Assessment of Public Comments on the Proposed Second Amendment to Part 450 (Insurance Regulation 219) of, and Addition of New Parts 453 (Insurance Regulation 223), 454 (Insurance Regulation 224), and 455 (Insurance Regulation 225) to, 11 NYCRR

The Department of Financial Services ("Department") received comments from one pharmacy benefit manager ("PBM"), two trade organizations representing health plans, one trade organization representing PBMs, one trade organization representing drug wholesale distributors, and one trade organization representing healthcare providers. One commenter expressed overall support of and appreciation for the regulation and did not suggest any revisions to the regulation.

Comment: Two commenters expressed concerns with the current definition of a "substantial number of beneficiaries" under Part 450 because it would include self-funded Employee Retirement Income Security Act ("ERISA") plans and PBMs have no way to identify health plan members who actually work within the borders of New York.

Response: The term "a substantial number of beneficiaries who work or reside in this state" was originally adopted as part of Insurance Regulation 221 (11 NYCRR 451) on August 31, 2022. The Department responded to all comments regarding that term in the Assessment of Public Comments for Insurance Regulation 221. This amendment to Part 450 reorganizes the definitions contained in Chapter XXI and does not alter that already-defined term, but rather merely amends the "Definitions" section of that Part to incorporate this term as a technical matter. Furthermore, the Department does not agree with the commenters' statements that PBMs have no way to identify health plan members who actually work within the borders of New York, as all PBMs currently registered in New York already have provided the Department with a list of all health plans (including ERISA plans) for which they perform services that meet the "substantial number of beneficiaries" threshold as part of the registration application requirements. Finally, the Department has provided further guidance on how to determine

whether 50 percent or more of the beneficiaries of the health plan work or reside in New York[1] and circulated that guidance to all registered PBMs. No PBM has objected to that guidance. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: Three commenters expressed concerns about the addition of the definition of "pharmacy services administrative organization or PSAO" under Part 450. One commenter suggested that the definition be changed to exclude wholesalers and distributors from the list of entities with which a PSAO might conduct business on a pharmacy's behalf because, the commenter stated, PSAOs do not conduct business with wholesale distributors on behalf of pharmacies and while some wholesale distributors offer their independent pharmacy customers PSAO services, these are separate business entities that operate independently of one another. Two commenters suggested that the portion of the definition limiting PSAOs to those entities "operating in this state" should either be extended to all other entities defined in the definitions section (e.g., wholesalers, rebate aggregators, switch companies) or stricken from this definition to ensure consistency in the definitions.

Response: Any business that PSAOs conduct relating to interactions between wholesalers and distributors and pharmacies is outside the scope of this rulemaking and as such, the suggested change would not affect the purpose or intent of the rulemaking. Therefore, the Department made the suggested change to remove wholesalers and distributors from the definition. However, this should not be taken as agreement that PSAOs and wholesalers and distributors are not connected. Removing the language "operating in this State" from the definition does not change the intent of the regulation as the specific sections in the regulation related to PSAOs clarify that the Department is referring to only PSAOs with membership located in this State and could be viewed as redundant when read in conjunction with the definition. Furthermore, the Department agrees that limiting the definition of PSAOs to only those entities "operating in this State" may be confusing and inconsistent with definitions of other entities and therefore is removing the language "operating in this State" to clarify the intent.

[1] Guidance available at https://www.dfs.ny.gov/apps_and_licensing/pharmacy_benefit_managers.

Comment: Three commenters expressed concerns about the addition of the definition "rebate aggregator" to Part 450. One commenter noted that the definition may not be broad enough to encompass all the types of entities that the commenter believes should be included, such as group purchasing organizations ("GPOs"). Two commenters suggested that the definition should "be limited to exclude those organizations which perform more extensive PBM services" and clarify what a rebate aggregator does not do, i.e., "offer formularies, networks, etc." because the definition may encompass "entities that are not typically considered rebate aggregators."

