Assessment of Public Comments on the Consolidated Proposed First Amendment to Part 6 (Insurance Regulation 195) of and Addition of New Part 452 (Insurance Regulation 222) to 11 NYCRR

The Department of Financial Services ("Department") received comments from three pharmacy benefit managers ("PBMs"), one biopharmaceutical research company, one trade organization representing health plans, one trade organization representing PBMs, and one hospital association on the proposed new Insurance Regulation 222. Two commenters expressed their overall support and appreciation for the regulation and did not suggest any revisions to the regulation. The Department did not receive any comments on the first amendment to Insurance Regulation 195.

Comment: Two commenters expressed appreciation for the exemption for PBMs that provide pharmacy benefit management services only for health plans that provide workers' compensation insurance from the requirements in Public Health Law sections 280-a(2)(b) (c), and (d) as set forth in sections 452.2 and 452.3 of the regulation. One of the commenters suggested that the Department expand these exemptions to include PBMs that provide pharmacy benefit management services to health plans that provide auto insurance because PBM services provided to auto insurance claimants under first party no-fault or medical expense benefits are handled quite similarly to how workers' compensation PBM services are handled and that in many instances, the New York auto insurance prescription drug rules borrow provisions from the workers' compensation prescription drug rules, The commenter also requested an exemption for workers' compensation and auto insurance from section 452.4(a)(7), because section 452.4(a)(7) deals with copay coupons, cards, and other methods that are used to offset cost-sharing requirements, and workers' compensation and auto insurance do not impose cost-sharing requirements on claimants, which would render this section inapplicable.

Response: The disclosures to a health plan required by section 452.(a)(7) must be disclosed only upon a health plan's request. Therefore, if a PBM does not have any applicable documents or information, the paragraph

would not be applicable, and an exemption is not necessary. Thus, no change was made in relation to this portion of the comment.

With regard to sections 452.2 and 452.3, in the pre-rulemaking request for public comments on the provisions of Public Health Law section 280-a, the Department received several comments related to exemptions for PBMs performing services for workers' compensation plans based on the preexisting supervision of the Workers' Compensation Board ("Board") over the pharmacy benefits under those plans. As noted in the Regulatory Impact Statement, the Department agreed with the comments and found the protections offered by the supervision of the Board to be sufficient to protect plan interests. The Department did not receive any similar comments regarding PBMs acting for automobile insurers under the no-fault insurance law; therefore, the proposed rule did not include an exemption for PBMs performing services for automobile insurers. However, given the Department's existing supervision of the no-fault insurance space, the Department agrees with the commenter that extension of the exemption to cover PBMs performing services for automobile insurance is consistent with the intent of the proposed rule. Therefore, the only change made in response to this comment is to add automobile insurance to the exemptions under sections 452.2 and 452.3.

Comment: One commenter suggested that the Department add provisions that further expand upon the duty of good faith and fair dealing that a PBM owes to covered individuals and pharmacies and the scope of what constitutes a conflict of interest in section 452.4(a)(7), as well as limit the administrative fees a PBM may charge as authorized under Public Health Law section 280-a. This commenter also suggested that the Department receive the disclosures outlined in section 452.4 in addition to the health plans to aid in providing further oversight and regulation of PBMs.

Response: This regulation is limited to disclosure and reporting requirements set forth under Public Health Law section 280-a(b), (c), (d), and (e), which only apply to disclosure to health plans. The Department plans to

address the duty of good faith and fair dealing and PBM administrative fees in future rulemakings. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter recommended clarifying in section 452.4(a)(7) that accumulator adjustment programs are already prohibited under Chapter 117 of the Laws of 2023.

