NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
PROPOSED

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

FIRST AMENDMENT TO 11 NYCRR 454
(INSURANCE REGULATION 224)
FILINGS AND OTHER REQUIREMENTS FOR ISSUANCE AND MAINTENANCE OF A LICENSE

NEW 11 NYCRR 456
(INSURANCE REGULATION 226)
CONTRACTING WITH NETWORK PHARMACIES AND OTHER OBLIGATIONS

NEW 11 NYCRR 457
(INSURANCE REGULATION 227)
ACQUISITION OF CONTROL OF PHARMACY BENEFIT MANAGERS

NEW 11 NYCRR 458
(INSURANCE REGULATION 228)
CONSUMER PROTECTION

NEW 11 NYCRR 459
(INSURANCE REGULATION 229)
REQUIREMENTS FOR AUDITS AND INVESTIGATIONS OF PHARMACIES

I, Adrienne A. Harris, Superintendent of Financial Services, pursuant to the authority granted by Financial Services Law sections 102, 201, 202, 301, 302, 304, and 305; Insurance Law sections 301, 316, 2904, 2905, 2906, and 2911; and Public Health Law sections 280-a and 280-c do hereby promulgate the following Third Amendment to Part 450 and First Amendment to Part 454 of, and the addition of new Parts 456, 457, 458, and 459 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, covered individual, health plan, pharmacy benefit manager, pharmacy benefit management services, and maximum allowable cost price* shall have the same meanings as set forth in Public Health Law section 280-a.

(h) *Financial product or service* shall have the same meaning as set forth in Financial Services Law section 104.

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

(j) *National average drug acquisition cost* shall mean the price listed for a drug on the monthly survey of retail pharmacies conducted by the federal Centers for Medicare and Medicaid Services.

(k) *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.

(l) *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.

(m) *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.

(n) *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.

(o) *Wholesale acquisition cost* shall mean, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or
other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(p) *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.

A new section 450.7 is added to Part 450 as follows:

**Section 450.7 Applicability.**

(a) Applicability. The following provisions of this Chapter shall not apply to a pharmacy benefit manager’s provision of pharmacy benefit management services to a Medicare prescription drug plan offered pursuant to the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003,” codified at 42 U.S.C. section 1395w-101 et. seq., as amended; section 456.2(a)(2) to (4), section 456.2(a)(7)(i) to (7)(iv), section 456.6, section 458.2(d), section 458.4, and Part 459 of this Title. To the extent a pharmacy benefit manager is providing services for other health plans in addition to Medicare prescription drug plans, the provisions of this Chapter shall continue to apply to the pharmacy benefit manager in its performance of pharmacy benefit management services to those other health plans.

(b) Severability. Any provision of this Chapter, or any application of any provision of this Chapter that is held to be invalid or ruled to violate or be inconsistent with any applicable law or regulation by a court of competent jurisdiction, shall not affect the validity, effectiveness, or application of any other provision of this Chapter. In particular, if a court of competent jurisdiction were to hold that any provision of this Chapter as applied to a pharmacy benefit manager providing pharmacy benefit management services to any category of health plan is preempted by federal law, then such application shall be excluded from such regulation only to the extent preempted and shall not exclude application of the provision to the same pharmacy benefit manager performing pharmacy benefit management services for other health plans.

(All of the following material is new)

A new subdivision (f) is added to section 454.1 as follows:

(f) No pharmacy benefit manager shall provide pharmacy benefit management services in this State under any trade name that is not also listed in the pharmacy benefit manager’s license application unless the pharmacy benefit manager provides notice to the department pursuant to subdivision (e) of this section.

A new Part 456 is added as follows:

**PART 456**

*(INSURANCE REGULATION 226)*

**CONTRACTING WITH NETWORK PHARMACIES AND OTHER OBLIGATIONS**

Sec.
456.1 Applicability.
Section 456.1 Applicability.

(a) Subject to the exclusions set forth in section 450.7 of this Title, this Part shall apply to any contract issued, assigned, renewed, recredentialed, extended, amended, or otherwise modified on or after January 1, 2024. Notwithstanding the foregoing, any provision in a contract between a pharmacy benefit manager and a pharmacy that conflicts with the provisions of this Part shall be deemed void and unenforceable on and after January 1, 2025.

(b) Definitions.

As used in this Part:

(1) *Pharmacy* shall mean a pharmacist or pharmacy licensed by the New York State Board of Pharmacy, or any agent or representative acting on behalf of the pharmacist or pharmacy, located in this State.

(2) *Pharmacy benefit manager* shall include any representative, subcontractor, affiliate, subsidiary, or other individual or entity acting on behalf of a pharmacy benefit manager.

(3) *Pharmacy Contract* shall mean any contract or agreement, including a pharmacy provider manual, and any amendments or other appropriate items incorporated by reference, entered into by a pharmacy benefit manager with pharmacists, pharmacies, or a pharmacist or pharmacy’s contracting agent, such as a pharmacy services administrative organization in this State, in administration of pharmacy benefit management services for health plans.

Section 456.2 Pharmacy contract standards for pharmacy benefit managers.

