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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1089 Session of 2013

INTRODUCED BY TOMLINSON, RAFFERTY, VULAKOVICH, ARGALL, FONTANA, HUTCHINSON, WHITE, MENSCH, ERICKSON, McILHINNEY, STACK, BAKER, LEACH, SCARNATI, TEPLITZ, ALLOWAY, SOLOBAY, BLAKE AND GREENLEAF, SEPTEMBER 9, 2013

REFERRED TO CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, SEPTEMBER 9, 2013

AN ACT

Providing for regulation of pharmacy benefit managers; imposing duties on the Insurance Commissioner and the Insurance Department; providing for enforcement; and imposing penalties.

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

CHAPTER 1

PRELIMINARY PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Pharmacy Benefit Manager Act.

Section 102. 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:

"Board." The State Board of Pharmacy.

"Commissioner." The Insurance Commissioner of the Commonwealth.

"Covered entity."

(1) Includes:

(i) A hospital plan corporation, professional health services corporation, insurer, third-party payer, health coverage plan, health maintenance organization or PBM.

(ii) A health program administered by the Commonwealth in the capacity of provider of health coverage.

(iii) A managed care organization.

(iv) An employer, labor union or other entity

organized in this Commonwealth that provides group or individual health coverage to covered individuals who are employed or reside in this Commonwealth.

(v) A Medicare Part D plan.

(2) The term does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.

"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 a policy, contract or plan for a covered individual.

"Department." The Insurance Department of the Commonwealth.

"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 PBM. The term includes a pharmacy which generally dispenses outpatient prescriptions to covered individuals or which 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 management." 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) Any of the following services provided with regard to 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.

(x) Retention of any spread or differential between what is received from health plans as reimbursement for prescription drugs and what is paid to pharmacies by the PBM for such drugs.

"Pharmacy benefits manager" or "PBM." An individual, business or other entity that performs pharmacy benefits

management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management and includes mail service pharmacy and specialty drug programs.

"Specialty drugs." A drug that meets at least one of the following criteria:

(1) A high-cost medication used to treat and is prescribed for a person with a complex, chronic or rare medical condition.

(2) The drug is not typically available at community retail pharmacies.

(3) The drug requires special handling, storage or has distribution or inventory limitations.

(4) The drug has a complex dosing regimen or requires special administration.

(5) The drug is considered to have limited distribution by the FDA.

(6) The drug requires complex and extended patient education or counseling, intensive monitoring or clinical oversight.

(7) The drug has significant side effects or risk profile.

CHAPTER 3

REGULATION OF PHARMACY BENEFIT MANAGERS

Section 301. Certificate of authority.

(a) Authority to act as preferred provider organization.--A PBM that provides services to residents of this Commonwealth shall apply for, obtain and maintain a certificate of authority to operate as a preferred provider organization subject to section 630 of the act of May 17, 1921 (P.L.682, No.284), known

as The Insurance Company Law of 1921. A PBM that obtains a certificate of authority under this subsection is authorized to operate as a PBM under this act.

(b) Authority to act as risk-bearing preferred provider organization.--A PBM shall obtain a certificate of authority as a risk-bearing preferred provider organization if the PBM:

(1) makes contractual commitments to a covered entity regarding the prices and terms and conditions under which prescriptions will be dispensed to covered individuals;

(2) collects rebates, discounts, or allowances from drug manufacturers or distributors based on volume and types of prescriptions dispensed;

(3) makes commitments regarding the return, payment or credit of all or any portion of such rebates, discounts or allowances to or for the benefit of covered entities; or

(4) otherwise shares in the profits or losses of a covered entity.

(c) Fee.--

(1) The department shall establish the fees to cover the annual expenses and costs of administering this act. An initial fee for a preferred provider organization authorized to operate as a PBM shall be set by the department but shall not be less than $500 per year.

(2) Each PBM shall renew its authorization annually as set by the department.

(d) Penalty for failure to renew.--Any lapse in renewing authorization to act as a PBM shall be subject to penalties established by the department to bring noncomplying entities into full compliance with this act.

