NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
PROPOSED

THIRD AMENDMENT TO 11 NYCRR 450
(INSURANCE REGULATION 219)
GENERAL PROVISIONS

FIRST AMENDMENT TO 11 NYCRR 452
(INSURANCE REGULATION 222)
GENERAL DUTIES, ACCOUNTABILITY, AND TRANSPARENCY PROVISIONS FOR PHARMACY BENEFIT MANAGERS

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 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, 305, and 306; 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, First Amendment to Part 222, 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:

(All of the following material is new)

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

Section 450.7 Applicability.

(a) 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)(1) and (2), section 458.2(d), 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) Except for Part 454 of this Title, this Chapter shall not apply to a pharmacy benefit manager's provision of pharmacy benefit management services to a health plan governed by the Workers Compensation Law of this State. To the extent a pharmacy benefit manager is providing services for other health 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.

(c) If any provision of this Chapter is held to be illegal or invalid for any reason by a court of competent jurisdiction, the illegality or invalidity shall not affect the remaining provisions of this Chapter, but such provision shall be fully severable and this Chapter shall be construed and enforced as if the illegal or invalid provision had never been included in 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 a health plan is preempted by federal law or regulations promulgated thereunder, then such provision shall be fully severable only to the extent preempted and this Chapter shall be construed and enforced as if the provision did not apply to the pharmacy benefit manager providing pharmacy benefit management services to that specific health plan to the extent preempted and the provisions shall not be construed and enforced as not applying to the same pharmacy benefit manager performing pharmacy benefit management services for other health plans for which there is no preemption.

(All of the following material is new)

A new section 452.5 is added to Part 452 as follows:

Section 452.5 Compliance Cost Disclosure

(a) To the extent that any pharmacy benefit manager states that an increase in the amount that the pharmacy benefit manager charges to a health plan for providing pharmacy benefit management services is attributable to the cost of complying with the requirements of this Chapter, the pharmacy benefit manager shall, at the request of the health plan, provide such health plan with:

(1) a list of the requirements in this Chapter that have resulted in the cost increase;

(2) the cost of complying with each requirement that is attributable to such plan; and

(3) any amount in addition to the cost of complying with the regulations that the pharmacy benefit manager is charging to such plan.

(b) A pharmacy benefit manager shall retain all records evidencing how the costs of complying with the requirements of this Chapter were calculated and how the charges for such costs were allocated to health plans. Such documents shall be retained in accordance with the provisions of Part 455 of this Title.

(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 and definitions.
456.2 Pharmacy contract standards for pharmacy benefit managers.
456.3 Credentialing, certification, and accreditation requirements.
456.4 Provisions related to termination of a pharmacy from a network.
456.5 Contracts with parties related to pharmacy benefit management services.

Section 456.1 Applicability and definitions.

(a) Subject to the exclusions set forth in section 450.7 of this Title, this Part shall apply to any pharmacy contract signed, issued, assigned, renewed, extended, amended, or otherwise modified on or after July 1, 2025. Notwithstanding the foregoing, any provision in a pharmacy contract that conflicts with the provisions of this Part shall be deemed void and unenforceable on and after January 1, 2027.

(b) As used in this Part:

(1) *Affiliated Pharmacy* shall mean, for each pharmacy benefit manager, a pharmacy that controls, is controlled by, or under common control with such pharmacy benefit manager.

(2) *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 who or that is physically located in this State or who or that is under contract with a pharmacy benefit manager to provide pharmacy services via the mail to covered individuals in this State.

(3) *Pharmacy benefit manager* shall have the same meaning as defined in Public Health Law section 280-a(1)(c) and shall include any representative, subcontractor, affiliate, subsidiary, or other individual or entity acting on behalf of a pharmacy benefit manager. A pharmacy benefit manager shall not include an affiliated pharmacy.

(4) *Pharmacy Contract* shall mean any agreement and any amendments or other information incorporated by reference into such agreement, including a pharmacy provider manual, entered into by a pharmacy benefit manager with a pharmacy or a pharmacy's contracting agent.

