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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.

Drafting Note: This Act also is not intended to address prescription drug formularies and other pharmaceutical benefit management procedures health carriers or their designees may use for purposes of workers' compensation. States typically regulate workers' compensation under an independent, standalone law, which will include provisions, if the state has determined they are appropriate, concerning prescription drug formulary criteria and other related requirements specifically related to workers' compensation.

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~~The covered person's treating health care professional only when the covered person is unable to provide consent or a family member of the covered person; 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. "Drug substitution" means:

(1) For generics, the substitution of a generic version of a brand name drug that the U.S. Food and Drug Administration (FDA) in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the FDA *Orange* Book, has determined to be a therapeutic equivalent; or

(2) For biologics, the substitution of an interchangeable biosimilar product, which is a biosimilar product, as that term is defined in 42 USC §262(i), the FDA has determined to be interchangeable in accordance with the standards set forth in 42 USC §262(k)(4) and listed as such in the latest edition of or supplement to the FDA *Lists of Licensed Biological Products with Reference to Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, also known as the *Purple Book*.

Drafting Note: Subsection G defines the term "drug 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 drug substitution. In addition, states should review whether the definition of "drug" in relevant state law includes biologics.

~~G~~H. "Facility" means an ~~institutional provider of~~institution providing [physical, mental or behavioral] 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, urgent care centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

I. "FDA" means the U.S. Food and Drug Administration.

~~H~~J. "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~~K. "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~~L. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.

~~L~~M. "Health care professional" means a physician, pharmacist or other health care practitioner who is licensed, accredited or certified to perform specified [physical, mental or behavioral] 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~~N. "Health care provider" or "provider" means a health care professional or a facility.

~~N~~O. "Health care services" means services for the diagnosis, prevention, treatment, cure or relief of a physical, mental or behavioral health condition, illness, injury or disease, including mental health and substance abuse disorders.

~~O~~P. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a ~~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.

Drafting Note: Section 2791(b)(2) of the PHSA defines the term "health insurance issuer" instead of "health carrier." The definition of "health carrier" above is consistent with the definition of "health insurance issuer" in Section 2791(b)(2) of the PHSA.

~~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~~National Formulary;

(5) Peer-reviewed or expert consensus ~~Findings~~findings, including the studies or research used to reach the findings, ~~conducted~~developed 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 federal Centers for Medicare & Medicaid Services;

(f) The ~~federal Food and Drug Administration~~FDA;

(g) The federal Centers for Disease Control and Prevention;

(h) The U.S. Preventive Services Task Force;

(i) The U.S. Health Resources & Services Administration; and

~~(g)~~(i) 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).

Drafting Note: States should note that in some limited instances, guidelines developed by the federal government or national specialty medical organizations that are nationally recognized as setting the standard of care for a condition (*e.g.* U.S. Department of Health and Human Services (HHS) antiretroviral treatment guidelines and the hepatitis C recommendations developed by the American Association of the Study of Liver Diseases and the Infectious Diseases Society of America) may initially lack broad expert consensus or peer-review because of an urgent need to make drugs that improve or maintain critical life functions available as they are approved and/or treatment data is released. Such information can be helpful to the P&T committee as it determines coverage updates and/or changes.

R. "Participating provider" means a provider ~~that~~who, under a 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) The grouping of drugs into different categories;

~~(2)~~(3) Dose restrictions;

~~(3)~~(4) Prior authorization requirements; or

~~(4)~~(5) Step therapy requirements.

Drafting Note: The definition of "pharmaceutical benefit management procedure" refers to commonly used utilization management criteria. It is possible that a health benefit plan may utilize new or different utilization management criteria. States should consider whether additional utilization management criteria should be included in the definition of "pharmaceutical benefit management procedure."

