

## HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

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### Section 1. Title

This Act shall be known and may be cited as the Health Carrier Prescription Drug Benefit Management Act.

**Drafting Note:** In some states existing statutes may provide the commissioner with sufficient authority to promulgate the provisions of this Act in a regulation format. States should review existing authority and determine whether to adopt this model as an act or adapt it to promulgate as a regulation.

### Section 2. Purpose and Intent

The purpose of this Act is to provide standards for the establishment, maintenance and management of prescription drug formularies and other pharmaceutical benefit management procedures used by health carriers that provide prescription drug benefits.

**Drafting Note:** This Act is not intended to address the off-label use of prescription drugs. The “off-label use” of a prescription drug occurs when a prescription drug that has been approved by the federal Food and Drug Administration (FDA) for one or more indications, but the prescription drug is used for indications or in doses other than those stated in the labeling approved by the FDA. Many states have enacted “off-label use” laws or regulations to address this situation. States that have enacted “off-label use” laws or regulations should review the provisions of this Act to determine whether any provisions of this Act should be modified or clarified in light of those laws or regulations.

### Section 3. Definitions

For purposes of this Act:

A. “Authorized representative” means:

- (1) A person to whom a covered person has given express written consent to represent the covered person for the purpose of filing a medical exceptions request under Section 7 of this Act;

- (2) A person authorized by law to provide substituted consent for a covered person;
  - (3) A family member of the covered person or the covered person's treating health care professional when the covered person is unable to provide consent; or
  - (4) For the purpose of filing a medical exceptions request under Section 7 of this Act on behalf of a covered person, the covered person's prescribing, treating or dispensing provider.
- B. "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocol and practice guidelines used by the health carrier to determine the medical necessity and appropriateness of health care services.
- C. "Commissioner" means the Commissioner of Insurance.

**Drafting Note:** Use of the title of the chief insurance regulatory official wherever the term "commissioner" appears. If the jurisdiction of certain health carriers, such as health maintenance organizations, lies with some state agency other than the insurance department, or if there is dual regulation, a state should add language referencing that agency to ensure the appropriate coordination of responsibilities.

- D. "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of the health benefit plan.
- E. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.
- F. (1) "Dose restriction" means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period.
- (2) "Dose restriction" does not include:
- (a) A restriction set forth in the terms of coverage under a health carrier's health benefit plan for prescription drug benefits that limits the number of doses of a prescription drug that will be covered during a specific time period; or
  - (b) A restriction on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.
- G. "Facility" means an institutional provider of health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.
- H. "Formulary" means a list of prescription drugs that has been developed by a health carrier or its designee, which the health carrier or its designee references in determining applicable coverage and benefit levels.

- I. “Generic substitution” means the substitution of a generic version of a brand name prescription drug that has the same active ingredients, strength and intended use as the brand name prescription drug.

**Drafting Note:** Subsection I defines the term “generic substitution” for use in Section 6C of this Act. States should review the language of this definition and the use of this defined term in Section 6C of this Act to determine whether the language of this definition needs to be modified or clarified in light of any other existing state law regulating generic substitution.

- J. “Grievance” means a complaint submitted by or on behalf of a covered person regarding:

- (1) The availability, delivery or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;
- (2) Claims payment, handling or reimbursement for health care services; or
- (3) Matters pertaining to the contractual relationship between a covered person and a health carrier.

- K. “Health benefit plan” means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

- L. “Health care professional” means a physician, pharmacist or other health care practitioner who is licensed, accredited or certified to perform specified health care services consistent with state law.

**Drafting Note:** States may wish to specify the health care professionals to whom this definition may apply (e.g. physicians, pharmacists, psychologists, nurse practitioners, etc.). This definition applies to individual health care professionals, not corporate “persons.”

- M. “Health care provider” or “provider” means a health care professional or a facility.

- N. “Health care services” means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.

- O. “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 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 maintenance organization, a nonprofit 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.

- P. “Health maintenance organization” means a person that undertakes to provide or arrange for the delivery of health care services to covered persons on a prepaid basis, except for covered person’s responsibility for copayments, coinsurance or deductibles.

- Q. “Medical and scientific evidence” means evidence found in the following sources:

- (1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
  - (2) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline), and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);
  - (3) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;
  - (4) The following standard reference compendia:
    - (a) The American Hospital Formulary Service–Drug Information;
    - (b) Drug Facts and Comparisons;
    - (c) The American Dental Association Accepted Dental Therapeutics; and
    - (d) The United States Pharmacopoeia–Drug Information;
  - (5) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:
    - (a) The federal Agency for Healthcare Research and Quality;
    - (b) The National Institutes of Health;
    - (c) The National Cancer Institute;
    - (d) The National Academy of Sciences;
    - (e) The Centers for Medicare & Medicaid Services;
    - (f) The federal Food and Drug Administration; and
    - (g) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or
  - (6) Any other relevant data that is comparable to the sources listed in Paragraphs (1) through (5).
- R. “Participating provider” means a provider that, under contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

- S. “Person” means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, and any entity or any combination of the foregoing.
- T. “Pharmaceutical benefit management procedure” or “PBMP” includes any of the following that is used to manage prescription drug benefits:
- (1) A formulary;
  - (2) Dose restrictions;
  - (3) Prior authorization requirements; or
  - (4) Step therapy requirements.
- U. “Pharmacy and Therapeutics (P&T) committee” means an advisory committee or committees or equivalent body or bodies that is comprised of individuals who are either employed by or under contract with the health carrier or its designee, a majority of whose membership includes health care professionals, such as physicians and pharmacists, who, collectively, have current knowledge and expertise in:
- (1) Clinically appropriate prescribing, dispensing and monitoring of outpatient prescription drugs; and
  - (2) Drug use review, evaluation and intervention.

**Drafting Note:** The definition of “Pharmacy and Therapeutics (P&T) committee” is intentionally broad in order to permit health carriers to establish, or have established, one or more advisory committees or equivalent bodies to carry out one or more of the functions a P&T committee or committees are to perform, as described under Section 5 of this Act, related to development and maintenance of a formulary or other pharmaceutical benefit management procedure (PBMP). For example, a health carrier may choose to use one advisory committee or equivalent body to develop a formulary and another advisory committee or equivalent body to develop other PBMPs. The definition also is intentionally broad in order to provide health carriers with the flexibility to choose individuals for membership on an advisory committee or equivalent body who are employees of the health carrier or its designee and those who are not employees of the health carrier or its designee.

- V. “Prescriber” means any licensed, certified or otherwise legally authorized health care professional authorized by law to prescribe a prescription drug.
- W. “Prescription drug” means a drug that has been approved or is regulated and for which full marketing is otherwise permitted by the federal Food and Drug Administration and that can, under federal and state law, be dispensed only pursuant to a prescription drug order from a licensed, certified or otherwise legally authorized prescriber.

**Drafting Note:** States with laws that mandate coverage for patient costs associated with clinical trials and laws that mandate coverage for the off-label use of prescription drugs should review those laws to determine what impact, if any, this definition of “prescription drug” has on those laws. In particular, states should assess its impact in light of the definition’s reference to “full marketing.” This reference was included in order to exclude coverage under this Act for treatment investigational new drugs (INDs).

- X. “Prescription drug order” means an order from a prescriber or the prescriber’s designated agent to a pharmacist for a prescription drug to be dispensed.
- Y. “Prior authorization” means the process of obtaining prior approval for coverage of a prescription drug.

- Z. “Step therapy” means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition are to be prescribed.

**Section 4. Applicability and Scope**

- A. This Act shall apply to health carriers that provide benefits for outpatient prescription drugs under a health benefit plan issued by the health carrier where the health carrier or its designee administers coverage for this benefit through the use of a formulary or through the application of any other pharmaceutical benefit management procedure.
- B. Nothing in this Act shall be construed to apply to prescription drugs that are categorically or contractually excluded from a covered person’s health benefit plan. A provision in the benefit contract that purports to exclude all nonformulary prescription drugs shall not be considered a categorical exclusion for purposes of this Act.

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

- A.
  - (1) Each health carrier that provides benefits for prescription drugs and manages this benefit through the use of a formulary or other PBMP shall establish, or have established, one or more P&T committees that the health carrier considers appropriate to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.
  - (2) The health carrier shall ensure that any P&T committee established pursuant to this subsection has policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with developers or manufacturers of prescription drugs.
- B.
  - (1) The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process to:
    - (a) Evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary; and
    - (b) Evaluate applicable medical and scientific evidence concerning the safety and effectiveness of prescription drugs when developing any other PBMP.
  - (2) The health carrier shall ensure that any P&T committee maintains documentation of the process required under Paragraph (1) and makes any records and documents relating to the process available, upon request, to the health carrier for record keeping purposes under Section 8 of this Act.
- C. The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process to enable it, in a timely manner, but at least annually, to consider the need for and implement appropriate updates and changes to the formulary or other PBMPs based on:

- (1) Newly available scientific and medical evidence or other information concerning prescription drugs currently listed on the formulary or subject to any other PBMP and scientific and medical evidence or other information on newly approved prescription drugs and other prescription drugs not currently listed on the formulary or subject to any other PBMP to determine whether a change to the formulary or PBMP should be made;
  - (2) If applicable, information received from the health carrier with respect to medical exception requests made under Section 7 of this Act to enable the P&T committee to evaluate whether the prescription drugs currently listed on the formulary or subject to any other PBMP are meeting the health care service needs of covered persons; and
  - (3) Information relating to the safety and effectiveness of a prescription drug currently listed on the formulary or subject to any other PBMP or relating to clinically similar prescription drugs not currently listed on the formulary or subject to any other PBMP from the health carrier's quality assurance activities or claims data that was received since the date of the P&T committee's most recent review of that prescription drug.
- D. Subject to Section 9 of this Act, a health carrier may contract with another person to perform the functions of a P&T committee as described in this section.

