

**NEW YORK STATE DEPARTMENT OF FINANCIAL SERVICES
PROPOSED**

**SECOND AMENDMENT TO 11 NYCRR 450
(INSURANCE REGULATION 219)
PHARMACY BENEFITS BUREAU**

**NEW 11 NYCRR 453
(INSURANCE REGULATION 223)
PHARMACY BENEFIT MANAGER ASSESSMENTS**

**NEW 11 NYCRR 454
(INSURANCE REGULATION 224)
FILINGS AND OTHER REQUIREMENTS FOR ISSUANCE AND MAINTENANCE OF A LICENSE**

**NEW 11 NYCRR 455
(INSURANCE REGULATION 225)
REPORTING AND RECORD KEEPING REQUIREMENTS**

I, Adrienne A. Harris, Superintendent of Financial Services, pursuant to the authority granted by Financial Services Law sections 102, 201, 202, 301, 302, 304, 305, and 306, Insurance Law sections 301, 316, 2904, 2905, 2906, and 2914, and Public Health Law section 280-a, do hereby promulgate the following amendment to Part 450 of and the addition of new Parts 453, 454, and 455 to Title 11 of the Official Compilation of Codes, Rules and Regulations of the State of New York, to take effect upon publication of the Notice of Adoption in the State Register, to read as follows:

(New matter is underlined; Matter in brackets is deleted)

Section 450.1 is amended as follows:

As used in this [part] Chapter, the following words and terms shall have the following meanings, unless otherwise specified:

(a) A substantial number of beneficiaries who work or reside in this state shall mean where 50 percent or more of the beneficiaries of the health plan work or reside in New York.

(b) Aggrieved shall mean having or allegedly having an interest adversely affected by the acts or omission of a pharmacy benefit manager.

[(a)] (c) Board shall mean the Drug Accountability Board established by Insurance Law section 202.

[(b)] (d) Bureau shall mean the Pharmacy Benefits Bureau established by this Part.

[(c)] (e) Chair shall mean the chair of the Drug Accountability Board appointed by the superintendent.

(f) Claim shall mean a bill, invoice, or request for payment related to a prescription drug.

(g) Controlling person, health plan, pharmacy benefit manager, and pharmacy benefit management services have the same meanings as set forth in Public Health Law section 280-a.

(h) Manufacturer shall mean an entity engaged in the manufacture of prescription drugs sold in this State.

(i) Pharmacy services administrative organization or PSAO shall mean 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.

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

(k) Switch company shall mean 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.

(l) Total operating cost shall mean the aggregate amount to be assessed to all registrants and licensees pursuant to this Part and shall be the sum of:

(1) the total operating expenses of the department that are solely attributable to its oversight of registrants and licensees; and

(2) the proportion deemed just and reasonable by the superintendent of the other operating overhead expenses of the department that may be assessed against registrants and licensees under Insurance Law section 2914.

(m) Wholesaler shall mean an entity that bottles, packs or purchases drugs, devices, or cosmetics for the purpose of selling or reselling to pharmacies or to other channels.

(All of the following material is new)

A new Part 453 is added as follows:

**PART 453
(INSURANCE REGULATION 223)**

PHARMACY BENEFIT MANAGER ASSESSMENTS

Sec.

453.1 Applicability.

453.2 Billing and assessment process.

453.3 Computation of assessment.

453.4 Penalties for noncompliance.

453.5 Special assessments.

Section 453.1 Applicability.

Pursuant to Insurance Law section 2914, this Part sets forth how pharmacy benefit managers licensed or registered pursuant to Insurance Law article 29 shall be assessed by the superintendent for the operating expenses of the department that are attributable to regulating such pharmacy benefit managers in such proportions as the superintendent shall deem just and reasonable.

Section 453.2 Billing and assessment process.

The New York State fiscal year begins April 1 and ends March 31 of the following calendar year. Each registrant or licensee subject to assessment pursuant to this Part is billed five times for a fiscal year: four quarterly assessments (each approximately 25 percent of the anticipated annual amount) based on the estimated budget to cover the total operating cost at the time of the billing, and a final assessment (or true-up), based on the actual total operating cost for the fiscal year. Any registrant or licensee that is registered or licensed for any part of a quarter shall be assessed for the full quarter. Such amounts shall be paid within 30 days of the date of such billing.