U. "Pharmacy and Therapeutics ~~(P&T)~~ committee" or "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,~~ that 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.~~ Although this definition is broad, states should take note of the federal rules implementing the federal Affordable Care Act (ACA) effective January 1, 2017, which will require health carriers providing essential health benefits in the individual and small

group markets to meet a range of requirements related to the use of a P&T committee (see Title 45 CFR – Subpart B – Essential Health Benefits, Section 156.122(a)(3).

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). States should note that under Section 2709 of the Public Health Service Act, as added by the ACA, a health carrier, (1) is prohibited from denying a qualified individual from participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

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 or program the health carrier utilizes that ~~specifies the~~establishes a sequence ~~in which different~~of covered 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.

Drafting Note: The provisions of Section 4 above should not be construed to have this Act: 1) apply to a health benefit plan that does not cover outpatient prescription drugs; 2) require coverage of a prescription drug for a medical condition that is not covered under the health benefit plan; or 3) require coverage of a prescription drug categorically excluded from coverage under a health benefit plan unless an express exception is made pursuant to Section 7 of this Act.

Drafting Note: The reference to "designee" in Section 4 is intended to be construed broadly to apply to any person or entity the health carrier contracts with to perform, or carry out on its behalf, specified activities required under this Act or applicable regulations, such as pharmacy benefit manager (PBM). Section 10 of this Act provides that the health carrier is responsible for monitoring all of activities carried out by, or on behalf, of the health carrier by a designee that the health carrier has contracted with to perform that activity and ensuring that the designee is complying with the requirements of this Act and any applicable regulations related to that activity. If a state has enacted or intends to enact a specific law or regulation directly regulating certain persons or entities that may be designees under this Act, such as PBMs, those states should review the provisions of this Act, such as Section 10 of this Act, to determine whether any provisions of this Act should be modified or clarified to encompass such persons or entities in light of that law or regulation.

~~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~~coverage 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~~ meeting the requirements of this section.

B. (1) Any P&T committee established under Subsection A shall include members the health carrier considers appropriate who represent a sufficient number of clinical specialties to adequately meet the needs of covered persons, the majority of which are practicing physicians, practicing pharmacists and other practicing health care professionals licensed to prescribe prescription drugs, to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

(2) A P&T committee established under Subsection A shall seek outside expert advice, as appropriate, to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

~~(2)~~(3) The health carrier shall ensure that any P&T committee established ~~pursuant to this subsection~~under Subsection A has the following policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with the carrier and any ~~developers~~pharmaceutical developer or manufacturer~~s of prescription drugs.~~:

(a) At least 20% of the P&T committee membership has no conflict of interest with respect to the health carrier and any pharmaceutical developer or manufacturer;

(b) Prohibits any P&T committee member with a conflict of interest with respect to the health carrier or a pharmaceutical developer or manufacturer from voting on decisions with regard to a particular prescription drug or class of prescription drugs for which the conflict exists; and

(c) Each P&T committee member, and any individual who advises the P&T committee, signs a conflict of interest statement, which reveals any economic or other relationships the P&T committee member, or other individual advising the P&T committee, has with any person affected by drug coverage decisions that could influence P&T committee decisions.

(4) (a) Each P&T committee shall establish procedures outlining its conflict of interest standards for its members and any individuals providing expert advice to the P&T committee, which, at a minimum, are consistent with Paragraph (3).

(b) The procedures shall require the P&T committee to have a system in place to maintain the signed conflict of interest statements described in Paragraph (3)(c) and to document any P&T committee member recusals from voting.

(c) The procedures and information under Subparagraph (b) of this paragraph shall be available for regulatory review and provided to the commissioner upon request.

Drafting Note: State regulators should be aware that any conflict of interest standards a P&T committee establishes might need to permit the P&T committee to receive information from a non-voting individual who may have significant conflicts of interest with the health carrier or a pharmaceutical developer or manufacturer because the individual has special information, knowledge, or expertise related to the particular prescription drug or class of prescription drugs under consideration.