Response: The Department defined "rebate aggregator" to include all entities that "provide formulary rebate administrative services for pharmacy benefit managers or otherwise negotiate rebates with manufacturers on behalf of" the license applicant. The purpose of this definition is to capture all entities or persons that or who engage in these activities, regardless of whether such entities or persons also perform additional services outside of that definition, such as services typical of a GPO or PBM, regardless of the title the entity or person assumes. Likewise, the Department did not include in the definition a list of what a rebate aggregator does not do because such language would exclude entities that provide other services in addition to those services provided by a rebate aggregator. Accordingly, the Department does not agree that the definition of "rebate aggregator" is overly broad or too limited as suggested by the commenters, but rather sufficiently captures all entities performing those defined activities. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter requested that the Department cite the statute that authorizes the Department to collect information on "rebate aggregators" and "switch companies".

Response: Citations to all relevant statutory authority are contained in certain State Administrative Procedure Act ("SAPA") documents that were filed with the proposed rule, as required by SAPA, and which were published in the State Register and posted on the Department's website. The Department respectfully refers the commenter to those documents. No changes to the regulation are necessary in response to this comment.

Comment: Three commenters expressed overall concerns with the assessments calculations and billing structure contained in Part 453. Specifically, two commenters stated that the assessments and billing process may cause administrative burdens because the frequency of quarterly assessment billings with a year-end "true up" are unique to New York, PBMs will have to spend a considerable amount of time to make sure that they pay each invoice timely, and the 30-day period to pay such claims may prevent accurate financial forecasting. One of the commenters suggested cutting down on the total number of payments as an alternative. Two commenters expressed concerns about the dollar amount of assessments on each PBM, including that they may "disproportionately affect small and mid-sized PBMs . . . even though they are based on the number of claims for each PBM" and the uncertainty in the range of assessments because the Department did not provide an estimate or permissible range for operating expenses. They also commented that it would be helpful to have insight into the Department's operating expenses and how the funds are used. These commenters also raised concerns with paying the assessments, in addition to the registration or license application fees, because they believe that the combination of these fees are excessive and punitive.

Response: Insurance Law section 2914 requires that all "pharmacy benefit managers that file a registration with the department or are licensed by the department shall be assessed by the superintendent for the operating expenses of the department that are attributable to regulating such pharmacy benefit managers in such proportions as the superintendent shall deem just and reasonable". Accordingly, it is the statute, and not this regulation, that requires PBMs to be assessed by the Department for the costs of regulating PBMs. In developing a framework to implement the assessment requirement imposed by the legislature, the Department implemented the same assessment billing structure that applies to all of the regulated entities that are assessed by the Department. Specifically, all of the Department's regulated entities are assessed using four quarterly assessments with a year end "true-up", including the Department's virtual currency, banking, and insurance entities. The Department, therefore, will assess PBMs in the same manner that other entities that are required to be assessed by the

Department for the cost of regulating those entities to ensure consistency and because such assessment methodology has proven to be successful with those other entities.

Regarding the request for insight into the Department's operating expenses related to the PBB, the Department notes that the annual state operations appropriations bill, which is accessible from the New York State Division of the Budget's website, places a cap on the operating expenses of the Department's Pharmacy Benefits Bureau ("PBB") based on the estimated costs of the PBB. The annual state operations appropriations bill provides PBMs with insight into the estimated costs of the PBB.

The comment that assessments and licensing fees are redundant misconstrues the licensing and assessment process. Assessments are based on the actual operating expenses of the PBB. The amount of the assessments charged will be reduced by the licensing and registration fees received from PBMs each year. Assessments and licensing and registration fees are, accordingly, both used to pay the PBB's operating expenses each year. Similarly, assessments will be reduced by any settlements or other enforcement fees, fines, or penalties collected by the PBB each year, as those funds also go into the PBM regulatory fund. Accordingly, assessments and application fees are complimentary, not redundant.

