Assessment of Public Comments for the Adoption of the Consolidated Third Amendment to Part 450 (Insurance Regulation 219), First Amendment to Part 452 (Insurance Regulation 222), and First Amendment to Part 454 (Insurance Regulation 224) of, and Addition of New Part 456 (Insurance Regulation 226), New Part 457 (Insurance Regulation 227), New Part 458 (Insurance Regulation 228), and New Part 459 (Insurance Regulation 229) to 11 NYCRR

Summary

The Department received three hundred sixty-nine comments during this comment period. The vast majority of those comments, three hundred and eighteen, were from independent pharmacy members or supporters of the Pharmacy Society of the State of New York that were supportive of the proposal and, in a number of instances, requested the Department adopt additional protections for independent pharmacies. Most of the additional protections so requested were previously considered and either removed from a prior draft of the consolidated regulation or not included for various reasons. The other fifty-one comments were submitted by commenters who represented unions or union health benefit funds; health plans or health plan organizations; pharmacy organizations; local chambers of commerce and business representatives, educational organizations, healthcare and community advocates; PBM organizations; and local government representatives. Including the proposed consolidated rulemaking that was published in the State Register on August 16, 2023, and withdrawn on November 15, 2023 (the "Prior Proposal"), and the comments the Department received during the 10-day pre-proposal of this regulation, this represents the third set of comments received on the subjects covered by this consolidated rulemaking.

The Department carefully considered the comments submitted on the Prior Proposal and incorporated substantial changes to the consolidated rulemaking to address those comments and comments received as part of the pre-proposal outreach process. The Department also collected comments over an eighteen-month period between the enactment of the legislation and before publishing the Prior Proposal on various subjects covered by this rule.

The consolidated rulemaking is a product of this extensive outreach and reflects the Department's consideration of the substantial feedback received by the Department since the authorizing statute, Insurance Law Article 29, was enacted approximately three years ago. Over that time, the consolidated rulemaking has been revised substantially to address, as appropriate, the comments received on the text of the regulations while the Department sought to satisfy the mandate imposed by the Legislature to draft regulations addressing a broad range of issues that are a matter of general public concern. The Department notes its appreciation for the groups and individuals who have submitted comments throughout this process as the Department has worked to fulfill the legislative mandate of Insurance Law 2906 to promulgate these regulations.

Discussion of Comments

Comment: The majority of the comments opposed to the consolidated rulemaking argued that the regulations as applied to PBM services provided to ERISA self-funded plans are preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"). The commenters advancing this position cite to a recent case in another federal circuit which found that another state's laws regulating PBM behavior were preempted by ERISA. Taking an expansive view of the holding in that case, these commenters assert that, the rulemaking represents an improper attempt to regulate ERISA plans under the analysis in that decision. In addition to ERISA

preemption, some commenters also suggested that the consolidated rulemaking would be preempted by the Medicare Act.

Response: The argument that New York's authority to regulate the PBM practices addressed in the consolidated rulemaking is preempted by ERISA was raised at the time that the authorizing statute was enacted and rejected by the Legislature. Specifically, section 4 of Chapter 828 of the Laws of 2021, as amended by Chapter 128 of the Laws of 2022, and the text of the sponsor's memo in the Assembly, make clear that the Legislature's intent was to cover services provided to ERISA plans. For this reason, the Legislature rejected the narrower definition of "health plan" proposed by the Executive, expressing its intent that Insurance Law Article 29 should apply as broadly as possible to include PBMs who provided services to ERISA self-funded plans. Accordingly, the Legislature's clear position was that PBM services provided to ERISA self-funded plans would be subject to regulation unless a court were to invalidate the legislation. The Department will not second guess the will of the Legislature and exempt PBMs under contract with ERISA self-funded plans from the rules.

The decision cited by the public comments in support of the argument that the consolidated rulemaking is preempted, an opinion from another circuit, does not require a different result. Indeed, that decision reversed a well-reasoned district court decision which upheld the state laws regulating PBM services provided to ERISA self-funded plans as not preempted by ERISA. In overturning that well-reasoned decision, the appellate court declined to address the US Department of Justice argument that the laws at issue were saved from preemption by the ERISA Savings Clause and ignored relevant Supreme Court precedent.

