STATE OF NEW YORK

7304

2023-2024 Regular Sessions

IN ASSEMBLY

May 17, 2023

Introduced by M. of A. McDONALD -- read once and referred to the Committee on Insurance

AN ACT to amend the insurance law, in relation to prescription drug supply chain transparency; and to amend the state finance law, in relation to deposits into the pharmacy benefit manager regulatory fund

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

Section 1. This act shall be known and may be cited as the "prescription drug supply chain transparency act of 2023".

§ 2. The insurance law is amended by adding a new article 30 to read as follows:

ARTICLE 30

PRESCRIPTION DRUG SUPPLY CHAIN TRANSPARENCY

Section 3001. Definitions.
3002. Electronic filing requirement.
3003. Special reports and other powers.
3004. Registration of pharmacy services administrative organizations.
3005. Required disclosures by pharmacy services administrative organizations.
3006. Registration of pharmacy switch companies.
3007. Required disclosures by pharmacy switch companies.
3008. Registration of rebate aggregators.
3009. Required disclosures by rebate aggregators.
3010. Deposit of penalties and fees.

§ 3001. Definitions. (a) For the purposes of this article, the definitions contained in section two hundred eighty-a of the public health law shall apply to this article as if specifically set forth herein.

(b) For the purposes of this article, the following words or phrases shall have the following meanings, unless the context otherwise requires:

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD11150-01-3

(1) "Manufacturer" means an entity engaged in the manufacture of prescription drugs sold in this state.

(2) "Pharmacy services administrative organization" or "PSAO" means an entity that is operating in this state and that contracts with a pharmacy for the purpose of conducting business on the pharmacy's behalf with wholesalers, distributors, health plans or pharmacy benefit managers.

(3) "Rebate aggregator" means an entity that provides formulary rebate administrative services for pharmacy benefit managers or otherwise negotiates rebates with manufacturers on behalf of pharmacy benefit managers.

(4) "Switch company" means an entity that acts as an intermediary between a pharmacy and a pharmacy benefit manager or health plan for the purpose of routing insurance claims data to or from a pharmacy.

§ 3002. Electronic filing requirement. Notwithstanding any law to the contrary, any filing or submission required under this article shall be made electronically unless the entity required to make such filing or submission demonstrates undue hardship, impracticability or good cause as required by section three hundred sixteen of this chapter.

§ 3003. Special reports and other powers. (a) The superintendent may address to any entity required to register or report information under this article, or its officers, or any agent or employee thereof any inquiry in relation to its business or any matter connected therewith. Every individual or entity so addressed shall reply in writing to such inquiry promptly and truthfully, and such reply shall be, if required by the superintendent, subscribed by such individual, or by such officer or officers of the entity, or by such agent or employee of the entity as the superintendent shall designate, and affirmed by them as true under the penalties of perjury.

(b) In the event any individual or entity does not submit a good faith response to an inquiry from the superintendent pursuant to subsection (a) of this section within a time period specified by the superintendent of not less than fifteen business days, the superintendent is authorized to levy a civil penalty, after notice and hearing, against such person not to exceed one thousand dollars per day for each day beyond the date specified by the superintendent for response to the inquiry.

(c) In addition to all other powers granted by law, the superintendent is hereby empowered to order any person or entity required to register or report information under this article to cease and desist from violations of this article and, following issuance of such an order, may bring and maintain an action in any court of competent jurisdiction for an injunction or other appropriate relief to enjoin threatened or existing violations of this article, or of the superintendent's orders or regulations. Such action may specifically seek restitution on behalf of persons aggrieved by a violation of this article or orders or regulations of the superintendent.

(d) In addition to all other powers granted by law, whenever it shall appear to the superintendent, either upon complaint or otherwise, that in the course of its business within or from this state that any entity shall have employed, or employs, or is about to employ any business practice or shall have performed, or is performing, or is about to perform any act in violation of this article or orders or regulations of the superintendent, or the superintendent believes it to be in the public interest that an investigation be made, the superintendent may, in the superintendent's discretion, either require or permit such entity or any agent or employee thereof, to file with the department a statement in writing under oath or otherwise as to all the facts and circum-

stances concerning the subject matter that the superintendent believes is in the public interest to investigate and for such purpose may prescribe forms upon which such statements shall be made. The superintendent may also require such other data and information as the superintendent may deem relevant and may make such special and independent investigations as the superintendent may deem necessary in connection with the matter. It shall be the duty of all public officers, their deputies, assistants, subordinates, clerks or employees and all other persons to render and furnish to the superintendent, when requested in connection with an investigation under this subsection, all information and assistance in their possession or within their power.

