Regulatory Impact Statement for the Consolidated Proposed 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

1. Statutory authority: 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.

Financial Services Law section 102 creates the Department of Financial Services ("Department" or "DFS") and sets forth the legislative goals for the agency.

Financial Services Law section 201 authorizes the Superintendent of Financial Services ("Superintendent") to take any actions as necessary to eliminate financial fraud or other criminal abuse or unethical conduct in the industry, to protect users of financial products and services, and to encourage high standards of honesty, transparency, fair business practices and public responsibility in regulated industries.

Financial Services Law section 202 establishes the office of the Superintendent.

Financial Services Law section 301 authorizes the Superintendent to effectuate any power accorded to the Superintendent by the Financial Services Law, Insurance Law, or any other law, and to conduct investigations and track and monitor complaints.

Financial Services Law section 302 authorizes the Superintendent to effectuate any power accorded to the Superintendent by the Financial Services Law, Insurance Law, or any other law in which the superintendent is given authority, and to prescribe regulations interpreting these laws.

Financial Services Law section 304 establishes procedures for the Superintendent to provide notice to any person entitled to a hearing of any authorized action or proposed action under the Financial Services Law, Insurance Law, or any other law.

Financial Services Law sections 305 and 306 provide the authority to the Superintendent, or the person authorized by the Superintendent, to provide notice and administer hearings, and make findings, reports, and recommendations.

Insurance Law section 301 authorizes the Superintendent to prescribe regulations governing the practices of the Department.

Insurance Law section 316 authorizes the Superintendent to prescribe regulations that require a person or entity making a filing with the Superintendent to do so by electronic means.

Insurance Law section 2904 requires pharmacy benefit managers ("PBMs") operating in New York to submit annual reports to the Superintendent and authorizes the Superintendent to establish, by regulation, other statements that must be filed with the Superintendent and the form, content, and manner of submission of such annual reports and other statements.

Insurance Law section 2905 requires that a PBM be licensed to operate in New York and authorizes the Superintendent to impose penalties on a PBM for acting without a license.

Insurance Law section 2906 provides that the Superintendent may issue a PBM license to any person or entity that meets the requirements of Article 29, and authorizes the Superintendent to establish, by regulation, minimum standards for the issuance of a license to a PBM.

Insurance Law section 2911 imposes additional obligations on PBMs, including requiring PBMs to be responsible for the actions of any subcontractor, affiliate, subsidiary, or other individual or entity performing pharmacy benefit management services on behalf of the PBM and authorizes the Department to enforce any violation of the Public Health Law by a PBM as if it were a violation of the Insurance Law.

Public Health Law section 280-a authorizes the Superintendent to make regulations relating to the duties, obligations, and requirements imposed on PBMs.

Public Health Law section 280-c, in conjunction with Insurance Law section 2911, prohibits PBMs from violating any provision of the Public Health Law applicable to PBMs and imposes obligations on PBMs when conducting pharmacy audits.

2. Legislative objectives: In accordance with Insurance Law Article 29 and Public Health Law sections 280-a and 280-c, the legislative objectives addressed by this consolidated rulemaking are to establish, by regulation, standards for PBMs to be licensed and maintain such license, including minimum standards related to conflicts of interest, deceptive, anti-competitive, and unfair claims practices in connection with the performance of pharmacy benefit management services, contracting with pharmacies and consumer protection.

3. Needs and benefits: This proposed consolidated rulemaking is necessitated by the enactment of Insurance Law Article 29 and Public Health Law section 280-a. That legislation recognizes that the State has an interest in the prudent regulation of the industry, which impacts health insurance premium costs, patient access to drugs, and the pharmacy industry in this State, and tasks the Department with promulgating regulations establishing standards governing the conduct of pharmacy benefit management services. Specifically, this consolidated rulemaking is required by Insurance Law section 2906 to establish the minimum standard requirements for maintenance of a license by a PBM.

Specifically, Insurance Law sections 2905 and 2906 require every PBM operating in New York to be licensed by the Department and to follow minimum standards to maintain its license. Insurance Law sections 2906(a) and (b) require the Superintendent to establish these minimum standards by regulation and specify that such standards shall address, without limitation, conflicts of interest between PBMs and health plans or insurers, deceptive, anti-competitive, and unfair claims practices in connection with the performance of pharmacy benefit management services, pricing models used by PBMs both for their services and for the payment of services to the PBM, 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, and the protection of consumers. Public Health Law section 280-a(2)(a) further requires a PBM to have a duty of good faith and fair dealing with all parties, including but not limited to covered individuals and pharmacies with whom it interacts in the performance of pharmacy benefit management services.