(5) The P&T committee shall meet at least quarterly and shall maintain documentation of its rationale for all decisions regarding formulary drug list development or revision.

C. Each health carrier that offers coverage for prescription drugs shall ensure that it offers a formulary based on the recommendations of the carrier's P&T committee and covers at least the greater of:

(1) One drug in every United States Pharmacopeia (USP) category and class; or

(2) The same number of prescription drugs in each category and class as the essential health benefits (EHB)-benchmark plan.

Drafting Note: States should be aware the provisions of Subsection C above are a requirement under federal regulations implementing the ACA for plans providing essential health benefits (EHBs) in the individual and small group markets (Title 45 CFR – Subpart B – Essential Health Benefits Package Section 156.122(a) (Prescription Drug Benefits)).

~~B~~D. (1) The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process and documents and procedures to base clinical decisions on the strength of:

(a) ~~Evaluate medical~~Medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including the FDA label indications of the prescription drug and available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to review and include on a formulary; and

Drafting Note: Any P&T committee shall base formulary decisions, in part, on whether prescription drugs included for a therapeutic category or class are effective for all populations, including racial and ethnic minorities, and shall consider whether the formulary includes prescription drugs that have proven efficacy in all patient subgroups, including racial and ethnic minority populations. In making these considerations, the P&T committee shall consider medical and scientific evidence, as well as medical treatment guidelines developed or endorsed by specialty organizations.

(b) ~~Evaluate applicable~~Applicable medical and scientific evidence concerning the safety and effectiveness of prescription drugs and the therapeutic advantages of prescription drugs when developing any ~~other~~ PBMP.

(2) In the case of rare or ultra-rare diseases, the P&T committee process under Paragraph (1) shall include the review, as the P&T committee considers appropriate and necessary, of clinically appropriate and relevant information when there is no or limited medical and scientific evidence concerning the safety and effectiveness of prescription drugs or drug classes used to treat rare and ultra-rare diseases.

Drafting Note: Paragraph (2) above is meant to require the P&T committee, when deciding what prescription drugs to review and include on a formulary or when developing any PBMP, to have as part of this review process procedures in place to review the best available and appropriate information at the time concerning a prescription drug or drugs to include on a formulary that may be used to treat rare or ultra-rare diseases. Such diseases have been described as from a population of one million people, 650 have a rare disease and fewer than 20 have an ultra-rare disease.

~~(2)~~(3) The health carrier shall ensure that any P&T committee maintains documentation of the process required under Paragraph (1) to ensure appropriate prescription drug review and inclusion and makes any records and documents relating to the process available, upon request, to the health carrier for record keeping purposes under Section ~~8~~9 of this Act.

~~C~~E. (1) 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)~~(a) 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~~new FDA~~-~~-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;

(b) The strength of medical and scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data and other such information the P&T committee considers appropriate;

~~(2)~~(c) ~~If applicable, information~~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)~~(d) 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.

(2) The P&T committee also shall:

(a) Review and approve appropriate updates and guidance related to the medical exceptions process under Section 7 of this Act and other utilization management processes, including any PBMP requirements such as drug utilization review, quantity limits and therapeutic interchange;

(b) Review and approve appropriate updates and changes to all clinical prior authorization criteria, step therapy protocols and quantity limit restrictions applied to each covered prescription drug; and

(c) Review new FDA-approved prescription drugs and new uses for existing prescription drugs.

Drafting Note: A health carrier's P&T committee also should ensure the health carrier's formulary drug list covers a range of prescription drugs across a broad distribution of therapeutic categories and classes and recommend prescription drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of covered persons, and provides appropriate access to prescription drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

F. (1) A health carrier shall allow covered persons to access outpatient prescription drug benefits at in-network retail or mail order pharmacies, unless:

(a) The drug is subject to restricted distribution by the FDA; or

(b) The drug requires special handling, provider coordination or patient education that a retail pharmacy cannot provide.