Finally, the Department does not believe that the assessment costs will disproportionately affect small or mid-sized PBMs because 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 directly according to the size of the PBM, and those PBMs that process fewer claims (those PBMs that are smaller in size) should effectively pay less in assessments as the proposed regulation intended. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: Two commenters requested that the Department provide a clear definition of "claims" as that word is used in proposed section 453.2 in the calculation of assessments, to ensure that all PBMs are counting the same types of claims in their assessment calculation.

Response: The proposed regulation defines "claim" in section 450.1(f). In an effort to further clarify the regulation in response to these comments, the Department has changed the word "processed" to "adjudicated" to further demonstrate the intent that each claim submitted by a pharmacy located in New York for adjudication should be counted in the claims reported under Part 453 to determine the assessment allocation.

Comment: Given that the Department may immediately suspend, terminate, or revoke a PBM's license or registration for any late disclosure of claims, one commenter requested adding "cure period" language to section 453.4 in order to give PBMs the opportunity to rectify any late disclosure or notification of their claims for the prior year, especially during the initial years of the Department's implementation of the new regulatory framework while PBMs adjust to the new regulations.

Response: In order for the Department to timely calculate and notify PBMs of their assessments, it is critical for PBMs to report the number of claims they adjudicated for the prior calendar year by the deadline of January 15 as outlined in the proposed rulemaking. Additionally, the Department only received this single comment regarding the January 15 deadline, which did not state any reason that the deadline is not feasible for PBMs to meet. Therefore, no changes to the regulation are necessary in response to this comment.

Comment: Two commenters expressed general concerns regarding the special assessment provisions in section 453.5. One commenter believes that this language is unsupported by statute and asked for the parameters, thresholds, and specific metrics that trigger a special assessment be explicitly spelled out in the regulation. This commenter also suggested that the Department follow the example of other states that provide an invoice to cover the costs associated with market conduct exams.

Response: Insurance Law section 2914 and Financial Services Law section 206 require the Department to assess PBMs for the operating expenses of the Department "in such proportions as the superintendent shall deem just and reasonable." The special assessments provision gives effect to the legislative mandate, making clear that there may be instances in which the costs of conducting an examination, investigation or review of a particular licensee should be assessed to just that licensee and not spread across the industry. The special assessments provision in section 453.5 is consistent with provisions applied to other Department-regulated entities, being nearly identical to those special assessment provisions that apply to the Department's virtual currency licensees and the banking division. The Department, therefore, will assess PBMs in the same manner that it assesses other entities that are registered or licensed with the Department to ensure consistency and because such assessment methodology has proven to be successful with those other entities. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: Three commenters expressed concerns regarding the $24,000 application fee to obtain a license, stating that such fee exceeds most other states' licensing fees, and suggested that the amount of the license application fee be lowered. One commenter asked that the frequency for payment of this license application fee be clarified, and another commenter expressed concerns that the application fee would affect small or mid-sized PBMs disproportionately and deter new competition within New York's PBM market.

Response: This regulation does not set the application fee for a PBM license, or the frequency for such payment; rather, it is statute that imposes the fee and when it must be paid. Specifically, Insurance Law section 2906(d) provides that, "[b]efore a pharmacy benefit manager's license shall be issued or renewed, the prospective licensee shall properly file in the office of the superintendent an application . . . and pay a fee of eight thousand dollars for each year or fraction of a year in which a license shall be valid," and that, "[e]very pharmacy benefit manager's license shall expire thirty-six months after the date of issue." Accordingly, the statute provides that a license is valid for three years after the date of issue and that the fee is $8,000 per year. This means that a PBM

applying for a license must pay a $24,000 initial application fee, which shall remain in effect for three years, and must pay such fee every three years to maintain its license thereafter. Further, the Department cannot lower the license application fee for any size PBM as the fee is set by statute. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter requested that the words "or any matter" be stricken from section 454.1(b)(7), which requires a PBM to "identify any entity that is in the same corporate/ownership structure with which the pharmacy benefit manager contracts in relation to its provision of pharmacy benefit management services or any matter connected therewith" because the commenter believes that this language is beyond the scope of the underlying statute and the Department's authority.

