**A 10985** Gottfried Same as <u>S 8934</u> RIVERA Public Health Law

TITLE....Provides for pharmacy benefit management and the procurement of prescription drugs at a negotiated rate for dispensation; repealer 05/29/18 referred to health

S8934 RIVERA Same as A 10985 Gottfried ON FILE: 06/06/18 Public Health Law TITLE....Provides for pharmacy benefit management and the procurement of prescription drugs at a negotiated rate for dispensation; repealer 06/06/18 REFERRED TO RULES

# STATE OF NEW YORK

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## IN ASSEMBLY

May 29, 2018

Introduced by M. of A. GOTTFRIED -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to pharmacy benefit managers; and to repeal certain provisions of such law relating thereto

# The People of the State of New York, represented in Senate and Assembly, do enact as follows:

- Section 1. Section 280-a of the public health law is REPEALED and a new section 280-a is added to read as follows:
  - $\S$  280-a. Pharmacy benefit managers. 1. Definitions. As used in this section, the following terms shall have the following meanings:
  - (a) "Health plan or provider" means an entity for which a pharmacy benefit manager provides pharmacy benefit management including, but not limited to: (i) a health benefit plan or other entity that approves, provides, arranges for, or pays for health care items or services, under which prescription drugs for beneficiaries of the entity are purchased or which provides or arranges reimbursement in whole or in part for the purchase of prescription drugs; or (ii) a health care provider or professional, including a state or local government entity, that acquires prescription drugs to use or dispense in providing health care to patients.
  - (b) "Pharmacy benefit management" means the service provided to a health plan or provider, directly or through another entity, and regardless of whether the pharmacy benefit manager and the health plan or provider are related, or associated by ownership, common ownership, organization or otherwise; including the procurement of prescription drugs to be dispensed to patients, or the administration or management of prescription drug benefits, including but not limited to, any of the following:
- 23 (i) mail service pharmacy;
- 24 (ii) claims processing, retail network management, or payment of 25 claims to pharmacies for dispensing prescription drugs;
- 26 (iii) clinical or other formulary or preferred drug list development 27 or management;

EXPLANATION--Matter in  $\underline{italics}$  (underscored) is new; matter in brackets [-] is old law to be omitted.

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- (iv) negotiation or administration of rebates, discounts, payment differentials, or other incentives, for the inclusion of particular prescription drugs in a particular category or to promote the purchase of particular prescription drugs;
- (v) patient compliance, therapeutic intervention, or generic substitution programs; and
  - (vi) disease management.

- (c) "Pharmacy benefit manager" means any entity that performs pharmacy benefit management for a health plan or provider.
- (d) "Maximum allowable cost price" means a maximum reimbursement amount set by the pharmacy benefit manager for therapeutically equivalent multiple source generic drugs.
- (e) "Controlling person" means any person or other entity who or which directly or indirectly has the power to direct or cause to be directed the management, control or activities of a pharmacy benefit manager.
- (f) "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a health plan or provider.
- (g) "License" means a license to be a pharmacy benefit manager, under subdivision seven of this section.
- 2. Duty, accountability and transparency. (a) The pharmacy benefit manager shall have a fiduciary relationship with and obligation to the health plan or provider, and shall perform pharmacy benefit management with care, skill, prudence, diligence, and professionalism.
- (b) All funds received by the pharmacy benefit manager in relation to providing pharmacy benefit management shall be received by the pharmacy benefit manager in trust for the health plan or provider and shall be used or distributed only pursuant to the pharmacy benefit manager's contract, or other terms in the absence of a contract, with the health plan or provider or applicable law; except for any fee or payment expressly provided for in the contract, or other terms in the absence of a contract, between the pharmacy benefit manager and the health plan or provider to compensate the pharmacy benefit manager for its services.
- (c) The pharmacy benefit manager shall periodically account to the health plan or provider for all funds received by the pharmacy benefit manager. The health plan or provider shall have access to all financial and utilization information of the pharmacy benefit manager in relation to pharmacy benefit management provided to the health plan or provider.
- (d) The pharmacy benefit manager shall disclose in writing to the health plan or provider the terms and conditions of any contract or arrangement between the pharmacy benefit manager and any party relating to pharmacy benefit management provided to the health plan or provider.
- (e) The pharmacy benefit manager shall disclose in writing to the health plan or provider any activity, policy, practice, contract or arrangement of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the pharmacy benefit manager's relationship with or obligation to the health plan or provider.
- (f) Any information required to be disclosed by a pharmacy benefit manager to a health plan or provider under this section that is reasonably designated by the pharmacy benefit manager as proprietary or trade secret information shall be kept confidential by the health plan or provider, except as required or permitted by law, including disclosure necessary to prosecute or defend any legitimate legal claim or cause of action.
- (g) The commissioner shall establish, by regulation, minimum standards for pharmacy benefit management services which shall address the eliminate of the commissioner shall establish, by regulation, minimum standards for pharmacy benefit management services which shall address the eliminate of the commissioner shall establish, by regulation, minimum standards for pharmacy benefit management services which shall address the eliminate of the commissioner shall establish the commissioner shall

- nation of conflicts of interest between pharmacy benefit managers and health insurers, plans and providers; and the elimination of deceptive practices, anti-competitive practices, and unfair claims practices.
- 3. Prescriptions. A pharmacy benefit manager may not substitute or cause the substituting of one prescription drug for another in dispensing a prescription, or alter or cause the altering of the terms of a prescription, except with the approval of the prescriber or as explicitly required or permitted by law.