Section 453.3 Computation of assessment.

(a) The assessment shall be equal to the total operating cost and shall be assessed to all registered and licensed pharmacy benefit managers pursuant to this Part.

(b) The total operating cost shall be divided pro rata among registrants and licensees based upon each registrant's or licensee's share of the aggregate number of claims processed for pharmacies in this State by registered or licensed pharmacy benefit managers. The aggregate number of claims processed for pharmacies in this State and each registrant's or licensee's share of that number shall be calculated based on the report that registrants and licensees are required to submit by January 15 of each year stating the total number of claims each entity processed for pharmacies located in this State for the preceding calendar year (January 1 to December 31).

Section 453.4 Penalties for noncompliance.

In the event that a registrant or licensee fails to submit their reported number of claims by January 15 of each year, the registrant or licensee will immediately receive notice of the superintendent's intent to suspend, revoke, or terminate a registrant or licensee's registration or license pursuant to Insurance Law section 2907, or such other actions as the superintendent may deem appropriate.

Section 453.5 Special assessments.

If the superintendent determines that the expenses associated with a specific examination, investigation, or review are best allocated solely to an individual registrant or licensee subject to such examination or investigation, such expenses shall be billed separately as provided for in this section. The time of each person associated with such examination or investigation shall be multiplied by average costs of the examiners and specialists at their respective grade levels assigned to such examination or investigation, plus expenses for travel outside of this State, and the resulting amount shall be assessed separately to each such registrant or licensee subject to such examination, investigation, or review in such amounts as the superintendent shall deem appropriate. Alternatively, if the superintendent contracts with another entity or person to perform an examination, investigation, or review

of an individual registrant or licensee, the expenses associated with such examination, investigation, or review shall be the amount of the contract for such services and such portion of the department's administrative expenses associated with such contract as the superintendent shall deem appropriate. The resulting amount shall be assessed separately to each such registrant or licensee subject to such examination, investigation, or investigation in such amounts as the superintendent shall deem appropriate. Such special assessments shall be billed within 180 days after the calendar quarter within which such expenses were incurred. Such amounts shall be paid within 30 days of the date of such billing. In making a determination to make a special assessment and to allocate such assessment between one or more registrants or licensees, the superintendent shall include such factors as the superintendent shall deem appropriate, including, but not limited to: the significance of the examination to the conduct of business by a given registrant or licensee or group thereof; the potential seriousness of any violations of law or regulation identified by, or under review in, such examination, investigation, or review; the likelihood that such violations are common among registrants or licensees; and the extent to which a registrant or licensee attempted to cover up or failed to disclose the existence of such violations.

A new Part 454 is added as follows:

**PART 454
(INSURANCE REGULATION 224)**

FILINGS AND OTHER REQUIREMENTS FOR ISSUANCE AND MAINTENANCE OF A LICENSE

Sec.

454.1 Required filings for issuance of a license.

454.2 Certification of cybersecurity compliance.

Section 454.1 Required filings for issuance of a license.

(a) Applicability.

(1) A pharmacy benefit manager applying for a license shall pay to the superintendent a non-refundable license application fee of \$24,000. Payment of the fee shall be made electronically in a manner provided by the superintendent.

(2) Each entity seeking to be licensed as a pharmacy benefit manager shall electronically file an application with the department on an electronic form and in a manner prescribed by the superintendent and made available on the department's publicly accessible website.

(3) If an application for a license shall have been filed with the superintendent, including payment of the non-refundable license application fee, on or before November 1, 2023, then the license sought shall be deemed to be in full force and effect either until the issuance by the superintendent of the license applied for or until five days after the superintendent shall have refused to issue such license and given notice of such refusal to the applicant.