(a) A pharmacy benefit manager shall not, by contract or otherwise:

(1) charge a pharmacy a fee related to enrollment or participation in a pharmacy network, including:

(i) an application fee;

(ii) a credentialing or re-credentialing fee;

(iii) a change of ownership fee; or

(iv) a fee for the development or management of claims processing services or claims payment services;
(2) charge a pharmacy a fee related to the adjudication of a claim, including a fee for the submission, receipt, or processing of a claim;

(3) reimburse a pharmacy an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy owned by or affiliated with the pharmacy benefit manager for providing the same covered services, calculated on a per-unit basis using the same generic product identifier or generic code number paid to the pharmacy benefit manager-owned or pharmacy benefit manager-affiliated pharmacy;

(4) retroactively deny or reduce reimbursement for a claim after returning a paid claim response as part of the adjudication of the claim, unless:

(i) the claim was submitted fraudulently;

(ii) done to correct errors identified in an audit; or

(iii) an adjustment was agreed upon by the pharmacy prior to the denial or reduction;

(5) prohibit a pharmacy from communicating about the pharmacy benefit manager with elected officials or a governmental agency, in any manner, including in a public forum, even if the statements made could reasonably be held to reflect negatively on the pharmacy benefit manager;

(6) prohibit, restrict, or limit disclosure of information by a pharmacy to the superintendent;

(7) prohibit a pharmacy from:

(i) discussing with a covered individual information regarding the total cost for pharmacy services for a prescription drug;

(ii) disclosing to a covered individual the availability of any therapeutically equivalent alternative medications;

(iii) selling a more affordable alternative to a covered individual if a more affordable alternative is available;

(iv) providing a covered individual with the option of paying the pharmacy’s cash price for the purchase of a prescription drug and not filing a claim with the covered individual’s health plan if the cash price is less than the covered person’s cost-sharing amount;

(v) offering and providing mail or delivery services to a covered individual as an ancillary service of the pharmacy;

(vi) charging a shipping, handling, or delivery fee to a covered individual requesting a prescription to be mailed or delivered; provided, however, that (a) the pharmacy benefit manager is not required to reimburse a shipping, handling, or delivery fee charged by a pharmacy for a delivery described in this clause unless the fee is specified in the pharmacy contract; and (b) the pharmacy benefit manager is not prohibited from requiring a pharmacy, in the pharmacy contract, to disclose to a covered individual the
cost of any shipping, handling, or delivery fees charged by the pharmacy and that such fees may not be covered by the covered individual’s health plan; or

(8) arbitrarily, unfairly, or deceptively, by contract or any other means, reduce, rescind, or otherwise claw back any reimbursement payment, in whole or in part, to a pharmacy for a prescription drug’s ingredient cost or dispensing fee.

(b) A pharmacy benefit manager shall:

(1) allow a pharmacy to submit electronically all documents and information required as part of any application for enrollment or participation in a pharmacy network and, to the extent consistent with applicable law, allow for the use of electronic signatures for such enrollment or participation;

(2) transmit all pharmacy contracts directly to the effected pharmacy on or prior to the effective date of such pharmacy contract, regardless of whether the pharmacy benefit manager also requires a pharmacy services administrative organization or other contracting agent to transmit such pharmacy contract to the pharmacy;

(3) make unilateral changes or updates to a pharmacy contract only at the time of contract renewal upon 60 days’ notice to the pharmacy;

(4) include a direct telephone number and email address for pharmacy inquiries in every pharmacy contract and on any website of the pharmacy benefit manager. The telephone number shall allow for the delivery of a voice message in the event a pharmacy benefit manager does not have sufficient staff to immediately answer and respond to inquiries from pharmacies. A pharmacy benefit manager shall acknowledge receipt, in writing, either by email, fax, or regular mail, of any email or voicemail received from a pharmacy within three business days of the date when the voicemail was left or email sent and provide a timeframe for when the pharmacy benefit manager will respond to any such inquiry;

(5) disclose in each pharmacy contract the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered prescription drugs available under the health plan administered by the pharmacy benefit manager;

(6) if the pharmacy benefit manager denies a pharmacy’s application for enrollment or participation in a pharmacy network, notify the pharmacy, in writing, either electronically, by fax, or postal mail, within 30 days from submission of a complete application for enrollment or participation in the pharmacy network of the denial, together with a detailed explanation of the reason for why the pharmacy was denied enrollment or participation into the network. The 30-day period shall begin from the date of postmark if the completed application for enrollment or participation is sent via postal mail or from the date of transmittal if the completed application for enrollment or participation is sent electronically or by fax;

(7) after denying a pharmacy’s application for enrollment or participation in a pharmacy network, allow the pharmacy to reapply to be accepted into the pharmacy benefit manager network not later than one year from the date of the pharmacy benefit manager’s determination to deny such participation or enrollment, provided that the pharmacy provides the pharmacy benefit manager with documentation demonstrating that the reason for the original denial has been cured or is no longer applicable;
(8) if a pharmacy benefit manager exercises a right of non-renewal of a pharmacy contract for any reason, notify the pharmacy of the determination of non-renewal at least 60 days prior to the expiration of the pharmacy contract, together with a detailed explanation of the reason for non-renewal; and

(9) if a pharmacy benefit manager determines not to renew a pharmacy contract, allow the pharmacy to reapply to be accepted into the network not later than one year from the date of the pharmacy benefit manager’s determination of non-renewal of the pharmacy contract, provided that the pharmacy provides the pharmacy benefit manager with documentation demonstrating that the reason for the original non-renewal has been cured or is no longer applicable.

(c) No pharmacy benefit manager shall purchase, rent, or otherwise use any pharmacy network created by a third-party unless such third-party’s pharmacy network contracts comply with this Part.

Section 456.3 Credentialing, certification, and accreditation requirements.

(a) For purposes of credentialing a pharmacy as a condition for participating in a pharmacy benefit manager’s network, a pharmacy benefit manager shall not require a pharmacy to renew credentialing more frequently than once every three years.

(b) A pharmacy benefit manager shall notify a pharmacy, in writing, of any: (1) credentialing requirements for participation or enrollment in a pharmacy network upon request by a pharmacy within 14 days from the date of the request; and (2) any re-credentialing requirements for continued participation or enrollment in a pharmacy network at least 30 days prior to the date the pharmacy is required to submit the requested information and documents for such re-credentialing to the pharmacy benefit manager. The 30-day period shall begin from the date of postmark if the notification is sent via postal mail or from the date of transmittal if the notification is sent electronically or by fax.

(c) A pharmacy benefit manager shall allow a pharmacy to submit all documents and information required as part of any credentialing and recredentialing requirements electronically and, to the extent consistent with applicable law, allow for the use of electronic signatures.

