments received. Numerous interested parties participated in the drafting process. The interested parties represented all stakeholder groups, including consumers, insurers, providers, and PBM representatives. Each draft of proposed revisions was posted to the Subgroup’s web page on the NAIC website. All comment letters received were also posted. The Subgroup met in open meetings throughout the drafting process. In addition to the Subgroup’s drafting process, during its discussions of the PBM model, the Regulatory Framework (B) Task Force also held open meetings and posted all comment letters on its website.

6. A Discussion of the Significant Issues (items of some controversy raised during the drafting process and the group’s response)

There was one significant item of controversy raised and ultimately resolved during the drafting process. The item of controversy concerned the proposed drafting note to Section 8. The proposed drafting note provided state statutory citations for 15 topic areas reflecting current PBM business practices that some states might want to consider when developing their state legislation regulating PBMs. The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup took this approach as a compromise between some states that wanted the PBM model to focus only on the licensing and registration by state departments of insurance (DOIs) and other states that wanted to go further to include substantive provisions related to these PBM business practices. The 15 topic areas are those areas where the Subgroup found, at this time, a lack of national consensus to include in the proposed PBM model. During the Regulatory Framework (B) Task Force and the Health Insurance and Managed Care (B) Committee discussion of the PBM model, concerns were raised about the potential of a lack of uniformity in adoption by the states, which is a key component of the NAIC model law development procedures, if states selected different provisions to include in their state law in implementing the PBM model. Given this concern, some stakeholders suggested that the options approach in the Section 8 drafting note was not the appropriate approach to take and instead suggested that the Task Force consider a charge to the Subgroup to develop a white paper that would examine current and emerging state laws related to the PBM business practices outlined in the drafting note. Following its adoption of the PBM model, during its June 15 meeting, the Task Force adopted such a charge for the Subgroup. During its June 22 meeting, the Committee decided to delete the Section 8 drafting note, given the adoption of the Subgroup charge to develop a white paper and the issues related to the drafting note.

Another issue that arose was whether to defer adoption of the PBM model because of the *Rutledge* decision, which upheld an Arkansas law regulating certain PBM business practices. Those suggesting deferring the PBM model adoption asserted that the *Rutledge* decision supported state efforts to enact laws regulating PBM business practices, and the PBM model should be revised to include substantive provisions related to these PBM business practices. The Task Force decided to move forward with the PBM model, as drafted by the Subgroup, because of the different interpretations of the *Rutledge* decision as it relates to Employee Retirement Income Security Act of 1974 (ERISA) preemption of state laws regulating PBM business practices. To address this issue, the Task Force included in its charge to the Subgroup to develop a white paper language requiring the Subgroup to also examine the impact of the *Rutledge* decision on states seeking to enact laws regulating certain PBM business practices. In its discussions related to this issue, the Committee supported addressing this issue through the white paper.

The Subgroup also received comments concerning Section 6. Some commenters suggested that the gag clause provision in this section should mirror the federal gag clause language. The Subgroup did not accept that suggestion.

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

None.