Response: The commenter did not provide any reason why the identification of an entity in a PBM's corporate structure, with which the PBM contracts in relation to any matter connected with the PBM's provision of pharmacy benefit management services to health plans, is beyond the scope of the Department's authority under Insurance Law Article 29. For example, Insurance Law section 2904 allows the Department 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." Similarly, Insurance Law section 2911 provides that a PBM "shall be responsible for the actions of any subcontractor, affiliate, subsidiary, or other individual or entity who violates any provision of this article in performance of any pharmacy benefit management services for such pharmacy benefit manager . . .". Finally, Insurance Law section 2906(g) authorizes the Department to "promulgate regulations establishing methods and procedures for facilitating and verifying compliance with the requirements of [Insurance Law section 2906] and such other regulations as necessary." Accordingly, the identification of a PBM-affiliated entity that provides services connected with that PBM's performance of pharmacy benefit management services is within the scope of the authority granted to the Department under Insurance Law Article

29 to ensure pharmacy benefit management services are provided in accordance with the provisions of Article 29. Therefore, no changes to the regulation are necessary in response to this comment.

Comment: One commenter requested that the requirement that a PBM license applicant submit "such information as the Superintendent may require" be deleted from section 454.1(b)(9) because the commenter believes the language is overbroad, beyond the scope of the underlying statute and the Department's authority, and provides no predictability. The commenter also requested that the Department remove the requirement that a PBM license applicant submit "other applicable documents" as set forth in section 454.1(c)(1) and the requirement in section 454.1(c)(4) that an applicant disclose a list of contracted pharmaceutical manufacturers and the identification of those manufacturers with which the applicant holds any ownership or affiliation.

Response: The Department is authorized under Insurance Law section 2906 to determine the "form or forms and supplements thereto" of the PBM license application. The "such information as the Superintendent may require" language is necessary to ensure that the Department is able to request any additional necessary supplemental information from a PBM should the initially requested records prove insufficient to show the PBM is in compliance with the provisions of Insurance Law Article 29.

The language "other applicable documents" in paragraph 454.1(c)(1) is made with reference to the disclosure of organizational documents contained in that provision and is meant to capture any and all "other" types of organizational documents because other states have different naming conventions for organizational documents that New York may not use, and that the Department may not have captured in that provision.

Finally, section 454.1(c)(4) is necessary to identify which manufacturers a PBM contracts with in performing pharmacy benefit management services and whether the PBM is affiliated with the manufacturer. Such information is crucial to the Department in identifying and minimizing potential conflicts of interest between PBMs and health plans, deceptive and anti-competitive practices in connection with the performance of pharmacy benefit management services, and excessive concentration and vertical integration of markets, all of which are

statutory priorities of the Department, as mandated by Insurance Law section 2906(b). Accordingly, the foregoing requirements are well within the scope of the underlying statute and the Department's authority.

Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter stated that greater clarity is needed on "other required filings" within the license application, such as "corporate bylaws and documents regulating internal affairs" as the administrative burden of preparing these documents is another cost that will diminish the ability of small and mid-sized PBMs to remain competitive. Another commenter requested that the Department strike the requirement to provide bylaws, rules, regulations, or other documents regulating internal affairs, stating that these documents may be confidential and proprietary and that providing such documents to the Department is beyond the scope of the underlying statute and the Department's authority.

Response: Other states, including Arkansas, Delaware, Kansas, Maine, Massachusetts, Rhode Island, South Carolina, and West Virginia, require PBMs to provide copies of their bylaws, rules and regulations or similar documents that regulate the conduct of the internal affairs of the PBMs as part of their registration or licensing applications. Further, the Department already requires PBMs seeking registration in New York to provide "the bylaws, rules, regulations or other primary document regulating the internal affairs of the pharmacy benefit manager" as part of their registration applications, as outlined in 11 NYCRR section 451.1. Accordingly, PBMs already must disclose this information to the Department. Moreover, none of the 67 PBMs that are currently registered with the Department expressed any uncertainty as to what was required at the time of their initial registration submissions. Internal affairs documents are commonly disclosed to government agencies as such documents are meant to outline the governance structure of the entity and are necessary to determine compliance with laws governing such entities and such documents are routinely provided by other entities regulated by the Department. As such, no changes to the regulation are necessary in response to these comments.