New Section 450.7 establishes the applicability of the rules relating to PBM conduct. New Section 452.5 establishes a disclosure that PBMs are required to make to the health plans to which they provide services when such PBM attributes increased costs of those services based on compliance with DFS regulations. This section was added in response to comments, received as part of pre-proposal outreach conducted by the Department prior to this proposal, from PBMs and PBM affiliates claiming DFS regulations would increase costs, and other comments from health plans seeking DFS action to increase disclosures and limit costs.

This proposed consolidated rulemaking replaces a prior proposed consolidated rulemaking that was published in the State Register on August 16, 2023 and withdrawn on November 15, 2023 (the "Prior Proposal"). The Department received a significant number of public comments on the Prior Proposal. While there was significant support for the Prior Proposal, other comments raised concerns about the potential impact the Prior Proposal would have on health plans. A significant number of these comments evidenced confusion about the intent of certain provisions of the Prior Proposal or stated that the Prior Proposal would have unintended impacts on the health plans that PBMs service. Moreover, a number of the comments on the Prior Proposal raised potential issues that were not identified as part of the public feedback process undertaken by the Department before the Prior Proposal was published. The Department therefore withdrew the Prior Proposal. After reviewing the comments submitted on the Prior Proposal, the Department is proposing this revised consolidated rulemaking.

Part 456 establishes minimum standards governing contracting, credentialing, and terminating network pharmacies. Section 456.1 sets forth a compliance schedule that requires PBMs to bring their pharmacy contracts into compliance with Part 456 by January 1, 2025. Section 456.2 prohibits PBMs from reimbursing PBM-owned

pharmacies a greater amount than non-PBM-owned or affiliated pharmacies, retroactively denying or reducing reimbursements for claims absent fraud or other specified indicia of wrongdoing, prohibiting or limiting a pharmacy's ability to communicate with officials or a State agency about a PBM, even in a public forum. Additionally, section 456.2 ensures that PBMs allow a pharmacy to submit documents and information electronically, including the use of electronic signatures where consistent with law, and require a PBM to provide a copy of the pharmacy's contract to the pharmacy, provide various notices to pharmacies for clear and timely communication, provide a direct telephone number and email address for pharmacy inquiries, disclose the sources used to calculate the drug product reimbursement paid for covered prescription drugs in the pharmacy contract, provide a pharmacy with notice and a specific explanation for being denied participation in a pharmacy network or contract renewal, and allow pharmacies to reapply to be accepted into a network after one year provided the pharmacy provides documentation proving the reason for denial or non-renewal has been cured.

Section 456.3 requires that credentialing, certification, and accreditation requirements imposed by PBMs are clear, fair, and align with the legislative intent of Insurance Law section 2906(b) and Public Health Law section 280-a(2)(a). Section 456.4 sets forth the permissible reasons a PBM may immediately terminate a pharmacy from its network. Further, it requires a PBM to provide a pharmacy with notice and a specific explanation for such termination, and maintain their obligations to the terminated pharmacy for services properly rendered prior to the date of termination.

Insurance Law section 2904 authorizes the Superintendent to request copies of the terms and conditions of any contract or arrangement between a PBM and any other party related to pharmacy benefit management services provided to health plans. Insurance Law section 2911(c) requires that no PBM shall permit any subcontractor, affiliate, subsidiary, or other individual or entity performing pharmacy benefit management services for a PBM to take any action that would violate any provision of law if taken by the PBM and, should any subcontractor, affiliate, subsidiary, or other individual or entity of the PBM take such action, the PBM is

responsible for their actions whether or not the PBM was aware of, or sanctioned, the conduct. Section 456.5 clarifies these requirements and ensures that PBMs exclude confidentiality provisions related to disclosures to the Department from their contracts and transmit any requested copies of contracts to the Department within 15 business days of such request, unredacted and in full. This section further makes clear that a PBM shall be responsible for the actions of any affiliated party performing pharmacy benefit management services on behalf of the PBM.