(e) Any entity who violates an order under subsection (c) or (d) of this section shall be subject to a civil penalty, after notice and a hearing, of not more than ten thousand dollars per act in violation, in addition to any other penalty provided by law.

(f) Any communications or documents sent or received in connection with an investigation under this article and any materials referring to such information in the possession of the superintendent shall be confidential and not subject to disclosure. Notwithstanding the foregoing, the superintendent may release such confidential communications or documents to the extent necessary to address criminal or other unlawful behavior. This subsection shall not apply to information, documents and materials in the possession and under the control of an entity other than the superintendent.

§ 3004. Registration of pharmacy services administrative organizations. (a) No PSAO shall operate in this state after March thirty-first, two thousand twenty-four without first registering with the department.

(b) A PSAO seeking registration shall file, in a form and manner determined by the superintendent, information that includes at a minimum:

(1) the legal name of the entity;

(2) any trade or other names used by the entity;

(3) the organizational structure of the entity;

(4) the pharmacies located within this state with which the entity provides services;

(5) the persons who exercise control of the entity;

(6) a primary point of contact for the entity;

(7) an agent for service of process;

(8) a set of audited financials for the prior fiscal year; and

(9) such other information as the superintendent shall require.

(c) The superintendent shall accept a registration only if the superintendent determines that all the required information has been provided in a satisfactory form and has received payment of a nonrefundable registration fee of five thousand dollars. Notwithstanding the requirements of this subsection the superintendent may, in his or her sole discretion and upon good cause shown, reduce the registration fee for any PSAO to an amount not less than one-tenth of one percent of the fees earned by the PSAO from all pharmacies located in New York in the prior calendar year.

(d) If any of the information contained in the registration shall change, the PSAO shall notify the department of such change in a form and manner prescribed by the superintendent for such purpose within twenty-one days of the change. The requirement to update shall include the filing of a new set of audited financials upon adoption. For any change other than new audited financials, the filing shall not be deemed complete unless accompanied by a payment of a fee of fifty dollars.

(e) Every PSAO registration issued pursuant to this section shall expire twelve months after the date of issue. A PSAO may renew its registration for another twelve months upon the filing of an application in conformity with this section.

(f) Before a PSAO registration shall be renewed, the PSAO shall file an application for renewal in such form as the superintendent prescribes and pay a fee of five thousand dollars. Notwithstanding the requirements of this subsection, the superintendent may, in his or her sole discretion and upon good cause shown, reduce the registration fee for any PSAO to an amount not less than one-tenth of one percent of the fees earned by the PSAO from all pharmacies located in New York in the prior calendar year.

(g) If a PSAO files a renewal application with the superintendent at least one month before its expiration, then the registration sought to be renewed shall continue in full force and effect either until the issuance by the superintendent of the renewal registration applied for or until five days after the superintendent shall have refused to issue such renewal registration and given notice of such refusal to the applicant, otherwise the PSAO registration shall expire and the registrant shall have no expectation of renewal.

§ 3005. Required disclosures by pharmacy services administrative organizations. (a) (1) Each PSAO shall at the time of registration pursuant to section three thousand four of this article disclose to the department the extent of any ownership or control of the PSAO or by the PSAO of any parent company, subsidiary, or affiliate that:

(A) provides pharmacy services;

(B) provides prescription drug or device services; or

(C) manufactures, sells, or distributes prescription drugs, biologicals, or medical devices.

(2) A PSAO shall furnish a copy of the disclosure made at the time of registration to all pharmacies located in this state with which it has a contract in place at the time of the registration. A PSAO shall not collect any fee for any services provided to a pharmacy for any period beginning five days after the filing of a registration with the department until such disclosure is sent to the pharmacy.

(3) Not later than April first, two thousand twenty-five, the department shall publish all disclosures received under this section on a publicly accessible online database, which shall be searchable at least by PSAO name. All disclosures shall be posted not later than ten business days after a registration is accepted and shall remain on the database for the duration of the registration of the PSAO.

(b) (1) Prior to entering into any contract with any pharmacy located in this state, including a contract with a group of pharmacies at least one of which is in this state, a PSAO shall furnish to the pharmacy a written disclosure of the information required to be disclosed in subsection (a) of this section. No contract with a pharmacy shall be enforceable against the pharmacy by a PSAO unless such PSAO makes such disclosure prior to the agreement. In addition to any other power conferred by law, the superintendent may prescribe the form and manner of such disclosures.

