January 22, 2016

Mr. J.P. Wieske
Wisconsin Office of the Commissioner of Insurance
c/o National Association of Insurance Commissioners
Hall of States, Suite 701
444 North Capitol Street, N.W.
Washington, DC 20001-1509

Ms. Jolie H. Matthews
Senior Health and Life Policy Counsel
National Association of Insurance Commissioners
Hall of States, Suite 701
444 North Capitol Street, N.W.
Washington, DC 20001-1509

RE: Support for Consumer Representatives' Recommendations for Changes to NAIC's Health Carrier Prescription Drug Benefit Management Model Act (#22)

Dear Mr. Wieske and Ms. Matthews:

The undersigned organizations write in support of the NAIC Consumer Representatives' comments to the NAIC's Health Carrier Prescription Drug Benefit Management Model Act (#22). We represent millions of patients and consumers who need access to prescription drugs to treat disease and stay healthy.

Updating this Model Act is important, as it was last updated in 2003. Several major changes have happened in healthcare since then, notably the implementation of Medicare Part D program and the Affordable Care Act. Many of the changes proposed by the Consumer Representatives ensure consistency with federal standards for qualified health plans, and Medicare standards, where appropriate. As the Subgroup begins its work to update this Model Act, the undersigned groups wish to show our support for the following guiding principles:

<u>Plan formulary drug lists must be transparent and easy to understand.</u>
Plan members and prospective enrollees need to have easy access to an up-to-date, easy to understand, and comprehensive formulary. Plans should be required to provide information about any prior authorization or other actions required by the plan for using a certain medication. Plans should also be required to disclose drug list tiering and make as clear as possible what patients must pay to use medications. It also is important for plans to provide information on drugs covered under medical benefits (not just under the prescription drug benefit). All of this information should be provided to prospective enrollees as well as current members, as it is vital for making healthcare enrollment decisions. We support the changes proposed by the Consumer Representatives that institute these requirements.

<u>Plan members must be able to submit appeals to formulary coverage, tiering or requirements.</u>
Treatment is not one-size-fits-all, and some patients need drugs that are not included in formularies. Additionally, some patients need exceptions to utilization management requirements or cost-sharing tiering requirements. Plans should be required to have an appeals process in place and make members aware of their options to appeal. Plans should respond to these appeals promptly, and responses

should be expedited when medically necessary. We support the changes proposed by the Consumer Representatives that ensure these processes are in place.

Health carriers should not be able to use their formularies to discriminate against members.
Plans must not be allowed to use their formularies (or utilization management tools) to discourage enrollment by certain eligible individuals. This discrimination must be prohibited based on health status, including medical condition (related to mental as well as physical illness), race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. We support the Consumer Representative's changes that ensure plans are not able to use discriminatory practices.

Plan members who decide to enroll in a clinical trial should not be denied coverage.
Clinical trials offer hope to patients and opportunities to advance medical science, and patients should be able to enroll when appropriate. Plans should not be able to prohibit members from enrolling in a clinical trial, or deny coverage of an enrolled patient's routine medical expenses. We support the Consumer Representative's proposed changes to ensure plans don't prohibit patient participation in clinical trials.

Attached is a copy of the Consumer Representative's proposed changes to the Health Carrier Prescription Drug Benefit Management Model Act. If you have any questions, please contact Anna Howard, Policy Principal at the American Cancer Society Cancer Action Network, at anna.howard@cancer.org or 202-585-3261.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
Arthritis Foundation
Autism Speaks
Community Catalyst
Disability Rights Education and Defense Fund (DREDF)
Epilepsy Foundation
Georgians for a Healthy Future
Hematology/Oncology Pharmacy Association
Leukemia & Lymphoma Society
National Alliance on Mental Illness
National Alliance of State & Territorial AIDS Directors
National Kidney Foundation
National Multiple Sclerosis Society
National Patient Advocate Foundation
The AIDS Institute
US Public Interest Research Group

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

Table of Contents

Section 1. Title
Section 2. Purpose and Intent
Section 3. Definitions
Section 4. Applicability and Scope
Section 5. Requirements for the Development and Maintenance of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures
Section 6. Information to Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons
Section 7. Medical Exceptions Approval Process Requirements and Procedures
Section 8. Participation in Approved Clinical Trials
Section 9. Record Keeping and Reporting Requirements
Section 10~~9~~. Oversight and Contracting Responsibilities
Section 11~~0~~. Disclosure Requirements
Section 12~~1~~. Nondiscrimination
Section 13. Regulations
Section 14~~2~~. Penalties
Section 13~~5~~. Separability
Section 16~~4~~. Effective Date

Section 1. Title

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

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

Section 2. Purpose and Intent

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

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

Section 3. Definitions

For purposes of this Act:

A. "Authorized representative" means:

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

(2) A person authorized by law to provide substituted consent for a covered person;

(3) A family member of the covered person or the covered person's treating health care professional only when the covered person is unable to provide consent; or

(4) For the purpose of filing a medical exceptions request under Section 7 of this Act on behalf of a covered person, the covered person's prescribing, treating or dispensing provider.