Part 457 implements the legislative intent of Insurance Law section 2906(b), specifically as it relates to minimizing excessive market concentration and vertical integration of the market in New York. According to the U.S. Senate, three PBMs currently control nearly 80% of the prescription drug market. To minimize the impact of further concentration, Part 457 requires any person or entity wishing to acquire control of any licensed PBM to obtain the Superintendent's prior approval, and conditions such approval on the Superintendent's determination that the proposed acquisition is in the interests of the people of this State. In making such determination, Part 457 specifies that such determination consider the financial condition of the acquiring person or entity and the PBM, the trustworthiness of the acquiring person or entity or any of its officers or directors, a plan for the proper and effective conduct of the PBM's operations, the source of funds or assets for the acquisition, the fairness of any exchange of shares, assets, cash, or other consideration for the shares or assets to be received, whether the effect of the acquisition may contribute to excessive concentration and vertical integration of markets, and 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.

Part 458 implements the provisions of Insurance Law section 2906(b) and Public Health Law section 280-a(2)(a) relating to consumer protection and the duty of good faith and fair dealing imposed on PBMs in dealing with all parties, including covered individuals and pharmacies with whom it interacts in the performance of pharmacy benefit management services. Section 458.2 sets forth a set of prohibited acts and practices, including

false, deceptive, or misleading advertisements, promotions, proposals or offers. The section goes on to prohibit a PBM from engaging in any unfair or deceptive acts or practices. The section also provides for specific prohibitions against penalizing a consumer accessing drugs, among other prohibited conduct, meant to ensure patient access to the drugs and pharmacy services they need.

Section 458.3 requires PBMs to provide formulary and provider directories to consumers. Such information is vital in ensuring that patients are fully informed of the available options for using their prescription drug coverage, including any limits thereon. The requirements are consistent with the requirements on health plans to provide information about coverage and network providers required by State and federal law.

Section 458.4 requires PBMs to promptly comply with requests for information to enable the Department to resolve complaints submitted from consumers and pharmacies across the State in a timely fashion. It further requires PBMs submit responses electronically and bars retaliation against complainants, which has been a major concern raised to the Department.

Insurance Law section 2911 prohibits PBMs from violating any of the provisions of the Public Health Law that are applicable to PBMs. Public Health Law section 280-c regulates pharmacy audit practices conducted by PBMs. On February 23, 2023, the Department requested public comment concerning pharmacy audits performed by PBMs. Over 80% of the responses urged the Department to take regulatory action to address PBM audit practices. In response to the previously withdrawn rulemaking on this subject, a number of commenters suggested DFS lacks authority to address audit practices at all. On the other hand, a number of commenters also suggested that the rules should be strengthened further and that the Department should place more restrictions on PBM audit practices consistent with its authority in the Public Health and Insurance Laws. The Department reviewed all the comments and this proposed Part 459 creates audit rules that supplement, and do not conflict with, the statutory rules set forth in Public Health Law section 280-c. Further, the Department determined that

these provisions implement the legislative mandate in Insurance Law section 2904(b), in particular in relation to limiting deceptive, anti-competitive and unfair claims practices used in contracting with network pharmacies.

The proposed amendment to Part 454 prohibits PBMs from using misleading or deceptive trade names, while the proposed amendment to Part 450 amends the definition section of that Part to include additional definitions for certain terms used throughout Chapter XXI and adds an applicability section that clarifies how the Department will enforce the provisions of Chapter XXI as they relate to PBMs operating in this State. Section 450.7 ensures that the consolidated rulemaking does not conflict with federal standards, by exempting PBMs from certain provisions of the rulemaking as applied to a PBM's provision of pharmacy benefit management services to Medicare prescription drug plans.

4. Costs: This consolidated rulemaking may impose costs on PBMs operating in New York; however, the Department has determined that such costs will not substantially adversely affect PBMs, and are necessary to effectuate the Department's authority to regulate PBMs under Insurance Law Article 29 and Public Health Law section 280-a. To the extent possible, the Department sought to limit the cost impact of the rulemaking while complying with the mandate imposed by Legislature.