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

- A. (1) Each health carrier or its designee shall maintain and make available to prescribers and pharmacies that are either participating in the health carrier's network or providing health care services to covered persons, by electronic means or, upon the request of a prescriber or pharmacy, in writing, the following:
- (a) Its current formulary list by major therapeutic category;
  - (b) Information indicating which prescription drugs, if any, are subject to a PBMP that has been developed and maintained pursuant to Section 5 of this Act; and
  - (c) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, information on how and what written documentation is required to be submitted in order for covered persons or their authorized representatives to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.
- (2) Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been

withdrawn from the market by the drug's manufacturer, the health carrier or its designee shall provide notice of that change to:

- (a) Prescribers at least sixty (60) days prior to the effective date of the change, unless the health carrier will provide coverage for up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person;
  - (b) Pharmacies participating in the health carrier's network by the effective date of the change; and
  - (c) Prescribers, who did not receive advance notice of the change because of the exception allowed under Subparagraph (a) of this paragraph, by the effective date of the change.
- B. (1) Each health carrier or its designee shall make available to covered persons and prospective covered persons electronically and, upon request, in writing in a manner calculated to be understood by a layperson:
- (a) Its current formulary list and any updates and changes to that list;
  - (b) Information indicating which prescription drugs, if any, are subject to a PBMP that has been developed and maintained pursuant to Section 5 of this Act; and
  - (c) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, information on how and what written documentation is required to be submitted in order for a covered person or the covered person's authorized representative to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.
- (2) In addition to the information to be provided under Paragraph (1), a health carrier or its designee electronically or in writing, upon request, shall explain the following in a manner calculated to be understood by a layperson that:
- (a) The amount that the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time;
  - (b) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and
  - (c) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug is



appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.

- C. (1) Whenever a health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a prior authorization or step therapy requirement that causes a particular drug not to be covered until the requirements of that PBMP have been met, the health carrier or its designee shall do one of the following:
- (a) At least sixty (60) days prior to its effective date, the health carrier or its designee shall notify covered persons, who are currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of the new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, of the change, in writing or, if the covered person has agreed to receive information in this manner, by electronic means; or
  - (b) Whenever a covered person, who is currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of a new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, requests a refill of the drug, the health carrier or its designee shall cover up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person during that time period and inform the covered person or the covered person's authorized representative of the change, unless:
    - (i) The covered person's prescribing provider agrees to a request from the health carrier or pharmacist to change the prescription in accordance with the formulary change or new or revised PBMP; or
    - (ii) For a formulary change or a new or revised PBMP pertaining to generic substitution, the prescription drug order does not prohibit generic substitution, the covered person agrees at the pharmacy to generic substitution, or generic substitution is required by state law.
- (2) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, the notice provided pursuant to Paragraph (1)(a) or as part of the information to be provided pursuant to Paragraph (1)(b) shall include information on how and what written documentation is required to be submitted for the covered person or the covered person's authorized representative to file a medical exceptions request in accordance with the health carrier's medical exceptions process set forth in Section 7 of this Act.
- (3) A health carrier or its designee shall not be required to provide the notice required pursuant to Paragraph (1)(a) or cover up to a 60-day supply of a prescription drug pursuant to Paragraph (1)(b) whenever:

- (a) The prescription drug is being discontinued from coverage on the formulary for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; or
- (b) The change in or a new PBMP for the prescription drug is for safety reasons.

## **Section 7. Medical Exceptions Approval Process Requirements and Procedures**

- A. Each health carrier that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met shall establish and maintain a medical exceptions process that allows covered persons or covered persons' authorized representatives to request approval for:
  - (1) Coverage of a prescription drug that is not covered based on the health carrier's formulary;
  - (2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary for reasons other than safety or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; or
  - (3) An exception to a PBMP that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses.

**Drafting Note:** This section is not intended to apply to requests for an exception to a pharmaceutical benefit management procedure (PBMP) involving a prior authorization requirement. Those types of requests for benefits for which a health carrier requires prior authorization are to be resolved under a health carrier's utilization review process.

- B. (1) A covered person or the covered person's authorized representative may file a request under Subsection A only if the covered person's prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person's disease or medical condition because:
  - (a) There is not a prescription drug listed on the formulary to treat the covered person's disease or medical condition that is an acceptable clinical alternative;
  - (b) The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:
    - (i) Has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

- (ii) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person; or
  - (c) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
- (2)
- (a) A health carrier may require the covered person or the covered person's authorized representative upon request to provide a written certification from the covered person's prescribing provider of the determination made under Paragraph (1).
  - (b) The health carrier may require the written certification to include any of, but no more than, the following information:
    - (i) The patient's name, group or contract number, subscriber number or other information necessary to identify the covered person;
    - (ii) Patient history;
    - (iii) The primary diagnosis related to the requested prescription drug that is the subject of the medical exceptions request;
    - (iv) Based on Paragraph (1)(a), (b) or (c), the reason:
      - (I) Why the formulary drug is not acceptable for the individual patient;
      - (II) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the individual patient; or
      - (III) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the individual patient;
    - (v) The reason why the prescription drug that is the subject of the medical exceptions request is needed for the individual patient or, if the medical exceptions request involves a dose restriction, why an exception to the dose restriction is needed for the individual patient; and
    - (vi) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

- (3) Participation by a provider on behalf of a covered person in the medical exceptions process established under this section shall be construed as being the same as a provider's advocating on behalf of a covered person within the utilization review process established by the health carrier for purposes of [insert reference to state law equivalent to Section 6J of the Managed Care Plan Network Adequacy Model Act].

**Drafting Note:** Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act provides that a health carrier may not prohibit a participating provider from advocating on behalf of covered persons within the utilization review or grievance processes established by the carrier or a person contracting with the carrier. The medical exceptions process established under this section for the review of requests for approval for exceptions to a formulary or being subject to a dose restriction or step therapy requirement is similar to the expedited utilization review process that health carriers may be required to establish for the review of health care service benefit requests. Paragraph (3) is intended to ensure that providers participating in the medical exceptions process established under this section have the same protections given to participating providers under Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act.

- C.
  - (1) Upon receipt of a request made pursuant to Subsection A, the health carrier shall ensure that the request is reviewed by appropriate health care professionals who, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person for whom the request has been made using documented clinical review criteria that:
    - (a) Are based on sound clinical evidence and medical and scientific evidence; and
    - (b) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health carrier's P&T committee or any other practice guidelines developed by the federal government, national or professional medical or pharmacist societies, boards and associations.
  - (2) The health care professional or professionals designated by the health carrier to review the request under Paragraph (1) shall ensure that the decision reached on the request is consistent with the benefits and exclusions under the covered person's health benefit plan with the health carrier.
- D.
  - (1) The medical exceptions process under this section shall require the health carrier to make a decision on a request made pursuant to Subsection A and provide notice of the decision to the covered person or the covered person's authorized representative as quickly as the covered person's particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under Subsection B(2).
    - (2) (a) If the health carrier fails to make a decision on the request and provide notice of the decision within the time frame required under Paragraph (1):
      - (i) The covered person shall be entitled to have coverage for, up to one month's supply of the prescription drug that is the subject of the request; and

- (ii) The health carrier shall make a decision on the request prior to the covered person's completion of the supply provided in Item (i).
  - (b) If the health carrier fails to make a decision on the request and provide notice of the decision prior to the covered person's completion of the supply provided for in Subparagraph (a) of this paragraph, the health carrier shall maintain coverage, as specified in Subparagraph (a) of this paragraph, on the same terms on an ongoing basis, as long as the prescription drug continues to be prescribed for that covered person and is considered safe for the treatment of the covered person's disease or medical condition until a decision is made on the request and notice of that decision is provided, unless there is a material change in the covered person's terms of coverage or the applicable benefit limits have been exhausted.
- E.
  - (1) Whenever a request made under this section is approved, the health carrier shall not require the covered person to request approval under this section for a refill, or a new prescription to continue using the prescription drug after the refills for the initial prescription have been exhausted, for the same prescription drug that was previously approved under this section for coverage or continued coverage or that was previously approved under this section as an exception to the health carrier's PBMP for that drug, subject to the terms of coverage under the health carrier's health benefit plan for prescription drug benefits as long as:
    - (a) The covered person's prescribing provider continues to prescribe the prescription drug to treat the same disease or medical condition of the covered person; and
    - (b) The prescription drug continues to be considered safe for treating the covered person's disease or medical condition.
  - (2) In addition to Paragraph (1), whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug.
  - (3) A health carrier shall not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

**Drafting Note:** A state that requires health carriers to establish specific formulary tiers with specific cost-sharing requirements for each tier should modify the language in Paragraph (3) to take into account the requirements of its law.