This appellate decision is now the subject of an application for a Writ of Certiorari to the United States Supreme Court. A majority of state Attorneys General, including New York's, have joined an amicus brief urging the Supreme Court to grant the writ and overturn the decision cited in the comments. Given that the appellate decision cited by the commenters runs contrary to a recent Supreme Court decision noting that state authority over PBMs does not trigger ERISA preemption, the issue of ERISA preemption where, as here, a state seeks to regulate the conduct of a third-party contractor of an ERISA self-funded plan is not sufficiently settled to conclude that the consolidated rulemaking is preempted.

Additionally, the Department notes that in both this consolidated rulemaking and the Prior Proposal, the Department sought to limit indirect impacts on all health plans. Language protecting plan design choices and plan decisions were included in the Prior Proposal, and this consolidated rulemaking includes even further clarifications based on the comments the Department received. Nothing in the consolidated rulemaking requires a health plan to take or forego any action. Instead, the requirements and restrictions apply to PBMs and PBMs alone, regardless of the types of health plans to which a PBM provides services.

As case law is clearer on the scope of Medicare preemption, the Department included a detailed exemption for PBMs providing certain services to Medicare plans. In addition, one commenter suggested the Medicare exemptions should be expanded to other types of Medicare plans. The Department understands this to be a misunderstanding of the language and intent of the rule. Medicare comprises multiple parts, i.e., Part A, Part B, Part C, and Part D. Only Part D applies to prescription drugs. It would not be appropriate to apply any exemptions to the other Medicare Parts. The Medicare exemption in the rules exempts all PBM activities related to any health plan subject to the Medicare Act, which offers drug coverage, no matter nomenclature associated with the plan. The Department has made a clarifying addition to the exemption to make clear that PBMs performing services for any health plan which is subject to Medicare rules are exempt consistent with the language of the exemption.

Comment: Some commenters suggested that the Department redefine the term "health plan" contained in Public Health Law Section 280-a by this regulation. Some commenters also proposed changes to the previously adopted definition of the phrase "a substantial number of beneficiaries who work or reside in this state."

Response: The definition of health plan is contained in the statute. The Department cannot change it by regulation.

The definition of the phrase "a substantial number of beneficiaries who work or reside in this state" was defined in a previous rulemaking required by the text of Public Health Law Section 280-a. That language has been in effect for two years and was not at issue in this consolidated rulemaking.

Comment: Some commenters representing union health plan sponsors sought changes to exempt plans subject to collective bargaining from the application of the rules. In support of this argument, commenters suggested that certain recent additions to the Insurance Law, which exempt collectively bargained plans from certain drug coverage requirements, shows that the Legislature intended to exempt collectively bargained plans from this rulemaking.

Response: The drug coverage requirements cited by the commenters show that the Legislature, when it intends to exempt a group of plans from the application of a law, knows how to clearly draft language making that exemption clear. Here, there is no language like that in the other statute referenced by the commenters to evidence that the Legislature intended a similar exemption here.

The Department understands that collectively bargained plans likely represent a substantial portion of the plans to which ERISA preemption argument addressed above would apply. As discussed above, in passing Chapter 828 of the Laws of 2021 as amended by Chapter 128 of the Laws of 2022, the Legislature chose not to exclude PBMs performing PBM services for health plans subject to ERISA from the application of the law and thus from the application of the regulation required by the statutes it enacted. Absent some clear indication from the Legislature that it expressly intended to cover services provided to plans subject to ERISA but then exempt a substantial portion of those plans, the Department is unwilling to exempt PBM services provided to collectively bargained plans from the application of the consolidated rulemaking.

Although some commenters assert that the regulations either restrict or burden health plans, the Department notes that the consolidated rulemaking does not require a health plan to take or refrain from taking any action. Further, based on the feedback received throughout the Prior Proposal comment periods and other outreach the Department made further clarifications to the text of the rule in proposing this consolidated rulemaking to make clear that health plan design and plan choices are preserved.

Comment: Some commenters oppose the disclosures required by new Section 452.5 which require a PBM to provide, upon request of a health plan, information related to the asserted costs for compliance with New York's PBM regulations. These commenters assert that this disclosure requirement is really a gag clause that would discourage a frank discussion of costs. Other commenters heralded the new disclosure as an important step to increasing transparency into opaque PBM pricing practices.

Response: During the preproposal comment period, the Department received several comments from health plans asking that the Department take concrete steps to prohibit PBMs from passing on the costs of complying with the regulations to plans. While the Department saw no realistic mechanism to prohibit plans from

passing on compliance costs, the comments underscored health plans' concern that the regulations could potentially be used by PBMs as a justification to increase costs exponentially. To foster an honest and open conversation between plans and PBMs about the costs of complying with these regulations, and to address the concerns raised by health plans, the Department added Section 452.5 to the proposal.