(d) A pharmacy benefit manager shall provide to a pharmacy, within 30 days of receipt of a written request from the pharmacy, a written notice of any certification or accreditation requirements used by the pharmacy benefit manager as a determinant of network participation. A pharmacy benefit manager that has provided written notice to a pharmacy under this subdivision shall not change its accreditation requirements for such pharmacy until at least 12 months from the date the pharmacy benefit manager provided such written notice.

(e) If the pharmacy benefit manager determines not to renew a pharmacy contract for any reason related to recredentialing, certification, or accreditation requirements used by the pharmacy benefit manager, the pharmacy benefit manager shall notify the pharmacy of the non-renewal determination in writing, together with a detailed explanation of the reason for such non-renewal. Such explanation shall have a rational basis.
Section 456.4 Provisions related to termination of a pharmacy from a network.

(a) No pharmacy contract shall provide for immediate termination of a pharmacy from a network except in the following circumstances: (1) when a pharmacy makes an assignment for the benefit of creditors; (2) when a pharmacy files a petition in bankruptcy (voluntary or involuntary); (3) when a pharmacy is adjudicated insolvent or bankrupt; (4) where a receiver or trustee is appointed with respect to a substantial part of the pharmacy’s property, or any proceeding is commenced against it that will substantially impair the pharmacy’s ability to perform under a contract; (5) where any court or governmental agency issues to the pharmacy an order to cease and desist from providing pharmacy services; (6) where there is a change in who holds the ownership interests of the pharmacy; (7) where the right to control the operation of the business of the pharmacy is transferred to a third party; (8) where a levy, writ of garnishment, attachment, execution or similar item is served upon the pharmacy and not removed within 14 days from the date of service; (9) where no claims are submitted by the pharmacy within 90 days; (10) where the pharmacy is found to have knowingly and willingly executed, or attempted to execute, a scheme or artifice to defraud any health plan; or (11) where the pharmacy’s license to operate lapses.

(b) Except as provided for in subdivision (a) of this section, in no event shall termination of a pharmacy from a pharmacy network be effective earlier than 60 days from the receipt by the pharmacy of a written notice of termination. Such notice of termination shall be sent by registered mail.

(c) If a pharmacy benefit manager makes the determination to terminate a pharmacy, the pharmacy benefit manager shall provide the pharmacy with a detailed explanation as to why such pharmacy contract was terminated, in writing, together with the notice of termination required by subdivision (b) of this section. Such explanation shall have a rational basis.

(d) A pharmacy, after being terminated by a pharmacy benefit manager from a network, may reapply to the pharmacy benefit manager network after no more than one year has passed from the date of termination, provided that the pharmacy provides the pharmacy benefit manager with documentation demonstrating that the reason for termination has been cured or is no longer applicable.

(e) Termination of a pharmacy from a pharmacy benefit manager network does not release the pharmacy benefit manager from the obligation to make any payment due to the pharmacy for services properly rendered according to the terms of the pharmacy contract prior to the date of termination.

Section 456.5 Contracts with parties related to pharmacy benefit management services.

(a) Pursuant to Insurance Law section 2904, the department is authorized to request copies of the terms and conditions of any contract or arrangement between a pharmacy benefit manager and any other party relating to pharmacy benefit management services provided to health plans. Pharmacy benefit managers are prohibited from including in any such contracts any confidentiality provisions related to disclosures to the department and such contracts shall not require prior approval from any party prior to disclosure to the department. Upon the superintendent’s request, the pharmacy benefit manager shall further transmit any such contracts to the department within 15 business days, unredacted and in full.

(b) Any pharmacy benefit manager that contracts with a subcontractor, affiliate, subsidiary, or other individual or entity to perform pharmacy benefit management services on behalf of the pharmacy benefit manager shall have in its contract with such subcontractor, affiliate, subsidiary, or other individual or entity that the
Section 456.6 Maximum allowable cost lists and appeals.

(a) This section shall apply to pharmacy benefit managers engaging in maximum allowable cost pricing and shall be in addition to the requirements contained in Public Health Law section 280-a(4).

(b) A pharmacy benefit manager shall:

(1) when placing a drug on a maximum allowable cost price list, ensure that the drug meets the following requirements:

   (i) there are at least two therapeutically equivalent multi-source generic drugs or at least one generic drug available from at least one manufacturer generally available for purchase by network pharmacies from wholesalers registered pursuant to Education Law section 6808(4); and

   (ii) it is not obsolete;

(2) include in pharmacy contracts a section for maximum allowable cost price appeals, and include therein:

   (i) the sources used to determine maximum allowable cost pricing, which shall not include dispensing fees received by a pharmacy;

   (ii) directions to where a pharmacy may access the maximum allowable cost list in a readily accessible, secure, and usable electronic format; and

   (iii) instructions detailing how a pharmacy may search for a drug or drugs on the maximum allowable cost list;

(3) review and make necessary adjustments to the maximum allowable cost of each drug on a maximum allowable cost price list using the most recent data sources available at least once every seven days;

(4) provide upon request by a contracting pharmacy, directions to where a pharmacy may access the most up-to-date maximum allowable cost price list or lists used by the pharmacy benefit manager for covered individuals served by that pharmacy in a readily accessible, secure, and usable electronic format;

(5) provide in the maximum allowable cost price appeals process section of a pharmacy contract and on the pharmacy benefit manager’s website, the maximum allowable cost price appeals procedure and include therein the telephone number and email address at which a contracting pharmacy may directly contact the group responsible for processing maximum allowable cost price appeals for the pharmacy benefit manager, which shall provide options to either directly speak to an individual or leave a voice message for an individual who is responsible for processing appeals;
(6) upon receipt of an appeal and prior to rendering a determination on an appeal, send to a pharmacy that files an appeal an email message acknowledging receipt of the appeal and respond to any inquiries posed by the appealing pharmacy in relation to the appeal within three business days;

(7) if an appeal is denied, provide the appealing pharmacy or the appealing pharmacy’s agent:

(i) the national drug code of an equivalent drug that may be purchased by a similarly situated pharmacy at a price that is equal to or less than the maximum allowable cost of the appealed drug;

(ii) the price of the equivalent drug; and

(iii) the name of a wholesaler registered pursuant to Education Law section 6808(4) that has a therapeutically equivalent drug available for purchase at that price;

(8) if following the denial of an appeal, a contracting pharmacy or a representative of the contracting pharmacy files a complaint with the department, upon request, provide the department with any and all documents and information related to or used in denying the appeal, including the information in paragraph (7) of this subdivision and such other information used in determining the denial of the appeal; and

(9) if an appeal is upheld, adjust the maximum allowable cost price of the appealed drug for all pharmacies that are in the network of the health plan for which the appeal is upheld and all pharmacies in this State that are in the network of other health plans for which the pharmacy benefit manager provides pharmacy benefit management services.