(b) Required information. The application form for a pharmacy benefit manager license shall require the pharmacy benefit manager to submit the following information to the department:

(1) the name of the pharmacy benefit manager;

(2) the address, contact telephone number, and website of the pharmacy benefit manager;

(3) the federal employer identification number for the pharmacy benefit manager;

(4) the name, address, email address, and telephone number of the primary contact person authorized to act on behalf of the pharmacy benefit manager;

(5) the name, address, email address, and telephone number of the pharmacy benefit manager's agent for service of process in this State;

(6) the name, position, and email address of each individual who is a controlling person of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee;

(i) if the pharmacy benefit manager is a partnership or other unincorporated association, each partner or member;

(ii) if the pharmacy benefit manager is a corporation, each of its officers, and stockholders holding 10% or more of the voting stock of the pharmacy benefit manager; and

(iii) if the pharmacy benefit manager is a limited liability company, each officer, manager, or member;

(7) a detailed corporate/ownership organizational chart (schematic or table format) displaying a reporting and relationship hierarchy and structure beginning with the pharmacy benefit manager applying for a license and continuing up to parent companies that own 10% or more of the pharmacy benefit manager and down to subsidiary companies until no party owns 10% or more of the subsidiary company; such chart shall also identify any entity that is in the same corporate/ownership structure with which the pharmacy benefit manager contracts in relation to its provision of pharmacy benefit management services or any matter connected therewith;

(8) the total number of claims the pharmacy benefit manager processed for pharmacies located in this State for the prior calendar year; and

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

(c) Required documents. An applicant for a pharmacy benefit manager license shall submit the following documents to the department:

(1) all organizational documents of the pharmacy benefit manager, including any operating agreement, articles of organization, certificate of incorporation, articles of association, charter, partnership agreement, trade name certificate, trust agreement, shareholder agreement, certificate of authority and other applicable documents, and all amendments to such documents;

(2) the bylaws, rules, regulations, or other documents regulating the internal affairs of the pharmacy benefit manager;

(3) a list of each pharmacist or pharmacy located in this State and any PSAO with membership located in this State with which the pharmacy benefit manager contracts in the administration of pharmacy benefits for health plans, including identification of whether the pharmacy benefit manager has any ownership interest in, financial interest in, or other affiliation with, any such pharmacist, pharmacy, or PSAO;

(4) a list of each manufacturer with which the pharmacy benefit manager contracts in the administration of pharmacy benefits for health plans, including identification of whether the pharmacy benefit manager has any ownership interest in, or affiliation with, such manufacturer;

(5) a list of each rebate aggregator with which the pharmacy benefit manager contracts for the administration of pharmacy benefits for health plans, including identification of whether the pharmacy benefit manager has any ownership interest in, or affiliation with, such rebate aggregator;

(6) a list of each switch company with which the pharmacy benefit manager contracts for the administration of pharmacy benefits for health plans, including identification of whether the pharmacy benefit manager has any ownership interest in, or affiliation with, such switch company;

(7) a list of each wholesaler with which the pharmacy benefit manager contracts for the administration of pharmacy benefits for health plans, including identification of whether the pharmacy benefit manager has any ownership interest in, or affiliation with, such wholesaler;

(8) a copy of each and every fully executed contract currently in effect (and any other documents incorporated by reference therein) into which the pharmacy benefit manager has entered with each pharmacist or pharmacy located in New York, or any PSAO with membership located in New York in administration of pharmacy benefit management services for health plans;

(9) a list of each health plan with which the pharmacy benefit manager has a current and in force contract to perform pharmacy benefit management services in this State, including a description of which pharmacy benefit management services the pharmacy benefit manager is providing to each individual health plan and the number of enrollees or beneficiaries covered by each individual health plan for the preceding calendar year;

(10) a copy of each and every provider manual currently in effect that the pharmacy benefit manager uses for the administration of pharmacy benefit management services for health plans, including any and all amendments thereto whether or not made consistently;

(11) a copy of the pharmacy benefit manager's most recent fiscal year-end audited financial statements for the pharmacy benefit manager applying for the license, which shall not include any parent company; and

(12) such other information as the superintendent may require.

(d) All documents submitted pursuant to this Part shall be fully legible, without omissions or redactions, and in such condition that legible copies can be reproduced from them.

(e) Notification of changes in license application.

(1) A pharmacy benefit manager shall notify the department in writing within 30 days of a change in any of the information or documents required to be disclosed on the pharmacy benefit manager's license application under this Part.