Describing Section 452.5 as a "gag clause" is inaccurate. A gag clause, like the ones PBMs imposed upon independent pharmacies which prevented pharmacists from providing truthful information to their patients about costs and therapeutic alternatives that were available, is a provision that prohibits a party from discussing a particular topic. In contrast, Section 452.5 requires the PBM, as an agent of the health plan, to provide truthful information related to the plan about the costs of compliance with the PBM regulations. It does not bar any speech nor prevent a PBM from having frank conversations about the costs of compliance. This section only provides that, if a PBM asserts that it is increasing its costs due to the costs of complying with the PBM regulation and the health plan requests the data behind such assertions, the PBM must provide a truthful response supported by data.

Moreover, pursuant to 11 NYCRR 452.2 health plans are already able to require a PBM to provide a full accounting of PBM services costs. This new targeted disclosure allows plans to address a narrower question, specific cost increases associated with compliance with the consolidated rulemaking, in a more tailored manner.

Comment: Some commenters suggested that a requirement to compensate independent and affiliated pharmacies at the same rate in Section 456.2(a)(1) is anti-competitive and will prohibit plans from developing "value-driven pharmacy networks."

Response: Three PBMs control 83% of the New York market for PBM services and each of those companies is affiliated with a major pharmacy group. Accordingly, a substantial part of the PBM market has financial incentives to steer health plans to use their affiliated pharmacies when they help health plans create pharmacy networks. These relationships create a clear conflict of interest that incentivize PBMs to favor their own affiliated pharmacies to the detriment of local, independently-owned pharmacies. To protect independent pharmacies from these inherent conflicts of interest, the Legislature expressly directed the Department to promulgate regulations establishing "standards and practices used in the creation of pharmacy networks and contracting with network pharmacies and other providers, including promotion and use of independent and community pharmacies and patient access and minimizing excessive concentration and vertical integration of markets." Insurance Law § 2906(b)(6).

Pursuant to this legislative mandate, 11 NYCRR 456.2(a)(1) provides that a PBM may not "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." There is nothing about this provision that is anti-competitive or prevents a PBM from formulating a value-driven pharmacy network for a health plan. This regulation creates a level playing field for all pharmacies and seeks to correct the market imbalance which currently favors PBM-affiliated pharmacies. In fact, if the commenters' argument is that affiliated pharmacies are cheaper to use, and thus drive value, the rule would allow a PBM to reimburse affiliated pharmacies lower than other pharmacies within a particular network.

Comment: Some commenters suggested that the three-day requirement to provide an acknowledgment of a complaint was too short and would prevent the due diligence and care sometimes required to respond to complaints. Other commenters suggested lowering the requirement to a single day to provide an acknowledgement.

Response: Commenters suggesting the time to respond is too short likely misunderstand the requirement in the consolidated rulemaking. Pursuant to 11 NYCRR 456.2(b)(4), a PBM is only required to acknowledge that the inquiry has been received within three-days, not to conduct an investigation and respond to the issues raised therein. Given that an acknowledgement is all that is required the arguments regarding needing more time to investigate are without merit.

Comment: Some commenters suggested that an authorized representative for a consumer, using a specified form, should be accepted by a PBM as presumptive evidence of the representative's authority to act on behalf of a consumer.

Response: The rules do not specify who can speak to a PBM on behalf of a consumer and nothing in the rules would change existing laws or change the extent to which a representative can be utilized to interact with a health plan or PBM.

Comment: Commenters suggested that the Department should eliminate any restrictions on PBM's ability to change certifications standards.

Response: The Department received a significant number of pharmacy complaints regarding the frequency with which PBMs changed pharmacy accreditation standards with little or no advance warning. As drafted, the consolidated rulemaking allows PBMs to change accreditation standards to keep pace with a changing environment while limiting the burden on independent small business pharmacies, which have reported spending significant time and money to meet the standards only to be told they changed without notice after they began the process. Although the primary industry trade group for PBMs suggested that the Department remove this provision, the language in the consolidated rulemaking is based on the suggestion made by that trade group to eliminate the language in the Prior Proposal that would only allow PBMs to change accreditation standards for each pharmacy once every twelve months, which the trade group asserted would be difficult to track, to the current language in the consolidated rulemaking that allows PBMs to change the accreditation standards once every twelve months for all pharmacies. The organization that accredits PBMs praised the consolidated rulemaking for fairly preserving uniform accreditation requirements.