(c) A pharmacy benefit manager shall not:

(1) retaliate against a contracting pharmacy for exercising its right to appeal under this section or filing a complaint with the department; or

(2) charge a contracted pharmacy a fee related to the re-adjudication of a claim or claims resulting from an appeal under Public Health Law section 280-a(4), regardless of whether such appeal is upheld or denied.

Section 456.7. Pricing models.

(a) Pharmacy reimbursements. A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.18. If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a pharmacy benefit manager shall not reimburse in an amount that is less than the wholesale acquisition cost of the drug plus a professional dispensing fee of $10.18.

(b) Spread pricing. A pharmacy benefit manager shall offer a health plan the option of paying the pharmacy benefit manager the same price for a prescription drug as the pharmacy benefit manager pays a pharmacy for the prescription drug.
Section 456.8. Prohibition on certain dispensing restrictions.

(a) A pharmacy benefit manager shall not restrict a pharmacy from dispensing a prescription drug to a covered individual on the basis of:

(1) volume of claims as measured by number of claims, quantity dispensed or dollars paid;

(2) therapeutic categories; or

(3) dispensing rates of other pharmacies.

(b) Notwithstanding subdivision (a) of this section, a pharmacy benefit manager may apply to the department for authorization to restrict a pharmacy from dispensing a prescription drug covered by the covered individual’s health plan on the basis of any category set forth in subdivision (a). The application shall include:

(1) a copy of the proposed restriction, together with a list of all network pharmacies to which the restriction would apply;

(2) a list of all prescription drugs to be included in the restriction, the national drug code of each prescription drug, and the RX BIN numbers managed by the pharmacy benefit manager that are effected; and

(3) a detailed reasoning of the basis for the proposed restriction and an objective analysis on the impact to covered individuals and network pharmacies.

(c) Upon receipt of a complete application submitted pursuant to subdivision (b) of this section, the department shall publish the pharmacy benefit manager’s proposed restriction on the department’s publicly accessible website for public comment for a period of no less than 60 calendar days. After the expiration of the public comment period, the department shall review the application, all comments submitted during the comment period, and make a determination whether to approve or deny the application based on whether such application complies with the requirements of Public Health Law section 280-a(2)(a)(ii) and such restriction listed in the application would not directly or indirectly harm consumers.

A new Part 457 is added as follows:

PART 457
(INSURANCE REGULATION 227)

ACQUISITION OF CONTROL OF PHARMACY BENEFIT MANAGERS

Sec.
457.1 Definitions.
457.2 Prior approval required for acquisition of control of licensed pharmacy benefit managers.

Section 457.1 Definitions.

(a) As used in this Part:
(1) *Control*, including the terms *controlling, controlled by* and *under common control with*, means the possession direct or indirect of the power to direct or cause the direction of the management and policies of a pharmacy benefit manager, whether through the ownership of voting securities, by contract or otherwise; but no person shall be deemed to control a pharmacy benefit manager solely by reason of the person being an officer or director of such pharmacy benefit manager. Subject to subdivision (c) of section 457.2 of this Part, control shall be presumed to exist if any person directly or indirectly owns, controls or holds with the power to vote 50 percent or more of the voting securities of any pharmacy benefit manager.

(2) *Person* means an individual, partnership, firm, association, corporation, joint-stock company, trust, any similar entity or any combination of the foregoing acting in concert.

**Section 457.2 Prior approval required for acquisition of control of licensed pharmacy benefit managers.**

(a) No person shall acquire control of any licensed pharmacy benefit manager, whether by purchase of its securities or otherwise, unless such person receives the superintendent’s prior approval.

(b) The superintendent shall disapprove such acquisition if the superintendent determines, after notice and an opportunity to be heard, that such action is reasonably necessary to protect the interests of the people of this State. The following factors may be considered in making such determination:

1. the financial condition of the acquiring person and the pharmacy benefit manager;
2. the trustworthiness of the acquiring person or any of its officers or directors;
3. a plan for the proper and effective conduct of the pharmacy benefit manager’s operations;
4. the source of the funds or assets for the acquisition;
5. the fairness of any exchange of shares, assets, cash or other consideration for the shares or assets to be received;
6. whether the effect of the acquisition may contribute to excessive concentration and vertical integration of markets; and
7. whether the acquisition is likely to be hazardous or prejudicial to health plans, covered individuals, pharmacies, or any other stakeholders in the pharmaceutical supply chain.

(c) The superintendent may determine upon application that any person does not or will not upon the taking of some proposed action control a pharmacy benefit manager. The superintendent may prospectively revoke or modify the superintendent’s determination, after notice and opportunity to be heard, whenever in the superintendent’s judgment revocation or modification is consistent with this article.