(e) Form.--To obtain a certificate of authority, a PBM shall

submit a form developed by the department. At a minimum the form must contain the following information and any additional requirements as may be established by the department:

(1) A PBM that maintains a mail-order pharmacy that ships or mails prescription drugs to residents of this Commonwealth must provide license numbers of all mail-order pharmacies owned by the PBM and also be registered or licensed by the board.

(2) Basic organizational documents of the PBM, such as the articles of incorporation, articles of association, bylaws, partnership agreements, trade name certificate, trust agreement, shareholder agreement and other applicable documents and all amendments to the documents as the department finds necessary.

(3) A certificate of compliance issued by the board indicating the PBM's plan of operation is consistent with the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, and that the PBM's pharmacist in charge holds a current Pennsylvania pharmacist license and is in good standing with the board.

(4) A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies or other administrative services to be provided.

(5) All incentive arrangements or programs such as rebates, discounts, disbursements or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company or insurer, that relates to

prescription drug or device services, including educational grants.

(6) A financial statement of income for the previous and current year prepared by an independent certified public accountant showing the assets, liabilities, direct or indirect income and any other sources of financial support sufficient as deemed by the commissioner to show financial stability and viability to meet its full obligations to participants and participating pharmacies.

(f) Revocation, suspension, denial or restriction.--

(1) The commissioner may revoke, suspend, deny or restrict a certificate of authority of a PBM for violation of this act or on other grounds or violations of Federal or State laws or regulations as determined necessary or appropriate by the commissioner.

(2) In the event that a certificate is revoked, suspended or denied, the commissioner may permit further operation of the PBM for a limited time not to exceed a 60-day period under conditions and restrictions as determined by the commissioner for a period as necessary for the beneficial interests of the participants and pharmacy providers.

(3) The commissioner shall provide written notice to a PBM of any revocation, denial, suspension or restriction including the specific reasons. The PBM shall have the same rights to notice, hearings and other provisions as provided to insurers or third-party administrators, respectively, under the laws of this Commonwealth.

(4) The commissioner shall provide to the board, upon request, copies of applications, correspondence and any other documents provided by the PBM to the commissioner, and with

notices, findings, determinations and other documents provided by the commissioner to the PBM.

Section 302. Disclosure of ownership.

(a) Disclosure.--A PBM also must disclose to the department any ownership interest of any kind with:

(1) Any insurance company responsible for providing benefits directly or through any plan for which the PBM provides services.

(2) Any parent company, subsidiary or other organization that is related to the provision of pharmacy services, the provision of other prescription drug or device services or a pharmaceutical manufacturer.

(b) Notification.--A PBM shall notify the department in writing within five business days of any material change in ownership.

Section 303. Prohibitions.

(a) Prohibited conduct.--No pharmacy benefit manager may:

(1) Mandate that a covered individual use a specific retail pharmacy, mail-order pharmacy, specialty pharmacy or other pharmacy if the PBM has an ownership interest in the pharmacy.

(2) Intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of:

(i) influencing the prescriber's choice of therapy; or

(ii) altering the prescription information, including, but not limited to, switching the prescribed drug without the express authorization of the prescriber.

(3) Mandate that a pharmacist or pharmacy change a

covered person's prescription unless the prescribing physician and the covered person authorize the change to be made.

(4) Transfer a health benefit plan to another payment network unless it receives written authorization from the insurer.

(5) Require more stringent recordkeeping by a pharmacy than that required by Federal or State law.

(6) Require a pharmacist or pharmacy to provide services to the covered individuals of one covered entity or participate in one network in order to provide services to covered individuals of another covered entity or participate in another network.

(7) Exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network, including a specialty network, if the pharmacist or pharmacy accepts the standard terms, conditions and reimbursement rates for ingredient costs, professional pharmacy services and the quality of dispensing established by the PBM, a government program or an employee benefit plan, which, except as provided by subsection (b) shall apply on an equal basis to all pharmacies in the provider network. As a condition for participating in one network or type of network, a PBM may not require a pharmacist or pharmacy to accept the terms and conditions of another network for prescriptions dispensed by the first network.

(8) Automatically enroll a pharmacy or its agent in a contract or modify an existing contract without agreement from the pharmacy or pharmacist. The pharmacy or its agent shall sign a contract before assuming responsibility to fill

prescriptions.