Comment: Some commenters suggested that the provisions contained in the consolidated rulemaking related to communications sent by PBMs to consumers about incentives related to affiliated or mail order pharmacies are in conflict with other provisions which allow a health plan to elect a narrow network. These commenters further suggest that the provision lacks a rational basis as it prevents a PBM from communicating with plan participants but allows a plan to communicate the same information.

Response: The consolidated rulemaking does not interfere with or override a health plan's ability to communicate with consumers or to direct a PBM to communicate with consumers if the plan chooses. The consolidated rulemaking merely states that a PBM may not take advantage of its position as a service provider to a health plan to promote the interests of an affiliated pharmacy. There is a clear rational basis to prohibit PBM's from unilaterally promoting its own interests.

Comment: Some commenters felt that the process surrounding complaints filed with DFS related to PBM actions was unclear in the unconsolidated rulemaking and should be spelled out in further detail.

Response: The consolidated rulemaking made significant changes to the provisions relating to the complaint process outlined in the Prior Proposal. These changes were made to address comments from the PBM industry that the process laid out in the Prior Proposal was rigid, burdensome, and would not be practical. The consolidated rulemaking establishes a clear, straightforward process in which the Department will receive and review complaints relating to PBM conduct and forward any complaint the Department believes merits review to the relevant PBM for its response. Once a complaint is forwarded, the PBM has 15 business days to respond to the Department. The PBM may request additional time if necessary to respond to the complaint. The consolidated rulemaking further provides that PBMs must file their response to a complaint with the Department electronically and that the Department will share the PBM's response with the complainant.

Comment: Some commenters representing PBMs and health plans suggested that the Department lacks the authority to enact various provisions of the consolidated rulemaking. Such provisions include the restriction on advertising only affiliated pharmacies on a PBM-produced identification card; the prohibition on PBMs restricting pharmacies from discussion of lower cost alternatives; the rules relating to audits; collection of unredacted contracts; and requirement on PBM's to ensure that subcontractors comply with DFS document demands.

Response: The Department is expressly required by Insurance Law Section 2906 to implement regulations addressing a broad range of issues. The specific instances that commenters raised as beyond the scope of authority granted to the Department pursuant to Insurance Law Article 29 are addressed below.

The requirement that a PBM include unaffiliated pharmacies on an identification card if the PBM includes an affiliated pharmacy protects consumers from PBMs limiting consumer choice; specifically, this requirement prohibits PBMs from using their position to suggest that only affiliated pharmacies are available within a particular network. The requirement is consistent with the statutory mandate that the rules promote the "use of independent and community pharmacies" and address deceptive and anti-competitive practices. This requirement only applies if non-affiliate pharmacies are in the network. When this rule applies, a PBM may satisfy the requirements by including at least two unaffiliated pharmacies on the identification card. Based on some commenter confusion about the extent of the requirement to include unaffiliated pharmacies on the cards, if any exist within a network, the Department made clarifying changes to 458.2(c)(2) to ensure the provision was clear in its requirements.

Regarding the prohibition on PBMs restricting pharmacies from communicating with consumers about lower cost alternatives, the Department notes that such conduct is and has been illegal under Public Health Law 280-a since 2018. The fact that industry commenters have suggested that the rule should not be included because it would impact existing quality control standards indicates that the industry is not aware of or choosing not to comply with this existing consumer protection. This provision in the consolidated rulemaking is consistent with the mandate in Article 29 to ensure consumers are protected and to regulate the standards and practices used in contracting with pharmacies.

As to rules relating to audits, under Insurance Law Section 2906, the Department is required to promulgate regulations related to "deceptive practices," "anti-competitive practices," and "unfair claims practices in connection with the performance of pharmacy benefit management services." While there is no question that audits play a critical role limiting prescription fraud, audits must be conducted fairly and equitably to protect the legitimate interests of independent pharmacies. PBMs are sometimes auditing their affiliated pharmacies' competitors, representing a clear conflict of interest. In fact, the Department regularly receives complaints

alleging that PBMs use unduly harsh audit standards when auditing independent pharmacies to demand unwarranted reimbursements.

While there are statutory audit rules in Public Health Law 280-c, they apply to a subset of audits and are limited in scope. When the Legislature subsequently passed Insurance Law Article 29, the Legislature mandated that the Department promulgate rules to protect independent pharmacies and, in particular, granted the Department the authority to enforce violations of the Public Health Law as violation of the Insurance Law under Section 2911. The consolidated rulemaking does just that by expanding and building on the requirements in the Public Health Law. The consolidated rulemaking is consistent with and does not conflict with Public Health Law Section 280-c. Moreover, pursuant to the requirement in Insurance Law Section 2906, the Department consulted with the Department of Health to, among other things, ensure that the requirements of the consolidated rulemaking are consistent with the existing audit requirements.