B. "Clinical review criteria" means the ~~written~~ screening procedures, decision abstracts, clinical protocol and practice guidelines used by the health carrier to determine the medical necessity and appropriateness of health care services.

C. "Commissioner" means the Commissioner of Insurance.

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

D. "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of the health benefit plan.

E. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

F. (1) "Dose restriction" means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period. This term also includes restrictions based on the strength of a drug.

(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~~ a restriction on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.

G. "Facility" means an institution~~al~~ providing physical, mental or behavioral ~~provider of~~ health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers,

skilled nursing centers, residential treatment centers, urgent care centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

H. "Formulary" means a list of prescription drugs – including drugs covered under the medical and prescription drug benefits – 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, including tiered cost-sharing.

I. "Generic substitution" means the substitution of an equivalent approved generic version of a brand name prescription drug as listed by the FDA in the "Orange Book" ~~that has the same active ingredients, strength and intended use as the brand name prescription drug~~. This term also includes biosimilar substitution where the FDA has designated the biosimilar product to be interchangeable with the branded product.

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

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

(1) The availability, delivery or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;

(2) Claims payment, handling or reimbursement for health care services; or

(3) Matters pertaining to the contractual relationship between a covered person and a health carrier.

K. "Health benefit plan" means a policy, contract, certificate or agreement 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. "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 their scope of practice under state law.

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

M. "Health care provider" or "provider" means a health care professional, a pharmacy, pharmacy benefit manager, mail order facility, or a facility.

Drafting Note: The term "pharmacy" is intended to encompass subcategories of pharmacies, including but not limited to specialty pharmacies, compounding pharmacies, and mail order pharmacies.

N. "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. "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~~P. "Medical and scientific evidence" means evidence found in the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(2) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline), and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);

(3) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;

(4) The following standard reference compendia:

(a) The American Hospital Formulary Service–Drug Information;

(b) Drug Facts and Comparisons;

(c) The American Dental Association Accepted Dental Therapeutics; and

(d) The United States Pharmacopoeia–Drug Information;

(5) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:

(a) The federal Agency for Healthcare Research and Quality;

(b) The National Institutes of Health;

(c) The National Cancer Institute;

(d) The National Academy of Sciences;

(e) The Centers for Medicare & Medicaid Services;

(f) The federal Food and Drug Administration; and

(g) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or

(6) Any other relevant data that is comparable to the sources listed in Paragraphs (1) through (5).

~~R~~Q. "Participating provider" means a provider who~~that~~, 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~~R. "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~~S. "Pharmaceutical benefit management procedure" or "PBMP" includes any of the following that is used to manage prescription drug benefits, but not limited to:

(1) A formulary, including the use of tiered cost-sharing;

(2) Dose restrictions, including dose strength restriction;

(3) Prior authorization requirements;

(4) Mail-order-services; 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 "pharmacy benefit management procedure."

~~U~~T. "Pharmacy and Therapeutics ~~(P&T)~~ committee" or "P&T committee" means an advisory committee or committees or equivalent body or bodies that advise the health benefit plan regarding the proper use of prescription drugs.

~~meets at least quarterly and 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 practicing health care professionals who are licensed to prescribe drugs, such as physicians and pharmacists, and who, collectively, represent a sufficient number of clinical specialties to adequately meet the needs of enrollees and 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) that go into effect Jan. 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~~U. "Prescriber" means any licensed, certified or otherwise legally authorized health care professional authorized by law to prescribe a prescription drug.

~~W~~V. "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: The term "prescription drug" is intended to encompass all prescription drugs including, but not limited to brand name, generic drugs, biologic, and biosimilar prescription drugs.

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 Affordable Care Act 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~~W. "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~~X. "Prior authorization" means the process of obtaining prior approval for coverage of a prescription drug.

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

Z. "Tiered cost-sharing" means a process of grouping covered drugs into different cost sharing levels within a health benefit plan's formulary.

Section 4. Applicability and Scope

A. This Act shall apply to health carriers that provide benefits for outpatient prescription drugs under a health benefit plan issued by the health carrier where the health carrier or its designee administers coverage for this benefit through the use of a formulary or through the application of any other pharmaceutical benefit management procedure.

