

Regulatory Impact Statement for the Consolidated Proposed Second Amendment to Part 450 (Insurance Regulation 219), and the Addition of New Part 453 (Insurance Regulation 223), New Part 454 (Insurance Regulation 224), and New Part 455 (Insurance Regulation 225) 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 2914; and Public Health Law section 280-a.

Financial Services Law section 102 consolidates the Departments of Insurance and Banking into the Department of Financial Services (“Department”).

Financial Services Law section 201 authorizes the Superintendent of Financial Services (“Superintendent”) to take actions as necessary to eliminate financial fraud or other criminal abuse or unethical conduct in the industry.

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, and to prescribe regulations interpreting the Insurance Law.

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, make findings, reports, and recommendations, and to subpoena witnesses, compel the attendance of witnesses, administer oaths, examine any

person under oath, compel any person to subscribe to their testimony, and require the production of any books, papers, records, correspondence, or other such documents that the Superintendent deems necessary as part of hearings or investigations.

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 an insurer or other person 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, the form, contents, and manner of submission of those reports.

Insurance Law section 2905 authorizes the Superintendent to impose penalties on a PBM for acting without a license.

Insurance Law section 2906 authorizes the Superintendent to establish, by regulation, minimum standards for the issuance of a license to a PBM.

Insurance Law section 2914, notwithstanding Insurance Law section 206, authorizes the Superintendent to establish, by regulation, assessments of PBMs registered or licensed with the Department for the operating expenses of the Department that are attributable to regulating such PBMs, in such proportions as the Superintendent may deem reasonable.

Public Health Law section 280-a authorizes the Superintendent to make regulations defining, limiting, and relating to the duties, obligations, requirements, and other provisions relating to PBMs.

2. Legislative objectives: In accordance with Insurance Law Article 29 and Public Health Law section 280-a, the legislative objectives are to empower the Superintendent to establish by regulation licensing and

reporting requirements for PBMs, including the broad regulatory authority to implement minimum standards for the issuance of licenses to PBMs. The consolidated rulemaking will establish these methods and procedures.

3. Needs and benefits: This consolidated rulemaking will establish the licensing and reporting standards for a PBM to perform pharmacy benefit management services in New York. This proposed consolidated rulemaking is necessitated by the enactment of Insurance Law Article 29 and Public Health Law section 280-a, providing the Superintendent with broad independent regulatory authority over PBMs, which have previously been largely unregulated in this State. The 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, the pharmacy industry in the State, and more.

Specifically, Insurance Law section 2914 requires PBMs registered or licensed with the Department to be assessed and pay such assessments, in an amount determined by the Superintendent, in order to cover the Department's operating expenses as they relate to regulating PBMs. Therefore, Part 453 is needed to establish such assessment requirements determining the frequency of and cost calculations for these assessments.

Insurance Law sections 2905 and 2906 require every PBM operating in New York to file a license application with the Department on or before January 1, 2024 and authorize the Superintendent to establish minimum licensing standards required for PBMs. The proposed Part 454, therefore, is needed to establish those minimum licensing requirements, including the form, content, and manner of submission of the required licensing materials. Additionally, the Superintendent promulgated 23 NYCRR Part 500, which went into effect on March 1, 2017, to establish cybersecurity requirements for financial services companies. The individuals and entities required to comply with the provisions of 23 NYCRR Part 500 include, but are not limited to, partnerships, corporations, branches, agencies, and associations operating under, or required to operate under, a license, registration, charter, certificate, permit, accreditation, or similar authorization under the Banking Law, the

Insurance Law, or the Financial Services Law. As such, Section 454.2 is needed to ensure PBMs are in compliance with those provisions prior to being licensed with the Department.

Insurance Law section 2904 requires PBMs operating in New York to submit annual reports to the Superintendent on or before July 1 of every year. Under that section, the Superintendent is expressly authorized to promulgate regulations governing the form, contents, and manner of submission of those reports. Part 455, therefore, is needed to set the contents, manner, and form for submission of those reports to the Department. Additionally, Public Health Law section 280-a and Insurance Law section 2904 both require PBMs to disclose and report certain information to health plans and to the Department, respectively. The Superintendent has been granted express authority to promulgate regulations defining, limiting, and relating to the duties, obligations, requirements, and other provisions regarding PBMs reporting to the health plans under Public Health Law section 280-a(2)(g). Likewise, Insurance Law section 2904 authorizes the Superintendent to address to any pharmacy benefit manager or its officers any inquiry in relation to its provision of pharmacy benefit management services or any matter connected therewith, and to require the filing of quarterly or other statements. Part 455, therefore, is also needed to ensure PBMs operating in New York comply with those requirements, by maintaining copies of those documents related to such compliance and to disclose such documents to the Department upon request. It should be noted that the Department has consulted with over a dozen other states to align these reporting requirements, including the form and content thereof, to the extent possible, with the existing requirements in other states.