Regarding the Department's authority to obtain unredacted contracts from PBMs, Insurance Law Section 2904 is clear that the Department has the authority to collect such information. Specifically, that section provides that "the terms and conditions of any contract or arrangement, including other financial or other reimbursements, incentives, inducements or refunds between [a PBM] and any other party relating to a health plan" each year. The Department notes that the contracts produced to the Department pursuant to this requirement are expressly protected from disclosure by Section 2904(c).

As to the requirement that PBM subcontractors, affiliates, subsidiaries, or other individuals or entities performing pharmacy benefit management services for the PBM ("Third-Party Service Providers" comply with DFS document demands, Insurance Law Section 2911(c) requires PBMs to ensure that service providers comply with New York law in performing their pharmacy benefit management services for a PBM. The statute specifically states that a PBM may not permit a Third-Party Service Provider to take any action which would violate any provisions if taken by the PBM and that a PBM is liable if the Third-Party Service Provider violates those provisions. The requirement to include language in PBM contracts with its Third-Party Service Providers to provide documents to DFS is to ensure that the Department can investigate PBM compliance with this statutory requirement. It further prevents a PBM from attempting to hide any violation of Insurance Law Article 29 or its supporting regulations by claiming that documents relating to PBM services are held by a Third-Party Service Provider and cannot be made available to the Department.

Moreover, the Department notes, common service contract provisions require a service provider to make all documents relating to services it provides to a principal. Here, given that PBMs are liable for the conduct of their service providers, the Department anticipates that PBMs already include similar access language in their service contracts.

Comment: In addition to the provisions listed above, commenters in particular took issue with the Department's authority to regulate changes in control of PBMs. These commenters stated that there are no competitive issues connected to the PBM market and expressly cited two pre-2020 FTC reports on the PBM market.

Response: Insurance Law Section 2906 requires the Department to promulgate rules "minimizing excessive concentration and vertical integration of markets." The statute therefore specifically requires the Department to promulgate rules on this subject. And despite the suggestion that the Federal Trade Commission ("FTC") already addressed this issue, the FTC recently stated that its prior findings and guidance on the PBM

industry should be ignored. In fact, a recent FTC report found excessive concentration within the PBM industry, stating that "PBMs are part of complex vertically integrated health care conglomerates, and the PBM industry is highly concentrated." Therefore, the rule is both required by statute and justified by the continuing concentration of the PBM market in New York and across the country.

Comment: Certain commenters connected to the PBM industry suggest that there is insufficient clarity over what constitutes a prohibited act or practice under the rules.

Response: The language used in the consolidated rulemaking is consistent with well-known standards that are already applicable to the industry under federal law. The rule does not need to opine on every possible circumstance that could constitute a prohibited act or practice, and it would not be possible or practical to do so. The Department, as it does in other regulated industries, will issue guidance when appropriate and as necessary.

Comment: Some commenters raised legal arguments related to provisions of the consolidated rulemaking representing restrictions on commercial speech and allege that such restrictions violate the Constitution.

Response: This is a legal argument that the Department is not required to respond to in this forum. The Department notes, however, that it has reviewed the provisions alleged to restrict commercial speech and has determined that such provisions remain necessary and appropriate.

Comment: Commenters suggested that the restrictions on PBMs communicating only about affiliated network pharmacies when unaffiliated pharmacies are also in network should not apply to mail order and specialty drug programs.

Response: The Department has determined there is no reason to distinguish here between different types of pharmacy networks. In fact, many of the false or misleading communications reported to the Department relate to mail order programs, including falsely suggesting that consumers must use mail order programs when they are not required by the plan to do so. Further, the proposal specifically authorizes communication about affiliates as long as the PBM provides "accurate information regarding unaffiliated pharmacies participating in the network, if any, in such communications." Nothing in the rule prevents a PBM from providing truthful information about the existence of specialty or mail order networks within the plan design, even if those networks contain only affiliates.

Comment: One commenter suggested that the restrictions on PBMs sharing consumer information with affiliated pharmacies be amended to allow for disclosure for commercial purposes or where required by health plan design.

