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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 669 Session of 2015

INTRODUCED BY ALLOWAY, WHITE, TARTAGLIONE, TOMLINSON, SCARNATI, FONTANA, MENSCH, VULAKOVICH, RAFFERTY, STEFANO, McGARRIGLE, LEACH, SCAVELLO, BLAKE, McILHINNEY AND BAKER, APRIL 28, 2016

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, APRIL 28, 2016

AN ACT

Providing for registration of pharmacy benefits managers and for maximum allowable cost transparency.

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 Pharmaceutical Transparency 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:

"Covered individual." A member, participant, enrollee, contract holder or policyholder or beneficiary of a covered entity who is provided health coverage by the covered entity. The term includes a dependent or other person provided health coverage through the policy, contract or plan of a covered individual.

"Covered entity." A member, participant, enrollee, contract holder or policy holder providing pharmacy benefits to a covered individual under a health coverage plan pursuant to a contract administered by a pharmacy benefit manager.

"Department." The Department of Health of the Commonwealth.

"Maximum allowable cost." The maximum amount that a pharmacy benefits manager will reimburse a pharmacy for the cost of a drug or a medical product or device.

"Maximum allowable cost list." A list of drugs, medical products or devices, or both, for which a maximum allowable cost has been established by a pharmacy benefits manager.

"Multiple source drug." A covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

"Network." A pharmacy or group of pharmacies that agree to provide prescription services to covered individuals on behalf of a covered entity or group of covered entities in exchange for payment for its services by a pharmacy benefits manager or pharmacy services administration organization. The term includes a pharmacy that generally dispenses outpatient prescriptions to covered individuals or dispenses particular types of prescriptions, provides pharmacy services to particular types of covered individuals or dispenses prescriptions in particular health care settings, including networks of specialty, institutional or long-term care facilities.

"Pharmacy." As defined in section 2(12) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

"Pharmacy benefits manager" or "PBM." A person, business or other entity that performs pharmacy benefits management for covered entities.

"Pharmacy benefits management." Performing any of the following:

(1) The procurement of prescription drugs at a negotiated contracted rate for dispensation within this Commonwealth to covered individuals.

(2) The administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals.

(3) The provision of any of the following services in conjunction with the administration of pharmacy benefits:

(i) Mail-service pharmacy.

(ii) Claims processing.

(iii) Retail network management.

(iv) Payment of claims to pharmacies for prescription drugs dispensed to covered individuals via retail or mail-order pharmacy.

(v) Clinical formulary development and management services, including, but not limited to, utilization management and quality assurance programs.

(vi) Rebate contracting and administration.

(vii) Certain patient compliance, therapeutic intervention and generic substitution programs.

(viii) Disease management programs.

(ix) Setting pharmacy reimbursement pricing and methodologies, including maximum allowable cost, and determining single or multiple source drugs.

"Pharmacy Services Administration Organization" or "PSAO."

Any entity that contracts with pharmacies to assist with third-party payer interactions and can provide a variety of other administrative services. The administrative services vary but may include contracting with PBMs on behalf of pharmacies and managing pharmacies' claims payments from third-party payers.

Section 3. PBM registration.

(a) General rule.--To conduct business in this Commonwealth, a PBM must register with the department annually by:

(1) Submitting the registration form prescribed under subsection (c).

(2) Paying a registration fee promulgated by the department.

(b) Registration renewal.--The department shall prescribe rules for the annual renewal of a PBM registration, and the following shall apply:

(1) A PBM shall pay a renewal fee adopted by the department.

(2) Any lapse in registration under this section shall be subject to penalties or late fees, or both, as established by the department.

(c) Registration form.--The department shall develop a registration form, which a PBM shall submit to the department. The form must contain the following information, along with any additional requirements as may be established by the department:

(1) The identity, address and telephone number of the PBM.

(2) The name, business address and telephone number of the contact person for the PBM.

(3) When applicable, the Federal employer identification number for the PBM.

(4) For a PBM that maintains a mail-order pharmacy that ships or mails prescription drugs to residents of this Commonwealth, the identity, business address and telephone number of the licensed pharmacist in charge and the license number of any mail-order pharmacy owned by the PBM to the department.

(d) Inspection.--The department may conduct announced or unannounced random inspections annually of a registered PBM, which shall encompass the following:

(1) The operation of the PBM.

(2) Review of records as selected by the department.

(3) Adherence to other requirements of this act.

(e) Revocation, suspension, denial or restriction.--The department may revoke, suspend, deny or restrict registration of a PBM for violation of this section or on other grounds or violations of Federal or State laws or regulations as determined necessary or appropriate by the department.

Section 4. Maximum allowable cost list and reimbursement.

(a) General rule.--Before a PBM places a drug on a maximum allowable cost list, the PBM must ensure that:

(1) the drug is listed as "A" or "AB" rated in the most recent version of the Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" or is an authorized generic;

(2) two or more therapeutically equivalent, multiple source drugs or authorized generics available for purchase by network retail pharmacies from wholesalers servicing this Commonwealth; and

(3) dispensing fees are not included in the calculation of maximum allowable cost price reimbursement to pharmacy

providers.