B. This Act is intended to apply to prescription drugs that are included in a health benefit plan as covered under its medical benefit and not solely under its prescription drug benefit.

C. A health carrier is prohibited from utilizing a formulary or other PBMP designed to substantially discourage enrollment by certain eligible covered persons on the basis of health status, including medical condition (related to mental as well as physical illness), race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Carriers or designees may be asked to submit justification, with supporting documentation, explaining how a plan design is not discriminatory.

~~B. Nothing in this Act shall be construed to apply to prescription drugs that are categorically or contractually excluded from a covered person's health benefit plan. A provision in the benefit contract that purports to exclude all nonformulary prescription drugs shall not be considered a categorical exclusion for purposes of this Act.~~

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

A. ~~(1)~~ Each health carrier that provides benefits for prescription drugs and manages this benefit through the use of a formulary or other PBMP shall establish, or have established, one or more P&T committees ~~that the health carrier considers appropriate~~ to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

~~(2)~~B. The health carrier shall ensure that any P&T committee established pursuant to this subsection has the following policies and disclosure requirements in place: ~~that~~

(1) Membership:

(a) P&T committee members must come from various clinical specialties that adequately represent the needs of health plan enrollees.

(b) A majority of P&T committee members must be practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(c) At least 20 percent of the P&T committee membership must have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(d) P&T committees must have at least 15 members.

(2) Conflict of Interest:

(a) P&T committee members must sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

(b) Any P&T committee member with a conflict of interest with respect to the issuer, its pharmacy benefit manager or pharmaceutical manufacturers shall not vote on any matters for which the conflict exists.

Drafting Note: States may want to impose requirements on what constitutes a conflict of interest.

(3) The P&T committee must meet on a regular basis, but no less than quarterly.
~~(a) address potential conflicts of interest that members of a P&T committee may have with developers or manufacturers of prescription drugs.~~

~~B~~C. (1) The health carrier shall ensure that any P&T committee established in accordance with Subsections A and B has and uses a process to:

(a) Base clinical decisions on the strength of ~~Evaluate~~ medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including the FDA indication of the prescription drug and available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary and in which formulary tier the prescription drug is placed; ~~and~~

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

(c) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, dose restrictions and dose strength restriction, and therapeutic interchange;

(d) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually;

(e) Review and approve all clinical prior authorization criteria, step therapy protocols, dose restrictions, dose strength restrictions, and quantity limit restrictions applied to each covered drug; and

(f) Ensure the health carrier's formulary drug list:

(i) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(ii) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

Drafting Note: States may choose to require P&T committees to ensure that the health carrier's formulary drug list include prescription drugs to address molecular subtypes of diseases.

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

(b) The health carrier shall ensure that any P&T committee maintains written documentation of the rationale for all decisions regarding formulary drug list development or revision.

~~C~~D. The health carrier shall ensure that any P&T committee established in accordance with Subsections A and B has and uses a process to enable it, in a timely manner, but at least ~~annually~~quarterly, to consider the need for and implement appropriate updates and changes to the formulary or other PBMPs based on:

(1) Newly available scientific and medical evidence or other information concerning prescription drugs currently listed on the formulary or subject to any other PBMP and scientific and medical evidence or other information on newly approved prescription drugs and other prescription drugs not currently listed on the formulary or subject to any other PBMP to determine whether a change to the formulary or PBMP should be made;

(2) New FDA-approved prescription drugs (or new FDA-approved indication) within 90 days and make a decision on each new FDA-approved prescription drug (or new FDA-approved indication) within 180 days of its release onto market, or a clinical justification will be provided if this timeframe is not met;~~:~~

~~(2)~~(3) ~~If applicable, i~~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)~~(4) 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.

E~~D~~. 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.

Drafting Note: States should take note of the federal rules implementing the federal Affordable Care Act (ACA) that go into effect Jan. 1, 2016~~7~~, which will require health carriers providing essential health benefits in the individual and small group markets to meet a range of requirements related to prescription drug coverage, including the use of a P&T committee and associated standards (see Title 45 CFR – Subpart B – Essential Health Benefits Section 156.122).

F. A health carrier or its designee must not adopt or implement a benefit design that discriminates on the basis of health status, race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Carriers or designees may be asked to submit justification, with supporting documentation, explaining how a plan design is not discriminatory.

Drafting Note: States should identify and prohibit specific examples of potentially discriminatory benefit design, such as 1) the refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen (absent an appropriate reason for such refusal); and 2) placing most or all drugs that treat a specific condition on the highest cost tiers.