(d) Applications for a determination that a person does not, or will not upon the taking of some proposed action, control a pharmacy benefit manager shall contain the following information:
(1) the number of authorized, issued, and outstanding voting shares of the pharmacy benefit manager;

(2) with respect to such person and all persons controlling, controlled by, or under common control with such person:

(i) the number of shares of the pharmacy benefit manager’s securities that are held of record or known to be beneficially owned, and the number of shares concerning which there is a right to acquire, directly or indirectly;

(ii) any interests in any other securities of the pharmacy benefit manager, including its notes, bonds, and other corporate obligations; and

(iii) information as to all transactions in any securities of the subject that were effected during the past six months by such person;

(3) whether such person, including any person controlling, controlled by, or under common control with such person, is, or during the preceding 12 months was, engaged under an agreement, contract, or retainer with the subject as a supplier of goods or services or in some employment or consulting capacity, or whether there is any understanding, written or otherwise, that such person will be so engaged, for which compensation was, is or will be payable; the nature of the arrangement and amount of such compensation;

(4) whether such person is under common management, or shares any common officers or directors, with the pharmacy benefit manager and whether such person, if a natural person, or any member of the person’s immediate family, is an officer or director of the pharmacy benefit manager; and

(5) a detailed statement explaining why such person should not be considered to control the pharmacy benefit manager.

A new Part 458 is added as follows:

PART 458
INSURANCE REGULATION 228
CONSUMER PROTECTION

Sec.
458.1 Definition.
458.2 Prohibited market conduct practices.
458.3 Consumer resources.
458.4 Network adequacy.
458.5 Investigation of complaints.

Section 458.1 Definition.

As used in this Part, pharmacy benefit manager and pharmacy shall have the same meanings as defined in Part 456 of this Chapter.
Section 458.2 Prohibited market conduct practices.

(a) A pharmacy benefit manager or representative of a pharmacy benefit manager shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal or offer that is false, deceptive, or misleading.

(b) No pharmacy benefit manager shall engage in any unfair, deceptive, or abusive act or practice.

1. An act or practice is unfair when: (i) the act or practice causes or is likely to cause substantial injury to a covered individual that is not reasonably avoidable by the covered individual; and (ii) such substantial injury is not outweighed by countervailing benefits to the covered individual or to competition.

2. An act or practice is deceptive when: (i) the act or practice misleads or is likely to mislead a covered individual; (ii) the covered individual’s interpretation of the act or practice is reasonable under the circumstances; and (iii) the misleading act or practice is material.

3. An act or practice is abusive when: (i) the act or practice materially interferes with the ability of a covered individual to understand a term or condition of a financial product or service; or (ii) the act or practice takes unreasonable advantage of:

   (i) a lack of understanding on the part of the covered individual of the material risks, costs, or conditions of the financial product or service;

   (ii) the inability of the covered individual to protect the interests of the covered individual in selecting or using a financial product or service; or

   (iii) the reasonable reliance by the covered individual on a pharmacy benefit manager to act in the interest of the covered individual.

(c) A pharmacy benefit manager shall not directly or indirectly:

1. engage in marketing, advertising, or promotional activities to covered individuals or their prescribers for the purpose of gaining dispensing opportunities at pharmacies that are owned by or affiliated with the pharmacy benefit manager, including business models that engage in internet, third-party marketing, telehealth, or texting without the covered individuals’ knowledge or understanding that their pharmacy choices are not restricted. Subject to the foregoing, a pharmacy benefit manager may include an owned or affiliated pharmacy in communications to covered individuals and prospective covered individuals regarding network pharmacies and prices, provided that the pharmacy benefit manager includes information regarding nonaffiliated pharmacies participating in the network in such communications and that the information provided is accurate;

2. in any manner on any material, including identification cards, include the name of any pharmacy unless it specifically lists all pharmacies participating in the relevant pharmacy network;

3. transfer or share records relative to prescription information containing a covered individual’s identifiable or prescriber-identifiable data to a pharmacy benefit manager-owned or pharmacy benefit manager-
affiliated pharmacy for any commercial purpose, including for the purpose of soliciting, marketing, or referring the covered individual to a mail-order pharmacy or a pharmacy benefit manager-owned or pharmacy benefit manager-affiliated pharmacy; provided, however, that nothing in this paragraph shall be construed to prohibit:

(i) the exchange of prescription information between a pharmacy benefit manager and a pharmacy benefit manager-owned or pharmacy benefit manager-affiliated pharmacy for the limited purposes of pharmacy reimbursement, formulary compliance, pharmacy care, or utilization review;

(ii) a health plan’s use of pharmacy services data for the purpose of administering the health plan; or

(iii) a pharmacy benefit manager from notifying a covered individual that a less expensive option for a specific prescription drug is available through a mail-order pharmacy or a pharmacy benefit manager-owned or pharmacy benefit manager-affiliated pharmacy, provided the notification shall state that switching to the less expensive option is not mandatory;

(4) require a covered individual to purchase prescription drugs exclusively through a mail-order pharmacy unless contractually required to do so by the health plan;

(5) penalize a covered individual, including by requiring a covered individual to pay the full cost for a prescription, when the covered individual chooses not to use a pharmacy that is owned by or affiliated with the pharmacy benefit manager for the purpose of getting the covered individual to use a specific pharmacy that is owned by or affiliated with the pharmacy benefit manager;

(6) incentivize a covered individual to use a specific pharmacy that is owned by or affiliated with the pharmacy benefit manager;

(7) remove a drug from a formulary or deny coverage of a drug for the purpose of incentivizing a covered individual to seek coverage from a different health plan;

(8) charge a covered individual who uses an in-network pharmacy that offers to mail or deliver a prescription drug to a covered individual as an ancillary service a fee for the shipping, handling, or delivery of a prescription drug or any cost-sharing that is higher than the fee or the cost-sharing the covered individual would pay if the covered individual used an in-network pharmacy that does not offer to mail or deliver a prescription drug to a covered individual as an ancillary service; or

(9) prohibit or limit any covered individual from selecting an in-network pharmacy of the individual’s choice unless specifically required by the health plan for a particular covered individual.

(d) Maximum Payment Costs. A pharmacy benefit manager shall not require a covered individual purchasing a covered prescription drug to pay an amount greater than the lesser of:

(1) the cost-sharing amount under the terms of the health plan;

(2) the maximum allowable cost for the drug; or
(3) the amount the covered person would pay for the drug if the covered individual were paying the cash price.

