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NYS DFS Revisits PBM Regulation with Scaled-Back Draft Rules

Health Care Law Brief on **February 16, 2024**

On February 6, 2024, the New York State Department of Financial Services ("DFS") released "pre-proposed" consolidated rulemaking related to the business practices of Pharmacy Benefit Managers ("PBMs") licensed to operate in New York.

The draft regulations represent DFS's latest attempt to promulgate PBM market conduct rules following state PBM licensing legislation that was enacted in 2021. In August 2023, DFS issued proposed regulations addressing consumer protection, conflicts of interest, and transparency issues related to PBM industry practices, including a dispensing fee of $10.18 per drug claim to be paid to pharmacies, but the proposed regulations were later withdrawn by the agency in October 2023 following the public comment period.

DFS's announcement of the draft regulations and pre-proposal comment period stated that the draft regulations were informed by DFS's "extensive outreach to industry, health plans, pharmacy groups, state and federal regulators, and the general public."

Proposed Changes

Although not as stringent as DFS's August 2023 proposed regulations, the latest draft regulations seek to restrict a wide range of PBM practices and impose certain administrative requirements, including a more onerous notification requirement in the event of a PBM change in control. If ultimately adopted by DFS, the draft regulations would:

- Prohibit PBMs from barring in-network pharmacies from providing mail order or delivery services;
- Require PBMs to allow pharmacies to exchange information with PBMs electronically;
- Require PBMs to maintain accurate, online drug formularies (lists of covered prescription drugs) and pharmacy directories;
- Require PBMs to publicly post a telephone number and email address for consumer inquiries and impose mandatory PBM response timelines for consumer inquiries;

- Prohibit PBM “steerage” towards larger pharmacies that have an affiliation or other relationship with the PBM;
- Set reimbursement for pharmacies at no less than what an affiliated PBM pharmacy receives in the same network;
- Prohibit certain other PBM practices, including removing a drug from a formulary or denying drug coverage without regard to the plan design, or imposing “gag clauses” on pharmacies; and
- Require PBMs to apply consistent audit and recoupment standards across pharmacies.

Notably absent from the draft regulations is the proposed minimum “professional dispensing fee” of $10.18 from the August 2023 proposed rules.

The draft regulations contemplate an enforcement date beginning July 1, 2025. Existing contract terms that conflict with newly proposed network pharmacy contract restrictions would be voided and superseded by the draft regulations after January 1, 2027. ERISA/self-insured plans are not expressly excluded from the scope of the draft rules, unlike the Medicare Advantage and Worker’s Compensation plans that are excluded.

Next Steps

The 10-day “pre-proposal” outreach comment period for the draft regulations ends today, February 16, 2024. Should DFS elect to formally propose the draft regulations, the proposed regulations will be subject to a 60-day formal comment period upon publication in the State Register.

In addition to seeking initial public comments on the draft regulations, DFS announced it is soliciting information and data from the public by May 1, 2024 regarding the market conduct of PBMs as part of its continued regulatory efforts. DFS’s request for information specifically includes requests related to minimum network adequacy requirements, midyear formulary changes, drug manufacturer rebates and prescription drug dispensing restrictions.

Proskauer will continue to monitor and provide updates on developments related to the DFS PBM regulations.

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