- F.
  - (1) Any denial by a health carrier of a request made under Subsection A:
    - (a) Shall be provided to the covered person or, if applicable, the covered person's authorized representative in writing or, if the covered person has agreed to receive information in this manner, electronically;
    - (b) Shall be provided electronically to the covered person's prescribing provider or, upon request, in writing; and

- (c) May be appealed by filing a grievance pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act].
  - (2) The denial shall, in a manner calculated to be understood by the covered person or, if applicable, the covered person's authorized representative, set forth:
    - (a) The specific reason or reasons for the denial;
    - (b) A reference to the evidence or documentation, including the clinical review criteria, including practice guidelines, and clinical evidence and medical and scientific evidence considered in reaching the decision to deny the request;
    - (c) Instructions for requesting, a written statement of the clinical and medical or scientific rationale for the denial; and
    - (d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act], including any time limits applicable to those procedures.
- G. A health carrier that permits a covered person's prescribing participating provider to make formulary and other PBMP exceptions without having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F with respect to the prescription drug orders of these prescribing participating providers.
- H. A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F if the health carrier:
  - (1) Has an expedited utilization review process as set forth in [insert reference in state law equivalent to Section 10 of the Utilization Review and Benefit Determination Model Act]; and
  - (2) Allows covered persons or their authorized representatives to use this process to seek approval for coverage of a prescription drug that is not otherwise covered because of the health carrier's formulary or because of any other PBMP requirement that restricts coverage of the prescription drug until the PBMP requirement has been met.
- I. Nothing in this section shall be construed to allow a covered person to use the medical exceptions process set out in this section to request coverage for a prescription drug that is categorically or contractually excluded from coverage under the covered person's health benefit plan.

## **Section 8. Record Keeping and Reporting Requirements**

- A. (1) Each health carrier shall maintain written or electronic records sufficient to demonstrate compliance with this Act, including records documenting the application of a process for making decisions on formularies and other PBMPs that is required under Section 5 of this Act and, except for a health carrier that satisfies the requirements of Section 7G or H of this Act, records documenting the application of the medical exceptions process that is required under Section 7 of this Act.
- (2) The records shall be maintained for period of three (3) years or until the completion of the health carrier's next market conduct examination, whichever is later, and shall be made available to the commissioner upon request by the commissioner.
- B. Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, each health carrier shall maintain data on and, upon request, make available to the commissioner the following information with respect to medical exceptions requests made under Section 7 of this Act:
  - (1) The total number of medical exceptions requests;
  - (2) From the total number of medical exceptions requests provided under Paragraph (1):
    - (a) The number of requests made for coverage of a nonformulary prescription drug;
    - (b) The number of requests made for continuing coverage of a prescription drug that the health carrier was discontinuing from coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; and
    - (c) The number of requests made for an exception to being subject to a PBMP that subjects a prescription drug to dose restrictions or step therapy requirements;
  - (3) The number of medical exceptions requests approved and denied; and
  - (4) Any other information the commissioner may request.

## **Section 9. Oversight and Contracting Responsibilities**

- A. A health carrier shall be responsible for monitoring all activities carried out by, or on behalf, of the health carrier under this Act and for ensuring that all requirements of this Act and applicable regulations are met.
- B. Whenever a health carrier contracts with another person to perform activities required under this Act or applicable regulations, the commissioner shall hold the health carrier responsible for monitoring the activities of that person with which the health carrier contracts and for ensuring that the requirements of this Act and applicable regulations with respect to that activity are met.

## Section 10. Disclosure Requirements

- A. Each health carrier that uses a formulary or any other PBMP shall in the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons:
- (1) Disclose the existence of the formulary and any other PBMP and that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered;
  - (2) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, describe the medical exceptions process that may be used to request coverage of nonformulary prescription drugs or to obtain an exception to being subject to a dose restriction or step therapy requirement; and
  - (3) If applicable, describe the process for filing a grievance as set forth in [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act] to appeal a denial of a medical exceptions request.
- B. (1) In addition to Subsection A, the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons shall explain in layperson's terms information on the health carrier's formulary and other PBMPs, including what a formulary and each PBMP that that health carrier uses is, and state that a copy of the formulary list and information about which prescription drugs are subject to a PBMP will be provided to a covered person by the health carrier or its designee on request.
- (2) In addition to the information explained under Paragraph (1), a health carrier shall explain in layman's terms in a separate document or other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that:
- (a) The amount that the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time;
  - (b) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and
  - (c) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.



## **Section 11. Regulations**

The commissioner may promulgate regulations to carry out the provisions of this Act. The regulations shall be subject to review in accordance with [insert statutory citation providing for administrative rulemaking and review of regulations].

## **Section 12. Penalties**

A violation of this Act shall [insert appropriate administrative penalty from state law].

## **Section 13. Separability**

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the 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 14. Effective Date**

This Act shall be effective [insert date].

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*Chronological Summary of Action (all references are to the Proceedings of the NAIC).*

*2002 Proc. 4<sup>th</sup> Quarter 279, 323-333 (adopted by task force).*

*2003 Proc. 1<sup>st</sup> Quarter 175 (adopted by parent committee).*

*2003 Proc. 2<sup>nd</sup> Quarter 12, 16 (adopted by Plenary).*

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**This chart is intended to provide readers with additional information to more easily access state statutes, regulations, bulletins or administrative rulings related to the NAIC model. Such guidance provides readers with a starting point from which they may review how each state has addressed the model and the topic being covered. The NAIC Legal Division has reviewed each state’s activity in this area and has determined whether the citation most appropriately fits in the Model Adoption column or Related State Activity column based on the definitions listed below. The NAIC’s interpretation may or may not be shared by the individual states or by interested readers.**

**This chart does not constitute a formal legal opinion by the NAIC staff on the provisions of state law and should not be relied upon as such. Nor does this state page reflect a determination as to whether a state meets any applicable accreditation standards. Every effort has been made to provide correct and accurate summaries to assist readers in locating useful information. Readers should consult state law for further details and for the most current information.**

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**KEY:**

**MODEL ADOPTION:** States that have citations identified in this column adopted the most recent version of the NAIC model in a **substantially similar manner**. This requires states to adopt the model in its entirety but does allow for variations in style and format. States that have adopted portions of the current NAIC model will be included in this column with an explanatory note.

**RELATED STATE ACTIVITY:** Examples of Related State Activity include but are not limited to: older versions of the NAIC model, statutes or regulations addressing the same subject matter, or other administrative guidance such as bulletins and notices. States that have citations identified in this column **only** (and nothing listed in the Model Adoption column) have **not** adopted the most recent version of the NAIC model in a **substantially similar manner**.

**NO CURRENT ACTIVITY:** No state activity on the topic as of the date of the most recent update. This includes states that have repealed legislation as well as states that have never adopted legislation.

<b>NAIC MEMBER</b>	<b>MODEL ADOPTION</b>	<b>RELATED STATE ACTIVITY</b>
Alabama	NO CURRENT ACTIVITY	
Alaska	NO CURRENT ACTIVITY	
American Samoa	NO CURRENT ACTIVITY	
Arizona	NO CURRENT ACTIVITY	
Arkansas	NO CURRENT ACTIVITY	
California		2011 CAL. HEALTH & SAFETY 1367.241 (2011).
Colorado	NO CURRENT ACTIVITY	
Connecticut	NO CURRENT ACTIVITY	
Delaware	NO CURRENT ACTIVITY	
District of Columbia	NO CURRENT ACTIVITY	
Florida	NO CURRENT ACTIVITY	
Georgia	NO CURRENT ACTIVITY	
Guam	NO CURRENT ACTIVITY	

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<b>NAIC MEMBER</b>	<b>MODEL ADOPTION</b>	<b>RELATED STATE ACTIVITY</b>
Hawaii	NO CURRENT ACTIVITY	
Idaho	NO CURRENT ACTIVITY	
Illinois	NO CURRENT ACTIVITY	
Indiana	NO CURRENT ACTIVITY	
Iowa	NO CURRENT ACTIVITY	
Kansas	NO CURRENT ACTIVITY	
Kentucky	NO CURRENT ACTIVITY	
Louisiana	NO CURRENT ACTIVITY	
Maine	NO CURRENT ACTIVITY	
Maryland	NO CURRENT ACTIVITY	
Massachusetts	NO CURRENT ACTIVITY	
Michigan	NO CURRENT ACTIVITY	
Minnesota	NO CURRENT ACTIVITY	
Mississippi	NO CURRENT ACTIVITY	
Missouri	NO CURRENT ACTIVITY	
Montana	NO CURRENT ACTIVITY	
Nebraska	NO CURRENT ACTIVITY	
Nevada	NO CURRENT ACTIVITY	
New Hampshire	NO CURRENT ACTIVITY	
New Jersey	NO CURRENT ACTIVITY	
New Mexico	NO CURRENT ACTIVITY	

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<b>NAIC MEMBER</b>	<b>MODEL ADOPTION</b>	<b>RELATED STATE ACTIVITY</b>
New York	NO CURRENT ACTIVITY	
North Carolina	NO CURRENT ACTIVITY	
North Dakota	NO CURRENT ACTIVITY	
Northern Marianas	NO CURRENT ACTIVITY	
Ohio	NO CURRENT ACTIVITY	
Oklahoma	NO CURRENT ACTIVITY	
Oregon	NO CURRENT ACTIVITY	
Pennsylvania	NO CURRENT ACTIVITY	
Puerto Rico	NO CURRENT ACTIVITY	
Rhode Island		R.I. GEN. LAWS §§ 27-20.8-1 to 27-20.8-2 (2004/2008).
South Carolina	NO CURRENT ACTIVITY	
South Dakota		S.D. CODIFIED LAWS §§ 58-29E-1 to 58-29E-11 (2004).
Tennessee	NO CURRENT ACTIVITY	
Texas	NO CURRENT ACTIVITY	
Utah	NO CURRENT ACTIVITY	
Vermont	NO CURRENT ACTIVITY	
Virgin Islands	NO CURRENT ACTIVITY	
Virginia	NO CURRENT ACTIVITY	
Washington	NO CURRENT ACTIVITY	
West Virginia	NO CURRENT ACTIVITY	