(e) A pharmacy benefit manager that violates any of the provisions of this section shall be deemed to have committed a fraudulent, coercive or dishonest practice for purposes of Insurance Law section 2907.

Section 458.3 Consumer resources.

(a) Formulary Directories. This subdivision shall apply to all pharmacy benefit managers providing clinical or other formulary or preferred drug list development or management on behalf of health plans. Pharmacy benefit managers shall come into compliance with the provisions of this subdivision by July 1, 2024.

(1) A pharmacy benefit manager shall publish an up-to-date, accurate, and complete list of all covered prescription drugs on each health plan’s formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a prescription drug may be obtained, on the pharmacy benefit manager’s website and in a manner that is easily accessible to covered individuals and prospective covered individuals. The formulary drug list shall clearly identify the prescription drugs that are available without annual deductibles or coinsurance, including co-payments.

(2) Except as otherwise provided in paragraph (4) of this subdivision, a pharmacy benefit manager shall not:

(i) remove a prescription drug from a formulary;

(ii) move a prescription drug to a tier with larger cost-sharing requirements if the formulary includes two or more tiers of benefits providing for different cost-sharing requirements applicable to the prescription drugs in each tier; or

(iii) add utilization management restrictions to a prescription drug on a formulary, unless such changes occur at the time of enrollment, issuance, or renewal of coverage.

(3) Prohibitions provided in paragraph (2) of this subdivision shall apply beginning on the date on which a plan year begins and through the end of such plan year.

(4) A pharmacy benefit manager:

(i) that manages a formulary that includes two or more tiers of benefits providing for different cost-sharing requirements applicable to prescription drugs in each tier may move a prescription drug to a tier with a larger cost-sharing requirement if an AB-rated generic equivalent or interchangeable biological product for such prescription drug is added to the formulary at the same time;

(ii) may remove a prescription drug from a formulary if the federal Food and Drug Administration determines that such prescription drug should be removed from the market, including new utilization management restrictions issued pursuant to federal Food and Drug Administration safety concerns; and
(iii) managing a formulary that includes two or more tiers of benefits providing for different cost-sharing requirements applicable to prescription drugs may move a prescription drug to a tier with a larger cost-sharing requirement during the plan year, provided the change is not applicable to a covered individual who is already receiving such prescription drug or has been diagnosed with or presented with a condition on or prior to the start of the plan year that is treated by such prescription drug or is a prescription drug that is or would be part of the covered individual’s treatment regimen for such condition.

(5) A pharmacy benefit manager shall provide notice to covered individuals of its intent to remove a prescription drug from a formulary or alter cost-sharing requirements in the upcoming plan year, 90 days prior to the start of the plan year. To the extent that a health plan provides the same notice required under this section to covered individuals, the pharmacy benefit manager may meet its obligation under this paragraph by co-signing the health plan’s notice. Such notice of impending formulary and cost-sharing changes shall also be posted on the pharmacy benefit manager’s website and in any prescription drug finder system that the pharmacy benefit manager provides to the public.

(6) A pharmacy benefit manager shall provide the department with a link to where the department may access each health plan’s formulary on the pharmacy benefit manager’s website and shall provide the department with notice of any formulary changes 30 days prior to their taking effect.

(7) With respect to a prescription drug identified on a pharmacy benefit manager’s formulary list, where a covered individual received through the pharmacy benefit manager’s database described in paragraph (1) of this subdivision information with respect to such prescription drug and such information provided that the prescription drug was located on a formulary list applicable to such covered individual, and the covered individual reasonably relied on such information in obtaining such prescription drug from a pharmacy, the pharmacy benefit manager shall:

(i) not impose on such covered individual a cost-sharing amount for such prescription drug obtained that is greater than the cost-sharing amount that would apply to the covered individual had such prescription drug been listed on the applicable formulary list;

(ii) apply the deductible or out-of-pocket maximum, if any, that would apply if such prescription drug has been listed on the applicable formulary list; and

(iii) bear the burden of any additional costs associated with the requirements in subparagraphs (i) and (ii) of this paragraph, which shall not be passed on to the health plan or pharmacies.

(b) Network Pharmacy Directories. This subdivision applies to pharmacy benefit managers that perform retail network management or contract with network pharmacies on behalf of a health plan. Pharmacy benefit managers shall come into compliance with the provisions of this subdivision by July 1, 2024.

(1) A pharmacy benefit manager shall publish an up-to-date, accurate, and complete list for each health plan for which the pharmacy benefit manager performs pharmacy benefit management services that identifies each pharmacy with which the pharmacy benefit manager has a direct or indirect contractual relationship for the furnishing of items and services under each health plan, on the pharmacy benefit manager’s public website and in a manner that is easily accessible to covered individuals and prospective covered individuals. Such database shall also contain pharmacy directory information with respect to each pharmacy listed.
(2) For purposes of this subdivision, the term *pharmacy directory information* includes the name, address, any applicable specialty, telephone number, and email address of each pharmacy with which the pharmacy benefit manager has a contractual relationship for the furnishing of items and services for a health plan.

(3) A pharmacy benefit manager shall verify and update the pharmacy directory information included on its public website for each health plan within two business days of the addition or termination of a pharmacy from a health plan’s network.

(4) With respect to a covered prescription drug furnished to a covered individual by an out-of-network pharmacy, where the covered individual received through a database or provider directory described in paragraph (1) of this subdivision information that the pharmacy was an in-network pharmacy, and the covered individual reasonably relied on such information in obtaining such prescription drug from the pharmacy, the pharmacy benefit manager shall:

   (i) not impose on such covered individual a cost-sharing amount for such covered prescription drug so furnished that is greater than the cost-sharing amount that would apply to the covered individual had such covered prescription drug been furnished by an in-network pharmacy;

   (ii) apply the deductible or out-of-pocket maximum, if any, that would apply if such prescription drug were furnished by an in-network pharmacy; and

   (iii) bear the burden of any additional costs associated with the requirements in subparagraphs (i) and (ii) of this paragraph, which shall not be passed on to the health plan or pharmacies.