Response: Chapter 117 of the Laws of 2023 amended the Insurance Law to state that an insurance policy or contract delivered or issued for delivery in New York must apply any third-party payments, financial assistance, discount, voucher or other price reduction instrument for out-of-pocket expenses made on behalf of an insured individual for the cost of prescription drugs to the insured's deductible, copayment, coinsurance, out-of-pocket maximum, or any other cost-sharing requirement when calculating such insured individual's overall contribution to any out-of-pocket maximum or any cost-sharing requirement. Section 452.4(a)(7) requires a PBM to disclose certain information to a health plan where the PBM or any entity owned or affiliated with the PBM is responsible for managing, coordinating, or facilitating any program that restricts a manufacturer's contributions to copay discount cards or copay coupons from applying to the health plan's beneficiaries' cost-sharing requirements under the health plan. The definition of "health plan" under Public Health Law section 280-a is not limited to an insurance policy or contract delivered or issued for delivery in New York because it means an entity for which a PBM provides pharmacy benefit management services and that is a health benefit plan or other entity that approves, provides, arranges for, or pays or reimburses in whole or in part for health care items or services, to include at least prescription drugs, for a substantial number of beneficiaries who work or reside in this state. Therefore, some PBMs operating in New York still may be managing, coordinating, or facilitating accumulated adjustment programs and it would not be accurate to say that Chapter 117 prohibits accumulator adjustment programs in all cases. Therefore, no changes to the regulation are necessary in response to this comment.

Comment: One commenter supports further transparency in the industry but recommended additional clarification of provisions to lessen the burden on PBMs, such as not applying the rulemaking retroactively to

disclosure of contracts, allowing PBMs to submit disclosures up front to meet the disclosure requirements, further clarifying what is meant by "sufficient to demonstrate" that funds were used only pursuant to the contract, and addressing whether a PBM's administrative fees must be included in the accounting. This commenter also suggested adding a provision prohibiting manufacturers from including provisions in their contracts with PBMs that would require their consent for a PBM to disclose information relating to such contract when such disclosure is required by law, and to clarify that any fees paid to brokers should be specifically disclosed as brokers are not currently required to disclose financial conflicts of interest, such as payments or fees received by the broker from the PBM.

Response: The Department has reviewed these comments and has determined that any burden imposed on PBMs is a result of Public Health Law section 280-a(2) and not the rulemaking. This regulation seeks to balance between the needs of the industry with the legislative objectives embodied in the statute. Further, as to disclosure of contracts entered into prior to the effective date of this regulation, the regulation does not apply retroactively to all contracts. Rather, the provisions related to the disclosure of contracts is limited to only those contracts that relate to pharmacy benefit management services currently provided to a health plan; therefore, a PBM is not required to disclose all prior contracts that no longer relate to those services, which alleviates this burden.

Regarding the recommendation to allow PBMs to submit disclosures up front (by making such disclosure during the contracting process) rather than in response to a request from a health plan, such option is available to PBMs and would be permissible under the regulation. Indeed, it would likely lead to the absence of or limitation on such future disclosure requests made by health plans, as health plans are unlikely to request information that they already have, and therefore would further alleviate any burden on the PBMs.

The Department chose the phrase "sufficient to demonstrate" in recognition of the fact that each PBM may have different accounting and banking structures for the collection and distribution of funds in the performance of PBM services. Each PBM may also have differing contractual requirements as to when and how

such funds are collected or disbursed. In order that the regulation not upset those existing structures and contractual timelines, the Department determined that each PBM would be able to report to its health plans in a manner consistent with its existing systems. Therefore, to prescribe more stringent requirements on the specific manner of disclosure would in fact present a greater burden on some PBMs. The Department notes that while the specific manner of the disclosure is not prescribed, the requirement on its face mandates that what is shared must "demonstrate" that all "funds were used or distributed only pursuant to the pharmacy benefit manager's contract with the health plan or applicable law." That is the only requirement that must be met, and the term "demonstrate" is clear.

As to whether administrative fees must be included in the accounting, the regulation is clear that all fees received by a PBM for pharmacy benefit management services attributable to a health plan must be accounted for, and therefore, the Department has determined that the regulation is clear as to what is required to sufficiently demonstrate that all funds were used only pursuant to the contract with the health plan.

While the Department cannot prohibit manufacturers from including certain contractual provisions in their contracts with PBMs because the Department does not currently have authority to regulate manufacturers, the Department did account for the potential for any prior contractual notice requirements in the proposed regulation by providing the PBMs with a 30-day time period to disclose such information to the health plans, which the Department has determined to be an adequate amount of time for the PBMs to obtain any contractually required prior consent from a manufacturer who may have such a provision in its contract.