(2) Notwithstanding the requirements of this subdivision, the documents and amendments thereto required by paragraph (10) of subdivision (c) of this section shall be filed with the department on the same day as they are transmitted to a pharmacist or pharmacy located in this State, or any PSAO with membership located in this State. No provider manual or amendment thereto shall be effective against a pharmacist or pharmacy located in this State, or any PSAO with membership located in this State, without being filed with the department pursuant to this Part.

Section 454.2 Certification of cybersecurity compliance.

A pharmacy benefit manager is a covered entity under 23 NYCRR Part 500. Every pharmacy benefit manager shall be in compliance with the cybersecurity requirements contained in 23 NYCRR Part 500 and in order to qualify for issuance or maintenance of a license under 23 NYCRR Part 454 the pharmacy benefit manager shall file a certification of compliance with those requirements with the department prior to applying for a license to conduct pharmacy benefit management services in this State, unless otherwise exempt under section 500.19 of that Part.

A new Part 455 is added as follows:

PART 455 (INSURANCE REGULATION 225)

REPORTING AND RECORD KEEPING REQUIREMENTS

Sec.

455.1 Standards for maintenance and reproduction of records.

455.2 Required records to be maintained.

455.3 Required disclosure to the department.

455.4 Annual reporting requirements.

Section 455.1 Standards for maintenance and reproduction of records.

(a)(1) Records and indices of records required to be maintained under this Part may be maintained in any durable medium.

(2) Where the original record was not a paper document, a pharmacy benefit manager shall be able to produce information or data that accurately represents a record of communications between a person or entity and the pharmacy benefit manager or accurately reflects a transaction or event.

(3) Upon transfer of an original record to a durable medium, the pharmacy benefit manager may destroy the original record after assuring that all information contained in the original record, including signatures, handwritten notations, or pictures, is contained in the durable medium.

(4) If the pharmacy benefit manager does not retain the original paper record, or if there was no original paper record, a duplicate or back-up system sufficient to permit reconstruction of the record shall be established at a separate location. The record may be retained in any form permitted by this Part.

(b) The superintendent may perform on-site visits to determine that the pharmacy benefit manager is in compliance with this Part.

(c) A pharmacy benefit manager shall establish and maintain a records retention plan. The plan shall include a description of the types of records being retained, the method of retention, and the safeguards established to prevent alteration of the records. Such plan shall be provided to the superintendent upon request. The pharmacy benefit manager shall certify the accuracy of any records that are provided in accordance with its record retention plan.

Section 455.2 Required records to be maintained.

(a) In addition to any other requirement provided by law, a pharmacy benefit manager shall maintain copies of any documents necessary to respond to a health plan's request pursuant to Part 452 of this Title for a period of at least two years following the date on which the document is no longer necessary to respond to such request.

(b) If a health plan requests any documents referenced in Part 452 of this Title, the pharmacy benefit manager shall maintain a record of the request for at least two years from the date of the request, including: the documents requested by each health plan; the date each document was requested; the date each document was transmitted to the health plan; and any other relevant information deemed necessary by the superintendent.

(c) A pharmacy benefit manager shall maintain copies of the pharmacy benefit manager's audited financial statements for the pharmacy benefit manager, which shall not include any parent company, for at least five years from the end of the fiscal year to which they pertain.

(d) A pharmacy benefit manager shall maintain copies of any and all documents and information related to or used in denying an appeal under Public Health Law section 280-a(4)(e), including the national drug code, available purchase price, date of available purchase, and name of the wholesaler registered in this State, for at least one year after the denial is transmitted to the appealing party.

Section 455.3 Required disclosure to the department.

The department may, from time to time, request copies of any and all documents required to be maintained by subdivisions (b), (c), and (d) of section 455.2 of this Part. Upon such a request, a pharmacy benefit manager shall transmit the documents or information requested to the department within 15 business days of the department's written request. A pharmacy benefit manager shall be prepared to respond to such requests in full and an extension of time to respond will only be provided upon a showing of good cause.

Section 455.4 Annual reporting requirements.

Each pharmacy benefit manager shall electronically file an annual report with the department pursuant to Insurance Law section 2904 by July 1 on a form and in a manner prescribed by the superintendent consistent with instructions posted on the department's publicly accessible website.