



June 4, 2024

Joylynn Fix, Chair
PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700
Washington, DC 20001
EMAIL: JMatthews@naic.org

SENT VIA EMAIL

Re: 2024 Revised Proposed Charges – Draft 5/10/2024

Dear Chair Fix:

I write on behalf of the Pharmaceutical Care Management Association (“PCMA”) as a follow up to both our written comments to Regulatory Framework (B) Task Force (“Task Force”) Chair Glen Mulready on April 18, 2024, as well as on March 10, 2024, and our public comments to the Task Force, during a meeting on March 16, 2024, and to the Pharmacy Benefit Manager (“PBM”) Regulatory Issues (B) Subgroup (“Subgroup”), during a meeting on May 2, 2024.

PCMA member companies administer drug benefits for more than 275 million Americans, who have health coverage through employer-sponsored health plans, commercial health insurance plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

On behalf of both PCMA and our member companies, we would like to both thank the Task Force, the Subgroup, as well as the staff at National Association of Insurance Commissioners (“NAIC”), for the 2024 Revised Proposed Charges (“Charges”) as most recently drafted on May 10, 2024. Specifically, we appreciate the removal of consideration of the development of a model act related to PBMs. We believe this is the correct decision, based upon the reasons outlined in our letter to you from April 18, 2024.

We do suggest some minor edits to the new provision C of the May 10, 2024, version of the draft Charges, and seek additional clarity going forward.

Market Conduct Handbook

At present, the new provision C of the May 10 draft Charges states:

As the subject matter experts and to promote uniformity across the states, develop a chapter for inclusion in the Market Regulation Handbook establishing examination standards for PBMs and related regulated entities for referral and consideration by the Market Conduct Examination Guidelines (D) Working Group.



We do not oppose the language of the new provision C. However, PCMA respectfully requests some minor edits be made to the provision, to include language that matches the collaborative spirit of this process, with something along the lines of what is immediately below:

Work collaboratively with subject matter experts and the Market Analysis Procedures (D) Working Group, to promote uniformity across the states, by developing a chapter for inclusion in the Market Regulation Handbook establishing examination standards for PBMs and related regulated entities for referral and consideration by the Market Conduct Examination Guidelines (D) Working Group.

Additionally, we respectfully request further information related to the process forward, timelines, and the details related to market conduct exams as a subject matter. And because these details have not yet been determined, PCMA respectfully requests that we and our member companies be afforded the opportunity to be included in the process related to any new language in provision C.

As PBM laws have developed and matured across the country, new laws related to market conduct exams have followed. Because of the rapid pace of these ever-increasing number of laws, state regulators oftentimes grapple with an increasingly broad and complex set of issues relevant to a market conduct exam for a licensed PBM. Regular input from PCMA and its members throughout the development of a chapter for inclusion in the Market Regulation Handbook, will allow the NAIC to benefit from the knowledge that PCMA's member companies have gained through current market conduct exams in multiple jurisdictions.

PCMA and its member companies look forward to working with the NAIC and its various working groups and subgroups in their efforts regarding market conduct exams and potential changes to the Market Regulation Handbook. We believe PCMA is uniquely positioned to partner with the NAIC as it further develops this important work and we offer our partnership with any additional PBM efforts, including those related to the Charges, where the NAIC believes our involvement may be valuable.

We again thank the Subgroup, the Task Force, and NAIC staff, for considering our comments on this important matter. If you need any additional information, please reach out to me at: (pfjelstad@pcmanet.org).

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Legal & Regulatory Affairs
PCMA

CC:
Jolie Matthews, Senior Health and Life Policy Counsel, NAIC

Enclosures (1)



April 18, 2024

The Honorable Glen Mulready, Chair
Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700
Washington, DC 20001
EMAIL: JMatthews@naic.org

SENT VIA EMAIL

Re: 2024 Revised Proposed Charges – Draft 2/29/24

Dear Chair Mulready:

I write on behalf of the Pharmaceutical Care Management Association (“PCMA”) as a follow up to both our written comments to you on March 10, 2024, as well as our public comments to the National Association of Insurance Commissioners (“NAIC”) Regulatory Framework (B) Task Force (“Task Force”) meeting on March 16, 2024. Specifically, on behalf of both PCMA and our member companies, we would like to expand upon the NAIC’s 2024 Revised Proposed Charges (“Charges”) as drafted on February 29, 2024. Generally, these Charges as revised and proposed would make changes to the Pharmacy Benefit Manger (“PBM”) Regulatory Issues (B) Subgroup (“Subgroup”).