Finally, while outside of the scope of this regulation, the Department intends to examine issues with broker and consultant services and fees connected to pharmacy benefit management services in the near future and will address any concerns therewith in future regulations. Nevertheless, the Department notes that any payments made to brokers may be captured already in the accounting being disclosed to the health plans under section 452.2(b). Therefore, no changes to the regulation are necessary in response to these comments.

Comment: Two commenters suggested that the Department extend the 30-day timeframes for a PBM to comply with a health plan's request under sections 452.3 and 452.4 because they do not think it is sufficient, particularly when the issue at hand could be complex or nuanced, and that different disclosures will involve varying levels of work. For example, detailing the reimbursement structure for each drug at every network pharmacy would be extremely burdensome to complete within 30-days, particularly if multiple requests at once are received. One of these commenters also suggested that the allowance for a health plan to submit a written request under section 452.3 be changed from "once every six months" to no more than once per calendar year to provide both a complete and comprehensive reporting that provides all the disclosures at issue, because plan benefits may change each calendar year depending on the type of benefits a health plan client requests that a PBM administers on its behalf. The commenter also suggested that health plan requests for an accounting under 452.2 be limited to an annual or bi-annual basis because not providing such a limit could lead to limitless requests for such information.

Response: Public Health Law sections 280-a(2)(d) and 280(a)(2)(e) do not provide any timeframes for any of the statutorily required disclosures, nor do they limit the disclosure requirements to only when they are requested. As such, absent this regulation, a PBM would be required to disclose such information to the health plan on an on-going basis and regardless of whether a health plan has requested such disclosure. . The commenters' concern over hypothetical issues with the 30-day window to comply with the requirements lacks any justification or evidence within the comments suggesting that PBMs would not be able to comply within 30 days. In the first comment, the idea that a 30-day requirement will be unduly burdensome is based on the assumption that a significant number of health plans will request information and that such requests will come at the same time, but there is nothing to indicate that such a circumstance will occur. The other commenter suggests 60 days would alleviate the concerns with the timelines but provides no reasons why 60 days would be preferrable. Under Insurance Law section 2904, the Department may fine a PBM that fails to respond to an inquiry about its

business within 15 business days. Therefore, was thus the judgment of the Legislature that PBMs should be able to respond in such timeframes on these matters. The Department's rule provides a longer timeframe than if this was a demand under section 2904(a)(3) and no commenter has provided a concrete reason why additional time would be necessary. The Department believes that the proposal creates a fair balance between the need for transparency recognized in the statute and the industry need for certainty and a reasonable amount of time to comply with the disclosure requirements Therefore, the Department has determined that the current timeframes afforded to the PBMs under the regulation are sufficient and no changes to the regulation are necessary in response to these comments.

Further as it relates to section 452.2, under the proposed regulation the PBM has up to 60 days to produce an accounting. Even assuming a health plan exists that would submit "limitless requests", the health plan could only submit six such requests in a calendar year. Further, the statute makes clear the will of the Legislature that PBMs account to the health plans they serve in performing their duties. Thus, the Department has determined that the requirements of this regulation adequately balance the burdens on PBMs with the transparency and accountability that was intended by the Legislature.

Comment: Two commenters expressed concerns regarding the confidentiality of a PBM's proprietary information being provided to the health plan requesting such information, and one commenter suggested adding a mandate that a health plan must treat all information received from a PBM as confidential.

Response: Such disclosures, as required under this regulation, are a result of Public Health Law section 280(a) and not the rulemaking. While it is unclear what disclosures related to pharmacy benefit management services provided to a health plan would constitute confidential, proprietary information, section 452.3 does permit a PBM to appeal to the Department to make a disclosure determination if the health plan requests confidential information from a PBM. Also, the Department does not have authority under Public Health Law

section 280-a or Article 29 of the Insurance Law to require health plans to keep such information confidential. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter expressed overall support for the regulation and suggested adding additional provisions that would prohibit PBMs from discriminating against entities eligible to participate in the 340B Drug Program, including prohibiting PBMs from imposing requirements, exclusions, reimbursement terms, and other conditions that differ from those applied to non-340B covered entities and pharmacies.