Section 456.2 Pharmacy contract standards for pharmacy benefit managers.

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

(1) reimburse an in-network pharmacy an amount that is less than what an affiliated pharmacy that is within the same network is reimbursed for providing the same covered services. Nothing in this paragraph shall be construed to limit the ability of a health plan to maintain multiple networks in which reimbursements are different for providing different services, including specialty or mail-order networks;

(2) retroactively deny or reduce any reimbursement for a claim after adjudicating a claim and returning a paid claim response unless:

(i) the claim was submitted fraudulently;

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

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

(3) 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, provided however that nothing in this section shall authorize a pharmacy to:

(i) discuss information that is confidential or constitutes a trade secret; or

(ii) make a false statement of fact.

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

(5) arbitrarily, unfairly, or deceptively 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 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) mail or deliver a copy of all pharmacy contracts directly to the effected pharmacy, in a manner mutually agreed by the pharmacy and the pharmacy benefit manager, 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 uniliteral changes or updates to a pharmacy contract only at the time of contract renewal upon 60 days' notice to the pharmacy; provided, however, that nothing in this section shall be construed to limit the ability of a pharmacy benefit manager to make changes or updates to a formulary or to make changes or updates to rules, requirements, or compensation for any particular drug or service consistent with the health plan's direction;

(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 of any inquiry within three business days of the date when the voicemail was left or email sent and provide a reasonable 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) accept or deny an application by a pharmacy to enroll or participate in a network maintained by a pharmacy benefit manager and notify the pharmacy of the decision in writing within 30 days from submission of a complete application. If a pharmacy benefit manager denies the application, it shall provide a specific explanation for the denial. 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) notify the pharmacy of the determination of non-renewal at least 60 days prior to the expiration of the pharmacy contract, together with a specific explanation of the reason for non-renewal, if a pharmacy benefit manager exercises a right of non-renewal of a pharmacy contract for any reason; and

(8) where it determines not to renew a pharmacy contract, or denies a pharmacy's application to participate in a pharmacy network, 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, provided that the pharmacy provides the pharmacy benefit manager with documentation demonstrating that the reason for the original non-renewal was cured or no longer applies. Nothing in this section shall require the pharmacy benefit manager to accept such pharmacy into the network.

(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 enrolling or participating in a pharmacy benefit manager's network, a pharmacy benefit manager shall not require a pharmacy to recredential 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 must 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 shall not change its accreditation requirements more than once every 12 months.

(e) If a pharmacy benefit manager determines not to renew a pharmacy contract for any reason related to credentialing, certification, or accreditation requirements, the pharmacy benefit manager shall notify the pharmacy of the non-renewal determination in writing, together with a specific 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 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; (7) where the pharmacy is found by a court of competent jurisdiction or a government agency to have knowingly and willingly executed, or attempted to execute, a scheme or artifice to defraud any health plan; (8) where the pharmacy fails to maintain appropriate licensure; (9) where the pharmacy benefit manager has good cause to believe that the pharmacy's operation poses an imminent harm to patients; (10) where the pharmacy fails to maintain required insurance coverage; (11) where the federal government has debarred a pharmacy from participating in a federal program; or (12) where there is a material breach of a pharmacy contract by the pharmacy.

(b) Except as provided for in subdivision (a) of this section, in no event shall any 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 mailed or delivered by registered mail or other trackable method of delivery.

(c) If a pharmacy benefit manager makes the determination to terminate a pharmacy from a network, the pharmacy benefit manager shall provide the pharmacy with a specific 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) 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 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 department is authorized to request information directly from such subcontractor, affiliate, subsidiary, or other individual or entity related to the performance of pharmacy benefit management services for the pharmacy benefit manager, and such subcontractor, affiliate, subsidiary, or other individual or entity shall cooperate the department in connection with such request.

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 25 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) whether the applicant has 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. An application 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 a detailed statement explaining why such person should not be determined to control the pharmacy benefit manager and any other information the superintendent may request.