PCMA is a national trade association representing pharmacy benefit managers (“PBMs”). PCMA member companies administer drug benefits for more than 275 million Americans, who have health coverage through employer-sponsored health plans, commercial health insurance plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

We appreciate the Task Force’s willingness to revisit the purpose of the Subgroup and its Charges. As indicated during past Task Force and Subgroup meetings discussing the Charges, the Charges are not reflective of the current landscape of the pharmaceutical supply chain or the regulation of that supply chain at the state and federal levels.

Any New Working Group Should Focus on the *Entire* Pharmaceutical Supply Chain

As we have previously outlined in our written comments from March 10, 2024, as well as oral comments on March 16, 2024, to the Task Force, it is important to remember the relationships between **all of the parties** that are in the pharmaceutical supply chain. Payors, such as health plans, labor unions, employers, and government entities often contract with PBMs to manage the pharmacy component of the health benefit on the payor’s behalf. Payors dictate the terms of the contracts with the PBMs, and the PBMs perform the functions required of them. One of the

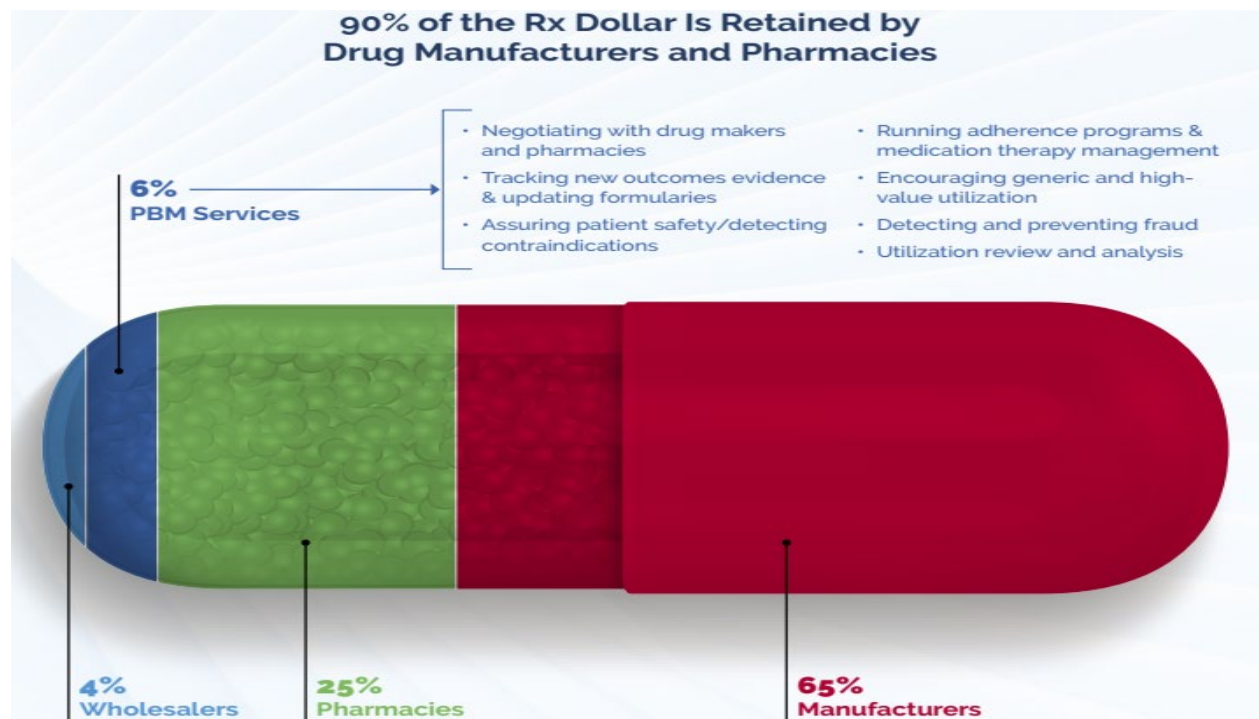
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key functions for a PBM in the context of this relationship is to contract with pharmacies that will dispense prescription drugs to the payor's enrollees.

The existing *2024 Revised Proposed Charges – Draft 2/29/24* document would change the Subgroup into a “Pharmaceutical Benefit Management Regulatory Issues (B) Working Group.” The Charges within the document focus primarily on PBMs. This is a mistake.