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<b>NAIC MEMBER</b>	<b>MODEL ADOPTION</b>	<b>RELATED STATE ACTIVITY</b>
Wisconsin	NO CURRENT ACTIVITY	
Wyoming	NO CURRENT ACTIVITY	



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Before adoption of the model, the working group conducted a state survey outlining prior drug formulary and pharmacy benefit manager regulation (PBM). **2000 Proc. 1<sup>st</sup> Quarter 157.** The working group also obtained drug formulary and PBM information from interested parties and received comments during an informational public hearing. **2000 Proc. 1<sup>st</sup> Quarter 170.**

The group decided to develop a new model act concerning the development, maintenance and management of health plan prescription drug formularies. Interested parties recommended that PBM and health processes be used as foundation for the new model. A discussion draft was developed from information obtained by the NAIC state survey on existing drug formulary and PBM regulation. **2000 Proc. 3<sup>rd</sup> Quarter 230.**

NAIC staff reviewed its model laws and regulations to determine whether drug formulary standards could be incorporated into an existing model. **2000 Proc. 3<sup>rd</sup> Quarter 232.**

#### **Section 1. Title**

#### **Section 2. Purpose and Intent**

The working group studied issues surrounding drug formulary regulation and pharmaceutical benefit management companies (PBMs). In particular, the task force focused on the concept of access as it relates to the cost of prescription drugs and drug formularies. **2000 Proc. 1<sup>st</sup> Quarter 304.**

A regulator requested comments from group members regarding state regulation of PBMs. The regulator was concerned with the absence of regulatory oversight over PBMs and the services PBMs provide to employers and health plans. Another regulator suggested that states also look into PBM involvement with the sale of noninsured discount drug cards. **2000 Proc. 1<sup>st</sup> Quarter 304.**

The group held a public hearing and heard testimony from interested parties on drug formulary development, maintenance and PBM services. During the course of the hearings, the group questioned and heard testimony from three (3) PBM representatives, one (1) provider representative, three (3) consumer representatives and three (3) health plan representatives. Important issues included dosage policies, PBM contractual relationships, drug rebate and discount negotiations, exception requests, regulatory oversight, hold-harmless contract provisions and formulary changes. **2000 Proc. 2<sup>nd</sup> Quarter 197.**

The group discussed consumer awareness of health plan formularies as well as consumer access to non-formulary prescription drugs. They delegated all downstream risk issues to another working group. **2000 Proc. 3<sup>rd</sup> Quarter 230.**

The group met by conference call and focused on regulating drug formularies as opposed to other PBM procedures. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The group requested information from interested parties regarding PBM procedures currently used by health carriers. **2001 Proc. 4<sup>th</sup> Quarter 221.**

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#### Section 3. Definitions

The working group discussed possible definitions for the term “formulary.” The group also considered removing the term “prescription” from the definition of “Prescription Drug.” A regulator was concerned that the inclusion of the term “pharmaceutical management procedures” extended the scope of the model beyond the subject of drug formularies. **2000 Proc. 4<sup>th</sup> Quarter 228.**

The working group agreed to develop a definition of “P&T Committee” for inclusion in the next draft of the model. **2000 Proc. 4<sup>th</sup> Quarter 228.**

The working group reviewed comments with respect to three definitions in Sections 3, 5 and 6 of the draft model. A regulator clarified that the definition of “Formulary” was intentionally broad so as to include all types of formularies, not just closed formularies. Another regulator noted that, even if the reference to “tiered list” was deleted, such formularies were implicitly covered by the definition. This was because the group added the phrase “that are eligible for coverage” to the definition. After much discussion, the group accepted a proposed definition of formulary that removed the specific reference to “tiered list,” but remained broad enough to include both closed and tiered formularies. **2001 Proc. 1<sup>st</sup> Quarter 163.**

The group put off the examination of the “Pharmaceutical Benefit Management Procedure” definition until after the completion of other sections. A regulator requested clarification of the reference to “class of drugs” in the description of “Open Formulary.” Another regulator expressed concern with an interested party’s proposed definition of nonformulary drugs. It was suggested that the topic was more appropriate for Section 6. **2001 Proc. 1<sup>st</sup> Quarter 163.**

The group discussed its goals with respect to formulary requirements. A regulator proposed requiring health carriers that use formularies to disclose the formulary list as well as information on the level of coverage to covered persons. Another regulator agreed and further suggested that the model should provide guidance on formulary makeup, including preferred drugs. **2001 Proc. 1<sup>st</sup> Quarter 163.**

The working group discussed the definition of “Medical or Scientific Evidence.” After considering several comments regarding Paragraph (2) the group agreed to delete that paragraph. The group also replaced the reference in Paragraph (1)(d)(ii) with a compendium entitled “Facts and Comparisons” and added a reference to the Food and Drug Administration in Paragraph (1)(e). **2001 Proc. 1<sup>st</sup> Quarter 163.**

The working group discussed the definition of “Pharmacy and Therapeutics (P&T) Committee.” After addressing interested parties’ comments, the group substituted the term “actively practicing” with “current.” The group accepted language offered by an interested party permitting a P&T committee to be “an advisory committee or equivalent body.” The group also accepted another interested party’s recommendation to replace “or” with “and” between paragraphs (1) and (2). **2001 Proc. 1<sup>st</sup> Quarter 163.**

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#### Section 3 (cont.)

A regulator pointed out that although the revised definition of “Pharmaceutical Management Procedures” deleted references to other types of PBMPs, two sections retained the original definition. The group also discussed the deletion of the term “devices.” The group agreed to develop a definition of “device” that addressed medical or clinical issues, not brand preference issues. The group again discussed the wording for the definition of “Formulary.” **2001 Proc. 1<sup>st</sup> Quarter 174.**

The working group revised the definition of “Formulary.” The group also revised the definition of “Medical or Scientific Evidence.” Finally, the group revised the definition of “Pharmacy and Therapeutics (P&T) Committee.” **2001 Proc. 3<sup>rd</sup> Quarter 90.**

The working group adopted a regulator’s direction to review and submit comments on the “Pharmaceutical Benefit Management Procedure Regulatory Matrix” for the purpose of finalizing the definition of “Pharmaceutical Benefit Management Procedures.” **2001 Proc. 4<sup>th</sup> Quarter 230.**

The group adopted an interested party’s suggestion to return the term “formulary” to the definition of “Pharmaceutical Benefit Management Procedures.” **2002 Proc. 1<sup>st</sup> Quarter 200.**

The group adopted a regulator’s recommendation creating a definition of "Dose Restrictions" based on the language from the definition of "Pharmaceutical Benefit Management Procedures." After discussing the term “formulary,” the group deleted Subsection N(2), substituted the word “use” for “coverage” and struck any language referring to reimbursement. The group rejected an interested party’s suggestion to alter the definition of “Step Therapy.” The group revised the definition of “Authorized Representative” allowing the provider to file medical exceptions requests without written consent. The group also deleted the definition of “Adverse Determination.” The group added the phrase "information submitted to" and substituted the phrase “relevant data” for “medical or scientific evidence” in the definition of “Medical or Scientific Evidence.” **2002 Proc. 2<sup>nd</sup> Quarter 235.**

The group rejected comments requesting that the phrase “actively practicing” be reinserted to the definition of “Pharmacy & Therapeutics (P&T) Committee.” The group also deferred making a decision on an interested party’s suggestion to amend the definition of “Prescription Drug.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group accepted an interested party’s proposed modification to the definition of "Pharmaceutical Benefit Management Procedures." **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group adopted an interested party’s suggested revisions including other types of providers in the definition of “Authorized Representative.” The group decided to leave the definition of “Clinical Review Criteria” unchanged despite the concerns of an interested party. The group also decided against expanding the definition of “Covered Benefits.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

After discussion, the group deleted the phrase “the number of doses for a particular dosage level” from the definition of “Dose Restriction.” The group disagreed with interested party comments and

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#### Section 3 (cont.)

did not add the phrase “through the use of a formulary of PBMP” to the same definition. The group revised the definition of “Generic Substitution” and included a reference to state law. The group rejected an interested party’s suggestion to narrow the definitions of “Grievance” and “Formulary.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The working group deleted the reference to "information submitted to" located in the lead-in paragraph to the definition of “Medical and Scientific Evidence.” The group also added the words “evidence found in” to the same paragraph. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group clarified the definition of “Pharmaceutical Benefits Management Procedure” by adding the word "requirements" after the words "prior authorization." Otherwise, the group left the definition unchanged. The group also rejected an interested party’s recommendations regarding the definition of “Pharmacy & Therapeutics (P&T) Committee.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group added language describing the phrase “full marketing” located in the definition of “Prescription Drug.” The group also included a drafting note cautioning states that have clinical trial laws or off-label use laws about this language. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

After discussion, the group accepted an interested party’s recommendation to amend the drafting note describing “off-label use.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group agreed to not define the term “coverage.” The group also rejected a regulator’s suggestion to alter the definition of “Prior Authorization.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group adopted an interested party’s suggestion that the drafting note for the applicability of state "off-label" use laws include language alerting states to review its own “off-label” use laws and regulations to determine whether any of the model’s provisions should be modified. **2002 Proc. 4<sup>th</sup> Quarter 321.**

The group added a drafting note to the definition of “Generic Substitution” alerting states that the language may affect other existing laws. The group revised the definition of “Health Maintenance Organization” to conform to revisions made in the NAIC Health Maintenance Organization Model Act. The working group also revised the definition of “Pharmacy and Therapeutics (P&T) Committee” to reflect the intent that the majority of the members of the committee include health care professionals. **2002 Proc. 4<sup>th</sup> Quarter 321.**

