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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2697 Session of 2008

INTRODUCED BY KENNEY, OLIVER, SONNEY, REICHLEY, BENNINGHOFF, WATSON, McILHATTAN, ROSS, MYERS, PAYTON, SAYLOR, CALTAGIRONE, GEORGE, DePASQUALE, KILLION, THOMAS, BELFANTI, RUBLEY, YOUNGBLOOD, HENNESSEY, HARPER, K. SMITH, PYLE, JAMES, HESS, PETRI, PRESTON, KORTZ, WANSACZ, GALLOWAY, COHEN, CAPPELLI, MANN, BLACKWELL, TURZAI, MAHER, PASHINSKI, McILVAINE SMITH, ADOLPH, BARRAR, MICOZZIE, RAYMOND, ROEBUCK AND REED, JULY 2, 2008

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, JULY 2, 2008

AN ACT

Providing for the establishment of the transparent review of prescription drugs for utilization in the Fee for Service component of the Medical Assistance Program.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Medicaid Pharmaceutical and Therapeutics Drug Utilization Review Procedures Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Committee." The Medical Assistance Pharmaceutical and Therapeutics Committee established under section 3.

"Department." The Department of Public Welfare of the Commonwealth.

"Secretary." The Secretary of Public Welfare.

Section 3. Medical Assistance Pharmaceutical and Therapeutics Committee.

(a) Establishment.--The department shall establish the Medical Assistance Pharmaceutical and Therapeutics Committee.

(b) Function.--The committee shall serve the secretary in an advisory capacity for the purposes of:

(1) Developing and maintaining a preferred drug list.

(2) Developing and maintaining drug utilization review controls for prescription drugs and medical devices as required by section 1927 of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(g)(3) et seq.).

(c) Membership.--Members shall serve on the committee at the discretion of the secretary. Members shall serve two-year terms. All members shall be provided civil immunity as a result of acts or omissions while serving on the committee.

(d) Composition.--The committee shall be composed of no fewer than 15 members and not more than 25 members. No less than 50% of members shall be actively licensed physicians. No less than 33% of the members shall be actively licensed pharmacists. The committee shall also include at least one nurse practitioner. All external appointees of the committee shall have a working knowledge of the therapeutic classes of drug classes under review and have experience treating the medical assistance population. Appointments made by the secretary shall include, but not be limited to:

(1) Family medicine practitioners.

(2) Internal medicine practitioners.

(3) Pediatricians.

(4) Cardiologists.

(5) Psychiatrists or neurologists.

(6) Obstetricians or gynecologists.

(7) Endocrinologists.

(8) Additional ad hoc professional specialist members as necessary.

No more than 20% of the members shall be employees of the Commonwealth or employees of contractors providing services to the Medical Assistance Program. This prohibition shall not apply to any individual who provides direct care services to medical assistance enrollees. The secretary may also appoint members to the committee from the public at large for the purpose of representing the views of medical assistance enrollees.

(e) Additional requirements.--

(1) Members shall be required to submit conflicts of interest disclosure statements and will have an ongoing duty to disclose any conflicts of interest to the committee chairperson and the secretary. The secretary shall not require or prohibit any member of the committee from engaging in discussions with stakeholders in the committee's review process. The secretary shall not require the disclosure of any such discussions among the committee members and the stakeholders. All conflict disclosure information shall be available to the general public.

(2) Members shall be required to keep confidential all pricing information and proprietary information disclosed regarding the preferred drug list.

(f) Leadership.--The chairperson and vice chairperson shall be nominated and seconded by members of the committee and

elected by a majority vote of the members of the committee. The chairperson shall preside over committee meetings. The chairperson shall coordinate all committee activities with the secretary. The vice chairperson shall assume all the powers and duties of the chairperson when the chairperson is absent from a meeting and in the event of a vacancy in the office. The vice chairperson shall also perform such other duties as requested by the committee or the chairperson. The chairperson or, in the absence of the chairperson, the vice chairperson shall serve to sign official committee documents, including, but not limited to, recommendations to the secretary concerning the preferred drug list and the implementation or modifications to drug utilization controls.

(g) Meetings.--The secretary shall publicize all meetings of the committee pursuant to 65 Pa.C.S. Ch. 7 (relating to open meetings), and the committee's deliberations, recommendations and decisions shall be considered official actions and shall be open to the public. Meeting notices and corresponding agendas shall also be provided on the department's Internet website at least 60 days prior to each meeting. A quorum shall be established when a simple majority of members are present. Minutes of each meeting shall be posted on the department's Internet website 30 days after each meeting. The minutes shall include detailed vote totals for each motion made.

Section 4. Preferred drug list.