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.

4. Costs: Insurance Law section 2906(d) requires a non-refundable license application fee of \$8,000 for every year or fraction of a year in which a license is valid and determines that a PBM's license expires 36 months

after the date of issue, which results in a \$24,000 license application fee. Such fee is imposed by the statute and not this consolidated rulemaking.

Insurance Law section 2914 requires registered and licensed PBMs to pay assessments to the Department for its operating costs relating to the regulation of such PBMs. The assessment costs are imposed by the statute, but the frequency and calculation of the assessment costs are to be determined by the Superintendent by regulation. Part 453 establishes that the assessments will be calculated by considering the total cost to the Department divided pro rata among registrants and licensees under Chapter XXI based on the aggregate total number of claims processed for New York pharmacies by the registered or licensed PBMs. The assessment cost for each PBM is based on such PBM's relevancy to and need to be regulated by the Department. PBMs that process a higher number of claims for pharmacies located in New York produce a higher volume of activity in New York that directly impacts New York's health care system and will require additional regulatory oversight; therefore, work conducted and associated expenses incurred by the Department will be assessed accordingly. In order to accomplish this, PBMs registered or licensed with the Department will be required to submit the total number of claims processed for their entity for pharmacies located in New York for the preceding calendar year (January 1 to December 31) by January 15 of each year.

Part 453 also establishes special assessments, which gives the Superintendent the authority to allocate any expenses associated with a particular examination, investigation, or review solely to an individual PBM and not include such expenses in the aggregate total that is divided amongst all PBMs each year based upon the total number of claims processed by each PBM, should the Superintendent deem it necessary.

The Department considered other methods for calculating the assessments, including basing the assessment portions on the size of the PBM entity as determined by either the total number of employees or gross profits of the PBMs and on the total number of health plans the PBM contracts within New York. However, these calculations were less equitable in relation to the relative volume of activities that each PBM is conducting in

New York. The number of claims processed within New York was determined to be the most equitable allocation as such a number directly translates to the PBM's volume of activity in New York; therefore the need to promulgate additional regulation by the Department.

Insurance Law sections 2904, 2905, and 2906 and Public Health Law section 280-a give rise to other costs for PBMs to comply with the reporting requirements (e.g., costs to apply for and maintain licensure in New York State, costs to compose and file annual reports, and costs to maintain and provide records to the Department). The Department sought to minimize these costs by aligning, to the extent possible, the licensing and reporting requirements in Parts 454 and 455, including the form and content thereof, with the existing requirements of other states. The proposed Parts 454 and 455 also require the license application and annual report filings to be made electronically, to alleviate some of the other statutory-driven costs by eliminating the need for PBMs to use paper, ink, envelopes, and postage fees, to result in cost savings. The record keeping requirements under Part 455 should not impose any significant additional costs to PBMs, as those merely require the PBMs to maintain records of documents and information that the PBMs already should have in their possession and will not require PBMs to create any new or additional documents. In order to mitigate costs associated with PBMs providing records to the Department, Part 455 only requires PBMs to provide records to the Department upon request, as opposed to more extensive reporting requirements, and does not restrict these records from being maintained and provided electronically.

Moreover, PBMs operating in New York should have the overall experience, resources, and systems to comply with these requirements given that a majority of other states already have laws in place regarding PBMs and any recordkeeping requirements already should align with ongoing business practices of PBMs generally. Furthermore, this consolidated rulemaking does not require a PBM to research, investigate, or procure data that is not easily and immediately accessible to them, and thus, any costs incurred as a result of this consolidated rulemaking will be insubstantial.

The Department anticipates absorbing any costs associated with this consolidated rulemaking, such as staff time needed to carry out the powers accorded to the Superintendent under the 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.