(c) Inquiries by Covered Individuals. A pharmacy benefit manager shall have a direct telephone number and email address listed on its website for inquiries by covered individuals. A pharmacy benefit manager shall have sufficient staff to answer and respond to inquiries from covered individuals in a reasonable amount of time.

Section 458.4: Network adequacy.

(a) A pharmacy benefit manager shall:

(1) offer a pharmacy network that meets the following requirements:

   (i) all covered individuals who reside in this State shall have access to at least one in-network 24-hour pharmacy within 30 minutes travel time (by car or public transportation) from the covered individual’s residence unless none are located within such a distance. If none are located within 30 minutes travel time from the covered individual’s residence, a pharmacy benefit manager shall include the closest 24-hour pharmacy in its network; and

   (ii) all covered individuals who reside in this State shall have access to at least three pharmacies, each within a 30-minute travel time (by car or public transportation) from the covered individual’s residence, regardless of the pharmacy’s hours, unless none are located within such a distance. If there are not three pharmacies located within 30 minutes travel time from the covered individual’s residence, a pharmacy benefit manager shall include the closest three pharmacies in its network;
(2) not use pharmacies that only provide mail order services to meet access standards; and

(3) not require covered individuals to use only pharmacies that are directly or indirectly owned by the pharmacy benefit manager, including for all regular prescriptions, refills or specialty drugs regardless of number of days’ supply.

(b)(1) A pharmacy benefit manager may apply for a waiver from the superintendent if the pharmacy benefit manager is unable to meet the network adequacy requirements under subdivision (a) of this section. A waiver application shall be submitted to the superintendent on a form prescribed by the superintendent and shall:

(i) demonstrate with specific data why the pharmacy benefit manager is not able to meet the requirements; and

(ii) include information as to the steps that were and will be taken to address network adequacy.

(2) If a waiver is granted by the superintendent, the waiver shall automatically expire at the same time that the pharmacy benefit manager’s license expires. If a pharmacy benefit manager applies for a renewal of the waiver, the pharmacy benefit manager must specify the steps that the pharmacy benefit manager has taken over the past three-year period to address network adequacy for the superintendent to consider when deciding whether to grant the waiver.

Section 458.5 Investigation of complaints.

(a) Upon the department’s receipt of any complaint that states facts relating to conduct of a pharmacy benefit manager, the pharmacy benefit manager shall file a statement regarding any and all matters in connection with the complaint that the department may require.

(b) A pharmacy benefit manager shall file the statement required pursuant to subdivision (a) of this section within five business days of receipt of the request by such means as the department may direct. Such statement shall be deemed an “other statement” pursuant to Insurance Law section 2904(a)(2).

(c) Such statement shall be considered filed only when the department receives a statement that addresses all matters required to be provided to the department.

(d) No pharmacy benefit manager shall require the department to use any external email or other system to read responses filed pursuant to subdivision (a) of this section.

(e) It shall be unlawful for any pharmacy benefit manager to take any retaliatory action in response to the filing of a complaint with the department, even if the department resolves the complaint in the pharmacy benefit manager’s favor.
A new Part 459 is added as follows:

PART 459
(INSURANCE REGULATION 229)

REQUIREMENTS FOR AUDITS AND INVESTIGATIONS OF PHARMACIES

Sec.
459.1 Applicability.
459.2 Audit and investigation conduct.
459.3 Audit and investigation reports and appeals.
456.4 Audit and investigation recoupment and fees.

Section 459.1 Applicability.

(a) This Part shall apply to all audits, investigations, and current or retroactive review of books or records of pharmacies conducted by pharmacy benefit managers, regardless of name or nomenclature used by the pharmacy benefit manager, and shall be in addition to the requirements contained in Public Health Law section 280-c.

(b) When a pharmacy benefit manager conducts an audit or investigation of a pharmacy, the pharmacy benefit manager may not consider unintentional clerical or record-keeping errors, including typographical errors, scrivener’s errors, or computer errors regarding a required document or record to be fraudulent activity. For purposes of this Part, fraudulent activity means an intentional act of theft, deception, material misrepresentation, or concealment committed by the pharmacy.

(c) As used in this Part, pharmacy shall have the same meaning as defined in Part 456 of this Chapter.

Section 459.2 Audit and investigation conduct.

(a) A pharmacy benefit manager conducting a remote audit or investigation of a pharmacy shall:

(1) notify the pharmacy no later than fifteen days before the start date of an initial remote audit or investigation, which notice shall:

(i) be in writing and delivered to the pharmacy either:

(a) by mail or common carrier with return receipt requested; or

(b) electronically with electronic receipt confirmation, addressed to the supervising pharmacist of record and pharmacy corporate office, where applicable; and

(ii) include the list of specific prescription numbers to be included in the audit or investigation that may or may not include the final two digits of the prescription numbers.
(b) A pharmacy benefit manager conducting either an in-person or remote audit or investigation of a pharmacy shall:

(1) in addition to the requirements set forth in Public Health Law section 280-c(2)(b) and subdivision (a) of this section, also include in the notice of an audit or investigation to the pharmacy the reason for the audit or investigation, a list of documents and records that are to be audited or investigated, and a list of specific claims to be included in the audit or investigation, including specific prescription numbers and the number and date of refills;

(2) except for audits or investigations initiated to address an identified problem, conduct no more than one audit or investigation per calendar year per pharmacy, regardless of form, unless fraudulent activity or other intentional or willful misrepresentation is reasonably suspected;

(3) when calculating 100 randomly selected prescriptions audited in a selected 12-month period as set forth in Public Health Law section 280-c(2)(f), exclude:

(i) refills that occurred for a particular prescription after the audit date; and

(ii) prescriptions that are filled after the audit date;