Additionally, PBMs may incur costs to comply with Parts 456, 457, 458, and 459, including costs related to revising PBM contracts and contractual terms with pharmacies, providing notices, information, and documents to pharmacies, creating formulary and network pharmacy directories, and audit procedures (should they not already exist), updating PBM websites, and providing records to the Department upon request. These costs, however, are ordinary costs of operating in a highly regulated space and are needed to address the statutory goals established by the Legislature. The Department sought to minimize these costs by aligning, to the extent possible, the provisions and other obligations located in this consolidated rulemaking with the existing requirements of dozens of other states with which PBMs already have to comply. Existing rulemaking already provides for electronic filing of all documents filed by a PBM with the Department. The proposed consolidated rulemaking

also allows for electronic communications when permitted by law. These provisions will alleviate some of the costs related to the use of paper, printing, envelopes, and postage fees. In order to further mitigate costs associated with PBMs providing records to the Department, section 456.5 only requires PBMs to provide certain records to the Department, and importantly only upon request, and does not restrict these records from being maintained and provided electronically.

The proposed amendment to Part 454, which requires PBMs to disclose any trade names in their license files, should not create any additional cost for PBMs outside of what is already required by Part 454.

The proposed amendment to Part 450 merely amends the definition section of that Part to include additional definitions for certain terms and words used throughout Chapter XXI and adds an applicability section that clarifies how the Department will enforce the provisions of Chapter XXI as they relate to PBMs operating in this State and does not create any costs to PBMs.

Moreover, PBMs operating in New York should have the overall experience, resources, and systems to comply with these requirements given that the majority of other states already have laws in place that impose similar requirements on PBMs such that the requirements established by these regulations should largely align with the existing business practices of PBMs. Furthermore, this consolidated rulemaking does not require a PBM to research, investigate, or procure data that is not easily and immediately accessible to them.

During the comment period for the Prior Proposal, a significant number of comments asserted that the Prior Proposal would have imposed secondary costs on health plans operating in this State. While the Prior Proposal only applied to PBMs' operations in New York, commenters suggested that its provisions would create costs that PBMs would pass on to the health plans. The major concerns raised by these comments, including a floor on pharmacy reimbursement paid by PBMs, a required minimum dispensing fee paid by PBMs, and limitations on use of skinny pharmacy networks by PBMs, have not been included in this proposal. In addition, this revised proposal seeks to clarify a number of provisions that were perceived, but not intended to, have adverse

impacts on health plans operating in New York, including clarifying a perceived ban on mail order networks and limitations on specialty networks and quality and safety standards. The proposed rulemaking contains revisions to address this confusion and make clear that health plan choices are preserved. As such the Department does not anticipate significant costs to health plans as the proposed rulemaking has addressed the important concerns raised.

The Department anticipates absorbing any costs to the Department associated with this consolidated rulemaking, such as staff time needed to carry out the powers accorded to the Superintendent under Insurance Law Article 29 and Public Health Law section 280-a, in its ordinary budget.

5. Local government mandates: The proposed consolidated rulemaking does not impose any program, service, duty, or responsibility upon a county, city, town, village, school district, fire district, or other special district. While the Prior Proposal only applied to PBMs' operations in New York, commenters suggested that its provisions would create costs that PBMs would pass on to local government employee health funds. The consolidated rulemaking has incorporated changes intended to address the indirect costs on these health plans raised by commenters. The Department believes that the consolidated rulemaking, as modified from the previously withdrawn rulemaking, should not adversely impact local governments in New York.

6. Paperwork: This consolidated rulemaking may impose reporting, recordkeeping, and other compliance requirements on PBMs operating in New York; however, the Department has determined that such requirements will not substantially adversely affect PBMs, and are necessary to effectuate the Legislative intent to regulate PBMs under Insurance Law Article 29 and Public Health Law section 280-a.

Any burden created by these requirements is minimal and further mitigated by the optional use of electronic transmittal of contracts, notices, applications, or other correspondences, and by aligning these provisions with the requirements set by a majority of other states. Additionally, these requirements largely codify good business practices that many PBMs already comply with in managing contracting, network participation,

and audit related communications between PBMs and pharmacies and are essential for upholding the legislative intent of ensuring that PBMs comply with a duty of good faith and fair dealings with consumers and pharmacies as required by Public Health Law section 280-a.

Moreover, PBMs operating in New York should have the overall experience, resources, and systems to comply with these requirements given that the majority of other states already have laws in place regarding PBMs and any minimal costs or recordkeeping requirements should align with ongoing business practices of PBMs generally.