#### Section 4. Applicability and Scope

A regulator questioned whether the working group agreed on the scope of the model. Another regulator stated that the group previously decided that the model should apply to other pharmaceutical management procedures. The group deferred further discussions on whether, and how much, the model should regulate other pharmaceutical management procedures. An interested party suggested that the medical exceptions process should not apply to tiered formularies. A regulator refuted this contention. Another interested party cautioned that regulating other

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#### Section 4 (cont.)

pharmaceutical management procedures would lead towards mandating plan benefit design. Two regulators supported this statement. **2000 Proc. 4<sup>th</sup> Quarter 228.**

After discussion, the working group added the words “or its designee” and substituted the word “administers” for the word “manages.” **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The group added "a provision in the benefit contract that purports to exclude all nonformulary prescription drugs shall not be considered a categorical exclusion for purposes of this Act" to Subsection 4(E). **2002 Proc. 4<sup>th</sup> Quarter 321.**

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

A regulator suggested soliciting information from interested parties on the development of drug formularies. This regulator also suggested obtaining language from policy forms concerning the use and maintenance of drug formularies. Another regulator requested that the group develop standardized definitions for (1) open formulary, (2) restricted formulary, and (3) closed formulary. The group discussed at length the problems and various solutions surrounding the issue of access to nonformulary drugs. The NAIC stated that a drug formulary regulation state survey would be complete by the Summer National Meeting. **2000 Proc. 1<sup>st</sup> Quarter 304.**

A regulator emphasized the need for a process providing enrollees with prior notice and explanations for drug coverage denials. Another regulator noted that creating such a process involves both utilization review and formulary development issues. **2000 Proc. 3<sup>rd</sup> Quarter 230.**

The group took no action on the issue of hold harmless provisions found in pharmacists contracts with PBMs. The group delegated the issues of (1) pharmacists' capitation contracts, (2) PBMs' capitation contracts, and (3) health plan & PBM solvency to another working group. The group took no action on the issue of the practice of PBMs commingling funds. However, the group took note that the Third Party Administrator (TPA) Model addressed this issue. **2000 Proc. 3<sup>rd</sup> Quarter 232.**

The group took no action of the issue of including a “prompt pay” feature within the model. The group noted that the TPA model as well as the Unfair Claims Settlement Practices Model Act addressed this issue. The group took no action on the issue of rebate influence on PBM and health plan formulary development and decision-making. **2000 Proc. 3<sup>rd</sup> Quarter 232.**

In response to interested party comments, the working group agreed that the activities of the P&T committee involved formulary development and maintenance. However, the group put off the decision of whether the P&T committee should be involved in the development and maintenance of other pharmaceutical management procedures. **2000 Proc. 4<sup>th</sup> Quarter 228.**

The group considered comments from interested parties on the P&T committee membership. An interested party suggested that the model include conflict of interest provisions for members. A

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**Section 5** (cont.)

regulator requested input from the group on this topic as there were several comments concerning the makeup of the P&T committee as well as the requisite knowledge of its members. **2000 Proc. 4<sup>th</sup> Quarter 228.**

After discussion, the group deleted the phrase “at a minimum” from Paragraph (2). The group also agreed to redraft this provision for clarity to reflect the working group’s intent that each member does not need both types of expertise, but collectively, the committee should have both types of expertise. The working group rejected the suggestion that Paragraph (2) requires a majority of the P&T committee members to be health care professionals. **2000 Proc. 4<sup>th</sup> Quarter 228.**

The group discussed Paragraph (3), which outlines the process that the P&T committee should use in developing and maintaining the formulary. The group agreed to revise this paragraph using language currently used by the NAIC Health Carrier External Review Model Act. **2000 Proc. 4<sup>th</sup> Quarter 228.**

The group discussed Paragraph (4) at length. This paragraph sets out requirements for the annual review of the formulary and list of preferred prescription drugs. In addition, this paragraph requires health carriers to have a process for promptly responding to requests to add or delete a prescription drug from the formulary or preferred drug list. The group did not make any final decisions regarding Paragraph (4). However, the group kept in mind the question of possible triggers requiring the review of a formulary or preferred list. **2000 Proc. 4<sup>th</sup> Quarter 228.**

After discussion, the working group inserted the term “if available” to Subsection (2)(a)(ii) and revised this subparagraph to reflect comments made by interested parties. The group rejected another interested party’s suggestion to include the requirement that the P&T committee consider the “clinical outcome” of each prescription drug, in addition to the drug’s safety and effectiveness. **2001 Proc. 1<sup>st</sup> Quarter 163.**

A regulator requested comments from group members on how evidence used to confer preferred status on a formulary indicates how those drugs are expected to produce similar or better results for a majority of the population. Some group members expressed confusion about the meaning of this subparagraph and whether it was needed at all. The group agreed to work with interested parties to revise the language of (A)(2)(b). **2001 Proc. 1<sup>st</sup> Quarter 163.**

The working group revised Subparagraph (3)(a) requiring the P&T committee to review the formulary, at a minimum, on an annual basis. The group also collapsed Subparagraph (3)(b) into one provision requiring the P&T committee to consider new information with respect to prescription drugs both on and off the formulary. The group also received comments from an interested party regarding Subsection 5(B). **2001 Proc. 1<sup>st</sup> Quarter 163.**

The working group discussed comments regarding the distribution of formulary lists. In particular, the group considered whether formulary lists should be available through the Internet. **2001 Proc. 1<sup>st</sup> Quarter 163.**

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**Section 5 (cont.)**

After discussion, the group revised Subparagraph (C)(1) requiring health carriers or their designees to make the current formulary list available electronically as well as provide, upon request, a written copy using one of the methods currently listed in Subparagraphs (C)(1)(a), (b) or (c). The only conclusion the group made as to Subsection D(1), was that the provision should require health carriers to provide both current and prospective enrollees with information on the health carrier's formulary list. This information is to be made available electronically and, upon request, in writing. **2001 Proc. 1<sup>st</sup> Quarter 163.**

A regulator reviewed the provisions of Section 5 – Scope and Content of Prescription Drug Formulary Development and Maintenance. All revisions re-focused the model on drug formularies. The regulator stated that the next draft will include the revisions requested at the 2000 Winter National Meeting. This regulator also assured interested parties that all comments submitted on the draft dated Oct. 24, 2000 would be considered at that meeting. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The group discussed a possible provision that would require the state's insurance department to approve a health plan's formulary. The group decided to review states' laws regulating drug formularies to determine whether it was appropriate to include a drafting note. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The group discussed an interested party's question on whether the language in Section 5 requires a health carrier to establish or have established a P&T committee or whether an equivalent body could perform the same functions. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The group revised Subsection D(1) requiring health carriers to provide electronic access to their formulary list and, upon request, provide a written copy. The group postponed the discussion of health carrier disclosures, particularly with respect to tiered formularies, until review of Section 9. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

After much discussion, the group postponed any decisions on Subsection D(2) until they received additional information about Louisiana's approach to the issue of advance notice of formulary changes. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

The working group adopted revision #7, to Subsection C, requiring health carriers or their designees to maintain and make the formulary list available to participating providers by electronic means or, upon request, in writing. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

The group adopted Revision # 8 to Subsection D(1) requiring health carriers or their designees to make their formulary lists available and any updates and changes to a list available to covered persons and prospective covered persons electronically and, upon request, in writing. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

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**Subsection 5(A)(1)**

The working group discussed the comments received on Subsection A(1)(b). One interested party suggested that the language specifically require P&T committee members to recuse themselves whenever they have a direct conflict of interest. A regulator noted the possibility that such a requirement could result in the situation where all P&T committee members would have to recuse themselves. After discussion, the working group decided to leave the paragraph unchanged. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

**Subsection 5A(2)**

The group agreed to develop a drafting note for Subsection (A)(2)(a) suggesting that states be mindful of existing state law or regulation impacting formulary development and maintenance. The group also adopted revisions to (A)(2)(a) requiring the P&T committee to consider the safety and effectiveness of each prescription drug based on medical or scientific evidence, and available appropriate practice guidelines. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

A regulator noted that the current draft of Subsection A(2) imposed a higher standard for making formulary development and maintenance decisions than the required standard for making utilization review decisions. The information that the P&T committee would be required to consider is more appropriate when making a decision with respect to a medical exceptions request under Section 6 of the proposed model, not for making formulary development and maintenance decisions. The same regulator suggested that Subsection A(2)(a) be revised to require the P&T committee to have a process to evaluate medical or scientific evidence on drug safety and effectiveness when deciding what prescription drugs to include or exclude from a formulary. This regulator also recommended deleting Subsection A(2)(b). After receiving comments from interested parties concerning the appropriate standard of review to be used for formulary development and maintenance, the working group revised Subsection A(2)(a) and deleted Subsection A(2)(b). **2001 Proc. 4<sup>th</sup> Quarter 230.**

The working group deleted the drafting note for Subsection A(2). **2001 Proc. 4<sup>th</sup> Quarter 230.**

A regulator noted that because the term "prescribing protocols" is not defined, there could be some confusion as to whose prescribing protocols would be subject to this subparagraph. After discussion, the working group eliminated all references to the term "prescribing protocols" and modified the definition of PBMP as well as the definitions of other terms used in the definition of PBMP. **2002 Proc. 1<sup>st</sup> Quarter 200.**

After discussion the working group agreed to include an interested party's suggestion and revised the term "medical or scientific evidence" including the definition of this term in Section 3V. **2002 Proc. 1<sup>st</sup> Quarter 200.**



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#### Subsection 5 A(2) (cont.)