It is important for the NAIC to focus on all of the parties to the transaction because manufacturers and pharmacies retain 90% of each dollar that enters into the prescription drug eco system, as outlined in the graphic below.



Regulatory action that impacts just one entity within the supply chain, will no increase transparency, nor will it lower the cost of prescription drugs.

Model #22 is not appropriate for PBM Regulation

PCMA opposes the adoption of Charge C within the Revised Proposed Charges. If adopted, Charge C would direct a future Working Group to “[r]eview and consider any necessary updates to the Health Carrier Prescription Drug Benefit Management Model Act (#22) out of the emergence of greater regulation in the prescription drug ecosystem.” PCMA believes this proposal is ill-advised and **should not be adopted** for several reasons.



First, there does not appear to be a consensus or even an appetite to develop model language regarding PBM regulation. One point that became clear during the discussion that occurred in 2021, during a meeting of the Plenary Committee on the then-proposed Pharmacy Benefit Manager Licensure and Regulation Model Act ("PBM Model"), is that there are several different approaches to regulating PBMs. It was also clear that states preferred their particular version of PBM regulation. And it was stated that it would be impossible to reach a consensus on one preferred approach. By the time the NAIC considered the PBM Model, almost every state legislature had already determined how they wanted to regulate PBMs. Moreover, most regulators did not want to adopt a model that did not conform with their state legislature's preferred approach.

There is no indication that anything has changed since the NAIC voted on the proposed PBM Model, which would warrant the NAIC considering new PBM model language. If anything, state legislatures and regulators are more wedded to their particular state approach now than before since they have been implementing and fine-tuning that approach over the last few years making it less likely that the NAIC could develop one preferred approach to regulate PBMs.

Second, the Health Carrier Prescription Drug Benefit Management Model Act ("Model 22") is an inappropriate vehicle for updating PBM regulation. Model 22 does not regulate PBMs; it regulates health carriers that utilize PBMs. This approach presents a couple of major issues. First, Model 22 does not apply to the entire PBM industry. As noted in a drafting note to the Purpose and Intent section of Model 22 (Section 2), Model 22 "is not intended to address prescription drug formularies and other pharmaceutical benefit management procedures health carriers or their designees may use for purposes of workers' compensation." Presumably, it would also not apply to the health component of auto insurance or other similar coverages since these carriers are not health carriers.

Additionally, as noted above, Model 22 regulates health carriers, not PBMs. This is not the approach taken at the state level. States have chosen to regulate PBMs either directly or as third-party administrators. It would not be a good use of NAIC resources to attempt to amend a model whose underlying foundation is outdated.

Finally, Model 22 has been rejected at the individual state level. As discussed at the last Task Force meeting, not a single state has adopted Model 22. It was noted that a number of states have adopted similar legislation or provisions of the legislation. However, the references to similar legislation in the Model 22 chart on activity, includes laws that vary significantly from both Model 22 and from each other and they usually only include a few provisions, if any, from Model 22. PCMA believes that the NAIC should only amend model laws that have been accepted by and are used in various states.

Historically, the NAIC has informally followed what is referred to as the "Walter Bell rule." This "rule" suggests that prior to adopting model laws or making significant changes to an existing model, the proposed model or changes should have a commitment from a super-majority of state insurance departments that they will seek to adopt the proposal in their home state. It is difficult to imagine a super-majority of regulators making a commitment to amend legislation when they



have not adopted the underlying language in their home state. Rather than discussing whether they should amend Model 22, the Task Force would be better served by asking whether they should archive the Model.

PBMs are currently being regulated extensively by the states

As outlined above, states have already adopted the regulations that they believe are necessary to oversee PBMs in their state. The Subgroup's website already boasts the following regulatory guides:

- [State Pharmacy Benefit Manager Registration and Licensing Laws](#) (2021)
- [Compilation of State Pharmacy Benefit Manager Business Practice Laws](#) (2023)

Together these two documents include **over 200 pages of state laws (statutes and rules/regulations)**, and importantly do not include any of legislation or regulations adopted since their publication, nor any of the pending legislation currently being considered in the 2024 legislative sessions. This shows that the states are actively regulating PBMs in the way that they believe is best for their state.