7. Duplication: The proposed consolidated rulemaking does not duplicate or conflict with any existing State or federal rules or other legal requirements.

Specifically, the Department reviewed the consolidated rulemaking provisions and determined that the rulemaking is not in conflict with nor interferes with any of the provisions of the Employee Retirement Income Security Act ("ERISA"). The Department notes that the issue of ERISA preemption connected to state regulation of PBMs has not yet been settled in New York or in the Second Circuit. While the Tenth Circuit Court of Appeals case *Pharmaceutical Care Management Association v. Mulready, et al,* Case No. 22-6074 found certain laws in that case to be preempted by ERISA, prior United States Supreme Court precedent in *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, a case specifically cited by the legislative history of the enabling statute here, found the state law there to be protected from preemption. Further, in its Amicus Curiae brief filed by United States of America on April 10, 2023, in the Tenth Circuit case, the U.S. Department of Labor and U.S. Department of Justice (collectively, the "Federal Government") assert that in nearly all situations, except those where a self-funded plan administers its pharmacy benefits itself, state laws regulating PBMs are not preempted by ERISA. Specifically, the Federal Government has clarified its position that state regulatory provisions regulating PBMs performing PBM services for an ERISA self-funded plan "are saved from preemption, and are thus enforceable, as applied to PBMs and other third-party entities with which ERISA plans contract. But to the extent an ERISA

plan itself were to engage directly in conduct covered by the Act . . . the deemer clause would shield the plan from direct state regulation, and enforcement of the provisions against the plan would be preempted." Thus, under that analysis, as the rules proposed here would not apply to an ERISA self-funded plan performing PBM services for itself, the rule would not be subject to preemption under ERISA per the controlling interpretation of the federal government. The Tenth Circuit declined to address that argument, declaring it was waived by Oklahoma below. The Department finally notes that the Tenth Circuit case is still being litigated.

The Centers for Medicare and Medicaid Services' ("CMS") Medicare Part D standards pursuant to the Social Security Act section 1856(b)(3), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 ("MMA"), do preempt certain provisions of this consolidated rulemaking as applied to PBMs in their performance of PBM services for Medicare Part D plans. However, section 450.7 ensures that the consolidated rulemaking does not conflict with those standards by exempting PBMs from certain provisions of the rulemaking as applied to a PBM's provision of pharmacy benefit management services to Medicare prescription drug plans.

8. Alternatives: Promulgation of the proposed consolidated rulemaking is required under Insurance Law Article 29 and Public Health Law section 280-a. Without the consolidated rulemaking, the Department would not be able to effectuate the legislative mandate; therefore, the alternative of not promulgating the consolidated rulemaking was rejected. Additionally, the Department considered various alternatives to each section of the consolidated rulemaking, as further detailed below, and the Department sought input from interested parties in drafting the same, including representatives from the PBM industry, independent pharmacies, chain pharmacies, health plans, academics, and consumer representatives, among others.

Specifically, the Department proactively sought feedback on and published requests for public comment and information with regard to the duty, accountability, and transparency requirements of PBMs under Public Health Law section 280-a (published on June 1, 2022), PBM services to Medicare Part D Plans (published on

June 8, 2022), reporting requirements (published on June 23, 2022), patient steering (published on June 11, 2022), credentialing (published on July 25, 2022), pricing models and pharmacy reimbursement practices (published on September 26, 2022), and audits of pharmacies conducted by PBMs (published on February 23, 2023). The Department received and reviewed comments and feedback from representatives from the PBM industry, independent pharmacies, chain pharmacies, health plans, and consumer representatives, among others, and considered various alternatives to the consolidated rulemaking based upon the 160 comments received. The Department also received and reviewed over 100 complaints from pharmacies and pharmacy associations over the last two years specifically related to alleged PBM misconduct, which the Department also took into consideration when deciding alternative provisions to this consolidated rulemaking.

The Department consulted with, and sought input from, the New York State Department of Health, including the staff of the Medicaid program. The Department also received significant public comments on the Prior Proposal, including a number of suggested alternatives to what was proposed at that time. A number of these suggestions were incorporated into this proposed rulemaking and so are not alternatives that are considered here. Other material alternatives suggested in those comments were considered and rejected for the reasons set forth below.