A regulator suggested adding language that would require the P&T committee to not only have a process, but to "use" that process to evaluate medical or scientific evidence. This regulator also suggested adding new section requiring the health carrier to maintain documentation of the evaluation process as part of a general requirement for the health carrier to maintain documentation sufficient to demonstrate compliance with entire model act. This regulator also noted that similar changes would have to be made to Section 5A(3)(b), which also requires the P&T committee to "have a process" for updating a formulary. Without objection, the working group adopted these suggestions. **2002 Proc. 1<sup>st</sup> Quarter 200.**

The working group deleted the word "periodically" from Revision # 6 to Subsection A(3). After discussion, the working group agreed to revise Subsection A(3)(b)(i) to include language requiring the P&T committee to implement revisions to the formulary based on new information concerning newly approved prescription drugs. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

Two regulators suggested deleting Subsection A(3)(a). Another regulator suggested modifying Subsection A(3)(a) to incorporate some of the elements of Subsection A(3)(b), namely, that an annual evaluation of a prescription drug currently on the formulary would only be required if there was new information about the drug. The group agreed to review Subsection A(3)(a), and possibly make changes to Subsection A(3)(b) at the same time, in order to avoid duplication of requirements. **2002 Proc. 1<sup>st</sup> Quarter 200.**

The group discussed interested parties' comments received on Subsection A(3). These comments proposed narrowing the kinds of information that a P&T committee may consider since the date of the most recent review of a particular prescription drug. After discussion, the working group accepted the suggested revisions. A regulator noted that several interested parties again questioned the timing of these reviews. Another regulator stated that unless a working group member wanted to revisit these comments, the working group would not discuss these comments again. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Subsection 5(C)(1)

The group discussed interested parties comments suggesting that the group delete the requirement that the information be provided only to participating providers or pharmacies. Interested parties also suggested deleting the specific reference to methods by which a carrier or its designee could provide the information in writing. An interested party suggested that this information be made available to any prescribing provider or pharmacy electronically and, in writing, by whatever means the carrier or its designee chooses. **2002 Proc. 1<sup>st</sup> Quarter 200.**

After discussion of the circumstances triggering advance notice of formulary or PBMP changes, the working group removed participating pharmacies from the 60-day advance notice requirement as well as that the notice be provided "by" the effective date of the change. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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#### Subsection 5D

After much discussion and input from interested parties, a regulator suggested that, unless the prescription drug is being removed from coverage under the formulary for safety reasons, health plans be required to provide: (1) a 60-day advance notice of a formulary change in writing to affected enrollees or, electronically, if an enrollee has agreed to receive information in this manner; or (2) a 60-day supply of the drug on the same terms as covered in the past whenever the enrollee learns of the formulary change at the pharmacy when requesting a refill of the drug and require the pharmacist to provide a notice to the enrollee that the enrollee should contact his or her physician about switching to an alternative formulary drug or use the medical exceptions process to continue coverage of the drug. In addition, for an enrollee who requests an exception under the medical exceptions process under Section 6, the enrollee would continue to receive refills of the prescription drug until the health carrier makes a decision on the request and notifies the enrollee of that decision. Without objection, the working group adopted this regulator's suggestion. In addition, the working group revised Section 5C to require the notice of formulary changes sent by health carriers to participating providers include a 60-day advance notice requirement. **2001 Proc. 4<sup>th</sup> Quarter 230.**

After additional discussion, the working group amended the requirement that a 60-day supply of the affected prescription drug be provided to covered persons. Subsection D(2) applies whenever a health carrier discontinues or changes the status of a formulary prescription drug. A health carrier or its designee would not have to provide a 60-day supply of the affected prescription drug if the covered person agrees to a generic substitution, or if generic substitution is required by state law. **2002 Proc. 1<sup>st</sup> Quarter 200.**

The working group revised Subsections C(1) and D(1) adding a new subparagraph providing covered persons and prospective covered persons information about the health carrier's medical exceptions process. **2002 Proc. 1<sup>st</sup> Quarter 200.**

A regulator pointed out a comment from an interested party suggesting that the information required under Subsection D(1) be provided in non-technical language that would be understood by lay readers. This regulator noted that the NAIC Utilization Review Model Act was being revised on this same point in order to comply with the federal Department of Labor claims procedure rule. The working group agreed to make similar changes to Subsection D(1). **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The working group discussed interested parties' comments regarding Subsection D(2). Several interested parties requested changes in the advance notice requirement contained in Subsection D(2)(i). A regulator stated that the working group extensively discussed this issue at previous meetings and that it would not revisit the issue again unless a working group member wished to do so. In addition, two interested parties suggested revising the language in Subsection D(2)(ii) in order to make clear that a covered person would not necessarily received the full 60-day supply at once, but that at least 60 days of the prescription drug would be covered if the drug were prescribed for at least that long. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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#### Subsection 5D (cont.)

As a compromise between high administrative costs or high out of pocket costs, a regulator suggested revising Subsection C(2) and Subsection D(2) so as to require health carriers to send advance notices to prescribers, participating pharmacies and covered persons only when the change would result in no coverage for the prescription drug under the formulary or no coverage for a prescription drug subject to a PBMP unless the PBMP requirement is satisfied. To fulfill this requirement, health carriers would still have the option of providing the 60-day advance notice or, if the health carrier chooses not to send advance notice, providing coverage for up to a 60-day supply of the prescription drug. This regulator also suggested revising Subsection D(1) to require disclosure to covered persons and prospective covered persons on changing co-payments and that they should check their health carrier's web site periodically for such changes. This regulator stated that the same language should also be added to Section 9, which describes other disclosure requirements. Without objection, the working group agreed to revise for both Subsection C(2) and Subsection D(2). The working group also agreed to remove Subsections C and D from Section 5 and create a new section. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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

The working group added a new provision to Section 6A(2) requiring health carriers to provide 60-day advance notice by the effective date of the change unless the health carrier will provide coverage for up to a 60-day supply of the drug. **2002 Proc. 4<sup>th</sup> Quarter 321.**

The working group adopted language revising Section 6A(2), Section 6C(1) and Section 7A, triggering the dose restriction requirements when application of the dose restriction "causes a prescription for a particular drug not to be covered for the number of doses prescribed." **2002 Proc. 4<sup>th</sup> Quarter 321.**

#### Subsection 6A

After listening to comments from interested parties and extensive discussion, the working group limited the scope of Section 6 to closed formularies. The working group agreed to make whatever revisions were necessary to Subsection A to clarify this intent. The working group condensed Subsection A(1) to state that the a covered person can make a medical exceptions request whenever they request a prescription drug that is not covered under the health carrier's formulary. The working group delayed making any decision with respect to Subsection A(2) until it reached a decision on whether covered persons should be provided notice of formulary changes, as currently provided in Subsection D. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

The working group discussed amending Subsection A(1) to make clear the working group's intent that Section 6 only applies to closed formularies. A contested issue was whether Section 6 would apply to formularies that are not entirely "closed," but have a co-payment or coinsurance requirement. The working group agreed that tiered formularies would fall within the scope of other sections of the model, particularly Section 5. The working group revised Subsection A(1). The group also amended Subsection B. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

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**Subsection 6A (cont.)**

After reviewing the comments received by interested parties for Subparagraph (A), the working group deleted the reference to “therapeutically equivalent” and substituted “there is not a prescription drug that is an acceptable clinical alternative.” **2001 Proc. 4<sup>th</sup> Quarter 230.**

**Subsection 6B**

The working group replaced the first use of the term "equivalent" with "therapeutically equivalent effect." The group deleted the second use of the term "equivalent." **2001 Proc. 2<sup>nd</sup> Quarter 158.** After extensive discussion, the working group retained the current language concerning the use of the word “certification,” but required that written certification be provided upon request. This gives health carriers the option of accepting verbal medical exceptions requests. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

The working group discussed the provisions of Subsection B(2)(b). A regulator suggested that the word "likely" be replaced with "reasonably expected." Another regulator questioned whether this provision would address the situation when the prescribing provider feels that the covered person needs the nonformulary prescription drug because of compliance issues. An interested party expressed the same concern and suggested that this subsection include another paragraph to address this concern. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

A regulator suggested revising Subparagraph (B) to include language from Subparagraph (C) as well as incorporate some of the comments from interested parties with respect to requiring the provider’s determination to be based on sound clinical and scientific or medical evidence. After discussion, the working group adopted this suggestion. **2001 Proc. 4<sup>th</sup> Quarter 230.**

A regulator suggested amending Subsection B(1) to specifically require health carriers to accept and act upon medical exceptions requests received from enrollees. Without objection, the working group rejected this suggestion. **2001 Proc. 4<sup>th</sup> Quarter 230.**

**Subsection 6C**

The working group deleted Subsection C. Subsection C required health carriers to develop a method to provide special notice to covered persons, or their authorized representatives, of a formulary change at the time the covered person is at an in-network pharmacy. The group believed that this subsection was no longer needed. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

**Subsection 6D**

The working group amended Subsection D(2) to include the review of appropriate practice guidelines developed by professional pharmacist societies in addition to professional medical societies. The working group also revised Subsection 5A(2)(ii). This subsection is identical to Subsection D(2). **2001 Proc. 2<sup>nd</sup> Quarter 158.**