Comment: Two commenters expressed concerns with the requirement to provide pharmacy and PSAO contracts under paragraph 454.1(c)(8). Both commenters stated that much of the information contained in one contract is duplicative of the other contracts. One of the commenters suggested that the required filings be limited to what is actionable and useful for the Department for the purposes of issuing a license. The other commenter suggested that the Department either only require contract templates as was required under the PBM registration requirements or strike this requirement entirely as these contracts also contain confidential and proprietary information. This commenter also pointed out that the ongoing requirement for PBMs to update their license application within 30 days of any change would also mean that PBMs would be required to constantly monitor their pharmacy networks and update the Department with new contract copies, which is burdensome. Further, this commenter stated that collecting any contracts related to Medicare Part D plans would go against what the Centers for Medicare and Medicaid Services ("CMS") requires and may violate the non-interference clause.

Response: The Department has removed this requirement from the final rule at this time. The Department may revisit this requirement at a later date.

Comment: One commenter expressed concern regarding the disclosure of PBM provider manuals, and amendments thereto, under section 454.1(c)(10). Specifically, this commenter requested that the Department either remove this requirement entirely or permit the submission of provider manual templates that omit any confidential or proprietary information.

Response: The Department has removed this requirement from the final rule at this time. The Department may revisit this requirement at a later date.

Comment: One commenter requested that the Department delete the requirement in section 454.1(d) that documents submitted to the Department be "without omissions or redactions" because it is overly burdensome and overbroad.

Response: This provision is necessary to clarify that the Department's regulated entities must provide requested documents in full and without redactions or other omissions, unless otherwise exempt by law because the Department has received an abundance of redacted documents, from PBMs in response to document requests, which makes it difficult for the Department to assess compliance with the law. It is unclear how submitting documents without redactions or omissions unredacted documents is burdensome or overbroad. Rather, the burden comes from having to redact or omit information submitted to the Department. Accordingly, the Department further understands the commenter's concern is really about the confidentiality of proprietary documents. Documents provided by a PBM to the Department, remain however, are confidential under Insurance Law Article 29 and will remain in the possession and under the control of the Superintendent, as required by Article 29. As such, no changes to the regulation are necessary in response to this comment.

Comment: One commenter requested greater specificity on the timeframe for maintaining records under section 455.2(a), which provides that a PBM "shall maintain copies of any documents necessary to respond to a health plan's request pursuant to Part 452 of this Title for a period of at least two years following the date on which the document is no longer necessary to respond to such request". The commenter stated that the time period is unclear due to the ambiguity of the wording "no longer necessary", and stated that a PBM should only be required to provide information to a health plan if it has entered into or renewed its contract with the plan on or after the effective date of a final rule, and that such information need not be provided for any period prior to the date of the commencement or renewal of the contract. The commenter explained that requests that look backward would require labor intensive manual review for each request to accommodate for systems that were not in place prior to the final rule's effective date.

Response: The phrase "no longer necessary" in section 455.2(a) refers to when a record or document is no longer relevant under the disclosure requirements outlined in Part 452. For example, under section 452.3, a PBM must disclose to a health plan, upon request, the terms and conditions of any contract or arrangement

between the PBM and any party relating to pharmacy benefit management services provided to the health plan. Accordingly, on the date such a relevant contract or arrangement expires or is no longer valid or enforceable, that document would be deemed "no longer necessary" to respond to the health plan's request, but the PBM would be required to maintain a copy of that contract or arrangement for a period of two years following that date under section 455.2. As another example, if a potential conflict of interest, as further detailed under Part 452, exists between a PBM and a health plan, then all records and documentation outlined in that section would be required to be maintained by the PBM for two years after the date that the potential conflict of interest no longer exists. Further, section 452.1 provides a safe harbor provision that allows a PBM to come into compliance with the provisions of that Part by December 31, 2023, which alleviates any need for a PBM to comply with those provisions prior to the effective date of that final rule (which was adopted on July 12, 2023).