A number of commenters on the Prior Proposal suggested excluding ERISA self-funded plans from the application of these rules. First, the Department notes that the proposed rulemaking imposes rules on PBMs, not on ERISA self-funded or any other type of health plan. Second, the legislation that requires the Department to promulgate these rules, not the rules themselves, state that the rules should broadly apply to services provided by PBMs to New York health plans. This is evident both from the text of the enabling legislation, which included an extremely broad definition of health plan, and a severability clause that makes that intent clear. It is also expressly stated in the legislative history, particularly the Assembly Sponsor's memo that specifically states that the Legislature intended for the supervision of the PBM industry because the Legislature concluded that the

legislation and the regulations it contemplated are not preempted by ERISA. Therefore, the Department has acted according to the express Legislative intent. The Department therefore rejected various alternatives that would have exempted PBMs operating in that space from portions or the entirety of the proposed rulemaking. The Department notes, however, that changes were made in response to comments that suggested the previously withdrawn proposed rulemaking would have impacted health plan choices as to design of benefits and other health plan choices. It was never the Department's intent to impact health plan design choices with its regulations, only to address and control PBM practices.

With respect to the provisions related to contracting with pharmacies under Part 456, the Department consulted with various other states regarding the alternatives they considered in drafting their regulations related to contracting with pharmacies and the issues they encountered when enacting same. The Department also reviewed over a dozen other states' statutory and regulatory provisions related to contracting with pharmacies. After careful consideration, the Department decided to align the provisions related to contracting with pharmacies to be consistent with requirements set by a majority of other states. The Department concluded that this approach provided a number of efficiencies while addressing many of the common complaints received by the Department and aligning with the intent of the New York State legislature. Other provisions were considered but deemed to be inconsistent with what PBMs already are required to do in other states, which the Department rejected as unnecessarily burdensome. The Department considered comments suggesting that provisions requiring commensurate reimbursements for all in-network pharmacies be removed but rejected those comments as they are inconsistent with the legislative mandate. The Department also considered and rejected comments on restrictions on clawbacks as the Department believes that the language in the proposal creates a good balance between the interests of pharmacies that rely in good faith on determinations made by a PBM while maintaining the ability of a PBM to seek repayments based on fraud.

While certain suggested changes to the grounds for immediate termination were included, suggestions to include waste and abuse were rejected. Waste and abuse are overly broad terms to justify immediate termination. The proposal still allows for immediate termination when there is a scheme to defraud though. PBMs also retain the right to terminate a pharmacy on 60 days' notice.

The Department also considered different timelines for having PBMs' pharmacy contracts come into compliance with the proposed rules. In the end, the options selected reflect a timeline alternative suggested by a commenter to the Prior Proposal that the Department believes reflects a balance between the need to avoid interference with multi-year contracts and ensuring that compliance with the rules does not drag out indefinitely based on contracts long-ago entered into.

The Department also considered having all required communications with and notices to pharmacies, any forms or documents required or requested to be provided to or by the pharmacy or the Department, and any filing of applications for prior approval for acquisitions or pharmacy drug restrictions with the Department to be transmitted by hard copy submission. However, the Department decided that this would not be the best option given the volume of papers that may need to be submitted, requiring the use of paper and postage, which would ultimately make this option more costly and burdensome. The Department therefore decided against this option in favor of electronic submission of all forms and documents, being the most cost effective and least burdensome.

For the provisions relating to reporting requirements and disclosures to pharmacies and the Department, the Department considered more extensive reporting requirements but determined the more cost effective and less burdensome alternative would be to only require PBMs to provide the pharmacy with a copy of the contract, notices regarding network participation or denial thereof, re-credentialing, audit information, and credentialing requirements. Additionally, PBMs only need to provide documents to the Department if the Superintendent deems it relevant and necessary so as not to impose any unreasonable or unnecessary burden on PBMs.

For the definition of fraudulent activity included in Part 459, the Department reviewed various other states' consumer protection regulations, CMS guidance documents, and definitions given by PBM trade groups in response to the Department's requests for comment. After careful consideration, the Department decided to keep its definition of fraudulent activity consistent with these sources, which are substantially consistent with each other, as using alternative language would be burdensome, illogical, and unnecessary.