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**Subsection 6D (cont.)**

An interested party suggested revising Subsection D(1) to include language clarifying that the clinical review criteria be "consistent with the scope of the benefit and with the reason for the benefit." The working group supported the idea behind this comment, but agreed that there was a better way of phrasing it and better place in the model for this language. A regulator suggested adding alternative language in an appropriate place in the model "consistent with benefits and exclusions under the policy." **2001 Proc. 2<sup>nd</sup> Quarter 158.**

A regulator requested comments from working group members concerning a suggested revision that added to the list of appropriate practice guidelines. Another regulator expressed concern about adding this language because the health carrier would use its own criteria when making the decision on a medical exceptions request. Another regulator said that this language was unnecessary because, as currently written, this provision allows health care professionals to use any appropriate practice guidelines. It does not limit what practice guidelines they can use. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

The group amended Subsection D(1). The amendments to Subsection D(1) are identical to the amendments already adopted by the working group for Section 5A(2)(a). The language added to Subsection D(2) requires health care professionals reviewing the medical exceptions request to ensure that their decision is consistent with the benefits and exclusions of the covered person's health benefit plan. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

A regulator stated that several comments had been received concerning these provisions suggesting areas that needed to be clarified. Particularly, the comments had suggested that the language be revised to ensure that an enrollee could not continue to receive a prescription drug that is no longer safe. The working group agreed to make those revisions to both Subsection D(2)(b) and Subsection E. **2001 Proc. 4<sup>th</sup> Quarter 230.**

A regulator pointed out an amendment to Subsection D(2)(b) offered by an interested party. This suggested revision would require a health carrier, whenever the health carrier fails to make a decision on the request in a timely manner, to maintain coverage of the prescription drug that is the subject of the medical exceptions request at the plan's lowest formulary co-payment tier until a decision is made on the request unless the plan contract is terminated or the enrollee or the plan sponsor terminates the pharmacy benefit provisions under the plan. The working group rejected part of the suggested revision that would specify the co-payment that the enrollee would have to pay for the prescription drug. The working group decided to reserve making a decision on the remainder of the suggested revision that would add language addressing the situation when the plan contract is terminated or the plan sponsor or the enrollee terminates the prescription drug benefit because it was unclear whether such a situation was not already implicitly addressed in the model. **2001 Proc. 4<sup>th</sup> Quarter 230.**

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#### Subsection 6E

The working group discussed several comments concerning the two-business days time frame for the health carrier. These comments ranged from suggesting three (3) business days to no time frame. A regulator noted that under the NAIC Utilization Model Act (UR model) health carriers are required to make a decision on a prospective review request within two (2) working days. After much discussion, a regulator suggested changing the time frame to three (3) business days (72 hours). This regulator also suggested revising Subsection E(2)(b) requiring the health carrier to reimburse up to one month's supply of the prescription drug that is the subject of the review, until the health carrier reaches a decision. **2001 Proc. 2<sup>nd</sup> Quarter 158.**

The working group considered proposed amendments that would require the health carrier to make a decision on the request within 72 hours after receipt of all of the information necessary to make a decision. Under Subsection E(2)(a), if the health carrier failed to make a decision within this time frame, the health carrier must pay for a month's supply of the prescription drug that is the subject of the request. If the health carrier failed to make a decision on the request prior to the completion of that supply, health carrier shall pay for a month-to-month supply of the prescription drug until a decision is made. A regulator offered alternative language for Subsection E(2)(b). After discussion, the working group adopted the regulator's alternative language. The working group agreed however, to allow interested parties to submit comments with respect to this language at its meeting during the NAIC 2001 Fall National Meeting. **2001 Proc. 3<sup>rd</sup> Quarter 90.**

The working group agreed to adopt a suggested revision from an interested party for Subsection E, clarifying that Subsection E also applies to new prescriptions for the same prescription drug that was the subject of a medical exceptions request whenever the enrollee has exhausted the number of refills provided for in the initial prescription for the drug. A regulator expressed concern about the use of the word "appropriately" in Subsection E(2). He suggested that it was no longer needed in light of the revisions just adopted by the working group for this subsection and language already in Subsection E(1) that requires that the prescription drug to still be prescribed by the enrollee's provider. **2001 Proc. 4<sup>th</sup> Quarter 230.**

#### Subsection 6F

A regulator noted that one comment suggested that the written denial include all the reasons for the denial, not just the principal reasons for the denial. This regulator also noted that there were other similar suggestions made by interested parties. Without objection, the working group agreed to review the NAIC Utilization Review Model Act and make this subsection consistent with that model's requirements. **2001 Proc. 4<sup>th</sup> Quarter 230.**

A regulator stated that several comments suggested permitting health carriers to maintain records electronically. Without objection, the working group adopted this suggestion. **2001 Proc. 4<sup>th</sup> Quarter 230.**

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**Section 7. Medical Exceptions Approval Process Requirements and Procedures**

The working group discussed the whether the denial of coverage for a prescription drug because it is not on the formulary should be considered an adverse determination. The working group agreed to review and discuss this issue further at its spring meeting. One regulator stated that it would be helpful if interested parties had experts at the working group's spring meeting who would be able to respond to members' questions on this issue. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The working group agreed to develop language requiring health carriers to have some sort of notice that could be given to the covered person at a pharmacy. This notice would provide information about the availability of a process to obtain coverage for the non-formulary drug. **2001 Proc. 1<sup>st</sup> Quarter 174.**

The working group discussed whether the medical exceptions process should be available when a covered person wants to continue to receive coverage for a drug that has been deleted from the formulary. After discussion, the working group included provisions allowing covered persons to access the medical exceptions process in two ways: 1) request a review of a denial based on a drug not being on the health carrier's formulary; and 2) request to continue to receive coverage for a drug that is being discontinued on the health carrier's formulary, unless the drug is being discontinued for safety reasons. **2001 Proc. 1<sup>st</sup> Quarter 174.**

An interested party was concerned about the flexibility of the exceptions process review standard. In response, the working group decided to review the NAIC Utilization Review Model Act to determine what standard is required under that model and what clinical and medical information is required when a health carrier reviews an exceptions request. The working group determined that two (2) business days is an appropriate time period for completing the review under the medical exceptions process. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

A regulator requested comments from working group members on whether it would be appropriate to include a provision that would deem the exceptions request approved if the health carrier did not respond within a required time period. After discussion, the working group agreed that there should be some provision allowing for deemed approval in that situation. Some working group members suggested, however, that this approval last for no longer than one month -- the usual length of a prescription. During this time period, the health carrier should have sufficient time to respond to the exceptions request. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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#### Subsection 7A

The comments received on this subsection included a suggestion to include other types of pharmaceutical benefit management procedures (PBMPs) instead of restricting it to dose restrictions and step therapy requirements. Other comments suggested expanding the types of situations eligible for a medical exceptions request to include co-payment or tiered exception requests that would permit a covered person to request an exception to pay a lower co-payment for a top tier prescription drug when the covered person for medical reasons cannot take the lower tier prescription drug. A regulator expressed support for such an expansion of this section and questioned the value of this section when most formularies today were open tiered formularies. The working group agreed that the focus of this section should be to address situations where the covered person had no access to the prescription drug that his or her prescribing provider felt was medically necessary. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

A regulator questioned why an exceptions process for prescription drug benefits was needed. Perhaps, the model could be revised to have all requests for prescription drug benefits go through utilization review rather than create a whole new process. After much discussion, the working group decided to retain Subsection A without revision. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

The working group added a drafting note reflecting the decision that exception requests involving a prior authorization requirement are handled under a health carrier's utilization review process, not under this section. The working group also agreed to review language for consistency with the working group's decision in Subsections 5C and D that health carriers be required to provide notice only when a change in a formulary or a change in a PBMP results in no coverage. A regulator noted that interested parties again suggested revising Subsection A to allow a covered person to file a request to pay a lower co-payment for a prescription drug when the covered person cannot use the lower co-payment prescription drug. Other interested parties suggested revising Subsection A to allow a covered person to file an exception to being subject to any PBMP, not just a step therapy or dose restriction requirement PBMP. The regulator stated that unless a working group member wanted to re-open the discussion, the group would not discuss these issues again. **2002 Proc. 4<sup>th</sup> Quarter 321.**

#### Subsection 7B

Some of the comments received on Subsection B(3) suggested specifically establishing what information must be included in the certification. This includes the patient's name, primary diagnosis related to the medication use and the reason the medication is needed for the individual patient. A regulator recommended that the working group accept this language and, if accepted, also include patient history as part of the information. Without objection, the working group adopted this recommendation. **2002 Proc. 2<sup>nd</sup> Quarter 235.**



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**Subsection 7B (cont.)**

Turning to Subsection B(4), a regulator noted that comments received on this section suggested that it was inappropriate to include it in this model because it was a contractual issue. Subsection B(4) prohibits a health carrier from refusing to enter into, terminate or refuse to renew a contract with a prescribing provider solely on the basis of the type or number of determinations the provider has made with respect to the medical exceptions requests filed under Section 6. One interested party found the reference to "types" of determinations particularly troubling. Another interested party echoed these concerns and expressed a belief that it was a contractual issue that did not belong in the model. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

A regulator suggested retaining the provision for now, recommended reviewing other NAIC models, such as the Utilization Review Model Act, to determine if similar provisions were included. She also suggested that industry be prepared to comment on this provision again during the working group's meetings at the 2002 NAIC Fall National Meeting. Without objection, the working group adopted this suggestion. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