(2) A PSAO that owns, is owned by, in whole or in part, or controls any entity that manufactures, sells, or distributes prescription drugs, biologicals, or medical devices shall not, as a condition of entering into a contract with a pharmacy, require that the pharmacy purchase any drugs or medical devices from an entity with which the PSAO has a financial interest, or an entity with an ownership interest in the PSAO.

(3) No PSAO shall enter into a contract with a pharmacy in this state unless such contract shall provide that all remittances for claims submitted by a pharmacy benefit manager or third-party payer on behalf of a pharmacy to the PSAO shall be passed through by the PSAO to the pharmacy within a reasonable amount of time, established in the contract, after receipt of the remittance by the PSAO from the pharmacy benefit manager or third-party payer.

(c) (1) A PSAO that provides, accepts, or processes a discount, concession, or product voucher, to reduce, directly or indirectly, a covered individual's out-of-pocket expense for the order, dispensing, substitution, sale, or purchase of a prescription drug shall make available to each pharmacy in this state that it contracts with or which it contracted with in the prior calendar year, an annual report that includes:

(A) an aggregated total of all such transactions, by the pharmacy; and

(B) an aggregated total of any payments received by the PSAO itself for providing, processing, or accepting any discount, concession, or product voucher on behalf of a pharmacy.

(2) A pharmacy in this state that is a party to a contract with a PSAO shall have a right to an accounting of the funds received by the PSAO for goods or services provided by the pharmacy to patients and customers.

§ 3006. Registration of pharmacy switch companies. (a) No switch company may do business in this state after June thirtieth, two thousand twenty-four without first registering with the department.

(b) A switch company seeking registration shall file with the department, in a form and manner determined by the superintendent, information including but not limited to:

(1) the legal name of the entity;

(2) any trade or other names used by the entity;

(3) the organizational structure of the entity;

(4) the pharmacies located within this state and the pharmacy benefit managers licensed in this state with which the entity provides services;

(5) the persons who exercise control of the entity;

(6) a primary point of contact for the entity;

(7) an agent for service of process;

(8) a set of audited financials for the prior fiscal year; and

(9) such other information or documents as the superintendent shall require.

(c) The superintendent shall accept a registration only if he or she deems that all the required information has been provided in a satisfactory form and manner and has received payment of a nonrefundable registration fee of one thousand dollars.

(d) If any of the information contained in the registration shall change, the switch company shall notify the department of the change in a form and manner prescribed by the superintendent for such purpose within twenty-one days of the change. Such requirement to update shall include the filing of a new set of audited financials upon adoption. For any change other than new audited financials, the filing shall not be deemed complete unless accompanied by a payment of a fee of fifty dollars.

(e) Every pharmacy switch company's registration shall expire twelve months after the date of issue. Every registration issued pursuant to this section may be renewed for the ensuing period of twelve months upon the filing of an application in conformity with this section.

(f) Before a pharmacy switch company's registration shall be renewed, the pharmacy switch company shall properly file in the office of the superintendent an application for renewal in such form as the superintendent prescribes and pay a fee of one thousand dollars.

(g) If an application for a renewal registration shall have been filed with the superintendent at least one month before its expiration, then the registration sought to be renewed shall continue in full force and effect either until the issuance by the superintendent of the renewal registration applied for or until five days after the superintendent shall have refused to issue such renewal registration and given notice of such refusal to the applicant, otherwise the registration shall expire and the registrant shall have no expectation of renewal.

§ 3007. Required disclosures by pharmacy switch companies. (a) Each switch company shall annually disclose to the department, in a form and manner prescribed by the superintendent, such information as the superintendent deems necessary for the proper supervision of the industry. Such information shall include:

(1) a list of services the switch company provides and the industries to which they are provided;

(2) information on electronic voucher services provided by the switch company, including:

(A) a list of manufacturers that the switch company has contracts with or for which it transmits electronic vouchers;

(B) a list of medications and the National Drug Codes (NDCs) for which the switch company may apply electronic vouchers; and

(C) the total amount of money collected from manufacturers related to transmission of electronic vouchers; and

(3) the number of transactions processed in this state and the total amount of revenue attributable to those transactions.

(b) A switch company shall disclose to each pharmacy benefit manager with which it does business any instance in which an electronic voucher was applied in the course of routing the claim.

§ 3008. Registration of rebate aggregators. (a) No rebate aggregator may do business in this state after September thirtieth, two thousand twenty-four without first registering with the department.