The committee shall develop and maintain a preferred drug list that promotes the use of safe and effective FDA-approved medications. The committee shall ensure that the pharmaceutical management is based on sound clinical evidence that is both safe and cost effective. The process shall include the review of

selected therapeutic classes of drugs to include on a preferred drug list. The process shall include the timely review of newly approved drugs to any class of therapies previously reviewed by the committee. Any new drug from a class of therapies previously reviewed shall be considered nonpreferred until it is reviewed by the committee. The committee shall review any new drug from a previously reviewed class at the next available meeting. This review shall occur provided that the drug's approval from the Food and Drug Administration occurred more than 60 days prior to the meeting. Drugs designated as nonpreferred on the preferred drug list shall require a prior authorization. Prior authorized drugs shall require the prescriber or the dispenser to verify with the department or its authorized agent that the drug is appropriate for the needs of the specific patient. Drugs in therapeutic classes not reviewed by the committee or designated preferred or nonpreferred shall be deemed as having preferred status.

Section 5. Committee review.

(1) The review process shall include the public review of monograph material presented and the receipt of public testimony. The chairperson shall establish and publish guidelines for the acceptance of oral and written testimony. The committee shall not limit the acceptance of oral testimony to less than one hour in the aggregate per meeting. The committee may limit the presentation of information by representatives of drug manufacturers to written testimony. The chairperson shall provide notice to all individuals or interested parties that wish to submit public testimony a listing of the names and corresponding subject matter of those individuals that are scheduled to present testimony to

the committee. This notice shall be posted on the department's Internet website at least ten days prior to the meeting. Following the review of monograph material and written testimony and the acceptance of oral testimony, the committee shall publicly announce their recommendation at the meeting. The chairperson shall communicate the committee's recommendations to the secretary.

(2) The secretary shall have ten business days to accept, reject or modify the committee's recommendations. The absence of action by the secretary within ten business days shall be deemed as an approval of the committee's recommendations.

(3) The department shall take appropriate steps to insure that providers are notified of the drugs selected for placement on the preferred drug list. Notice of the selected drugs shall occur at least 60 days prior to implementation of the prior authorization process. Notice shall be provided to all practicable parties, including, but not limited to, enrollees, pharmacy benefit managers and health care providers. The prior authorization process shall provide for a turnaround response within 24 hours of receipt of a completed prior authorization request from a prescribing provider by telephone, mail, fax or electronic communication. In emergency situations, providers may dispense at least a 72-hour supply of medication as mandated and pursuant to section 1927 of the Social Security Act (49 Stat. 620, 42 U.S.C. §1396r-8(g)(3) et seq.)

Section 6. Drug utilization review.

(a) Establishment.--The committee shall establish a drug utilization review process. The committee shall make

recommendations to the secretary regarding drugs to be considered for prior authorization. Recommendations may include prior authorizations pertaining to prescription quantity, dosage limits, duration of therapy, duplicate therapies and clinical appropriateness.

(b) Committee review.--The committee shall recommend procedures and criteria for the prior authorization approval of nonpreferred drugs. In developing these criteria, the committee shall consider the following:

(1) The preferred drug has been tried by the patient and has failed to produce the desired health outcomes.

(2) The patient has tried the preferred drug and has experienced unacceptable side effects.

(3) The patient has been stabilized on a nonpreferred drug and transition to the preferred drug would be medically contraindicated.

(4) Other clinical indications for the use of the nonpreferred drug, which shall include consideration of the medical needs of special populations.

(c) Secretary review.--Upon receipt of a prior authorization recommendation from the committee, the secretary may not accept, reject or modify the recommendation until:

(1) The proposed prior authorization has been shared with the Medical Assistance Advisory Committee and the Consumer Subcommittee of the Medical Assistance Advisory Committee for review and public comment.

(2) The department provides a copy of proposed prior authorization with appropriate patient advocacy groups for review and public comment.

(3) The department posts the prior authorization on the

department's Internet website for review and public comment.

(4) The secretary posts all public comments, including the department's corresponding response, on the department's Internet website.

(5) The secretary presents all public comments, including the department's corresponding response, to the Medical Assistance Advisory Committee at a regularly scheduled meeting.

Section 7. Appeals.

Final decisions made by the secretary pertaining to the designation of preferred status on the preferred drug list or prior authorization requirements for access to any drug may be appealed. An appeal may be made solely on a clinical basis or procedural omission or irregularity. The term irregularity shall be construed to include the committee's rejection of a vendor's recommendation of preferred status on the preferred drug list. Appeals shall be submitted to the secretary in written form within ten days of the secretary's disposition of a recommendation made by the Medical Assistance Pharmaceutical and Therapeutics Committee. The secretary shall refer the appeal to the Peer Review Committee for disposition.

Section 8. Peer Review Committee membership.

Members of the Peer Review Committee shall include no fewer than seven members and no more than 11 members as appointed by the secretary. The committee shall be chaired by the Office of Medical Assistance Programs medical director. The committee may not include more than three members of the Medical Assistance Pharmaceutical and Therapeutics Committee. The remaining members of the committee shall not be employees of the Commonwealth. Physicians appointed to the committee shall have a working

knowledge of the therapeutic classes of drug classes under review. Appointments made by the secretary shall include, but not be limited to:

(1) Family medicine physician.

(2) Internal medicine physician.

(3) Pediatrician.

(4) Cardiologist.

(5) Psychiatrist or neurologist.

(6) Obstetrician or gynecologist.

(7) More ad hoc professional specialist members as necessary.

Section 9. Effective date.

This act shall take effect in 60 days.