(2) The health carrier may charge covered persons different cost-sharing amounts based on the distribution method used to obtain the covered prescription drug. All in-network cost-sharing amounts paid shall count towards the health benefit plan's annual limit on cost-sharing paid by the covered person and shall be included in the actuarial value calculated for that plan.

~~D~~G. Subject to Section ~~9~~10 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.~~

(1) (a) Except as provided in Paragraph (6), a health carrier shall display on its website in plain language the prescription drug benefit information required in this subsection.

(b) For a health benefit plan providing group market health insurance coverage, a health carrier may require:

(i) A covered person to create or access an account or enter a plan or contract number to access the plan's formulary list and other prescription drug benefit information; and

(ii) A prospective covered person to access a plan's formulary list and other prescription drug benefit information by searching by plan name or contract number.

(c) For a health benefit plan providing individual market health insurance coverage, a health carrier may not require a covered person or prospective covered person to create or access an account or enter a plan or policy number to access a plan's formulary list or other prescription drug benefit information, but may require a covered person or prospective covered person to access a plan's formulary list and other prescription drug benefit information by searching, as appropriate, by plan name.

(2) (a) (i) The health carrier's formulary list(s) shall include each prescription drug covered under the carrier's plan(s) prescription drug benefit and outpatient medical benefit, which are prescription drugs administered by a health care professional or under the professional's direct supervision in an outpatient setting.

(ii) The health carrier may provide the information pertaining to prescription drugs covered under a plan's outpatient medical benefit as an addendum or link to the formulary, if applicable, provided the information is prominently displayed.

(b) The formulary shall be electronically searchable by drug name and any other means required by the commissioner.

Drafting Note: States should be aware that organizing formularies also by major therapeutic class can be helpful to consumers when determining whether the formulary offered under the health benefit plan is robust with respect to a specific disease or medical condition.

(c) The prescription drug benefit information shall include a notice for any individual reviewing the information that the inclusion of a prescription drug on a health benefit plan's formulary does not mean that a prescriber will prescribe that drug for the individual's specific medical condition.

(d) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, a health carrier shall include in the prescription drug benefit information 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.

(3) The health carrier shall include in the prescription drug benefit information a description in plain language of how an individual can access the following benefit information:

(a) An indication of whether the drug is preferred, if applicable, under the plan;

(b) A disclosure of any prior authorization, step therapy, quantity limits, pharmacy restrictions or other PBMP requirement; and

(c) The specific tier the drug falls under, if the plan uses a tiered formulary.

(4) (a) The health carrier shall include in the prescription drug benefit information a description in plain language of how an individual may find the benefit cost-sharing information for the prescription drugs on a formulary list that includes:

(i) Whether the prescription drug is subject to a deductible, and if so, the amount of the deductible;

(ii) The amount of the prescription drug copayment;

(iii) The amount of the prescription drug coinsurance; and

(iv) The amount of any cost-sharing difference between the days' supply of the prescription drug.

(b) For a health benefit plan providing individual market health insurance coverage, a health carrier may meet the requirements set forth in Subparagraph (a) of this paragraph by referring the individual to a summary of the plan's benefits and coverage displayed or linked to a place elsewhere on the carrier's website, provided that a covered person or prospective covered person is not required to create or access an account or enter a policy or plan number to access this information.

Drafting Note: States may want to look at the prescription drug benefit information that is to be provided to consumers in accordance with the requirements of this paragraph to see if that information can be easily found and is clear and understandable.

(5) A health carrier shall provide, upon request, a print copy of specifically requested prescription drug benefit information of a carrier's current, accurate and complete formulary.

(6) A health carrier may make available the prescription drug benefit information required in this subsection using electronic links associated with the specific health benefit plan for which the information applies.

(7) A health carrier shall ensure a formulary list(s), whether in electronic or print format, shall accommodate individuals with disabilities, and include a link to or information regarding available assistance for persons with limited English proficiency.