Response: Pursuant to the mandate to protect independent pharmacies, this provision in the consolidated rulemaking prevents PBMs from sharing consumer data with an affiliated pharmacy unless such information sharing is necessary for certain select purposes. This restriction prevents PBMs from providing a competitive advantage to an affiliated pharmacy. The proposal to add a commercial reason for disclosure to the list of exemptions would, in essence, gut this provision and eliminate the protection it is intended to afford to independent pharmacies.

Comment: One commenter suggested that the provision in section 458.2(c)(5) that states a PBM may not penalize a consumer, when the consumer chooses to use an unaffiliated pharmacy, by requiring, for example, that

the consumer pay the full cost for a drug, should be amended to only apply to retail pharmacies. Otherwise, the commenter posits, the restrictions in the consolidated rulemaking could apply to specialty and mail order pharmacies.

Response: The consolidated rulemaking is clear that this provision only applies to a consumer using an unaffiliated pharmacy that is in the same network. If a specialty or mail order pharmacy network contains both affiliated and unaffiliated pharmacies, the PBM cannot penalize a consumer for choosing one over the other. This does not mean that a health plan must include unaffiliated pharmacies in all or any of their networks. In short, the rule does not apply to specialty and mail order networks unless there are unaffiliated pharmacies within those specialty or mail order networks. Some commenter confusion over the application of the provision to plans with multiple networks led the Department to make clarification that a plan serviced by a PBM may have more than one network, and to clarify that a consumer may not select between pharmacies in separate networks under this provision.

Comment: Several commenters suggested that the audit provisions should be limited to on-site audits of pharmacies and requested clarification on the inclusion of investigations with audits.

Response: Throughout the outreach prior to proposing this rule, the Department received several complaints and comments indicating that PBMs are changing the nomenclature of an audit by calling it an "investigation," allegedly to avoid state law rules related to audits. The consolidated rulemaking makes clear that no matter the nomenclature, activities that serve the function of an audit shall be treated as an audit.

As with some of the other issues discussed above, audits present clear conflicts of interest by which PBMs with affiliated pharmacies are empowered to audit the competition of their affiliated entities. The provisions in the consolidated rulemaking are aimed at mitigating any potential abuses. Since the COVID19 pandemic, there has been a shift away from in-person on-site audits in favor of a remote audit process. Accordingly, the requested change would substantially limit the impact of this provision and undermine the goal of limiting any abuse of the audit process.

Comment: Commenters argue that PBMs should be permitted to use variable cost-sharing terms to encourage consumers to obtain covered drugs from pharmacies that provide high quality services at a lower cost.

Response: The NY Legislature has already spoken on this issue with the existing mail/retail parity law as it applies to the state-regulated fully-insured market (i.e., insurance policies), so such a regulatory requirement is unnecessary and contrary to existing law. Nothing in the proposed rule would limit such a plan design.

Comment: A commenter noted that state law already prohibits higher copays for retail pharmacies versus mail order and specialty pharmacies, if the pharmacy at issue agrees to the relevant reimbursement rate.

Response: The referenced rule is consistent with and not conflicting with or amending the statutory requirement. The definition of health plan for Article 29 purposes is broader than the statutory provision referenced by the commenter. The rule, therefore, provides uniformity.

Comment: Some commenters suggested that the listing of formularies and pharmacy networks required by the rulemaking should be eliminated because people tend to go to their plans for information and not to the

PBM that provides services to their plan. The commenter suggested that if it were still required, then the PBM should require consumers to have a login.

Response: There is no restriction on requiring a login to access a formulary or pharmacy network provided that it does not exclude prospective consumers. The goal of these provisions is to enable consumers to have a clear line of sight into the formulary they are subject to and shop around to determine the formulary that is best for them. As the manager of the pharmacy benefit who handles both the network and the formulary, it is rational to require the PBM to post this information as it is readily available for them.

Comment: Some commenters suggested that the requirement that PBMs provide a pharmacy contract to the pharmacy that signed the contract should not apply if a pharmacy services administrative organization was involved in negotiating on behalf of the pharmacy.

Response: This rule would require a PBM to provide a pharmacy with access to the contract that governs the relationship between a PBM and pharmacy. This is an issue of fundamental fairness and there is no basis for one party to a contract to refuse to provide a counterparty with access to the contract between the parties. Regardless of whether a pharmacy services administrative organization was involved or whether it provided a copy of a contract to the pharmacy, pharmacies need to have access to a complete copy of any contract that governs its relationship with a PBM.