(b) Removal from listing.--If a drug that has been placed on a maximum allowable cost list no longer meets the requirements of subsection (a), the drug shall be removed from the maximum allowable cost list by the PBM within seven business days after the date that the PBM becomes aware that the drug no longer meets the requirements of subsection (a).

Section 5. Availability of the maximum allowable cost list.

Upon each contract execution or renewal, a PBM shall make available, with respect to contracts between a PBM and a pharmacy, or alternatively, a PBM and a pharmacy's contracting representative or agent such as PSAO, the following:

(1) The criteria used to determine the maximum allowable costs for the drugs and medical products and devices on each maximum allowable cost list.

(2) The current maximum allowable cost list used by that PBM for covered individuals served by that contracted pharmacy.

(3) Upon request, every maximum allowable cost list used by that PBM for covered individuals served by that contracted pharmacy.

(4) In the event there are multiple lists under the same contract, the contract shall identify which maximum allowable cost lists are appropriately applicable.

Section 6. Updating maximum allowable cost list.

A PBM shall:

(1) Update each maximum allowable cost list at least once every seven business days.

(2) Make the updated lists available to every pharmacy with which the PBM has a contract, directly or through a

PSAO, in a readily accessible, secure and usable publicly accessible Internet website or other comparable format or process.

(3) Utilize the updated maximum allowable costs to calculate the payments made to the contracted pharmacies within three business days.

(4) A PBM shall provide a contractual commitment to deliver a particular average reimbursement rate for generics. The average reimbursement rate for generics shall be calculated using the actual amount paid to the pharmacy, excluding the dispensing fee, and shall not be calculated solely according to the amount allowed by the plan and shall include all generics dispensed, regardless of whether they are subject to maximum allowable cost pricing. The contract shall set forth the types of claims to be excluded from the methodologies to be used in the calculation of the average reimbursement rate.

(5) Maintain a procedure to eliminate products from the list of drugs subject to such pricing or modify maximum allowable cost rates within seven business days when such drugs do not meet the standards and requirements of this act as set forth in order to remain consistent with pricing changes in the marketplace.

Section 7. Maximum allowable cost appeals process.

(a) Process to be established.--All contracts between a pharmacy and a PBM or a pharmacy contracted directly with a contracting representative or agent such as a PSAO shall include a process to appeal, investigate and resolve disputes regarding the listed maximum allowable cost for a particular drug or medical product or device. The process shall be made available

on the PBM's publicly accessible Internet website and contain information about the appeals process, including, but not limited to, a telephone number or process that a pharmacy may use to submit maximum allowable cost appeals.

(b) Grounds.--A pharmacy may base an appeal on either of the following:

(1) the maximum allowable cost established for a particular drug or medical product or device is below cost at which the drug is available for purchase by that pharmacy in this Commonwealth from national or regional wholesalers; or

(2) the PBM has placed a drug on the list in violation of section 4.

(c) Time period for filing.--The right to appeal shall be limited to 30 days following the reimbursement for a drug by a PBM.

(d) Determination.--A PBM shall make a final determination within seven business days of receiving an appeal and shall notify the appealing party of the determination.

(e) Denial.--If a PBM denies an appeal, the PBM shall state the reason for the denial and provide the national drug code of an equivalent drug that is available for purchase by network retail pharmacies in the Commonwealth from wholesalers at a price that is equal to or less than the maximum cost for that drug.

(f) Filing of grievance.--A pharmacy may file a grievance with the department should a disagreement over denial between a PBM and a pharmacy occur. The department shall investigate the grievance and report its findings to the pharmacy within 30 business days.

(g) Approval.--If a PBM grants an appeal, the PBM shall

adjust the maximum allowable cost of the drug for the appealing pharmacy, along with all network pharmacies. The adjustment shall be paid to the pharmacy within one business day of the determination. The PBM shall notify all similarly situated network pharmacy providers as defined by the plan sponsor.

Section 8. Enforcement.

(a) Action by the department.--The department shall enforce the provisions of this act and shall take action or impose penalties to bring noncomplying entities into full compliance with this act.

(b) Violation of Unfair Trade Practices and Consumer Protection Law.--A violation of this act shall constitute a violation of the act of December 17, 1968 (P.L.1224, No.387), known as the Unfair Trade Practices and Consumer Protection Law.

(c) Financial penalties.--A violation of this act may subject the PBM to financial penalties as determined by the department. Additionally, the department may subject a pharmacy to financial penalties if the department finds the pharmacy has engaged in conduct that would constitute an abuse of the appeal process.

Section 9. Department authority.

The department shall promulgate regulations necessary to implement the provisions of this act.

Section 10. Effective date.

This act shall take effect in 90 days.