(b) Special payment arrangements.--To the extent Federal law allows a Medicare Part D plan to provide covered individuals using pharmacists or pharmacies in a preferred provider network reduced coinsurance or copayments in exchange for lower payments for ingredient costs and professional pharmacy services, a PBM administering a Medicare Part D plan shall allow any otherwise qualified pharmacist or pharmacy willing to accept the reduced payments to enroll in the preferred provider network. A PBM administering a preferred provider network shall permit covered individuals to obtain pharmacy services from a pharmacist or pharmacy that is not a member of a preferred provider pursuant to its standard terms and conditions as provided by subsection (a)(7) with any differential in coinsurance or copayments paid by covered individuals.

Section 304. Required practices.

(a) Performance of duties.--A PBM shall perform its duties with care, skill, prudence and diligence and by exercising good faith and fair dealing toward the covered entity.

(b) Claims related information.--A PBM shall provide, upon request by the department or any covered entity, all claims-related financial and utilization information requested relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity in a format that includes:

(1) National Drug Code numbers used.

(2) Quantity.

(3) Day's supply.

(4) Price paid to a pharmacy and price paid to a payer,

separating any administrative fee.

(c) Confidentiality.--A PBM providing information under this section may designate the material as confidential. Information designated as confidential by a PBM and provided to a covered entity under this section may not be disclosed by the covered entity to any person without the consent of the PBM, except that disclosure may be ordered by a court of this Commonwealth for good cause shown or made in a court filing under seal or until otherwise ordered by a court. Nothing in this section limits the Attorney General's use of civil investigative demand authority under the act of December 17, 1968 (P.L.1224, No.387), known as the Unfair Trade Practices and Consumer Protection Law, to investigate violations of this section. A payer must be offered this information for its internal auditing or outsourced auditing use.

(d) Disclosure.--A PBM shall provide, upon request by the covered entity, information on the nature, type and amount of all other revenue received from a pharmaceutical manufacturer or any other entity associated with the dispensing or distribution of prescription medication for programs that the covered entity offers or performs to its enrollees.

(e) Documentation required.--A PBM shall remit to the covered entity, in its monthly report or invoice detail, documentation of the amount paid to retail pharmacy or mail-order pharmacy and the amount billed to the covered entity for all claims at a detailed level such to disclose individual claim financial information, with personal health information redacted if necessary for privacy compliance under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1933).

(f) Substitution.--If a PBM makes a substitution in which the substitute drug costs more than the prescribed drug, the pharmacy benefits manager shall disclose to the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the PBM as a result of the substitution.

(g) Calculation.--When a patient's out-of-pocket cost or copay is percentage based, the PBM shall calculate the percentage owed or the amount of the copay based upon the amount actually paid to the pharmacy for the medication in question.

(h) Listing of specialty drugs.--A PBM shall make a listing of any specialty drugs available to and approved by the plan sponsor.

(i) Repackaged medications.--Repackaged medications must use the National Drug Code of the original manufacturer.

Section 305. Personal health care information.

A PBM shall:

(1) Notify a plan sponsor if the PBM intends to sell utilization or claims data that the PBM possesses as a result of an arrangement described in this section.

(2) Notify the plan sponsor in writing at least 30 days before selling, leasing or renting utilization or claims data and provide the plan sponsor with the name of the potential purchaser of the data and the expected use of the data by the purchaser.

(3) Not sell utilization or claims data unless the sale complies with all Federal and State laws and the PBM has received written approval for the sale from the plan sponsor.

(4) Not directly contact a covered individual by any means, including via electronic delivery, telephonic, source messaging service (SMS) text or direct e-mail, without the

express written permission of the plan sponsor and the covered individual.

(5) Not transmit any personally identifiable utilization of claims data to a pharmacy owned by the PBM if the patient has not voluntarily elected in writing to fill that particular prescription at the PBM-owned pharmacy.

(6) Provide each covered individual with an opportunity to affirmatively opt out of the sale of the individual's data prior to entering into any arrangement for the lease, rental or sale of the information.

Section 306. Maximum allowable cost list pricing disclosures.

Beginning on January 1 of each calendar year, the PBM shall, with respect to a contract between a PBM and a pharmacy:

(1) Provide or make readily available the applicable maximum allowable cost list to pharmacies.

