Assessment of Public Comment for New Insurance Regulation 221 (11 NYCRR 451)

The Department of Financial Services ("Department") received comments from two trade organizations representing health plans and two individual elected officials.

Comment: Two commenters commented on the provision of Regulation 221 that requires the disclosure of PBM contract templates to the Department. One commenter noted that the requirement "will dramatically increase transparency and oversight of the industry and the generic terms of their dealings with pharmacies, including potential "clawback" and gag-rule provisions that have been used by PBMs to prevent public knowledge of their internal practices", and stated that "regulations such as these will ensure that PBMs operate in a responsible manner that does not increase drug costs and co-payments or reduce access to life-saving medications for New Yorkers". Another commenter expressed concerns about the contract template disclosure requirement, and suggested that such contracts should not be required as a condition of registration "due to the risk for confusion and the highly proprietary nature of PBM agreements", and suggested that the collection of such contracts "should be limited to those related to fully-insured State regulated health plans" situated in New York or "otherwise subject to the Department's oversight by virtue of review and approval authority set forth in Section 3201(b) of the Insurance Law."

Response: The Department agrees with the first commenter that disclosure of the PBM's generic contract template for contracts entered into by the PBM with pharmacists, pharmacies or pharmacy service administration organizations in New York will give the Department insight into PBM practices in New York and allow for transparency and appropriate regulation of PBMs by the Department. The Department understands the second commenter's concern with regards to the confidentiality of such contracts and the risk of creating confusion given that final contract terms may vary after negotiations. The Department notes that such contracts disclosed by a PBM to the Department are confidential under the statutory language and will remain in the possession and under control of the Superintendent as required by Article 29 of the Insurance Law, and notes that the Department is

aware that such templates may vary from final executed contracts when reviewing such documents. Indeed, the fact that the contract can vary may be an area of interest for further rulemaking. Thus, no changes are necessary in response to these comments.

Comment: One commenter suggested that the reporting requirements contained in the first annual report be limited to those related to fully-insured, state regulated health plans situated in New York or otherwise subject to the Department's oversight by virtue of review and approval authority set forth in Section 3201(b) of the Insurance Law, and also suggested that reporting requirements should not extend to "Medicare Part D business, self-funded ERISA plans, business that is [situated] outside of New York and not subject to the review and approval of the Department pursuant to Section 3210(b) of the Insurance Law or non-ERISA municipal and church plans situated outside of New York."

Response: The reporting requirements contained in the first annual report are in fact limited to New York state-regulated health plans and as such, for the purposes of this regulation, the remainder of this comment is not applicable to Regulation 221 and need not be addressed at this time. Thus, no changes are necessary in response to these comments.

Comment: Two commenters expressed concern with the Department's definition of "a substantial number of beneficiaries who work or reside in this state". One commenter stated that the definition could narrow the intent of Public Health Law § 280-a and could "disqualify a health plan and its PBM from its statutory obligations" and that "this definition risks the potential to exempt from this law PBMs servicing large health plans with more members outside of New York, while PBMs servicing small plans with a majority of members in New York will be included and thus unevenly obligated to pay regulatory fees and meet more stringent requirements. This lopsided burden unnecessarily jeopardizes the protection of many New Yorkers against shady PBM practices if this definition were to be adopted." The commenter suggested that the Department instead define the term "using a dual quantitative threshold that ensures the highest number of plans and their members are covered under Public

Health Law § 280-a, which standard should embrace both meaningful percentages of a particular PBM's business or a reasonable (not negligible) number of covered individuals within our state."

Another commenter suggested that the Department's definition could "exclude New York beneficiaries from protection when they are enrolled in a national plan with more out-of-state members than in-state members" and suggested that "the regulation should be rewritten to exempt only national plans whose lives covered in New York are an insubstantial number".

Response: As stated in the Regulatory Impact Statement for the proposed Regulation 221, the Department's decision to define the term "a substantial number of beneficiaries who work or reside in this state" to mean where fifty percent or more of the beneficiaries of the plan work or reside in New York, was made after carefully weighing the legislative intent of having a broad enough definition to encompass as many New York health plans as possible, with the receipt of a wide variety of suggestions on limiting/expanding this definition from interested parties (including representatives from the pharmacy benefit manager industry, independent pharmacies, chain pharmacies, health plans, and consumer representatives, among others) and ensuring an appropriate nexus to the State. The Department weighed those interests and determined that this definition appropriately encompasses those health plans that primarily serve New York State residents and employees. It is important to note that the Department's authority over PBMs extends to all PBM conduct in the state, provided that the PBM is required to register and obtain a license, provided that there is not an issue of preemption over specific conduct.

Specifically, this definition was crafted in a way to ensure that the Department would not be overreaching its jurisdictional limits by requiring PBM disclosures and obligations to health plans where a majority of those health plan's beneficiaries are located outside of New York State. However, while PBM's may also provide pharmacy benefit services to non-New York health plans that have an insubstantial number of beneficiaries

located in New York, if those PBMs provide services to even one New York health plan meeting the definition, those PBMs are required to register and submit a first annual report under this regulation.

Moreover, the provisions of Section 280-a merely afford those health plans meeting the definition certain additional protections under the law, including requiring PBMs to hold funds in trust for those health plans, and requiring PBMs to report and/or disclose certain information to those New York health plans, among other things. As such, it is especially important that those provisions affording additional protections to the New York health plans are provided to small health plans that have 50% or more of their beneficiaries residing in New York, as the smaller health plans are more likely to have less negotiating powers when it comes to disclosure of information, while the example of large health plans with more members residing outside of New York are more likely to have significant leverage to negotiate such disclosures under their contracts given their size.

Finally, the Department has not received either in its extensive pre-rulemaking outreach or in comments on the proposed rule, any statistical analyses or data to support a definition that would better encompass as many New York health plans as possible while ensuring an appropriate nexus to New York. The Department had previously contemplated using a quantitative set number of covered individuals and determined that such would have the effect of either disqualifying a majority of small sized health plans and/or including large size health plans where only a miniscule percent of its beneficiaries work or reside in New York. Given this risk, the Department declined to adopt such a definition. Indeed, neither commenter provided the number of beneficiaries that would be appropriate to use, let alone a sufficient rational basis for the number chosen to withstand challenge. Thus, no changes are necessary in response to these comments.

Comment: One commenter expressed general concerns on both this Insurance Regulation 221 (11 NYCRR 451) and the first amendment to Insurance Regulation 219 (11 NYCRR 450) as they relate to workers compensation. The commenter noted that it had general concerns with any provisions that would limit the ability of workers compensation carriers and the employers insured by them to freely contract with PBMs and openly

negotiate to reduce costs, with any provisions that may add administrative burdens and drive up the cost of medical services provided to injured workers, and any provisions that would limit the ability to tailor prescription drug benefits to each employee's unique needs.

Response: As it relates to Regulation 221, the provisions of Regulation 221 establishes the registration and first annual reporting standards required for a pharmacy benefit manager to perform pharmacy benefit management services in New York; and specifically, to establish those minimum registration standards, including the form, contents, and manner of submission of the required registration materials, and to set the contents, manner, and form for submission of those first annual reports to the Department. Because this regulation relates solely to the form, contents, and manner of submission of the PBM's registration application and First Annual report, both of which are required by the statute, the Department has determined that this regulation will not result in any way in limiting the ability of workers compensation carriers and the employers insured by them to freely contract with PBMs and openly negotiate to reduce costs, will not add administrative burdens or drive up the cost of medical services provided to injured workers, and will not limit the ability to tailor prescription drug benefits to each employee's unique needs.