Therefore, PCMA respectfully requests that the Task Force, rename the proposed Working Group to the "Pharmaceutical Supply Chain (B) Working Group and change the Revised Proposed Charges as follows:

- A. Serve as a forum to educate state insurance regulators on issues related to ~~pharmacy benefit manager (PBM) regulation and other~~ stakeholders in the prescription drug ecosystem.
- B. Gather and share information, best practices, experience, and data to inform and support dialogue and information-sharing among state insurance regulators on issues related to PBM Pharmaceutical Supply Chain regulation, such as examinations and contracting, and pharmaceutical drug pricing and transparency.
- ~~C. Review and consider any necessary updates to the Health Carrier Prescription Drug Benefit Management Model Act (#22) out of the emergence of greater regulation in the prescription drug ecosystem.~~
- D. Maintain a current listing of PBM Pharmaceutical Supply Chain laws and regulations and case law for reference by state insurance regulators.
- E. Disseminate materials and reports, via the NAIC, to the states and the U.S. territories wishing to use the information gathered by the Working Group.
- F. Monitor, facilitate and coordinate with the states and federal agencies regarding compliance and enforcement efforts regarding PBMs the Pharmaceutical Supply Chain.



We again thank the Task Force for considering our comments on this important matter. PCMA looks forward to the opportunity to continue working with the Task Force as it considers critical issues regarding the pharmaceutical supply chain and all its complexities included therein. If you need any additional information, please reach out to me at: (pfjelstad@pcmanet.org).

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Legal & Regulatory Affairs

CC: Jolie Matthews
Senior Health and Life Policy Counsel, NAIC

Enclosures (1)

March 10, 2024

Commissioner Glen Mulready
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700,
Washington, DC 20001
EMAIL: JMatthews@naic.org

SENT VIA EMAIL

Re: 2024 Adopted Charges and Future of the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

Dear Chair Mulready:

I write on behalf of the Pharmaceutical Care Management Association ("PCMA") to provide our comments regarding both the 2024 Adopted Charges related to, as well as the future of, the Pharmacy Benefit Manager ("PBM") Regulatory Issues (B) Subgroup ("Subgroup"). We appreciate the willingness of the Regulatory Framework (B) Task Force's ("Task Force") to revisit the future purpose of the Subgroup and its adopted 2024 Charges. As indicated during 2023 meetings of both the Task Force and the Subgroup, the adopted 2024 Charges do not reflect the current landscape of the pharmaceutical supply chain, nor the relevant state and federal laws already enacted.

PCMA is a national trade association representing pharmacy benefit managers ("PBMs"). PCMA member companies administer drug benefits for more than 275 million Americans who have health coverage through employer-sponsored health plans, commercial health insurance plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others. PBMs use a variety of benefit management tools to help these plans provide high-quality, cost-effective prescription drug coverage to plan beneficiaries.

As PCMA has previously stated to both the Task Force and the Subgroup, it is important to remember the relationships between **all of the parties** in the pharmaceutical supply chain. Payors, such as health plan sponsors that include employers and labor unions, as well as government entities, often contract with PBMs to manage the pharmacy benefit for a health plan enrollee – the covered individual. Payors dictate the terms of the contracts with the PBMs. The PBMs then fulfil the contracted terms.

In building a network of pharmacies for their payor clients, PBMs enter into contracts with pharmacies on the payer's behalf. As part of the contract, the parties agree to reimbursement terms, which include ingredient costs (for the actual pharmaceutical dispensed) and dispensing fees (for the costs of dispensing the drug).

Many pharmacies contract into buying groups called pharmacy services administrative organizations ("PSAOs") that negotiate with PBMs on a pharmacy's behalf. From a pharmacy's perspective, this is done to secure favorable contract terms with PBMs on the reimbursement side and favorable price terms on the purchase of drugs from wholesale distributors (i.e., the wholesalers who own the largest PSAOs in the country). In fact, the largest three wholesale distributors in the country, who in turn own the largest PSAOs sell most of the pharmaceuticals in the country. These sales and their subsequent distribution are not limited to specific states or

regions. The terms of the contracts between payors and PBMs, just like those between PSAOs/wholesale distributors and pharmacies, are confidential. In other words, the prices that pharmacies pay to wholesale distributors for drugs are not known by the PBMs and payors.