- 4. Appeals. A pharmacy benefit manager shall, with respect to contracts between a pharmacy benefit manager and a pharmacy or, alternatively, a pharmacy benefit manager and a pharmacy's contracting agent, such as a pharmacy services administrative organization, include a reasonable process to appeal, investigate and resolve disputes regarding multi-source generic drug pricing. The appeals process shall include the following provisions:
- (a) the right to appeal by the pharmacy and/or the pharmacy's contracting agent shall be limited to thirty days following the initial claim submitted for payment;
- (b) a telephone number through which a network pharmacy may contact the pharmacy benefit manager for the purpose of filing an appeal and an electronic mail address of the individual who is responsible for processing appeals;
- (c) the pharmacy benefit manager shall send an electronic mail message acknowledging receipt of the appeal. The pharmacy benefit manager shall respond in an electronic message to the pharmacy and/or the pharmacy's contracting agent filing the appeal within seven business days indicating its determination. If the appeal is determined to be valid, the maximum allowable cost for the drug shall be adjusted for the appealing pharmacy effective as of the date of the original claim for payment. The pharmacy benefit manager shall require the appealing pharmacy to reverse and rebill the claim in question in order to obtain the corrected reimbursement;
- (d) if an update to the maximum allowable cost is warranted, the pharmacy benefit manager or covered entity shall adjust the maximum allowable cost of the drug effective for all similarly situated pharmacies in its network in the state on the date the appeal was determined to be valid; and
- (e) if an appeal is denied, the pharmacy benefit manager shall identify the national drug code of a therapeutically equivalent drug, as determined by the federal Food and Drug Administration, that is available for purchase by pharmacies in this state from wholesalers registered pursuant to subdivision four of section sixty-eight hundred eight of the education law at a price which is equal to or less than the maximum allowable cost for that drug as determined by the pharmacy benefit manager.
- 5. Contract provisions. No pharmacy benefit manager shall, with respect to contracts between such pharmacy benefit manager and a pharmacy or, alternatively, such pharmacy benefit manager and a pharmacy's contracting agent, such as a pharmacy services administrative organization:
- (a) prohibit or penalize a pharmacist or pharmacy from disclosing to an individual purchasing a prescription medication information regarding:
- (1) the cost of the prescription medication to the individual, or A. 10985

(2) the availability of any therapeutically equivalent alternative medications or alternative methods of purchasing the prescription medication, including but not limited to, paying a cash price; or

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- (b) charge or collect from an individual a copayment that exceeds the total submitted charges by the pharmacy for which the pharmacy is paid. If an individual pays a copayment, the pharmacy shall retain the adjudicated costs and the pharmacy benefit manager shall not redact or recoup the adjudicated cost.
- 6. Acting without a license. (a) No person or entity may act as a pharmacy benefit manager on or after January first, two thousand twenty without having a currently valid license under this section. However, a pharmacy benefit manager providing pharmacy benefit management on and before that date may continue to do so without a license under this section for a period of one hundred eighty days.
- (b) No health plan or provider may pay any fee or other compensation for pharmacy benefit management to any person or entity acting violation of this subdivision.
- (c) Any person or entity that violates this section shall be subject to penalties under sections twelve and twelve-b of this chapter.
- 7. Licensing of pharmacy benefit managers. (a) The commissioner may issue a pharmacy benefit manager license to any person or entity who or that applies for a license and has complied with the requirements this section. The commissioner may establish, by regulation, minimum standards for the issuance of a license to a pharmacy benefit manager. The term of each license shall be a period of five years and may be renewed by the commissioner.
- (b) (1) Before a pharmacy benefit manager's license shall be issued or renewed, the prospective licensee shall file a written application in such form or forms and supplements as the commissioner may require, and pay a fee of ten thousand dollars.
- (2) Every license issued pursuant to this section may be renewed by filing the application and paying the fees at least sixty days prior to the expiration of the license, upon which the license shall continue in full force and effect until either (A) the issuance by the commissioner of the renewed license or (B) five business days after the commissioner shall have given notice to the applicant that the commissioner has rejected the renewal.
- (c) The commissioner may refuse to issue or renew a pharmacy benefit manager's license if, in the commissioner's judgment, the applicant or any member, principal, officer or director of the applicant, is not trustworthy or competent to act as a pharmacy benefit manager, or if the commissioner is aware of cause for revocation or suspension of such license. The commissioner shall notify the licensee of a determination to reject the application for the license or renewal and an explanation of the cause for rejection, and shall provide a reasonable opportunity for the licensee to be heard under subdivision eight of this section.
- (d) Licensees shall be subject to examination at any time by the commissioner.
- 8. Revocation or suspension of a license. (a) The commissioner, upon his or her own investigation or complaint from another party, may revoke, suspend or refuse to renew a license if, after notice and hearing, the commissioner determines that the licensee, has, in relation to pharmacy benefit management or the operation of the pharmacy benefit
- (1) violated any law, regulation, subpoena or order of the commissioner, or of another state that would constitute a violation in New York;