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 Investigation of complaints.

Section 458.1 Definitions.

(a) As used in this Part:

(1) *Affiliated pharmacy, pharmacy benefit manager* and *pharmacy* shall have the same meanings as defined in Part 456 of this Chapter.

(2) *Unaffiliated pharmacy* shall mean, for each pharmacy benefit manager, a pharmacy that does not control, nor is controlled by, or under common control with such pharmacy benefit manager.

Section 458.2 Prohibited acts and practices.

(a) 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 or deceptive 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.

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

(1) engage in marketing, advertising, or promotional activities to covered individuals for the purpose of gaining dispensing opportunities at affiliated pharmacies, including providing incentives to a covered individual to use an affiliated pharmacy when unaffiliated pharmacies are available within the same network, provided, however, that nothing in this section shall be construed to restrict a pharmacy benefit manager from communicating or operationalizing any element of plan design elected by a health plan. Subject to the foregoing, a pharmacy benefit manager may include an affiliated pharmacy in communications to covered individuals and prospective covered individuals regarding network pharmacies and prices, provided that the pharmacy benefit

manager includes accurate information regarding unaffiliated pharmacies participating in the network, if any, in such communications;

(2) in any manner on any material produced by the pharmacy benefit manager, including identification cards, include the name of any affiliated pharmacy unless it specifically lists unaffiliated 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 an affiliated pharmacy; provided, however, that nothing in this paragraph shall be construed to prohibit:

(i) the transfer or sharing of such information necessary for the limited purposes of pharmacy reimbursement, formulary compliance, pharmacy care, or utilization review; or

(ii) 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 an 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 or refer a covered individual to a mail-order pharmacy or an affiliated pharmacy unless contractually required to do so by the health plan;

(5) penalize a covered individual for using an in-network unaffiliated pharmacy, including by requiring a covered individual to pay the full cost for a prescription. Nothing in this paragraph shall be construed to prohibit a health plan's election to use a network that only includes affiliated pharmacies;

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

(7) 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; or

(8) prohibit a pharmacy from:

(i) discussing with a covered individual information regarding the cost of the prescription to the covered individual;

(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, or charging a shipping, handling, or delivery fee for providing such service.

(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 individual would pay for the drug if the covered individual were paying the cash price the pharmacy would charge to a person without health plan coverage.

(e) A pharmacy benefit manager that willfully or recklessly 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, 2025.

(1) A pharmacy benefit manager shall publish on its website, in a manner that is easily accessible to covered individuals and prospective covered individuals, 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. The formulary drug list shall clearly identify the prescription drugs that are available without annual deductibles, co-payments, or coinsurance.

(2) If a covered individual reasonably relied on information on a pharmacy benefit manager's listing on its website as required by paragraph (1) of this subdivision in obtaining a prescription drug from a pharmacy, the pharmacy benefit manager shall:

(i) not impose a cost-sharing amount for such prescription drug that is greater than the cost-sharing amount that was listed on the website;

(ii) apply the deductible or out-of-pocket maximum, if any, that would apply based upon the website information on which the covered individual reasonably relied; and

(iii) not pass on to the health plan or pharmacies any cost associated with compliance with this paragraph.

(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, 2025.

(1) A pharmacy benefit manager shall publish on its website, in a manner that is easily accessible to covered individuals and prospective covered individuals, a list for each health plan for which the pharmacy benefit manager performs pharmacy benefit management services that identifies each pharmacy within each network. The website shall also contain pharmacy directory information with respect to each pharmacy listed, including the pharmacy's name, address, telephone number, and, if available, email address.

(2) A pharmacy benefit manager shall update the pharmacy directory information on its website for each health plan within five business days of the addition or termination of a pharmacy from a health plan's network.