Drafting Note: States should take note of the federal rules implementing the federal Affordable Care Act (ACA) that go into effect Jan. 1, 2016, which will require health carriers providing essential health benefits in the individual and small group markets to meet a range of requirements related to prescription drug coverage, including the use of a P&T committee and associated standards (see Title 45 CFR – Subpart B – Essential Health Benefits Section 156.122).

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

A. (1) A health carrier must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary list including:

(a) information on any tiering structure imposed by the health carrier, as well as specific cost-sharing that applies to each formulary tier;

(b) information on any restrictions on the manner in which a drug can be obtained (including, but not limited to quantity limits, dose restrictions, dose strength restrictions, prior authorization requirements, step therapy requirements, and any other pharmaceutical benefit management procedures imposed by the health carrier),

(c) information on prescription drugs covered under both the medical and prescription drug benefits;

(d) prescription drugs covered as a preventive service without cost-sharing to the enrollee, as noted by a symbol (such as an asterisk) if the formulary does not contain a designated preventive service tier;

(e) information on whether the health plan utilizes a separate prescription drug deductible or whether the medical deductible applies to prescription drugs; and

(f) information on any limitations and/or restrictions on the location from which a prescription can be filled.

Drafting Note: Some health carriers may impose access restrictions and/or impose differential cost-sharing on a prescription that limit the prescription to only being filled at brick and mortar retail pharmacy, if permitted by state law, limiting access to a prescription through mail order, and/or limiting the filling of a prescription to certain pharmacies. To the extent these requirements are imposed, they should be disclosed pursuant to this section.

(2) The formulary drug list provided under Paragraph (1) must be written in plain language and provided in a manner that is easily accessible to plan enrollees, prospective enrollees, the Commissioner, and the general public in such a manner so that:

(a) It can be viewed on the health carrier's public web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(b) If a health carrier offers more than one plan, an individual can easily discern which formulary drug list applies to which plan.

(3) (a) The health carrier shall ensure that the formulary list is updated not less than monthly and accurately lists all of the health plan's covered drugs at a given time, including prescription drugs covered under the medical and prescription drug benefits.

(b) The health carrier shall periodically audit at least a reasonable sample size of its formulary list and retain documentation of such an audit to be made available to the commissioner upon request.

(4) (a) A health carrier must make available the information described in Paragraph (1) and (2) of this section electronically and in a machine-readable format.

(b) In making the formulary list available electronically, the health carrier shall ensure that the general public is able to view all of the current covered prescription drugs for a plan through a clearly identifiable link or tab and without creating or accessing an account or entering a policy or contract number.

~~(3)~~ (5) (a) The health carrier shall provide a print copy, or a print copy of the requested formulary list information, of a current formulary list upon request of a covered person or a prospective covered person.

(b) The health carrier shall include a disclosure in the written formulary that the information included in the written formulary is accurate as of the date of printing and that prescribers, covered persons, or prospective covered persons should consult the carrier's electronic formulary on its website or call [insert appropriate customer service telephone number] to obtain current formulary information.

(6) A health carrier shall make clear for both its electronic and print formularies which formulary applies to which network plan.

(7) A health carrier's formulary drug list, provided in Paragraph (1) and (2) also must provide, in plain language, 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;

(8) A formulary, 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

B. (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~~An accurate and searchable formulary list in machine readable format by major therapeutic category, including drugs covered under the pharmacy and medical benefits, if applicable;

(b) Information indicating which tier the prescription drug is placed in and 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~~Information in plain language 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 appeal and/or exceptions process established pursuant to Section 7 of this Act.

(2) Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction (including dose strength restriction) that causes a prescription for a particular prescription drug not to be covered for the number of doses or strength of dose prescribed, limits the pharmacy that is permitted to dispense a prescription drug, changes the tiering placement of the prescription drug, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's

manufacturer, the health carrier or its designee shall provide notice of that change to:

(a) Prescribers at least sixty (60) days prior to the effective date of the change~~, unless the health carrier will provide coverage for up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person~~;

(b) Pharmacies participating in the health carrier's network at least sixty (60) prior to ~~by~~ the effective date of the change; and

(c) Covered persons who are currently taking the prescribed drug at least sixty (60) days 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.~~

(3) Except when the Food and Drug Administration deems the drug unsafe, the health carrier is prohibited from removing a covered drug from its formulary, imposing PBMP, or moving a drug to a higher formulary tier, between the beginning of the plan's open enrollment period and sixty (60) days after the beginning of the contract year.