Response: Under Public Health Law section 280-a, PBMs have a duty of good faith and fair dealing with ALL parties with whom or which they interact in performing PBM services. Thus this duty would apply to all pharmacies, including pharmacies participating in the 340B program, therefore it is not necessary to reiterate this requirement to specifically mention 340B covered entities in regulation.

Comment: One commenter expressed overall concern regarding the disclosure provisions of this regulation and requested clarity on whether sections 452.2(b) and 452.4(a)(2) are duplicative of Public Health Law section 280-a(2)(c).

Response: The disclosure provisions of concern to the commenter are provisions that are required by statute and are limited and clarified by the regulation, as authorized under Public Health Law section 280-a(2)(g). Therefore, the Department determined that it was necessary to reiterate the language of Public Health Law section 280-a(2)(c) in section 452.2(b) to clarify which section of the statute the regulation is limiting/clarifying. Further, while the language in 452.4(a)(2) is similar to the language in Public Health Law section 280-a(2)(c), Public Health Law section 280-a(2)(c), as clarified and limited by section 452.2(b), requires a PBM to account to a health plan for certain funds received by the PBM, while 452.4(a)(2) goes a step further and requires a PBM to disclose to the health plan whether an entity the PBM owns or is affiliated with (e.g., a rebate aggregator) is an entity receiving these funds that are not passed through to the health plan, and if so to specify how much of these funds

are being transmitted to the owned or affiliated entity, which acts may be considered a conflict of interest. Therefore, no changes to the regulation are necessary in response to these comments.

Comment: One commenter asserted that the actions listed under the conflicts of interest in section 452.4 could, in certain instances, not be considered conflicts of interest between the PBM and the health plan, and therefore suggested the underlined language be added to section 452.4: "Any of following activities, policies, practices, contracts, or arrangements shall be considered potential conflicts of interest for purposes of Public Health Law section 280-a(2)(e) and therefore the following information shall be disclosed to a health plan, upon written request by the health plan, within 30 days of such request."

Response: The Department agrees that the listed conflicts of interest do count as potential, rather than definitive, conflicts of interest and therefore made the suggested change.

Comment: One commenter stated that any information shared with the Department must be protected as confidential and treated as a trade secret.

Response: Section 452.3 provides that "[i]nformation obtained by the department under this section shall be treated as information obtained under Insurance Law section 2904." Insurance Law section 2904(c) in turn states in relevant part that all information, documents and material disclosed by a PBM and in the control of the Superintendent of Financial Services ("Superintendent") will be deemed confidential and not subject to disclosure except where the Superintendent determines that disclosure is in the public interest. Therefore, the Department did not make any changes in response to this comment.

Comment: One commenter asserted that Public Health Law section 280-a(2) is broadly preempted under the federal Employee Retirement Income Security Act ("ERISA") and the Centers for Medicare and Medicaid Services' Medicare Part D. In particular, the commenter asserts that the Centers for Medicare and Medicaid Services' Medicare Part D standards have already 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 stated that New

York may not impose the pseudo or de facto fiduciary duties contemplated by the statute on PBMs serving Part D plans because to do so is to dictate contractual terms between the PBM and plan, thereby regulating Part D plans.

Response: These comments are directed toward Public Health Law section 280-a(2), not the proposed regulation. They raise broad concerns about the requirements imposed by the statute without identifying any issue with the proposed regulation or suggesting alternative language for consideration by the Department. Moreover, the blanket preemption of Public Health Law section 280-a(2) asserted by the commenter is inconsistent with current case law and the position of the federal government. Accordingly, to the extent that this comment asserts that the proposed regulation is preempted in some manner because Public Health Law section 280-a(2) is preempted, the Department disagrees with this comment. The proposed regulation 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 ERISA self-funded 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.