(2) Include in the contracts the basis of the methodology and sources utilized to determine the maximum allowable cost pricing of the PBM, update pricing information on the pricing within at least seven calendar days and establish a reasonable process for the prompt notification of pricing updates to network pharmacies.

(3) Maintain a procedure to eliminate products from the list or modify maximum allowable cost rates within seven calendar days of a manufacturers price change in order to remain consistent with pricing changes in the marketplace.

(4) Provide a reasonable administrative appeals procedure to allow a pharmacy to contest a listed maximum allowable cost rate. The PBM must respond to a pharmacy or its agent, who has contested a maximum allowable cost rate through this procedure within 15 calendar days. If an update

is warranted, the PBM shall make the change retroactive to the date of dispensing and make the adjustment effective for all pharmacy providers in the network.

(5) Disclose whether a PBM utilizes a maximum allowable cost list for drugs dispensed at retail, but does not utilize a maximum allowable cost list for drugs dispensed by mail-order to a plan sponsor in writing or in the contract no later than 21 business days from the implementation of the practice.

(6) Disclose to the plan sponsor whether or not it is using the identical maximum allowable cost list with respect to billing the plan sponsor as it does when reimbursing all network pharmacies. If multiple maximum allowable cost lists are used, the PBM must disclose to the plan sponsor any difference between the amount paid to any pharmacy and the amount charged to the plan sponsor.

(7) Not require a pharmacy to dispense a medication if the reimbursement for the medication falls below pharmacy acquisition cost. A special process shall be created to handle situations that do not work under the terms of a contract.

Section 307. Inclusion of products on maximum allowable cost list.

(a) Requirements.--In order to place a particular generic prescription drug on a maximum allowable cost list, the PBM must, at a minimum, ensure that:

(1) The drug must have at least three or more nationally available, therapeutically equivalent, multiple source drugs with a significant cost difference, excluding outliers.

(2) The products must be listed as therapeutically and

pharmaceutically equivalent or A rated in the FDA's most recent version of the Orange Book.

(3) The product must be available for purchase without limitations by all pharmacies in this Commonwealth from national or regional wholesalers and not be an obsolete, discontinued product, or temporarily unavailable. Significant outliers shall not be used in calculation of a drug for placement on the maximum allowable cost list.

(4) Single source generic drugs will be paid as a branded product.

(b) Exception.--Specialty drugs shall not be eligible for inclusion on a maximum allowable cost list.

CHAPTER 5

ENFORCEMENT

Section 501. Enforcement.

(a) Action by commissioner.--The commissioner 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) Additional relief.--Regardless of whether any enforcement action is taken by the commissioner, a covered individual, pharmacy or pharmacist aggrieved by a violation of this act may seek relief to remedy the alleged violations involving at least one level of internal review and investigation as provided under section 2161(b) of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, and an opportunity to appeal to the department in the manner provided under section 2142 of The Insurance Company Law of 1921 unless, with respect to a pharmacy or pharmacist, an agreement with the insurance company or pharmacy benefit manager

establishes an alternative dispute resolution process as provided under section 2162(f) of The Insurance Company Law of 1921.

(c) 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.

CHAPTER 21

MISCELLANEOUS PROVISIONS

Section 2101. Applicability.

The requirements of this act shall apply to all PBMs notwithstanding any provision of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, or other law except to the extent an express exemption is provided from all of any portion of the requirements this act.

Section 2102. Intent.

It is the intent of the General Assembly that this act shall constitute a law regulating the business of insurance and shall apply to the fullest extent permitted by Federal law. In the event that any portions of this act are found to be preempted by Federal law either entirely or with respect to any type of covered entities, any provisions of this act not preempted by Federal law, either entirely or with respect to any type of covered entity, shall remain in effect. A certificate filed with the commissioner claiming that a PBM is governed and regulated under the provisions of the Employee Retirement Income Security Act of 1974 (Public Law 93-406, 88 Stat. 829) shall not exempt a PBM from application of all or any portion of this act, either entirely or with respect to any type of covered entity, except to the extent such an exemption is required by Federal law.

Section 2103. Effective date.

This act shall take effect in 90 days.