(4) include in its provider manual and on its website the procedures and processes for audits and investigations of pharmacies, including:

(i) list of documents and records that a pharmacy shall maintain that may be subject to audit or investigation and the period of time a pharmacy must maintain such documents and records; and

(ii) a direct telephone number and email address that a pharmacy can use to contact the individual or entity in charge of auditing or investigating the pharmacy on behalf of the pharmacy benefit manager. The telephone number shall allow for the delivery of a voice message in the event a pharmacy benefit manager does not have sufficient staff to immediately answer and respond to inquiries from pharmacies. A pharmacy benefit manager shall acknowledge receipt, in writing, either by email, fax, or United States postal mail, of any email or voicemail received within three business days of receipt of the initial voicemail or email and provide a timeframe for when the pharmacy benefit manager will respond to any such inquiry by the pharmacy;

(5) when using written and verifiable records pursuant to Public Health Law section 280-c(2)(d) to validate pharmacy records, consider prescriber notations such as “as directed” or “as needed”, which require the professional judgment of the pharmacist to determine that the dose dispensed is within normal guidelines;

(6) for an audit or investigation that involves clinical or professional judgment, conduct such audit or investigation by or in consultation with a pharmacist licensed under New York State Education Law section 6805;

(7) audit or investigate each pharmacy using the same standards and parameters as the pharmacy benefit manager would audit or investigate a similarly situated pharmacy that is owned by or affiliated with the pharmacy benefit manager;
(8) permit its auditors to enter the area behind the pharmacy prescription counter only when accompanied or authorized by a member of the pharmacy staff; and

(9) provide all audit and investigation documents and records in an electronic format or by certified mail to the pharmacy, upon request by an audited or investigated pharmacy.

(c) A pharmacy benefit manager conducting either an in-person or remote audit or investigation shall not:

1) conduct such audit or investigation on federal or state holidays unless requested or consented to by the pharmacy;

2) interfere with the delivery of pharmacist services to a consumer or fail to make a reasonable effort to minimize the inconvenience and disruption to the pharmacy operations during the audit or investigation process;

3) use fax to send a pharmacy notice of an audit or investigation; or

4) permit documents or records from an audit or investigation conducted by an auditing or investigating individual or entity to be shared with or used by another auditing or investigating individual or entity, except as required by state or federal law.

Section 459.3 Audit and investigation reports and appeals.

(a)(1) A pharmacy benefit manager shall establish a written process for report finalization and appeals of the findings of the preliminary report and shall include such written process in the pharmacy contract.

(2) The written process for report finalization and appeals shall include the following provisions:

(i) when providing a pharmacy with the preliminary audit or investigation report pursuant to Public Health Law section 280-c(2)(g), include within such report all documentation used by the pharmacy benefit manager in justifying its audit or investigation findings; and

(ii) when providing a pharmacy with the final audit or investigation report pursuant to Public Health Law section 280-c(2)(k), include a disclosure of the final audit chargeback and methodology by which the audit chargeback will be recovered by the pharmacy benefit manager.

(3) If a pharmacy’s reasonable request for an extension of time to address a discrepancy or audit or investigation finding as set forth in Public Health Law section 280-c(2)(j) is granted, the pharmacy benefit manager shall be permitted an extension of time in issuing the final audit report that shall be equivalent to the time permitted for the pharmacy’s extension.

Section 459.4 Audit and investigation recoupment and fees.

(a) A pharmacy benefit manager conducting either an in-person or remote audit or investigation of a pharmacy shall not:
(1) include dispensing fees in calculations of overpayments unless the claim is determined to not have been dispensed at all or to have been dispensed in error;

(2) assess a chargeback, recoupment, or other penalty against a pharmacy because a prescription is mailed or delivered at the request of a covered individual;

(3) recoup funds for clerical or record-keeping errors, including typographical errors, scriveners’ errors, and computer errors on a required document or record unless the error resulted in overpayment and such recoupment is limited to the amount of the overpayment;

(4) use probability sampling or other means that project an error using the number of covered individuals served who have a similar diagnosis or the number of similar prescriptions or refills for similar drugs in finding that a claim was incorrectly presented or paid or in calculating recoupments or penalties for audits;

(5) allege actual financial harm to the covered individual or health plan unless there is a direct relationship between the error and a quantifiable sum of money lost by the consumer or health plan;

(6) collect any recoupments, chargebacks, or penalties until the audit or investigation and all appeals thereof are final, unless the individual or entity conducting the audit or investigation is alleging fraudulent activity or other intentional or willful misrepresentation;

(7) recoup an amount in excess of the actual overpayment or overbilled amount; or

(8) use extrapolation in calculating recoupments, chargebacks, or penalties for audits or investigations unless required by state or federal law.

(b)(1) A pharmacy benefit manager shall not recoup by setoff any money for an overpayment or retroactive denial of a claim until the pharmacy has an opportunity of not less than 30 business days to review the pharmacy benefit manager’s findings pursuant to section 459.3 of this Part and file any appeal thereof.

(2) If a pharmacy appeals a pharmacy benefit manager’s finding of overpayment or retroactive denial, the pharmacy benefit manager may not recoup by setoff any money until after all appeals have been exhausted.

(3) Notwithstanding paragraph (1) of this subdivision, a pharmacy benefit manager may withhold future payments before the date the final audit or investigation report has been delivered to the pharmacy if the identified discrepancy for all disputed claims in a preliminary audit or investigation report for an individual audit exceeds $25,000, provided, however, that a pharmacy benefit manager shall not withhold more than 10% of each monthly payment to the pharmacy until the final audit report is issued.

(c) A pharmacy benefit manager that contracts with an independent third party to conduct an audit or investigation shall not agree to compensate the independent third party based on a percentage of, or otherwise connected to, the amount of overpayments recovered.

(d) A pharmacy benefit manager shall not disclose information obtained during an audit or investigation except to the department or any other government agency, the pharmacy subject to the audit or investigation or the health plan.