



## SUMMARY OF THE PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT AND ADOPTING STATES

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### PROPOSED UPDATE

NAIC proposed the model act summarized here in 2011. Earlier this year, NAIC sought suggestions from a variety of interested parties (e.g., the American Medical Association, pharmaceutical manufacturers, and others) to update the act.

NAIC published a [compilation](#) of the suggestions and is currently reviewing them. This report does not include the suggestions as they are extensive and have not yet been finalized by NAIC.

### ISSUE

Summarize the Prescription Drug Benefit Management Model Act and list the states that have adopted it.

### SUMMARY

The National Association of Insurance Commissioners (NAIC) developed the [Health Carrier Prescription Drug Benefit Management Model Act](#) to provide standards for the establishment, maintenance, and management of prescription drug formularies and other pharmaceutical benefits (model act, §§ 1-2).

NAIC conducted a 50-state survey prior to the model's adoption to review existing processes and regulations. The group also solicited feedback from interested parties, who recommended that pharmaceutical benefit managers (PBMs) and health processes be used as the foundation for the model. Existing NAIC model laws and regulations were reviewed to determine whether drug formulary standards could be incorporated into the new model.

Currently three states have adopted the model act. South Dakota (S.D. Codified Laws §§ 58-29E-1 to 58-29E-11) and Rhode Island (R.I. Gen. Laws §§ 27-20.8-1 to 27-20.8-2) adopted the act in 2004, and California (2011 Cal. Health & Safety 1367.241) adopted it in 2011.

Note that other states' statutes may provide the commissioner with sufficient authority to implement the model act as regulation, rather than legislation.



This report provides an overview of the model act by section.

## **MODEL ACT**

The following provides a brief summary of selected sections of the model act, omitting the sections that are minor or technical.

### ***Definitions (§ 3)***

There are 26 terms defined in section 3. A selection of terms is defined below.

- “Formulary” is defined as a list of prescription drugs developed by a health carrier or its designee.
- “Pharmaceutical benefit management procedure” (PBMP) refers to any of the following used to manage prescription drug benefits: (1) formularies, (2) dose restrictions, (3) prior authorization requirements, or (4) step therapy requirements.
- “Pharmacy and therapeutics (P&T) committee” is broadly defined as an advisory committee whose membership has (1) expertise in the appropriate prescribing, dispensing, and monitoring of outpatient prescription drugs and drug use review, evaluation, and intervention, and (2) is employed by the health carrier.

### ***Applicability and Scope (§ 4)***

The model act applies to health carriers (e.g., regulated insurers or health care providers) providing benefits for outpatient prescription drugs. It does not apply to prescription drugs excluded from a covered person’s health benefit plan.

### ***Requirements for the Development and Maintenance of Prescription Drug Formularies and Other PBMPs (§ 5)***

This section outlines the establishment, operation, and responsibilities of P&T committees. Carriers must ensure that P&T committees:

1. develop and maintain formularies or any other PBMP,
2. address potential conflicts of interest that committee members may have with drug manufacturers,
3. evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs when creating formularies and other PBMPs,

4. maintain documentation and provide it to the health carrier upon request, and
5. annually consider the need for and implement appropriate updates and changes to the formulary or other PBMPs.

Health carriers are permitted to contract with another person or entity to perform the functions of a P&T committee.

### ***Information to Prescribers, Pharmacies, Covered Persons, and Prospective Covered Persons (§ 6)***

Health carriers must both maintain a current formulary and information on which prescription drugs are subject to a PBMP. These must be made available to prescribers and pharmacies. If the health carrier changes the coverage of a particular prescription drug, prescribers, pharmacies, and covered persons must be notified within certain timeframes, generally 60 days.

If a person covered by the health carrier's plan requests, carriers must make the following available:

1. current formulary list, including which prescription drugs are subject to a PBMP;
2. information on what must be submitted for a medical exception;
3. an explanation of the amount the out-of-pocket charge may change;
4. an explanation that a person should check with the health carrier for changes in coverage before obtaining a refill; and
5. an explanation that, should there be a change in coverage, the covered person should consult their prescribing provider to determine whether the original prescribed drug is still appropriate or whether there is an acceptable alternative drug.

### ***Medical Exceptions Approval Process (§ 7)***

Health carriers must maintain a medical exceptions process allowing a covered person to request approval for:

1. coverage of a prescription drug that is not covered in the health carrier's formulary,
2. continued coverage of a prescription drug whose coverage has recently been discontinued, and
3. an exception to a PBMP that causes a prescription drug not to be covered.

This section provides details on the medical exceptions request and approval process and penalties for failure to follow it.

### ***Record Keeping and Reporting Requirements (§ 8)***

Health carriers are required to maintain records showing compliance with the act as implemented by the adopting state. The records must be maintained for three years or until the health carrier's next market conduct examination, whichever is later.

Data related to medical exceptions requests, including how many are granted or denied, must be maintained and made available to the commissioner upon request.

### ***Disclosure Requirements (§ 10)***

Health carriers using a formulary or other PBMP must:

1. disclose both the existence of the formulary or PBMP and the existence of other plan restrictions or requirements affecting prescription drug coverage,
2. describe the medical exceptions process (see § 7), and
3. describe the grievance-filing process for appeals of a medical exceptions request denial.

In layperson's terms, the health carrier must:

1. define what a formulary and PBMP is, and state that further information will be provided at the request of a covered person;
2. explain that out-of-pocket prescription drug expenses may change from time-to-time;
3. explain that the covered person should check with the health carrier for changes in coverage before obtaining a refill; and
4. explain that, should there be a change in coverage, the covered person should consult their prescribing provider to determine whether the original prescribed drug is still appropriate.

### ***Regulations & Penalties (§§ 11 & 12)***

The act does not specify such things as whether an adopting state will issue regulations or set penalties for violations. It simply provides placeholder sections for these items.

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