Comment: Commenters, without proposing an alternative, suggested that the effective date for the consolidated rulemaking should be extended. A significant number of other commenters suggest that the effective date should be accelerated and come into effect immediately.

Response: The Department already extended the effective date for the consolidated rulemaking, moving the effective date set in the Prior Proposal from January 1, 2024, and a requirement that all contracts comply with the new requirements by January 1, 2025, to the current effective date of July 1, 2025, and a requirement that all contracts comply with the requirements of the consolidated rulemaking by January 1, 2027. The effective date in the consolidated rulemaking accounted for the suggestions of commenters on the Prior Proposal that more time would be necessary. The Department recognizes the need to have some roll-out of the provisions in this newly regulated space, which is accounted for in the current effective dates. At this time the Department sees no compelling reason to modify (extend or reduce) the timeframe again.

Comment: Commenters suggested that the requirements of 456.2(b) to notify pharmacies of the reasons for their termination from a network create an "any willing provider" standard because the work required to document the reason for termination and allowing the pharmacy to reapply within a year is so burdensome that it will wear down PBMs and lead them to acquiesce and allow pharmacies back in a network.

Response: The consolidated rulemaking does not establish an "any willing provider" standard. As adopted, the consolidated rulemaking requires that a PBM provide a truthful reason for the rejection of a pharmacy from a pharmacy network and allow a pharmacy to reapply after the pharmacy has addressed the issue for termination. This is consistent with the requirement that a PBM has a duty of good faith and fair dealing with all pharmacies with whom it interacts. The consolidated rulemaking places no restrictions on what reason a PBM may cite for terminating a pharmacy; it simply requires the reason to be truthful, and to allow a pharmacy to reapply. The rule does not require a PBM to admit the pharmacy into a network upon reapplication. The rule is meant to provide

pharmacies with an understanding of the reason they are rejected from a network, which has been a major complaint from pharmacies, and enable pharmacies to take corrective action if necessary.

Comment: Commenters felt that the restrictions on immediate termination of a network pharmacy for fraud, waste, and abuse should not be included. Some of these commenters allege that the rule is inconsistent with state and federal practices regarding fraud, waste, and abuse. Other commenters felt that stricter rules regarding immediate termination should be imposed.

Response: The rule does not prevent PBMs for terminating pharmacies for fraud, waste, and abuse. PBMs may terminate a pharmacy immediately if there is a clear, neutral finding that the pharmacy engaged in fraud. Otherwise, a pharmacy may be terminated for waste and abuse identified by the PBM on 60 days' notice to the pharmacy. If a PBM terminates a pharmacy for fraud, waste, and abuse, the PBM can still obtain reimbursement from the pharmacy for any overpayment that occurred during the 60-day window for fraud, waste, or abuse. This requirement in the rulemaking addresses the significant volume of feedback the Department received asserting that PBMs use their existing ability to unilaterally determine what constitutes fraud, waste, and abuse to terminate pharmacies for trivial or pretextual reasons.

The alleged inconsistency with state and federal rules referenced by commenters relates to certain rules that apply to pharmacies participating in governmental programs. Here, the consolidated rulemaking addresses the power that a PBM has to terminate an independent pharmacy from a pharmacy network when that decision may be colored by a conflict of interest to promote the interests of the PBM's affiliated pharmacy. The rule maintains the ability of a PBM to terminate pharmacies that have been shown to engage in fraud immediately and to terminate pharmacies on notice where the PBM believes the pharmacy has engaged in fraud. Moreover, the rules allow a PBM to immediately terminate a pharmacy that is terminated from a government program so that if a government agency determines a pharmacy is a bad actor, the PBM can act immediately.

Comment: Some commenters took issue with the limitation to recover audit findings prior to those findings becoming final if the amount is under $25,000. Those commenters suggest that the rule actually encourages fraud below that amount.

Response: The relevant provision in the consolidated rulemaking provides pharmacies with the opportunity to respond to and appeal adverse audit findings, if necessary, and prohibits a PBM from forcing a pharmacy to pay a recovery under $25,000 while the pharmacy is still entitled to appeal a PBM's audit findings. This is consistent with the requirement that a PBM has a duty of good faith and fair dealing with all pharmacies with whom it interacts. There is no limit on recovering any amount identified in an audit after the audit is final. The Department finds no validity to the assertion that this would encourage low level fraud or abuse as the pharmacy is required to pay those funds back as soon as the audit finding is finalized. This same threshold has been implemented in other states and has not resulted in any reported increase in low level abuse.

Comment: One commenter asked for clarification on the application of these rules to programs run by the Department of Health including, in particular, Medicaid.

