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Amendment No. 1 to SB0389

Trail
Signature of Sponsor

AMEND Senate Bill No. 389 House Bill No. 262*

by deleting all language after the enacting clause and by substituting instead the following:

Section 1. This act shall be known and may be cited as the "Health Carrier Prescription Drug Benefit Management Act."

Section 2. 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.

Section 3. For purposes of this act:

(1) “Authorized representative” means:

(A) 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;

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

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

(D) 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.

(2) “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.

(3) “Commissioner” means the Commissioner of Insurance.

(4) “Covered benefits” or “benefits” means those health care services to which a covered person is entitled under the terms of the health benefit plan.

(5) “Covered person” means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

(6)

(A) “Dose restriction” means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period.

(B) “Dose restriction” does not include:

(i) 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

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on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug’s manufacturer.

(7) “Facility” means an institutional provider of health care services or a health care setting, including but not limited to hospitals and other licensed

inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

(8) “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.

(9) “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.

(10) “Grievance” means a complaint submitted by or on behalf of a covered person regarding:

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

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

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

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

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

(13) “Health care provider” or “provider” means a health care professional or a facility.

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

(15) “Health carrier” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

(16) “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.

(17) “Medical and scientific evidence” means evidence found in the following sources:

(A) 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;

(B) 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);

(C) Medical journals recognized by the secretary of health and human services under Section 1861(t)(2) of the federal Social Security Act;

(D) The following standard reference compendia:

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

(ii) Drug Facts and Comparisons;

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

(iv) The United States Pharmacopoeia–Drug Information;

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

(i) The federal agency for healthcare research and quality;

(ii) The national institutes of health;

(iii) The national cancer institute;

(iv) The national academy of sciences;

(v) The centers for medicare & medicaid services;

(vi) The federal food and drug administration; and

(vii) Any national board recognized by the national institutes of health for the purpose of evaluating the medical value of health care services; or

(F) Any other relevant data that is comparable to the sources listed in items (A) through (E).

(18) “Participating provider” means a provider that, under contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

(19) “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.

(20) “Pharmaceutical benefit management procedure” or “PBMP” includes any of the following that is used to manage prescription drug benefits:

(A) A formulary;

(B) Dose restrictions;

(C) Prior authorization requirements; or

(D) Step therapy requirements.

(21) “Pharmacy and Therapeutics (P&T) committee” means an advisory committee or committees or equivalent body or bodies that is comprised of individuals who are either employed by or under contract with the health carrier or its designee, a majority of whose membership includes health care professionals, such as physicians and pharmacists, who, collectively, have current knowledge and expertise in:

(A) Clinically appropriate prescribing, dispensing and monitoring of outpatient prescription drugs; and

(B) Drug use review, evaluation and intervention.

(22) “Prescriber” means any licensed, certified or otherwise legally authorized health care professional authorized by law to prescribe a prescription drug.

(23) “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.

(24) “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.

(25) “Prior authorization” means the process of obtaining prior approval for coverage of a prescription drug.

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

Section 4.

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

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

Section 5.

(a)

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

(2) The health carrier shall ensure that any P&T committee established pursuant to this subsection has policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with developers or manufacturers of prescription drugs.

(b)

(1) The health carrier shall ensure that any P&T committee established in accordance with subsection (a) has and uses a process to:

(A) Evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary; and

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

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

(c) The health carrier shall ensure that any P&T committee established in accordance with subsection (a) has and uses a process to enable it, in a timely manner, but at least annually, to consider the need for and implement appropriate updates and changes to the formulary or other PBMPs based on:

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

(2) If applicable, information received from the health carrier with respect to medical exception requests made under Section 7 of this act to enable the P&T committee to evaluate whether the prescription drugs currently listed on the formulary or subject to any other PBMP are meeting the health care service needs of covered persons; and

(3) Information relating to the safety and effectiveness of a prescription drug currently listed on the formulary or subject to any other PBMP or relating to clinically similar prescription drugs not currently listed on the formulary or subject to any other PBMP from the health carrier's quality assurance activities or claims data that was received since the date of the P&T committee's most recent review of that prescription drug.

(d) Subject to Section 9 of this act, a health carrier may contract with another person to perform the functions of a P&T committee as described in this section.

Section 6.

(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 7(g) or (h) of this act, information on how

and what written documentation is required to be submitted in order for covered persons or their authorized representatives to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this act.

(2) Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer, the health carrier or its designee shall provide notice of that change to:

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

(B) Pharmacies participating in the health carrier's network by the effective date of the change; and

(C) Prescribers, who did not receive advance notice of the change because of the exception allowed under item (a) of this subdivision, 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 7(g) or (h) of this act, information on how and what written documentation is required to be submitted in order for a covered person or the covered person's authorized representative to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this act.