~~B~~C. ~~(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~~

~~Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, information on how and what written documentation is required to be submitted in order for a covered person or the covered person's authorized representative to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.~~

~~(2) The health carrier shall include a disclosure in the written formulary that the information in Paragraph (1) included in the written formulary is accurate as of the date of printing and that prescribers, covered persons, or prospective covered persons should consult the carrier's electronic formulary on its website or call [insert appropriate customer service telephone number] to obtain current formulary information.~~

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

~~(a)~~ to the extent the health carrier utilizes coinsurance, rather than a copayment, ~~T~~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;

(2) ~~(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~~ If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using (including any changes in PBMP) 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.

D~~C~~. (1) Except as otherwise provided in this section, a health carrier that uses a formulary for prescription drugs available under either the medical and/or prescription drug benefit shall not:

(a) Remove a prescription drug from the formulary;

(b) If the formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a drug to a tier with a larger deductible, copayment or coinsurance during the plan year for which the formulary applies; or

(c) Impose additional PBMP requirements, except for safety reasons.

(2) A health carrier may:

(a) Remove a prescription drug from a formulary at any time if:

(i) The drug is not approved by the Food and Drug Administration;

(ii) The Food and Drug Administration issues a notice, guidance, warning, announcement or any other statement about the drug which calls into question the clinical safety of the drug; or

Drafting Note: While health carriers should be permitted to discontinue coverage of a prescription drug due to safety issues, states should be aware that in some cases safety issues for a particular prescription drug may not affect all subpopulations equally and the overall benefit-risk ratio of a given prescription drug may still suggest continued usage for certain subpopulations.

(iii) The prescription drug is approved by the Food and Drug Administration for use without a prescription.

(3) If the health carrier's formulary includes two or more tiers of benefits providing for different deductibles, copayments or coinsurance applicable to the prescription drugs in each tier, move a brand name prescription drug to a tier with a larger deductible, copayment or coinsurance if the individual carrier adds to the formulary a generic prescription drug that is approved by the Food and Drug Administration for use as an alternative to the brand name prescription drug at:

(a) The benefit tier from which the brand name prescription drug is being moved; or

(b) A benefit tier that has a smaller deductible, copayment or coinsurance than the benefit tier from which the brand name prescription drug is being moved.

(4) This section does not prohibit a health carrier from adding a prescription drug to a formulary at any time.

~~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)~~E. (1) Within the first 90 days of coverage under a new plan, a health carrier must provide a one-time, temporary supply of a nonformulary prescription drug (including prescription drugs that are on the health plan's formulary but

require PBMP) in order to accommodate the immediate needs of a covered person.

(2) The temporary supply provided under Paragraph (3)(A) must be for at least thirty (30) days of medication, unless the prescription is written by a prescriber for less than 30 days.

F. ~~Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, the~~The notice provided pursuant to Paragraph (A)(1)~~(a)~~ or as part of the information to be provided pursuant to Paragraph (B)(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)~~G. (1) A health carrier or its designee shall not be required to provide advance written notice ~~the notice~~ required pursuant to Paragraph (B)(1)~~(a)~~ or cover up to a 60-day supply of a prescription drug pursuant to Paragraph (B)(1)~~(b)~~ whenever~~:~~ the ~~(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.

(2) In cases where a prescription drug is determined by the Food and Drug Administration to be in short supply, the health carrier or its designee shall not be required to provide advance written notice pursuant to Paragraph (B)(2) or cover up to a 60-day supply of a prescription drug pursuant to Paragraph (B)(2), but where a prescription drug that is not in short supply has been determined by the FDA to be interchangeable with the prescription drug in short supply, the health carrier or its designee must provide coverage of the prescription drug that is not in short supply under the same terms as the prescription drug found to be in short supply throughout the drug shortage.

~~; 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 or strength restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed, the dose strength 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 appeals and/or exceptions process that allows covered persons, ~~or~~ covered persons' authorized representatives, or covered person's prescribing physician (or other prescriber, as appropriate) to request approval for:

(1) Coverage of a prescription drug that is not covered based on the health carrier's formulary;

(2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary for reasons other than safety or because the prescription drug is in short supply ~~cannot be supplied by~~ or has been withdrawn from the market by the drug's manufacturer; ~~or~~

Drafting Note: While health carriers should be permitted to discontinue coverage of a prescription drug due to safety issues, states should be aware that in some cases safety issues for a particular prescription drug may not affect all subpopulations equally and the overall benefit-risk ratio of a given prescription drug may still suggest continued usage for certain subpopulations.

