Request for Comments and Data on Additional Market Conduct Practices by Pharmacy Benefit Managers in New York State

The New York State Department of Financial Services ("Department") is inviting submissions of comments, data, or documented evidence from the public related to pharmacy benefit manager ("PBM") practices in New York State.

Insurance Law § 2906 requires the Department to establish, by regulation, minimum standards for the conduct of PBM's in New York. The statute requires the Department to make rules addressing "conflicts of interest[,]" "deceptive practices[,]" "anti-competitive practices[,]" "unfair claims practices[,]" "pricing models used by [PBMs] both for their services and for the payment of services to the [PBM,]" "contracting with network pharmacies and other providers," and "protection of consumers." Public Health Law § 280-a authorizes the Department to establish rules "defining, limiting, and relating to the duties, obligations, requirements and other provisions relating to pharmacy benefit managers" including the PBMs' duty and obligation to "perform pharmacy benefit management services with care, skill, prudence, diligence, and professionalism" and the PBM's "duty of good faith and fair dealing with all parties, including but not limited to covered individuals and pharmacies."

After the statute was signed into law, the Department sought input from the industry, health plans, pharmacy groups, state and federal regulators, and the general public on the issues facing the prescription drug distribution system and how the Department could best satisfy the mandate imposed by the Legislature. As part of that campaign, the Department published seven requests for information and established a public email account that allowed anyone to submit general inquiries, complaints, or comments concerning the PBM industry.

In August 2023, the Department proposed an initial set of PBM market conduct rules ("Proposed Regulations") based on stakeholder engagement. While there was significant support for the Proposed Regulations, some comments raised concerns about the potential impact the Proposed Regulations would have on health plans. Other comments showed there was widespread confusion over the intent of some provisions; therefore, the Department decided that the Proposed Regulations required additional review and potential revision.

While the Department withdrew the Proposed Regulations and is reproposing more tailored regulations ("Updated Regulations"), the Department believes that the Proposed Regulations sought to address important issues. As the Department weighs the best options to address these issues, the Department seeks public comments, evidence (including written datasets, cost analyses, comparative data, studies, and documented facts), and personal experiences from any interested parties related to the following areas related to PBM conduct in New York State:

- **Minimum Network Adequacy Requirements**
    1. What is the most appropriate way(s) to measure the adequacy of a pharmacy network? How should costs of establishing and maintaining that network be factored into the measurement?
    2. What impact(s) would requiring PBMs to offer pharmacy networks that meet certain patient access standards have on consumers and health plans?
    3. What impact(s) do limited pharmacy networks ("Skinny Networks") have on consumers access to pharmacy services? How do Skinny Networks affect costs for health plans and consumers?
    4. How much cost savings are attributable to the use of Skinny Networks? How does use of Skinny Networks benefit consumers?

- **Limits on Midyear Formulary Changes**
    1. What is the impact(s) of midyear formulary changes on consumers, e.g., when a drug is either removed from a formulary, or cost-sharing or usage requirements are materially increased midyear when the consumer is unable to switch to a new plan? How do these changes effect the medical treatment for consumers who are prescribed a drug subject to a midyear formulary change? How do these changes effect the overall cost of healthcare?
    2. Are sufficient options available to consumers to deal with the impact of a midyear formulary change that removes the drug or materially increases the cost-sharing for a prescription drug the consumer is prescribed?
    3. How much notice should be provided to consumers before a midyear formulary change goes into effect?
    4. What impact do midyear formulary changes have on costs for consumers?
    5. How much, on average, do midyear formulary changes save health plans?

- **Use of Drug Manufacturer Rebates**
    1. How do PBMs and/or health plans ensure that health plans have total transparency into the rebate process?
    2. Do rebates (and the incentives they create) conflict with the PBM's obligation to health plans to lower overall drug costs and foster patient access to generic options? If so, what are the best ways to address those conflicts?
    3. What impact(s) would a requirement to pass through all rebates to health plans have on costs of health coverage?
    4. Are there other ways to ensure that the benefits of drug rebates are passed through to consumers?

- **Aberrant Quantity/Product List Restrictions on Pharmacies**
    1. What is the purpose of aberrant quantity/product lists?
    2. What is the basis for a PBM to claw back payments from pharmacies related to the pharmacy dispensing "aberrant quantities" of prescriptions?
    3. What is the basis for a PBM to limit prescriptions dispensed by a pharmacy within a "therapeutic category"?
    4. Are these restrictions applied equally to all pharmacies, including pharmacies owned by or affiliated with PBMs?

5. How do these restrictions impact patient access to the drugs placed on such lists?
6. How do PBMs determine which drugs are placed on an aberrant products list?

The Department will accept comments on issues or concerns any interested parties or members of the public believe are relevant or appropriate for consideration. In particular, the Department would appreciate evidence, data, and descriptions of experience more than position statements. Please do not include any confidential information, including but not limited to protected health information.

Responses should be emailed to PBMregs@dfs.ny.gov by May 1, 2024, with "PBM2024-01" included in the subject line. Failure to include "PBM2024-01" in the subject line may result in your comment not being considered.