(8) A health carrier shall ensure the formulary list itself:

(a) Is accurate;

(b) Updated, as needed, to reflect changes in a health benefit plan's covered prescription drugs; and

(c) Includes the date it was last updated.

Drafting Note: Health carriers are required to maintain accurate formulary lists for their health benefit plans. State insurance regulators may want to closely monitor consumer complaints received to determine if there is a problem or pattern of complaints that might indicate a problem with the formulary list.

B.~~(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)~~(1) 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~~; and

~~(b)~~(2) Pharmacies participating in the health carrier's network ~~by~~prior to 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.~~

C. (1) Whenever a health carrier makes or approves a change in a formulary impacting prescription drug benefit coverage or PBMP administration, including, but not limited to, co-payment amounts, co-insurance percentage level, step therapy, drug substitution and mandatory generics, 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 impacted by the change currently receiving benefits for the drug of the change; or

(b) The health carrier or its designee shall cover a refill of a drug impacted by the change for any covered person currently receiving benefits for the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person and notify the covered person or the covered person's authorized representative at the time of the refill of the change.

Drafting Note: State insurance regulators should keep in mind that under certain circumstances notices to covered persons under this paragraph may not be needed if the health carrier decides to continue coverage of the prescription drug on the same terms and conditions as covered previously for covered persons currently receiving coverage for that drug as long as the drug continues to be prescribed for the covered person and the covered person is covered under the health benefit plan.

Drafting Note: State insurance regulators should be aware Paragraph (1) above does not obviate the requirement that the carrier or its designee provide a minimum 60-day advance notice before the effective date of a formulary change to consumers in order to provide sufficient time for consumers to discuss alternatives to the prescription drug impacted by the change with their physician or prescriber or file a request for approval of an exception under the health carrier's medical exceptions process.

(2) (a) As part of the information to be provided in a notice pursuant to Paragraph (1)(a) or Paragraph (1)(b), the health carrier or its designee shall include information on any available alternatives to the prescription drug impacted by the formulary change and direct the covered person to speak with the prescriber.

(b) 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 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 cover a refill 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;

(b) The prescription drug is not available because the drug's manufacturer no longer supplies the drug or has withdrawn the drug from the market; or

(c) The change in or a new PBMP for the prescription drug is for safety reasons.

D.~~(2)~~ In addition to the information to be provided under ~~Paragraph (1)~~Subsection A, a health carrier or its designee electronically or in writing, upon request, shall include in any notice provided under Subsection C information explaining ~~the following in a manner calculated to be understood by a layperson~~in plain language that:

(1) Any formulary change impacting prescription drug benefit coverage or PBMP administration could impact the covered person's out-of-pocket costs and the covered person may want to consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug impacted by the change 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;

(2) The covered person may want to review the health benefit plan's formulary from time-to-time or contact the health carrier or its designee to obtain any updated formulary information prior to obtaining a refill for a particular prescription drug the covered person is currently using to find out if there has been any change in the requirements for obtaining coverage for the drug or if there has been a change in the covered person's out-of-pocket costs for the drug and include the telephone number or electronic link that covered persons can use to contact the health carrier or its designee to obtain this information; and

(3) The amount the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time.

~~(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 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~~except when coverage for the drug is being discontinued for safety reasons or because the drug's manufacturer is no longer supplying the prescription drug ~~cannot be supplied by~~ or ~~has been withdrawn from the market by~~ the drug's manufacturer has withdrawn the prescription drug from the market; 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: States should ensure that health benefit plans have a process in place to address issues that may not fall under this section as a formulary exception, but would be considered a benefit exception.

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.

Drafting Note: This section also is not intended to apply to situations where the consumer may have issues with pharmacy access, such as an in-network pharmacy being too far from a covered person's home address or when a prescription drug a covered person is currently using changes from being available through a range of pharmacy options to mail order pharmacy only. In these situations, states should review the network access requirements in state law or regulation similar to the requirements in the *Health Benefit Plan Network Access and Adequacy Model Act* (#74).