(3) A formulary tiering exception in cases where the preferred prescription drug(s) would not be as effective as the requested drug for treating the covered person's condition and/or if the preferred prescription drug(s) would have adverse effects for the covered person; or

Drafting Note: A formulary tiering exception would permit a covered person, the covered person's authorized representative, covered person's prescribing physician (or other prescriber, as appropriate) to obtain a non-preferred prescription drug at the lower cost-sharing terms applicable to prescription drugs in a preferred tier.

(4) 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 and/or dose strength.

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

B. (1) A covered person, ~~or~~ the covered person's authorized representative, covered person's prescribing physician (or other prescriber, as appropriate) may file a request under Subsection A ~~only~~ if the covered person's prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person's disease or medical condition because:

(a) There is not a prescription drug listed on the formulary to treat the covered person's disease or medical condition that is an acceptable clinical alternative;

(b) The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(i) Has been ineffective in the treatment of the covered person's disease or medical condition or, based on the ~~both~~ sound clinical evidence and medical and scientific evidence, the prescription drug's FDA label, and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(ii) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person; or

(c) The number of doses or dose strength 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.

Drafting Note: States should be aware that Paragraph (1) refers to commonly used utilization management criteria. It is possible that a health plan may utilize new or different utilization management criteria. When adopting these requirements States should consider whether additional provisions are needed to address these new or different utilization management criteria.

(2) (a) A health carrier may require the covered person, ~~or~~ the covered person's authorized representative, covered person's prescribing physician (or other prescriber, as appropriate) 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) Portion of the patient~~Patient~~ history relevant to the prescription drug that is the subject of the medical exception request;

(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 tiering exception, why the preferred prescription drug would not be as effective or have an adverse effect for the covered person as the requested drug;

(IV) If the medical exceptions request involves a dose restriction or dose strength restriction, why the available number of doses or dose strength 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 or dose strength restriction, why an exception to the dose restriction is needed for the individual patient; and

(vi) Any other relevant information the provider deems reasonably necessary to evaluate the medical necessity of the medical exceptions request.

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

Drafting Note: Section 6J of the NAIC Health Benefit ~~Managed Care~~ Plan Network Adequacy Access and Model Act provides that a health carrier may not prohibit a participating provider from advocating on behalf of covered persons within the utilization review or grievance processes established by the carrier or a person contracting with the carrier. The medical exceptions process established under this section for the review of requests for approval for exceptions to a formulary or being subject to a dose restriction, dose strength, 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~~4) 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 Health Benefit ~~Managed Care~~ Plan Network Access and Adequacy Model Act.

C. ~~(1)~~ Upon receipt of a request made pursuant to Subsection A, the health carrier shall ensure that the request is reviewed by appropriate health care professionals who, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person for whom the request has been made using documented clinical review criteria that:

(1~~a~~) Are based on sound clinical evidence and medical and scientific evidence and FDA approved indication; and

(2~~b~~) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health carrier's P&T committee or any other practice guidelines developed by the federal government, national or professional medical or pharmacist societies, boards and associations.

~~(2) The health care professional or professionals designated by the health carrier to review the request under Paragraph (1) shall ensure that the decision~~

~~reached on the request is consistent with the benefits and exclusions under the covered person's health benefit plan with the health carrier.~~

D. (1) The medical exceptions process under this section shall require the health carrier to make a decision on a request made pursuant to Subsection A and provide notice of the decision to the covered person, ~~or~~ the covered person's authorized representative, and/or the covered person's prescribing physician (or other prescriber, as appropriate) as quickly as the covered person's particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under Subsection B(2).

(2) ~~(a)~~ If the health carrier fails to make a decision on the request and provide notice of the decision within the time frame required under Paragraph (1) ~~:~~

~~(i)~~ ~~The~~the ~~c~~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.~~

(3) (a) A health carrier must establish a process for a covered person, the covered person's authorized representative, or the covered person's prescribing physician (or other prescriber, as appropriate) to request an expedited review based on exigent circumstances.

(b) An exigent circumstance exists 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 or when a covered person is undergoing a current course of treatment using a non-formulary drug.

(c) In the event of an expedited review, a health carrier must:

(i) Make its coverage determination 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 24 hours following receipt of the request; and

(ii) Upon approval of the exception based on exigent circumstances, provide coverage of the non-formulary drug for the duration of the exigency.

E. ~~(1)~~ Whenever a request made under ~~this~~Section 7 ~~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 section (B)(7)~~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~~1) 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

(2~~b~~) The prescription drug continues to be considered safe for treating the covered person's disease or medical condition.

~~(2)~~F. In addition to Paragraph (C)(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 cost-sharing for the drug toward the plan's annual limitation on cost-sharing.