6. Paperwork: Insurance Law sections 2904, 2905, 2906, and 2914, and Public Health Law section 280-a impose reporting, recordkeeping, and other compliance requirements on PBMs operating in New York.

Insurance Law section 2914 requires PBMs registered or licensed by the Department to be assessed by the Superintendent for the operating expenses of the Department attributable to regulating same. Part 453 establishes these assessment procedures and calculations so that PBMs can adequately comply with the assessment requirements set by the statute. Specifically, under Part 453, PBMs are required to report to the Department the total number of claims processed for their entity for pharmacies located in New York for the preceding calendar year (January 1 to December 31). To alleviate this reporting requirement, the Department purposefully limited the reporting frequency to once each year as opposed to more frequently and may receive this information from the PBMs electronically, eliminating the need for PBMs to use paper, ink, envelopes, and postage.

Insurance Law sections 2905 and 2906 require every PBM operating in New York to file an application for a license with the Department on or before January 1, 2024 and authorize the Superintendent to establish, by regulation, minimum licensure standards for PBMs. Part 454 establishes those minimum licensure standards, including the form, manner, and content of the license application, so that PBMs can adequately comply with the registration requirement set by the statute. These licensing requirements are also required to be made

electronically, to alleviate some of the other statutory-driven reporting and recordkeeping requirements by eliminating the need for PBMs to use paper, ink, envelopes, and postage.

Insurance Law section 2904 requires PBMs operating in New York to submit annual reports to the Superintendent and imposes compliance requirements on PBMs with respect to inquiries made by the Department. Under that section, the Superintendent is authorized to establish, by regulation, the form, manner, and contents of the annual reports. Insurance Law section 2904 further authorizes the Superintendent to address to any PBM any inquiry in relation to its provision of pharmacy benefit management services or any matter connected therewith, and to require the filing of quarterly or other statements. Public Health Law section 280-a(2) establishes reporting, recordkeeping, and other compliance requirements as they relate to PBMs reporting to health plans. The Superintendent is further authorized to promulgate regulations defining, limiting, and relating to the duties, obligations, requirements, and other provisions relating to PBMs reporting to health plans under Public Health Law section 280-a(2)(g). Part 455 sets forth the form and manner of the reporting requirements contained in those statutory sections, as clarified by Part 452, by requiring PBMs to maintain copies of certain documents related to those provisions and to disclose such documents. The Department has consulted with more than a dozen other states to align the additional reporting requirements, including the form and content thereof, to the extent possible with the existing requirements of other states. To further alleviate the reporting and recordkeeping requirements, the annual reports are required to be made electronically, eliminating the need for PBMs to use paper, ink, envelopes, and postage. Additionally, the reporting and recordkeeping requirements to the Department are minimal as PBMs are asked only to maintain copies of documents that already are required to be produced under Insurance Law sections 2904, 2905, and 2906 and Public Health Law section 280-a. Part 455 does not require PBMs to create any new documents, and thus no PBM will experience any substantial reporting or recordkeeping burden. However, to the extent these requirements create any burden on a PBM, it is further mitigated by the fact that Part 455 only requires PBMs to provide records to the Department upon request by the Department, as

opposed to more extensive reporting requirements, and does not restrict these records from being maintained and provided electronically.

The amendment to Part 450 will not require pharmacy benefit managers to incur additional paperwork because the amendment merely defines certain words and terms.

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 has determined that this proposed consolidated rulemaking is neither in conflict with nor interferes with any of the provisions of the Employee Retirement Income Security Act (“ERISA”), or 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”).

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 its new statutory powers and responsibilities; therefore, the alternative of not promulgating the consolidated rulemaking was rejected. Additionally, the Department considered various alternatives to each section of the consolidated rulemaking and in general sought input from interested parties in drafting same, including representatives from the PBM industry, independent pharmacies, chain pharmacies, health plans, and consumer representatives, among others. The Department also consulted with, and sought input from, the New York State Department of Health and the Office of General Counsel of the Workers’ Compensation Board in drafting this regulation.

For the calculation of assessments to PBMs, the Department considered options such as basing the assessed amount on the size of a PBM with respect to revenue or total assets of the entity or dividing the PBMs into industry types, similar to banking division assessments, among other options as noted above. However, these

options were determined to be unreliable or unusable as many of the larger PBMs have vertically integrated structures that can potentially hide revenue or assets to make the actual PBM entity appear smaller than it is and were not necessarily based on the PBMs' volume of activities in New York. Additionally, the Department determined that there was no easy way to classify different types of PBM entities in order to create an assessment structure similar to banking division assessments, as there are no sub-classifications for PBMs like there are for financial institutions. The most equitable assessment cost determination method was found to be based upon the total number of claims processed in New York for each registered or licensed PBM.