(3) If a covered individual reasonably relied on information contained on a listing on a pharmacy benefit manager's website as required by paragraph (1) of this subdivision in selecting a pharmacy at which to receive prescription drug services, the pharmacy benefit manager shall:

(i) not impose a cost-sharing amount for such covered prescription drug 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) shall not pass on to the health plan or pharmacies any cost associated with compliance with this paragraph.

(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 Investigation of complaints.

(a) A pharmacy benefit manager shall respond to any complaint that is forwarded by the department to the pharmacy benefit manager within fifteen business days. A pharmacy benefit manager may request additional time to respond to a complaint.

(b) Any response filed by the pharmacy benefit manager pursuant to this section will be shared with the complainant.

(c) The information filed by a pharmacy benefit manager in response to a complaint shall be filed electronically.

(d) No pharmacy benefit manager may 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 OF PHARMACIES

Sec.
459.1 Applicability.
459.2 Conduct of an audit.
459.3 Audit reports and appeals.
456.4 Audit recoupment and fees.

Section 459.1 Applicability and definitions.

(a) The requirements of this Part shall be in addition to the requirements contained in Public Health Law section 280-c.

(b) As used in this Part:

(1) *Audit* shall mean any review or investigation of claims submitted by pharmacies, or 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.

(2) *Affiliated pharmacy* and *pharmacy* shall have the same meaning as set forth in Part 456 of this Chapter.

(3) *Fraudulent activity* means an intentional act of theft, deception, material misrepresentation, or concealment committed by the pharmacy.

Section 459.2 Conduct of an audit.

(a) A pharmacy benefit manager conducting a remote audit of a pharmacy shall notify the pharmacy no later than 15 days before the start date of a remote audit, which notice shall be mailed or delivered by registered mail or other trackable method of delivery and include the list of specific prescription numbers to be included in the audit 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 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, include in the notice of audit to the pharmacy the reason for the audit and a list of documents, records and claims, including specific prescription numbers and the number and date of any refills, that are to be audited;

(2) except for audits initiated to address an identified problem, or where fraudulent activity or other intentional or willful misrepresentation is reasonably suspected, conduct no more than one audit every six months;

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

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

(ii) a direct telephone number and email address that a pharmacy can use to contact an individual or entity charged with answering questions related to the audit. The telephone number shall allow for the delivery of a voice message if there are insufficient staff to immediately answer and respond to inquiries from pharmacies. Any such inquiry shall be acknowledged 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;

(4) 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;

(5) conduct any audit that involves clinical or professional judgment in consultation with a pharmacist;

(6) audit each pharmacy using the same standards and parameters as the pharmacy benefit manager uses to audit a similarly situated affiliated pharmacy;

(7) permit its auditors to enter the area behind the pharmacy prescription counter only when accompanied or authorized by a member of the pharmacy's staff; and

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

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

(1) conduct such audit 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 process;

(3) use fax to send a pharmacy notice of an audit unless requested by the pharmacy; or

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

Section 459.3 Audit reports and appeals.

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

(2) When providing a pharmacy with the preliminary audit 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 findings.

(3) When providing a pharmacy with the final audit 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.

(4) If a pharmacy's reasonable request for an extension of time to address a discrepancy or audit 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 recoupment and fees.

(a) A pharmacy benefit manager conducting either an in-person or remote audit 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 a pattern of such errors exists, fraudulent activity in the billing is alleged or the error resulted in overpayment and such recoupment is limited to the amount of the overpayment;

(4) claim 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 covered individual or health plan;

(5) collect any recoupments, chargebacks, or penalties until the audit and all appeals thereof are final, unless the individual or entity conducting the audit has a reasonable basis to believe the pharmacy is engaging or has engaged in_fraudulent activity or other intentional or willful misrepresentation;

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

(7) use extrapolation in calculating recoupments, chargebacks, or penalties for audits, 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 paragraphs (1) and (2) of this subdivision, a pharmacy benefit manager may withhold future payments before the date the final audit report has been delivered to the pharmacy if the identified discrepancy for all disputed claims in a preliminary audit 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 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 except to the department or any other government agency, the pharmacy subject to the audit, or the health plan.