~~(3)~~G. 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~~H. (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 an appeal ~~grievance~~ pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act].

(2) The denial shall, in plain language ~~a manner calculated to be understood by the covered person or, if applicable, the covered person's authorized representative,~~ set forth:

(a) The specific reason or reasons for the denial;

(b) A reference to the evidence or documentation, including the clinical review criteria, including practice guidelines, and clinical evidence and medical and scientific evidence considered in reaching the decision to deny the request;

(c) Instructions for requesting, a written statement of the clinical and medical or scientific rationale for the denial; and

(d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act], including any time limits applicable to those procedures.

(3) Health carriers must have a process in place for a covered person or the covered person's authorized representative to request that the original standard or expedited exception request and subsequent denial of such request be reviewed by independent review organization. Under this process, health carriers must:

Make a determination on the external exception request and notify t

(a) the covered person or the covered person's authorized representative of the coverage determination no later than 72 hours following the receipt of its request for a standard exception under Section 7(D)(1) or no later than 24 hours following the receipt of its request for an expedited exception request under Section 7(B)(3D)(3).

Upon approval of the exception, provide coverage of the non-formulary

(b) formulary drug for the duration of the prescription in the case of a standard exception request or the duration of the exigency in the case of an expedited exception request.

G. A health carrier that permits a covered person's prescribing participating provider to make formulary and other PBMP exceptions without having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F with respect to the prescription drug orders of these prescribing participating providers.

H. A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F if the health carrier:

(1) Has an expedited utilization review process as set forth in [insert reference in state law equivalent to Section 10 of the Utilization Review and Benefit Determination Model Act]; and

~~(2) Allows covered persons or their authorized representatives to use this process to seek approval for coverage of a prescription drug that is not otherwise covered because of the health carrier's formulary or because of any other PBMP requirement that restricts coverage of the prescription drug until the PBMP requirement has been met.~~

~~I. Nothing in this section shall be construed to allow a covered person to use the medical exceptions process set out in this section to request coverage for a prescription drug that is categorically or contractually excluded from coverage under the covered person's health benefit plan.~~

Section 8. Participation in Approved Clinical Trials

A. As used in this section, the following definitions apply:

(1) "Approved clinical trial" means a phase I, a phase II, a phase III or a phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or a life-threatening condition and is not designed exclusively to test toxicity or disease pathophysiology and the trial must be:

(a) Conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration (FDA);

(b) Exempt from obtaining an investigational new drug application; or

(c) Approved or funded by:

(i) The National Institutes of Health, the Centers for Disease Control and Prevention; the Agency for Health Care Research and Quality, the Centers for Medicare & Medicaid Services or a cooperative group or center of any of the entities described in this item;

(ii) A cooperative group or center of the U.S. Department of Defense or the U.S. Department of Veterans Affairs;

(iii) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or

(iv) The U.S. Departments of Veterans Affairs, Defense or Energy if the trial has been reviewed or approved through a system of peer review determined by the Secretary to:

(I) Be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

(II) Provide an unbiased scientific review by qualified individuals who have no interest in the outcome of the review.

(2) "Life-threatening condition" means a disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(3) "Qualified individual" means an individual covered under a health benefit plan who is eligible to participate in an approved clinical trial according to the trial protocol for the treatment of cancer or a life threatening condition because:

(a) The referring health care professional is participating in the trial and has concluded that the individual's participation in the trial would be appropriate; or

(b) The individual provides medical and scientific information establishing that the individual's participation in the trial is appropriate because the individual meets the conditions described in the trial protocol.

(4) (a) "Routine patient costs" include:

(i) All items and services that typically by the health benefit plan when the items or services are typically covered for an enrollee who is not a qualified individual enrolled in an approved clinical trial;

(ii) All items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

(iii) All items or services needed for reasonable and necessary care arising from the provision of an investigations item or service in particular, for the diagnosis or treatment of complications. covered.

(b) "Routine patient costs" do not include:

(i) An investigational item, device or service that is part of the trial;

(ii) An item or service provided solely to satisfy data collection and analysis needs for the trial if the item or services is not used in the direct clinical management of the patient;

(iii) A service that is clearly inconsistent with widely accepted and established standards of care for the individual's diagnosis; or

(iv) An item or service customarily provided and paid for by the sponsor of a trial.

B. A health carrier that offers a health benefit plan providing coverage in this state may not:

(1) Deny participation by a qualified individual in an approved clinical trial;

(2) Deny, limit or impose additional conditions on the coverage of routine patient costs for items or services furnished in connection with participation in a trial;

(3) Require prior authorization for standard-of-care services as part of a clinical trial unless those same services require prior authorization outside of a clinical trial; or

(4) Discriminate against an individual on the basis of the individual's participation in an approved clinical trial.