B. (1) A covered person or the covered person's authorized representative may file, and the health carrier shall review, 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) Is contraindicated; or

~~(ii)~~(iii) 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 in the prescriber's clinical judgment; ~~or~~

Drafting Note: States should be aware that this Act does not contemplate covered persons using the medical exceptions process established under this section to request a change in benefits, which, in some cases, could impact potential medical exception requests involving step therapy requirements. This Act contemplates benefit exception requests would be handled under a different state law or regulations related to utilization review or grievance processes. Given this, states should review their existing state laws for consistency when considering adoption of this section.

(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; or

(d) The covered person's condition and function are stable and based on the covered person's medical history a change in prescription drug would have the potential for adverse consequences or other risks.

(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.

(c) A prescriber may submit additional information the prescriber deems necessary to establish medical necessity for purposes 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~~*Health Benefit Plan Network Access and Adequacy Model Act* (#74)].

Drafting Note: Section 6J of the NAIC ~~Managed Care Plan Network Adequacy~~ *Health Benefit Plan Network Access and Adequacy Model Act* (#74) provides that a health carrier may not prohibit a participating provider from advocating on behalf of covered persons within the utilization review or grievance or appeals 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~~ *Health Benefit Plan Network Access and Adequacy Model Act* (#74).

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) (a) Except as provided in Subparagraph (b) of this paragraph, ~~The~~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).

(b) (i) A health carrier shall include in its medical exceptions process required under Subsection A an expedited medical exceptions review based on exigent circumstances.

(ii) Exigent circumstances exist when a covered person is suffering from a health condition that may seriously jeopardize the covered person's life, health, or ability to regain maximum function.

Drafting Note: Item (ii) above also is intended to apply when an infant's or a child's health condition may seriously jeopardize their ability to develop maximum function.

(iii) A health carrier shall make a decision on an expedited medical exceptions review request based on exigent circumstances made pursuant to Subsection A and notify the covered person or the covered person's authorized representative of its coverage decision no later than [24] hours following receipt of the request.

(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)(a) or Paragraph (1)(b):

(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 [and count the covered person's in-network cost-sharing for the drug toward the covered person's annual limitation on cost-sharing].

Drafting Note: States should be aware that the bracketed language above is a requirement under federal regulations implementing the ACA for plans providing essential health benefits (EHBs) in the individual and small group markets (see Title 45 CFR – Subpart B – Essential Health Benefits Package Section 156.122(c) (Prescription Drug Benefits)). As such, states will need to consider whether to include the bracketed language where it could have a broader application.

(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* (#72)].

(2) The denial shall, ~~in a manner calculated to be understood by the covered person or, if applicable, the covered person's authorized representative~~ in plain language, 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* (#72)], including any time limits applicable to those procedures.

G. A health carrier that permits a covered person's ~~prescribing participating provider~~prescriber 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.

Drafting Note: Subsection G above is intended to apply to carriers that are organized and operated as integrated care systems, such as a staff model HMO, where health care providers manage and provide covered health care services to covered persons without having to seek specific authorization from the carrier for the provision of those specific services.

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* (#75)]; 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.~~ A covered person may not use the process established under this section to request coverage for: (1) an investigational or a non-FDA-approved prescription drug; or (2) a prescription drug for a specifically excluded benefit under the covered person's health benefit plan.

Drafting Note: Subsection I reflects that health benefit plans exclude certain benefits from coverage by listing non-covered benefits, but do not exclude specific medical conditions from coverage.

Drafting Note: Also, with respect to Subsection I, states should be aware that an issue could arise in situations where an application for new drug approval has been submitted to the FDA, but, at the time a covered person submits a medical exceptions request for coverage of that prescription drug, the drug has not received FDA-approval.