Moreover, PBMs are already regulated extensively by the states. The Subgroup's website even lists many of these laws. However, since the NAIC's lists were last updated in 2021 and 2023, they do not include the many new state laws both enacted since they were last updated. Nor do they include those currently undergoing debate in state legislatures across the country. Here are links to a listing of state laws so far compiled by the Subgroup:

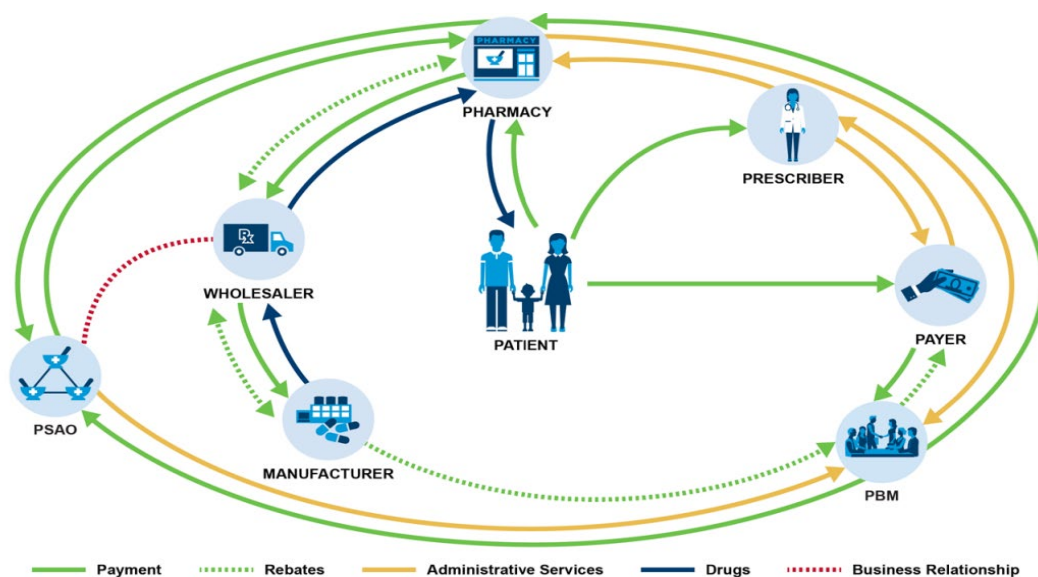
- [State Pharmacy Benefit Manager Registration and Licensing Laws](#) (2021)
- [Compilation of State Pharmacy Benefit Manager Business Practice Laws](#) (2023)

Together, these two documents include **over 200 pages of laws aimed at regulating PBMs.** This shows that states are more than active in their regulation of PBMs. And they are doing so in a manner that they feel best suits their specific state needs.

Recommendation for Subgroup

Adoption of the NAIC's PBM White Paper presents the Task Force with an opportunity to revisit how best to modify the focus of the Subgroup. Further, PCMA recognizes that certain states feel it important to have tools for the oversight of the pharmaceutical supply chain. .

Therefore, we recommend that the PBM Subgroup be disbanded, having completed its charges, and a new **Pharmaceutical Supply Chain Subgroup** be established. The creation of a new Subgroup provides a fresh start while also building on the previous work that the Task Force and the PBM Subgroup have already completed. As outlined in the graphic below, the pharmaceutical supply chain includes many different entities, even before an individual receives a prescription drug as a covered benefit.



By focusing on all aspects of the pharmaceutical supply chain, a re-focus of the Subgroup to this larger ecosystem allows regulators to ensure proper visibility of all of the entities that impact the costs and access associated with prescription drugs in their state.

Recommendations for 2024 Charges

Some proposed charges for this new Pharmaceutical Supply Chain Subgroup could include the following:

- Monitor, report, and analyze developments related to the pharmaceutical supply chain, including such entities as, pharmaceutical manufacturers, wholesale distributors, PSAOs, PBMs, health plans/insurers, and pharmacies – the role each entity plays in the supply chain and make recommendations to the Regulatory Framework (B) Task Force regarding NAIC strategy and policy with respect to those developments.
- Monitor, facilitate, and coordinate best practices with the states and the federal government related to the pharmaceutical supply chain and the role of the different entities within the chain.
- Survey state-enacted laws, including the relevant statutes and administrative rules/regulations, including those pertaining to pharmaceutical supply chain entities, to determine whether there are areas of consensus that could serve as a basis for findings to report to the Regulatory Framework (B) Task Force.

We thank the Task Force for considering our comments on this important matter. PCMA looks forward to the opportunity to provide input to the Task Force as it considers important pharmaceutical supply chain issues and all of the complexities included therein. If you need any additional information, please contact me at pfjelstad@pcmanet.org.

Sincerely,



Peter Fjelstad
Assistant Vice President, State Legal & Regulatory Affairs

CC: Jolie Matthews
Senior Health and Life Policy Counsel, NAIC