(2) In addition to the information to be provided under subdivision (1), a health carrier or its designee electronically or in writing, upon

request, shall explain the following in a manner calculated to be understood by a layperson that:

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

(B) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and

(C) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.

(c)

(1) Whenever a health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a prior authorization or step therapy requirement that causes a particular drug not 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 7(g) or (h) of this act, the notice provided pursuant to item (1)(a) or as part of the information to be provided pursuant to item (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 item (1)(a) or cover up to a 60-day supply of a prescription drug pursuant to item (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.

(a) Each health carrier that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met shall establish and maintain a medical exceptions process that allows covered persons or covered persons' authorized representatives to request approval for:

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

(2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary for reasons other

than safety or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; or

(3) An exception to a PBMP that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses.

(b)

(1) A covered person or the covered person's authorized representative may file a request under subsection (a) only if the covered person's prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person's disease or medical condition because:

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

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

(i) Has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known

characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

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

(C) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(2)

(A) A health carrier may require the covered person or the covered person's authorized representative upon request to provide a written certification from the covered person's prescribing provider of the determination made under subdivision (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 items (1)(a), (b) or (c), the reason:

(a) Why the formulary drug is not acceptable for the individual patient;

(b) 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

(c) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the individual patient;

(v) The reason why the prescription drug that is the subject of the medical exceptions request is needed for the individual patient or, if the medical exceptions request

involves a dose restriction, why an exception to the dose restriction is needed for the individual patient; and

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

(3) Participation by a provider on behalf of a covered person in the medical exceptions process established under this section shall be construed as being the same as a provider's advocating on behalf of a covered person within the utilization review process established by the health carrier for purposes of Tennessee Code Annotated, Title 56.

(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 subdivision (1) shall ensure that the decision reached on the request is consistent with the benefits and exclusions under the covered person's health benefit plan with the health carrier.

(d)

(1) The medical exceptions process under this section shall require the health carrier to make a decision on a request made pursuant to subsection (a) and provide notice of the decision to the covered person or the covered person's authorized representative as quickly as the covered person's particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under subdivision (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 subdivision (1):

(i) The covered person shall be entitled to have coverage for, up to one month's supply of the prescription drug that is the subject of the request; and

(ii) The health carrier shall make a decision on the request prior to the covered person's completion of the supply provided in item (i).

(B) If the health carrier fails to make a decision on the request and provide notice of the decision prior to the covered person's completion of the supply provided for in item (A) of this paragraph, the health carrier shall maintain coverage, as specified in item (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 subdivision (1), whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug.

(3) A health carrier shall not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(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 Tennessee Code Annotated, Section 56-32-210.

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

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

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

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

(D) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to Tennessee Code Annotated, Section 56-32-210, including any time limits applicable to those procedures.

(g) A health carrier that permits a covered person's prescribing participating provider to make formulary and other PBMP exceptions without

having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of subsections (b), (c), (d), (e)(1) and (2) and (f) with respect to the prescription drug orders of these prescribing participating providers.

(h) A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of subsections (b), (c), (d), (e)(1) and (2) and (f) if the health carrier:

(1) Has an expedited utilization review process; 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.

(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 7(g) 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 7(g) 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 subdivision (1):

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

(B) The number of requests made for continuing coverage of a prescription drug that the health carrier was discontinuing

from coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; and

(C) The number of requests made for an exception to being subject to a PBMP that subjects a prescription drug to dose restrictions or step therapy requirements;

(3) The number of medical exceptions requests approved and denied; and

(4) Any other information the commissioner may request.

Section 9.

(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.

(a) Each health carrier that uses a formulary or any other PBMP shall in the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons:

(1) Disclose the existence of the formulary and any other PBMP and that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered;

(2) Except for a health carrier that satisfies the requirements of Section 7(g) or (h) of this act, describe the medical exceptions process that may be used to request coverage of nonformulary prescription drugs or to obtain an exception to being subject to a dose restriction or step therapy requirement; and

(3) If applicable, describe the process for filing a grievance as set forth in Tennessee Code Annotated, Section 56-32-210, to appeal a denial of a medical exceptions request.

(b)

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

(2) In addition to the information explained under subdivision (1), a health carrier shall explain in layman's terms in a separate document or

other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that:

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

(B) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and

(C) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.

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Signature of Sponsor

AMEND Senate Bill No. 389 House Bill No. 262*

Section 11. The commissioner may promulgate regulations to carry out the provisions of this act. The regulations shall be subject to review in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

Section 12. A violation of this act shall subject the offender to any sanction permitted by Tennessee Code Annotated, Title 56, Chapter 8, Part 1.

Section 13. 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.

by deleting the effective date section and by substituting instead the following:

Section 14. This act shall take effect July 1, 2003, the public welfare requiring it.