Section 8. Nondiscrimination in Prescription Drug Benefit Design

A health carrier or its designee shall not adopt or implement a formulary or prescription drug benefit design that is discriminatory in violation of state or federal law.

Drafting Note: State insurance regulators should consider federal nondiscrimination laws and regulations requiring health carriers in the individual and small group health insurance markets to meet a range of requirements related to prescription drug benefit coverage, including nondiscrimination in prescription drug benefit design.

Drafting Note: State insurance regulators should consider the nondiscrimination provisions contained in state laws based on the *Individual Market Individual Health Insurance Coverage Model Act* (#36), the *Small Group Market Health Insurance Coverage Model Act* (#106); or the *Unfair Trade Practices Act* (#880).

Drafting Note: State insurance regulators should pay particular attention to the formulary and prescription drug benefit notices and disclosures health carriers are required under this Act to provide to covered persons to ensure that these notices and disclosures, whether provided electronically or in print, accommodate individuals with disabilities and individuals with limited English proficiency.

Section ~~8~~9. 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) The changes to its formulary or prescription drug benefit information made after the start of the plan year;] and

~~(4)~~(5) Any other information the commissioner may request.

Section ~~9~~10. 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~~11. 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 and where to find more specific information;

(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~~any PBMP 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* (#72)] 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~~plain language information on the health carrier's formulary and other ~~PBMPs~~prescription drug benefit information as provided in Section 6A~~, including what a formulary and each PBMP that that health carrier uses is,~~ and state ~~that~~ where the information is available electronically and a print copy of the formulary list and specific prescription drug information ~~and information about which prescription drugs are subject to a PBMP will~~can 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~~ plain language in a separate document or other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that:

(a) Any formulary change impacting prescription drug benefit coverage or PBMP administration could impact the covered person's out-of-pocket costs and the covered person may want to consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug impacted by the change 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;

(b) The covered person may want to review the health benefit plan's formulary from time-to-time or contact the health carrier or its designee to obtain any updated formulary information prior to obtaining a refill for a particular prescription drug the covered person is currently using to find out if there has been any change in the requirements for obtaining coverage for the drug or if there has been a change in the covered person's out-of-pocket costs for the drug and include the telephone number or electronic link that covered persons can use to contact the health carrier or its designee to obtain this information; and

~~(a)~~(c) 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~~12. 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~~13. Penalties

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

Section ~~13~~14. 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 that those to which it is held invalid, shall not be affected.

Section ~~14~~15. Effective Date

This Act shall be effective [insert date]. [If applicable:] The [insert year of adoption] amendments to this Act shall be effective [insert date].

Project History

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

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

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

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

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

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

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

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

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

"Utilize the Regulatory Framework (B) Task Force to review and, if necessary, consider revisions to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) to address issues related to: 1) transparency, accuracy and disclosure regarding prescription drug formularies and formulary changes during a policy year; 2) accessibility of prescription drug benefits using a variety of pharmacy options; and 3) tiered prescription drug formularies and discriminatory benefit design.—*Important*"

4. A General Description of the Drafting Process (e.g., drafted by a subgroup, interested parties, the full group, etc.; include any parties outside the members that participated)

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

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

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

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

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

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

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

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

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

None.

Section-by-Section Summary of Proposed Revisions

Section 1. Short Title

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

Section 2. Purpose and Intent

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

Section 3. Definitions

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

Section 4. Applicability and Scope

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

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

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

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

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

Section 7. Medical Exceptions Approval Process Requirements and Procedures

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

Section 8. Nondiscrimination in Prescription Drug Benefit Design

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

Section 9. Recordkeeping and Reporting Requirements

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

Section 10. Oversight and Contracting Responsibilities

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

Section 11. Disclosure Requirements

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

Section 12. Regulations

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

Section 13. Penalties

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

Section 14. Separability

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

Section 15. Effective Date

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

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