With respect to the audit provisions under Part 459, the Department reviewed the provisions of various other states and received over a dozen complaints that specifically relate to alleged misconduct in complying with the audit requirements contained in Public Health Law section 280-c, which the Department considered when drafting this consolidated rulemaking. After careful consideration, the Department decided to align the provisions related to audits of pharmacies to be consistent with requirements set by a majority of other states. These existing standards address many of the common complaints received by the Department and align with the legislative intent of the New York State legislature. Creating a distinct, inconsistent audit process was rejected as unnecessarily burdensome. Some commenters on the Prior Proposal suggested stricter rules while others suggested that the Department lacked the authority to address PBM audits at all and/or raised specific concerns about audit provisions. The Department rejected the suggestion to not take any action on PBM audits of pharmacies as inconsistent with the legislative mandates or Public Health Law section 280-a and Insurance Law sections 2906 and 2911. The Prior Proposal and this proposed consolidated rulemaking were drafted with the express purpose of creating a consistent, comprehensive audit framework. On the other hand, the Department made changes to Part 459 consistent with some concerns raised.

Additionally, as it relates to the requirements for audits of pharmacies in Part 459, the Department considered whether to allow PBMs to withhold future payments prior to a final audit report being delivered to the pharmacy if there was a disputed claim amount regardless of the claim amount in dispute. Ultimately, it determined that allowing a limited withholding of an amount not exceeding 10% of the monthly payment to the

pharmacy if the disputed claim amount for the audit exceeds $25,000 would be the best alternative because such a balance would benefit both PBMs and pharmacies to ensure that PBMs are able to be made whole when a large audit claim is disputed but ultimately determined to be valid, and alternatively to ensure that pharmacies continue to be paid monthly for their services so as to continue monthly operations and not be forced out of business due to non-payment by the PBM prior to a final audit report being issued. The Department also aligned, to the extent possible, these provisions regarding withholding audit claim payments with other states' provisions so that the requirements across different states are consistent.

The Department considered including additional provisions related to third party vendors who may perform audits on behalf of a PBM. However, as Insurance Law section 2911 already states that PBMs are responsible for any entity performing pharmacy benefit services on their behalf, it was determined that including such provisions would be duplicative and unnecessary.

Certain commenters on the previously withdrawn rulemaking suggested that a specific ban on PBMs passing through compliance costs be included in the regulations. The Department has made significant changes to the regulation proposed in the rulemaking and thus has determined that such a ban is not necessary and was not included. Additionally, such a ban is impractical in any event as it would be nearly impossible to police.

This proposed consolidated rulemaking is based upon the comments and complaints received by the Department, as well as the existing statutory language. As this revised proposal would be the Department's first adopted set of rules related to market conduct activities, it is the Department's intention to continue to monitor the industry and determine if these rules need to be amended in the future.

9. Federal standards: The proposed consolidated rulemaking does not exceed any minimum standards of the federal government for the same or similar subject areas, except as outlined below.

Specifically, the Department has reviewed the consolidated rulemaking provisions and determined that the rulemaking is not in conflict with nor exceeds any of the minimum standards imposed by the provisions of

ERISA. A discussion of the legal landscape of state regulations of PBMs and ERISA preemption is noted above and incorporated here.

The Department is aware that the CMS Medicare Part D standards pursuant to the MMA do preempt certain provisions of this consolidated rulemaking as applied to PBMs in their performance of PBM services for Medicare Part D plans. However, section 450.7 ensures that the consolidated rulemaking does not conflict with those standards by exempting PBMs from certain provisions of the regulations as applied to PBMs providing pharmacy benefit management services to Medicare prescription drug plans. The Department will not enforce these specific provisions with regards to any PBMs operating on behalf of, or otherwise providing services to, Medicare Part D plans in light of the Medicare Part D federal preemption. To the extent that a PBM provides services for Part D plans and other health plans, the provisions would only apply to the PBM's provision of services to other, non-Part D health plans.