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- (2) provided materially incorrect, materially misleading, materially incomplete or materially untrue information in a license application;
- (3) obtained or attempted to obtain a license through misrepresentation or fraud;
  - (4) used fraudulent, coercive or dishonest practices;
  - (5) demonstrated incompetence;

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- (6) demonstrated untrustworthiness;
- (7) demonstrated financial irresponsibility in the conduct of the business;
- (8) improperly withheld, misappropriated or converted any monies or
- (9) intentionally misrepresented the terms of an actual or proposed contract with any party;
  - (10) been convicted of a felony;
- (11) had a pharmacy benefit manager license, or its equivalent, denied, suspended or revoked in any other state, province, district territory; or
  - (12) ceased to meet the requirements for licensure under this section.
- (b) Before revoking, suspending or refusing to renew a license, the commissioner shall give notice to the licensee and shall hold, or cause to be held, a hearing as provided under section twelve-a of this chapter. The commissioner shall also give notice to health plans and providers under contract with the pharmacy benefit manager, to the extent known to the commissioner.
- (c) If a license is revoked or suspended, the commissioner shall give notice to the licensee and health plans and providers under contract with the pharmacy benefit manager to the extent known to the commissioner.
- Change of address. A registrant or licensee under this section shall inform the commissioner by a means acceptable to the commissioner of a change of address within thirty days of the change.
- 10. Violations. Any provision of a contract that violates the provisions of this section shall be deemed to be void and unenforceable.
- § 2. Severability. If any provision of this act, or any application of any provision of this act, is held to be invalid, or ruled by any federal agency to violate or be inconsistent with any applicable federal law or regulation, that shall not affect the validity or effectiveness 38 of any other provision of this act, or of any other application of any 39 provision of this act.
- 40 § 3. This act shall take effect on the ninetieth day after it shall 41 become a law and shall apply to any contract for providing pharmacy 42 benefit management made or renewed on or after that date. Effective 43 immediately, the commissioner of health shall make regulations and take 44 other actions reasonably necessary to implement this act on that date.

# NEW YORK STATE ASSEMBLY MEMORANDUM IN SUPPORT OF LEGISLATION submitted in accordance with Assembly Rule III, Sec 1(f)

BILL NUMBER: A10985

SPONSOR: Gottfried

TITLE OF BILL: An act to amend the public health law, in relation to pharmacy benefit managers; and to repeal certain provisions of such law relating thereto

#### PURPOSE OR GENERAL IDEA OF BILL:

This bill requires licensure for pharmacy benefit managers (PBMs) and specifies their duties and obligations as service providers.

### SUMMARY OF SPECIFIC PROVISIONS:

The bill amends Public Health Law § 280-a to provide that PBMs have a fiduciary relationship with health plan or health care provider clients, require that funds they receive belong to the client except for fees for services specifically provided for by contract, require full disclosure to clients, and bars the substitution of prescribed drugs (subdivisions 1-3).

Subdivision 4 is current subdivision 2 renumbered, and subdivision 5 renumbers a provision that was added as part of the 2018 state budget.

Subdivisions 6 through 9 require PBMs to be licensed, renewable every five years, with a fee of \$10,000. The bill establishes grounds and procedure for suspension, revocation or refusal to grant or renew a license. Existing PBMs are provided an additional 180 days to comply with the initial licensure. Grounds for disciplinary action include fraudulent applications or practices, incompetence, financial irresponsibility, and felony conviction, with appropriate notice and opportunity for a PBM to be heard and defend against the charges.

#### JUSTIFICATION:

PBMs are companies that manage prescription drug benefit programs for health plans. PBMs promote themselves as saving money for health plans and their members, but in reality, their negotiations and the discounts or rebates they get from drug companies are very secretive. PBMs commonly pocket payments from drug manufacturers that ought to be used to lower drug prices, and they accept payments in exchange for giving preference to more expensive drugs. Like a real estate broker or a lawyer, they ought to be required to act in the best interests of the client (i.e., fiduciary relationship). This bill would require that PBMs be licensed by the Health Department and conform to standards established by the Department.

#### PRIOR LEGISLATIVE HISTORY:

New bill

# FISCAL IMPLICATIONS:

None

EFFECTIVE DATE:
90 days after it shall become law.