STATE OF WISCONSIN
Department of Employee Trust Funds
**Robert J. Conlin**
SECRETARY

Wisconsin Department
of Employee Trust Funds
PO Box 7931
Madison WI 53707-7931
1-877-533-5020 (toll free)
Fax 608-267-4549
etf.wi.gov

# *Correspondence Memorandum*

**Date:** February 11, 2019

**To:** Group Insurance Board

**From:** Jeff Bogardus, Pharmacy Benefit Programs Manager
Office of Strategic Health Policy

**Subject:** Proposed Federal Regulation Affecting Drug Manufacturer Rebates

**This memo is for informational purposes only. No Board action is required.**

**Summary of the proposed regulation**
On January 31, 2019, the Department of Health and Human Services (HHS) announced a proposed rule change to eliminate the "safe harbor" provisions that currently allow rebates to be negotiated in the Medicare and Managed Medicaid lines of business. The proposed regulation (42 CFR Part 1001), has three provisions:

1. Removes the "safe harbor" for rebates for Medicare Part D plans and Employer Group Waiver Plans (EGWP). Currently, negotiated rebates are protected by the "safe harbor," which ensures that rebate business arrangements between buyers and sellers are not seen as "kickbacks" -- which are illegal under federal law. This proposed regulation would eliminate that "safe harbor".

2. Creates a new "safe harbor" for Point of Sale Rebates. As currently written, the proposed regulation would allow some rebates to be negotiated if the benefit of that rebate can be provided to the consumer at the point of sale (i.e., the pharmacy). These rebates would be administered as a chargeback between the pharmacy and the drug maker.

3. Creates a new "safe harbor" that allows PBMs to collect fixed administrative fees from drug makers. It is unclear whether the rule would allow these protected, fixed fees to be shared with a PBM's clients. Nonetheless, this "safe harbor" tries to limit the ability of traditional PBM models to make up for lost rebate revenues by charging drug makers other service and administrative fees, in place of rebate revenues.

Reviewed and approved by Eileen K Mallow, Director, Office of Strategic Health Policy
Eileen K Mallow Electronically Signed 2/13/19

| Board | Mtg Date | Item # |
|---|---|---|
| GIB | 2.20.19 | 9L |

**Proposed regulation timeline**
The proposed regulation is currently in the 60-day comment period, which ends on April 8, 2019. The administration has indicated it wants the regulation to go into effect on January 1, 2020, for Medicare Part D plans, including EGWP, and Managed Medicaid plans. However, to be in place by January 1, 2020, the provisions of this regulation would have to be considered in the pricing of Medicare Part D bid submissions, which is required in early June.

Based on feedback from Navitus Health Solutions, LLC (Navitus), the Board's contracted PBM, and other ETF research, the proposed rule includes provisions that either lack required detail to implement or are unclear about what is intended. Due to the April 8 deadline, there is a very short timeframe in which the proposed regulation could be updated with implementation details and clarifications and have Medicare Part D plans submit accurate bids and implement the new rules by January 1, 2020.

**Benefit programs that may be affected**
The Medicare Part D EGWP program administered by Navitus (MedicareRx) would be affected if this proposed regulation were implemented. The MedicareRx program provides prescription drug coverage to Medicare enrolled retirees covered by the State and WPE group health insurance programs (GHIPs).

While the proposed regulation focuses on the Medicare and Medicaid programs/plans, it should be noted that HHS and the Trump administration have also called on Congress to pass a law that extends the policy to private payors as well (e.g., commercial, non-Medicare lines of business). If Congress were to pass such legislation, the prescription drug benefit program for the non-Medicare population enrolled in our GHIPs would likely be affected.

**Potential financial impact**
Because the proposed regulation includes many areas that need clarification as well as implementation details, it is difficult to assess the financial effects on our programs until the rule is finalized. However, the following table, which lists the drug manufacturer rebates that our programs have or will collect for the 2017 and 2018 plan years, provides some perspective on potential impact:

| Year: | Commercial | Medicare Part D EGWP |
|---|---|---|
| 2017 | $ 42.3 million | $ 13.1 million |
| 2018 | $ 46.6 million | $ 16.1 million |

A list of articles covering this matter and a link to the proposed rule in the *Federal Register* can be found on the next page for reference. Staff will continue to follow this matter closely and provide updates to the Board as new information is available.

Staff will be at the Board meeting to answer any questions.

**Federal Register:**

Federal Register - 42 CFR 1001 - Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

**Articles for Reference:**

STAT News - 9/7/2018 - Rush to end drug rebates may be bad for patients, payers, and pharma

STAT News - 1/31/2019 - In bold new proposal, Trump administration pitches an end to certain drug rebates

Health Affairs Blog - 2/1/2019 - Trump Administration Releases Long-Awaited Drug Rebate Proposal

Kaiser Health News - 2/1/2019 - Winners And Losers Under Bold Trump Plan To Slash Drug Rebate Deals

STAT News - 2/1/2019 - Will Trump's new drug rebates proposal end PBMs? And 6 other burning questions about the idea

STAT News - 2/11/2019 - Prepare for grilling: 7 questions for 7 pharma execs who'll testify before Congress about prices