10. Compliance schedule: The proposed consolidated rulemaking will take effect immediately upon publication of the Notice of Adoption in the State Register, although compliance will not immediately be required for certain provisions. PBMs must create and publish the formulary and network directories under Part 458 by July 1, 2025. Finally, PBMs' new pharmacy contracts must be in compliance by July 1, 2025 with conflicting provisions deemed void and unenforceable after January 1, 2027, which is the date by which all PBMs must renew their licenses for the first time.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed 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 Will Not Have a Substantial Adverse Impact on Small Businesses and Local Governments

This consolidated rulemaking only applies to pharmacy benefit managers ("PBMs") operating in New York. In addition to the Department of Financial Services' ("Department") general experience in registering and licensing PBMs, the Department has made various inquiries to industry groups regarding whether there are any PBMs operating in New York that are small businesses as defined under the State Administrative Procedure Act. Based thereon, the Department has determined that there are no PBMs operating in New York that are small businesses.

This proposed consolidated rulemaking replaces a prior proposed consolidated rulemaking that was published in the State Register on August 16, 2023, and withdrawn on November 15, 2023 (the "Prior Proposal"). A number of comments submitted in connection with the Prior Proposal stated that the Prior Proposal would have had indirect impacts on health plans, including health plans that are small businesses. While the Prior Proposal applied only to PBMs, commenters suggested that its provisions would create costs that PBMs would pass on to health plans that are offered by small businesses and local governments. The Department carefully considered the comments submitted on the Prior Proposal and incorporated changes to the current proposed consolidated rulemaking to address the indirect costs that may be passed on to health plans that may be provided by small businesses or local governments.

The major concerns raised by the comments submitted about the Prior Proposal, including a floor on pharmacy reimbursement paid by PBMs, a required minimum dispensing fee paid by PBMs, and limitations on use of "skinny" pharmacy networks by PBMs, have not been included in this proposal. In addition, the

Department revised certain provisions in this proposal to minimize any potential administrative burden that could be passed on to any small businesses while complying with the legislative mandate to establish standards to address certain specified issues. Based on these changes, the Department believes that that the proposed consolidated rulemaking should not adversely impact health plans that are offered by small businesses or local governments in New York.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed 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 Will Not Have a Substantial Adverse Impact on Rural Areas

This consolidated rulemaking only applies to pharmacy benefit managers. The Department of Financial Services ("Department") has reviewed the records of all currently registered pharmacy benefit managers and has determined that there are no pharmacy benefit managers located in any rural area of New York. Therefore, this consolidated rulemaking will not impose any adverse impact on rural areas or reporting, recordkeeping, or other compliance requirements on public or private entities in rural areas.

This proposed consolidated rulemaking replaces a prior proposed consolidated rulemaking that was published in the State Register on August 16, 2023, and withdrawn on November 15, 2023 (the "Prior Proposal"). A number of comments submitted in connection with the Prior Proposal stated that the Prior Proposal would have indirect impacts on health plans. While the Department does not have information that any of those health plans are located in rural areas, and while the Prior Proposal applied only to PBMs, the Department notes here that such health plans may operate in rural areas. The indirect costs mentioned by commenters did not relate to reporting, record keeping or other compliance requirements on health plans, as the Prior Proposal only applied to PBM conduct, but instead related to costs passed on from PBMs. The Department carefully considered the comments submitted on the Prior Proposal and incorporated changes to the current proposed consolidated rulemaking to address the indirect costs on health plans.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed 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 Will Not Have a Substantial Adverse Impact on Jobs and Employment Opportunities

The Department of Financial Services ("Department") has determined that the consolidated rulemaking should not adversely impact jobs or employment opportunities in New York. PBMs should not need to hire additional staff to assist in complying with the requirements contained in this consolidated rulemaking. PBMs are highly sophisticated contractual parties and should have the overall experience, resources, systems and staff needed to bring the PBMs into compliance with these requirements, especially given that a number of other states already impose similar requirements.

This proposed consolidated rulemaking replaces a prior proposed consolidated rulemaking that was published in the State Register on August 16, 2023, and withdrawn on November 15, 2023 (the "Prior Proposal"). A number of comments submitted in connection with the Prior Proposal stated that the Prior Proposal would have indirect impacts on health plans. Specifically, while the Prior Proposal applied only to PBMs, commenters suggested that its provisions would create costs that PBMs would pass on to health plans. The Department carefully considered the comments submitted on the Prior Proposal and incorporated changes to the current proposed consolidated rulemaking to address the indirect costs on health plans that may be small businesses.

Accordingly, the Department has determined that the consolidated rulemaking, as modified from the previously withdrawn rulemaking, should not adversely impact jobs or employment opportunities in New York.