(b) A rebate aggregator seeking registration shall file, in a form and manner determined by the superintendent, information including but not limited to:

(1) the legal name of the entity;

(2) any trade or other names used by the entity;

(3) the organizational structure of the entity;

(4) the health plans and the pharmacy benefit managers licensed in this state for which the entity provides services;

(5) the persons who exercise control of the entity;

(6) a primary point of contact for the entity;

(7) an agent for service of process;

(8) a set of audited financials for the prior fiscal year; and

(9) such other information or documents as the superintendent shall require.

(c) The superintendent shall accept a registration only if he or she deems that all the required information has been provided in a satisfactory form and manner and has received payment of a nonrefundable registration fee of one thousand dollars.

(d) If any of the information contained in the registration shall change the rebate aggregator shall notify the department of such change in a form and manner prescribed by the superintendent for such purpose

within twenty-one days of the change. Such requirement to update shall include the filing of a new set of audited financials upon adoption. For any change other than new audited financials, the filing shall not be deemed complete unless accompanied by a payment of a fee of fifty dollars.

(e) Every rebate aggregator's registration shall expire twelve months after the date of issue. Every registration issued pursuant to this section may be renewed for the ensuing period of twelve months upon the filing of an application in conformity with this section.

(f) Before a rebate aggregator's registration shall be renewed, the rebate aggregator shall properly file in the office of the superintendent an application for renewal in such form as the superintendent prescribes and pay a fee of one thousand dollars.

(g) If an application for a renewal registration shall have been filed with the superintendent at least one month before its expiration, then the registration sought to be renewed shall continue in full force and effect either until the issuance by the superintendent of the renewal registration applied for or until five days after the superintendent shall have refused to issue such renewal registration and given notice of such refusal to the applicant, otherwise the registration shall expire and the registrant shall have no expectation of renewal.

§ 3009. Required disclosures by rebate aggregators. (a) Each rebate aggregator that has a contract or arrangement with a pharmacy benefit manager serving a health plan shall, on an annual basis, disclose in writing to the health plan the following:

(1) fee structure provisions of any contract or arrangement between the rebate aggregator and pharmacy benefit manager or drug manufacturer, including:

(A) fees collected for aggregating rebates due to the health plan; and

(B) such other information as the superintendent may require by regulation; and

(2) quantification of inflationary payments, credits, grants, reimbursements, other financial or other reimbursements, incentives, inducements, refunds or other benefits received by the rebate aggregator from the drug manufacturer and retained by the rebate aggregator, whether referred to as a rebate, a discount, or otherwise.

(b) (1) Each rebate aggregator shall, at the time of registration, disclose to the department the extent of any ownership or control of the rebate aggregator or by the rebate aggregator of any parent company, subsidiary, or other affiliated organization that provides pharmacy benefit management services.

(2) Each rebate aggregator shall on an annual basis disclose to the department the information requested by the superintendent, including:

(A) any payments made to a rebate aggregator by a drug manufacturer relating to a drug's utilization, including inflationary payments, credits, grants, reimbursements, other financial or other reimbursements, incentives, inducements, refunds or other benefits received by the rebate aggregator, whether referred to as a rebate, a discount, or otherwise;

(B) any payments made, including those described in subparagraph (A) of this paragraph and subsequently retained by a rebate aggregator;

(C) any fees charged by the rebate aggregator to the pharmacy benefit manager or drug manufacturer relating to a drug's utilization;

(D) any payments made to a rebate aggregator from a program administered by a drug manufacturer for the purpose of assisting patients with

the cost of prescription drugs, including copayment assistance programs, discount cards, and coupons; and

(E) the terms and conditions of any contract or arrangement between the rebate aggregator and a pharmacy benefit manager or drug manufacturer.

§ 3010. Deposit of penalties and fees. Penalties and fees collected pursuant to this article shall be deposited into the pharmacy benefit manager regulatory fund established pursuant to section ninety-nine-oo of the state finance law.

§ 3. Subdivision 3 of section 99-oo of the state finance law, as added by chapter 128 of the laws of 2022, is amended to read as follows:

3. Such fund shall consist of money received by the state as fees under [~~article~~] articles twenty-nine and thirty of the insurance law or penalties ordered under [~~article~~] articles twenty-nine and thirty of the insurance law and all other monies appropriated, credited, or transferred thereto from any other fund or source pursuant to law. All monies shall remain in such fund unless and until directed by statute or appropriation.

§ 4. This act shall take effect immediately.