A regulator suggested revising the substantive language in Subsections 7B(1)(b) and (c) to state what situations the working group intends "known characteristics" to apply to covered persons. As revised, Subsections 7B(1)(b) and (c) would state the "known relevant physical or mental characteristics of the covered person and the known characteristics of the drug regimen [that] is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance." This regulator also suggested that if the working group agreed to this revision the drafting note should be deleted because it is no longer needed. The working group adopted both suggestions. **2002 Proc. 4<sup>th</sup> Quarter 321.**

After discussion, the working group agreed to revise Section 7B(2)(b)(vi) permitting a health carrier to request that the written certification include "any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request." The working group also adopted the suggested revision to Section 7B(2)(b)(i) permitting the health carrier to request the group or contract number, subscriber number or other information necessary to identify the covered person. **2002 Proc. 4<sup>th</sup> Quarter 321.**

The working group added a drafting note to Subsection B(1)(b)(i) to clearly state the working group's intent that the language in this provision is intended to apply in cases where the prescribing provider anticipates non-compliance and, as such, the treatment would be ineffective. The working group revised Subsection B(2)(b) by striking "shall" and replacing it with "may." **2002 Proc. 4<sup>th</sup> Quarter 321.**

The working group deleted Subsection B(3) and considered incorporating that concept into the model in another manner by clarifying in an appropriate place that a medical exceptions request is equivalent to a request for a benefit that requires utilization review and, therefore, a provider advocating on behalf of a patient to receive a medical exception under Section 6 of this model is protected by the provision in the NAIC Managed Care Plan Network Adequacy Model Act. **2002 Proc. 4<sup>th</sup> Quarter 321.**

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#### Subsection 7C

An interested party suggested adding language requiring health carriers to develop a method of providing a notice to covered persons of the medical exceptions process through pharmacies. A regulator stated that carriers were not capable of setting up such a method. After discussion, the working group decided not to accept the suggestion. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

#### Subsection 7D

A regulator stated that all of the comments received on Subsection D(1) suggested shortening this time frame or, at a minimum, requiring the health carrier to make a decision as soon as possible, taking into account the covered person's medical condition, but in no event not more than 72 hours after receipt of the request. After discussion, the working group agreed to revise the time frame based on the comments. As revised, a health carrier would be required to make a decision on the request as quickly as warranted by the medical circumstances of the particular case, but in no event not later than 72 hours. In addition, the working group agreed to strike the word "dispensed" and substitute "coverage." Another regulator suggested a technical revision to Subsection D(2)(b) stating that the continued coverage required under Subsection D(2)(a) would be treated on the same terms "as specified in Subparagraph (a)." Without objection, the working group adopted this suggestion. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

An interested party suggested deleting the phrase "all of the information necessary," or alternatively, revising Subsection D(2) to provide that the information to be submitted would be the necessary information that the health carrier is required to provide as part of the notice under Subsection 5D(1)(c). A regulator expressed support for this provision and noted that the current language is not consistent with the proposed revisions to the NAIC Utilization Review Model Act. After discussion, the working group agreed to delete "all of the information necessary" as well as added a reference to the certification that a health carrier may require the covered person's prescribing provider to submit as part of the medical exceptions request under Subsection B(2). **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Subsection 7E

The working group added the language, "whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug and shall not impose upon the covered person a cost-sharing requirement that exceeds the maximum cost-sharing requirement set forth in the terms of coverage under the health carrier's health benefit plan for prescription drug benefits," to this subsection. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

The working group rejected an industry suggestion adding another provision to ensure that the prescription drug remains efficacious for treating the covered person's medical condition. After discussion, the working group decided not to accept this suggestion because it believed that current language already provided sufficient safeguards. The working group made a technical revision adding the word "provided" to the end of the introductory language for Subsection E(1). **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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#### Subsection 7E (cont.)

After discussion, the working group agreed to delete the drafting note for Subsection E(2)(b) and add language specifically prohibiting a health carrier from establishing a special co-payment tier for prescription drugs approved for coverage under the medical exceptions process. A specific prohibition would be easier for regulators to enforce rather than other language that could require regulators to delve into plan benefit design. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The working group agreed to add a drafting note addressing a situation encountered by staff model HMOs that do not have a tiered prescription drug benefit design, but are required to establish a tiered benefit scheme with a higher special tier. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Subsection 7F

The working group added language addressing financial incentives to ensure that health carriers do not use this exemption as a basis for not establishing a medical exceptions process, but provide financial incentives to their providers encouraging them not to make formulary exceptions. An interested party urged the working group to reject this suggestion because these issues were not previously discussed. A regulator noted that insurance departments do not regulate physicians. Without objection, the working group adopted this language, but drafted the language for the exemption as narrowly as possible to ensure that it is limited to exempting such carriers from having to establish a medical exceptions process. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

A regulator questioned whether this language completely addressed the group's concern, which was preventing a health carrier from creating a special co-payment or tier for prescription drugs approved through the medical exceptions process. Another regulator responded that that was the intent of the language. The working group added a drafting note to this section that would alert state insurance departments to be mindful when reviewing policy language to ensure that health carriers are not creating such tiers. **2002 Proc. 2<sup>nd</sup> Quarter 235.]**

A regulator recommended permitting health carriers to deny a medical exceptions request in electronic format rather than in writing if the covered person has agreed to electronic communication. The working group accepted this recommendation. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Subsection 7G

The working group deleted the annual reporting requirement in Subsection G(2) and the reference to "report" in Subsection G(3). The group also deleted the requirement that health carriers maintain data on the information specified in Subsection G(3) and make it available to the commissioner upon request. The working group also deleted Subsection G(3)(e). **2002 Proc. 2<sup>nd</sup> Quarter 235.**

This subsection exempts specified health carriers from having to establish a medical exceptions process, as required in Subsection A. It also exempts these carriers from having to comply with the specific provisions of Subsections B, C, D, E and F. The working group revised this subsection so that these health carriers are not exempted from having to comply with the requirements of Subsection E(2)(b). **2002 Proc. 3<sup>rd</sup> Quarter 270.**

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#### Subsection 7H

The working group agreed to add a new subsection. This subsection adds an additional exception for health carriers that have an expedited appeals process with requirements equivalent to those in this section. The group also added language specifically stating that the medical exceptions process is not available when the prescription drug is categorically excluded from coverage under the covered person's health benefit plan. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Section 8. Record Keeping and Reporting Requirements

#### Section 9. Oversight and Contracting Responsibilities

A regulator noted that the language for this section is identical to language in other NAIC models. An interested party suggested adding language ensuring that P&T committees have policies to address potential conflicts of interests. This language should prevent any financial incentives received by health carriers from interfering with the delivery of high quality, medically necessary care. A regulator supported including this language in Section 5 of the model. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

The working group agreed add language addressing the potential conflict of interest that P&T committee members may have with drug manufacturers. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

#### Section 10. Disclosure Requirements

After discussion, the working group deleted the reference to a covered person being able to use the medical exceptions process to request coverage of non-formulary prescription drugs “at the same level as that provided” for formulary drugs. The group agreed however, that the intent of the language needs to be included somewhere in the proposed model to prevent carriers from creating a new co-payment or coinsurance requirement for a prescription drug requested and approved using the medical exceptions process. The working group also decided to simplify the language in this section to make it easier to read. **2002 Proc. 2<sup>nd</sup> Quarter 235.**

The working group adopted an industry suggestion to delete "prescribed or dispensed" and substitute "covered" in Subsection A(1) because a health carrier does not prescribe or dispense prescription drugs. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

The working group did not accept a proposed revision that would provide disclosure to prospective covered persons. The group added language to Subsection B generally describing a PBMP. This language is similar to that already included in this subsection with respect to formularies. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

Subsection 10(B)(1) requires health carriers to explain, in laypersons' terms, information on the health carrier's formulary and other PBMPs. This explanation must include a copy of the formulary list and which prescription drugs are subject to a PBMP. For clarity, the working group substituted “about which” for “on what.” **2002 Proc. 4<sup>th</sup> Quarter 321.**

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#### Section 11. Regulations

A regulator stated that comments on this section requested restoring the language specifically requiring the commissioner to promulgate regulations after notice and a hearing. The regulator noted that, regardless of whether there is a specific requirement for notice and hearing, in most states, notice of the proposed regulation and a subsequent hearing is required under the state's Administrative Procedure Act. The working group agreed that restoring the specific language for notice and hearing was not necessary because the issue would be covered by a state's Administrative Procedure Act requirements. **2002 Proc. 3<sup>rd</sup> Quarter 270.**

#### Section 12. Penalties

#### Section 13. Separability

#### Section 14. Effective Date

The group adopted the draft of the Health Carrier Prescription Drug Benefit Management Model Act. The draft addresses formulary and other pharmaceutical benefit management procedures (PBMPs) used by health carriers when managing prescription drug utilization. It sets out standards for the establishment, maintenance and management of prescription drug formularies and other PBMPs to assure consumer access to prescription drugs. The draft also establishes a medical exceptions process that allows either consumers to request a non-formulary prescription drug, or an exception to a dose restriction or step therapy requirement. **2002 Proc. 4<sup>th</sup> Quarter 279.**

The Parent Committee adopted the Health Carrier Prescription Drug Benefit Management Model Act. This model establishes the same requirements for prior authorization requirements, dose restrictions, step therapy protocols and prescription drug formularies. The scope of this model also covers medical exception requests. **2003 Proc. 1<sup>st</sup> Quarter 175.**

The Executive Committee adopted the Health Carrier Prescription Drug Benefit Management Model Act. **2003 Proc. 2<sup>nd</sup> Quarter 7.**

**HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT  
MODEL ACT**

**Proceedings Citations**  
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