Response: The rule was shared with the Department of Health and there were no reported costs or objections to the rules as proposed. However, as the New York Medicaid program has transitioned to using NYRx, the rules would not apply to these programs because NYRx does not meet the definition of a PBM.

Comment: One commenter suggested that the limitation on unilateral changes to a pharmacy contract by PBMs should be limited to material changes. The commenter further suggested that allowing unilateral changes may be necessary to address new law in this area.

Response: The Department rejected this suggestion, because unilateral changes to a contract should not be permitted. Further, any changes to applicable law that impact existing contacts would preempt the contractual language anyway; as such, no specific carve out for this circumstance is required.

Comment: One plan sponsor commenter suggested that the consolidated rulemaking restricted the health plan's ability to use a network that does not comply with standards outlined in the regulation.

Response: The referenced network standards were contained in the Prior Proposal but were removed from this consolidated rulemaking. There are no restrictions on plans use of networks in this rulemaking.

Comment: Commenters continue to suggest that the term "cash price" is incorrect as used in the regulation referring to the price the pharmacy would charge to a consumer not utilizing insurance.

Response: Cash price is an understood and commonly used term in the industry that has been used by a number of other states to describe the relevant price in the same context. Further Public Health Law Section 280-a uses the term "cash price" in this context.

Comment: One commenter suggested that the requirement that a PBM must consider prescriber notations such as "as directed" or "as needed," requiring the pharmacists' professional judgment to determine whether the dose dispensed is within normal guidelines, was nonstandard and inappropriate. The terms "as directed" or "as needed" the commenter stated, are not included on prescription instructions to dictate dose, but refer to a patient's usage of a prescription.

Response: While the referenced phrases do not go to the dose of the drug, they do relate to the dosing of the drug and are relevant, for example, in determining a 30-day supply of a drug. Other states use nearly identical requirement without any reported issues.

Comment: A large number of commenters requested various changes that would revert the language in the consolidated rulemaking back to the Prior Proposal. In particular, commenters suggested a return of the NADAC floor and mandatory dispensing fee provisions which were removed from this proposal.

Response: While the Department will continue to examine ways to ensure transparency and fairness within the provision of PBM services in New York, at this time and based on the comments received on the Prior Proposal, the Department removed a number of provisions from the Prior Proposal in this consolidated rulemaking. While some of the provisions contained in the Prior Proposal are still under consideration, the Department has determined to obtain more information to more fully assess the most appropriate way to address some of the issues covered in the Prior Proposal.

Comment: Commenters representing the pharmacy industry sought additional protections related to PBM enforced performance measures and brand and generic effective rates. These commenters suggested these measures are not transparent and are used by PBM in abusive ways.

Response: The Department will continue to look at areas where there are allegations of abusive conduct by PBMs in New York and take appropriate action. Depending on the nature of the conduct, it may represent an unfair business practice that will be addressed by the consolidated rulemaking. To the extent these practices fall outside of the ambit of this regulation, the Department remains committed to collecting information on these practices and these issues may be the subject of future rulemaking as necessary.

Comment: Commenters representing the independent pharmacy industry requested limitations on fees charged by PBMs to pharmacies be added to the regulation.

Response: The consolidated rulemaking does not address this issue. The Department will continue to review and may take future regulatory action on this issue as necessary.

Comment: A number of commenters representing plan sponsors suggested that the rules would prevent health plans from using mail order or specialty networks or from compensating pharmacies at different rates. Additional heath plan sponsors make references to the limitation on mid-year formulary changes and the impact that would have on the plan.

Response: The rules do not prevent health plans from using mail order or specialty networks. In fact, the plain language of the rule expressly preserves each plan's ability to elect limited networks. Except for 11 NYCRR 456.2(a)(1), which prohibits PBMs from compensating unaffiliated pharmacies at a lower rate than they compensate affiliated pharmacies for providing the same services, nothing in the rule would prevent a PBM from compensating pharmacies at different rates and in particular the ability to charge different rates amongst retail, mail order, and specialty networks is expressly preserved. Finally, there are no restrictions on mid-year formulary changes in the rule, with changes to formularies specifically protected from the prohibition on unilateral changes to contracts.

Conclusion

The Department has reviewed all the comments it has received and considered the points and suggestions on all sides of the issues raised therein. In the end the Department remains convinced that the balance struck in the proposal is the appropriate balance in ensuring fairness to industry while fulfilling the statutory mandate to produce regulations addressing these issues.