Additionally, the Department had considered assessing in arrears as opposed to projected costs that are reconciled at the conclusion of that year. The Department determined that assessing in arrears would potentially allow a PBM to cease operations prior to the assessments being calculated and therefore avoid being charged the assessment fee owed by it. Calculating assessments in arrears would also differ from all other assessments conducted by the Department, so it was determined that the best course of action would be to conform with existing assessment procedures.

For the content, form, and manner in which PBMs would submit the license application and ongoing annual reports, the Department consulted with various other states regarding the alternatives they considered in drafting their licensure and reporting regulations and the issues they encountered when enacting same. The Department also reviewed various other states' licensure and reporting regulations. After careful consideration, the Department decided to align the annual report and licensing requirements to be consistent with requirements set by a majority of other states. An alternative to this consolidated rulemaking would be to require PBMs to submit documents in a manner that is inconsistent with what they already are required to do in other states, which the Department rejected as unnecessarily burdensome.

Additionally, the Department considered having license applications and annual reports to be filed by hard copy submissions. 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, ultimately making this option more costly and burdensome. The Department therefore decided against this option in favor of electronic filings of all forms and documents, being the most cost effective and least burdensome on those filing.

For the provisions relating to record keeping requirements and disclosures, the Department considered more extensive recordkeeping and reporting requirements but determined the more cost effective and less burdensome alternative would be to require only the PBMs to maintain the documents that they should have already in their possession, and to only report those documents to the Department if the Superintendent deems it relevant and necessary so as not to impose any unreasonable or unnecessary burden on the PBMs.

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

Specifically, the Department has determined that this proposed consolidated rulemaking is neither in conflict with nor interferes with any of the provisions of the Employee Retirement Income Security Act (“ERISA”), or 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”).

10. Compliance schedule: The proposed consolidated rulemaking will take effect immediately upon publication of the Notice of Adoption in the State Register. PBMs will be required to comply with the requirements contained in the consolidated rulemaking on and after the publication of the notice of adoption in the State Register.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed Addition of New Part 453 (Insurance Regulation 223), New Part 454 (Insurance Regulation 224), and New Part 455 (Insurance Regulation 225), and the Second Amendment to Part 450 (Insurance Regulation 219) 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 operating in New York. The Department of Financial Services (“Department”) has reviewed the records of all currently registered pharmacy benefit managers and has made various inquiries to industry groups regarding whether there are any pharmacy benefit managers operating in New York that are small businesses. Based thereon, the Department has determined that there are no pharmacy benefit managers operating in New York that are small businesses or local governments. Therefore, this consolidated rulemaking will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on small businesses or local governments.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed Addition of New Part 453 (Insurance Regulation 223), New Part 454 (Insurance Regulation 224), and New Part 455 (Insurance Regulation 225), and the Second Amendment to Part 450 (Insurance Regulation 219) 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.

Statement Setting Forth the Basis for the Finding that the Consolidated Proposed Addition of New Part 453 (Insurance Regulation 223), New Part 454 (Insurance Regulation 224), and New Part 455 (Insurance Regulation 225), and the Second Amendment to Part 450 (Insurance Regulation 219) 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. Part 453 establishes the procedures, computations, and additional special circumstances for assessments that pharmacy benefit managers (“PBMs”) are required to pay for the operating expenses of the Department; Part 454 establishes the licensure standards required for PBMs to perform pharmacy benefit management services in New York; and Part 455 establishes the annual reporting standards required for PBMs, as well as the reporting, recordkeeping, and other compliance requirements as they relate to PBMs reporting to the Department. PBMs already are required to comply with the above pursuant to Insurance Law sections 2904, 2905, 2906, and 2914 and Public Health Law section 280-a. This consolidated rulemaking is needed to implement those statutory requirements.

Further, the proposed amendment to Part 450 merely amends the definition section of that Part to include additional definitions for certain terms and words that are used in Chapter XXI. The amendment to Part 450 does not substantially change any provision that would impact jobs or employment opportunities in New York State in any way.