C. A network plan may require a qualified individual who wishes to participate in an approved clinical trial to participate in a trial that is offered through a health care provider who is part of the network plan if the provider is participating in the trial and the provider accepts the individual as a participant in the trial.

D. This section applies to a qualified individual residing in this state who participates in an approved clinical trial that is conducted outside of this state.

E. Nothing in this section shall be construed to limit a health carrier's coverage with respect to clinical trials.

Section 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 a 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. (1) ~~Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, each~~Each health carrier shall maintain data on and~~, upon request,~~ must make available to the commissioner on an annual basis the following information with respect to medical exceptions requests made under Section 7 of this Act:

(~~1~~a) The total number of medical exceptions requests;

(~~2~~b) From the total number of medical exceptions requests provided under Paragraph (1):

(~~a~~i) The number of requests made for coverage of a nonformulary prescription drug;

(~~b~~ii) 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

(~~e~~iii) The number of requests made for an exception to being subject to a PBMP that subjects a prescription drug to dose restrictions, dose strength restriction, tiering exceptions, or step therapy requirements;

(~~3~~c) The number of medical exceptions requests approved and denied for each category; and

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

(2) A health carrier must also provide, on an annual basis, the information provided in Paragraph (1) above to the public in a manner that is written in language appropriate for lay persons. Readability can be demonstrated through consumer testing and/or adherence to best practices in writing for lay persons. In addition, disclosures should be designed and formatted to facilitate consumer use. Appropriate design and format can be demonstrated through to adherence to best practices in designing documents to facilitate consumer use.in plain language.

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, entity or intermediary 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, entity or intermediary 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 11~~0~~. 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 information provided in Section 6 regarding the existence of the formulary and any other PBMP and that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered;

(2) ~~Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, describe~~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, ~~-~~ dose strength restriction, or step therapy requirement, including an expedited exception request; and

(3) If applicable, describe the process for filing a grievance as set forth in [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act] to appeal a denial of a medical exceptions request.

B. (1) In addition to Subsection A, the policy, certificate, membership booklet, ~~outline of coverage~~ or other evidence of coverage provided to covered persons shall explain ~~in layperson's terms~~ information provided in Section 6 A on the health carrier's formulary and other PBMPs, including what a formulary and each PBMP that that health carrier uses is, and state that a copy of the formulary list and information about which prescription drugs are subject to a PBMP will be provided to a covered person by the health carrier or its designee on request.

(2) In addition to the information explained under Paragraph (1), a health carrier shall explain ~~in layman's terms~~ in a separate document or other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that if ~~:~~

~~(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. Each health carrier that uses a formulary or any other PBMP shall in the Summary of Benefits and Coverage, provide an electronic link to the formulary discussed in Paragraph A above, consistent with the plain language requirements set forth in Paragraph D below..

D. All information provided to consumers through disclosures required in this Model Act must be written in language appropriate for lay persons. Readability can be demonstrated through consumer testing and/or adherence to best practices in writing for lay persons. In addition, disclosures should be designed and formatted to facilitate consumer use. Appropriate design and format can be demonstrated through to adherence to best practices in designing documents to facilitate consumer use.

Section 1~~1~~2. Nondiscrimination

A. A health carrier or its designee must not adopt or implement a benefit design that discriminates on the basis of health status, race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Carriers or designees may be asked submit justification, with supporting documentation, explaining how a plan design is not discriminatory.

Drafting Note: States should identify and prohibit specific examples of potentially discriminatory benefit design, such as 1) the refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen (absent an appropriate reason for such refusal); and 2) placing most or all drugs that treat a specific condition on the highest cost tiers.

Drafting Note: States should take note of the federal rules implementing the federal Affordable Care Act (ACA) that go into effect Jan. 1, 2016, which will require health carriers providing essential health benefits in the individual and small group markets to meet a range of requirements related to prescription drug coverage, including the use of a P&T committee and associated standards (see Title 45 CFR – Subpart B – Essential Health Benefits Section 156.122)

Section 13. 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~~14. Penalties

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

Section ~~13~~15. 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~~16. Effective Date

This Act shall be effective [insert date].

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

2002 Proc. 4th Quarter 279, 323-333 (adopted by task force).
2003 Proc. 1st Quarter 175 (adopted by parent committee).
2003 Proc. 2nd Quarter 12, 16 (adopted by Plenary).

This page is intentionally left blank