Finally, the Department disagrees with the commenter's suggestion that a PBM should only be required to provide information to a health plan if it has entered into or renewed its contract with the plan on or after the effective date of a final rule, and that such information need not be provided for any period prior to the date of the commencement or renewal of the contract. Such suggestion would allow a PBM to skirt the requirements of the regulation and intent of the legislation by, for example, purposefully entering into arrangements that would create a conflict of interest with a health plan prior to entering into a contract with that health plan so as not to be required to disclose such conflict. This rule sets forth document retention requirements related to disclosures to health plans. Previous rulemaking established the disclosure requirements. This rule, therefore, does not create any labor-intensive manual review that the commenter suggests. Comments about the labor necessary to respond to requests under Part 452 should have been raised at the time the Department adopted that rule. As such, no changes to the regulation are necessary in response to these comments.

Comment: One commenter suggested "striking and rewording" the language in section 455.4 that reads "…on a form and in a manner prescribed by the superintendent consistent with instructions posted on the

department's publicly accessible website" because it "would leave overly broad language in state law", and it would "allow [the Department] with subjective authority and permit the agency to act without offering any information as to what is expected to be filed by the affected PBMs. For example, the reporting requirements for this year are *much* more detailed than the license renewal application." Another commenter stated that the language seems very open ended and could vary year-to-year, and echoed the comment about this year's reporting requirements being more detailed.

Response: PBMs must provide annual reports to the Department on or before July 1 of each year pursuant to Insurance Law section 2904, which gives the Superintendent subjective authority to decide what information the Superintendent wants to request in those reports. The language in section 455.4 merely states that the form and contents of the annual reports will be posted on the Department's website each year prior to the annual report due date and since it will be posted on the website, the Department will be offering information as to what is expected to be filed by the affected PBMs. The Department affirms that the annual report will likely vary from year-to-year for the next few years as the Department gains further experience regulating the industry. As such, no changes to the regulation are necessary in response to this comment.

Comment: Three commenters asserted there is broad preemption of state PBM laws by ERISA and the Centers for Medicare and Medicaid Services' Medicare Part D. In particular, one commenter duplicated comments regarding preemption that the commenter submitted in response to the proposed addition of new Part 452 (Insurance Regulation 222) to 11 NYCRR (which rule has been adopted), asserting that the Centers for Medicare and Medicaid Services' Medicare Part D standards already have covered the field on pricing disclosures, rendering any effort to extend Public Health Law section 280-a(2) to Part D plans preempted. The commenter further reiterated that New York may not impose the pseudo or de facto fiduciary duties contemplated by Public Health Law section 280-a(2) on PBMs serving Part D plans because to do so is to dictate contractual terms between a PBM and plan, thereby regulating Part D plans. Two commenters also asserted that any application of

the regulations under this rulemaking to Medicare Part D or ERISA plans would increase costs for these federal programs and the demographics they serve, and that "the Department seeks to impose a host of reporting and contracting requirements".

Response: These comments are not directed toward any specific provisions of the proposed rule and, in fact, the majority of the comments deal with issues not addressed in the rule whatsoever, including comments on Public Health Law section 280-a(2), contracting requirements on PBMs, and pricing disclosures. They raise broad concerns about regulation of PBMs without identifying any issue with the proposed rulemaking or suggesting alternative language for consideration by the Department. Moreover, the blanket preemption of state laws related to PBMs asserted by the commenters are inconsistent with current case law and the position of the federal government. The proposed rulemaking is narrowly tailored to avoid any potential preemption by federal law, and even if parts of the regulation were found to be prohibited from applying to PBMs providing services to self-funded ERISA health plans or Part D plans, the Department would still adopt this proposal as it would apply to every other health plan. Therefore, no change is necessary in response to these comments.