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7/1/21

Mr. Victor Mullins
West Virginia Office of the Insurance Commissioner

RE: 114CSR99 Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country, including our member society in West Virginia, formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our nationwide coalition serves practicing rheumatologists in charge of patient care for these illnesses.

CSRO was encouraged by the passage of HB 2263, and the ensuing draft rulemaking published by your office. We offer the following comments on the draft rule for your consideration.

§114-99-1.6 – Applicability

CSRO has long believed that the states play an important role in health policy, and this role extends to the important work of regulating the practices of pharmacy benefit managers who play a central but under scrutinized role in pricing and access for prescription drugs. It is imperative that this important work has the maximum possible effect using the full scope of states' regulatory authority. The recent United States Supreme Court decision upholding Arkansas Act 900 in Rutledge v. Pharmaceutical Care Management Association (PCMA) affirmed that state laws which affect costs, pricing, or alter incentives are not pre-empted by the Employee Retirement Income Security Act of 1974 (ERISA).[1] Such regulatory schemes are neither impermissibly connected to ERISA plans nor do they interfere with uniform plan administration by virtue of their regulation of pharmacy benefit managers administering prescription drug benefits in conjunction with such a plan. CSRO was encouraged that the draft rule recognized this principle in considering the scope of the rule's application, particularly as it relates to §114-99-5 (Responsibilities and Prohibited Acts). **As such, CSRO encourages the insurance commissioner's office to implement and enforce section §114-99-1.6 as written.**

[1] 592 U.S. No. 18-540 (2020) (https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf)

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§114-99-2.24 – Definitions: "Rebate"

The draft rule defines a rebate to include any payments "that accrue to a PBM or its health plan client, directly or ***indirectly***, from a pharmaceutical manufacturer…associated directly or ***indirectly in any way*** with claims administered on behalf of a health plan client."[2] PBMs are infamous for their lack of transparency and ability to obfuscate the sources of their revenue generation. It is no coincidence that PBMs have been able to leverage a seemingly innocuous position in the middle of the pharmaceutical supply chain to become perhaps the most profitable entities involved in it. As scrutiny of PBMs anti-competitive and harmful contracting practices has increased, PBMs have endeavored to find new means to evade scrutiny and circumvent regulation.

One of the ways that PBMs have sought to accomplish this is through the use of rebate aggregators. These subsidiary organizations have allowed PBMs to obscure the true amount of rebate dollars they receive from their plan sponsor clients.[3][4][5] They do so by improperly passing rebate dollars through the aggregator, which many plan clients are unable to independently audit.

Use of these pass-through entities could seriously compromise West Virginia's ability to confirm that patient cost-sharing reductions commensurate with rebates received in connection with the patient's prescription under §114-99-5.15 accurately reflect the total rebate received by a PBM.

Luckily, the draft rule provides that rebates include amounts that accrue ***indirectly to a PBM in any way.*** Capturing information on these amounts that PBMs are increasingly accruing indirectly via rebate aggregators will be important for verifying compliance, and the definition of rebate in the draft rule accomplishes this purpose. **As such, CSRO encourages the office of the insurance commissioner to finalize the definition of rebate as written, and use the authority provided by the legislature to effectuate the provisions of §114-99-5.15 by policy to proactively monitor the indirect collection of rebates by PBM subsidiaries.**

§114-99-5.15 - Responsibilities and Prohibited Acts

[2] Emphasis added.
[3] https://www.frierlevitt.com/articles/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/#_ftn1
[4] https://www.frierlevitt.com/articles/service/pharmacylaw/recent-successes/frier-levitt-successfully-obtains-a-6-25-million-settlement-on-behalf-of-its-plan-sponsor-client-against-a-pharmacy-benefits-manager/
[5] https://www.lehighcounty.org/Portals/0/PDF/controller/General_Reports/Highmark%20Audit%20Final%20Issue%20Public%20Release.pdf?ver=Bi-kgiHO6hwG0v9G811WZw%3D%3D

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Patients across the country face untenable out-of-pocket costs for prescription drugs. The use of coinsurance based on the list price and not the negotiated price of a drug is a large contributing factor in this problem. Under this cost-sharing design, patients pay a percentage of a drugs list price, which can amount to thousands of dollars per dose. However, the true cost of the drug to a health plan is almost always substantially reduced by rebates. In many cases this can be over 50% of the drug's list price. In effect, PBMs and health plans use patients' utilization of prescription drugs to pocket rebate dollars while also extracting cost-sharing amounts from these same patients that are not commensurate with the true cost of the drug to the plan.

§114-99-5.15 requires that PBMs and health plans reduce patient coinsurance amounts commensurate with 100% of rebates received by a PBM in conjunction with the administration of that patient's claim. This provision directly addresses the aforementioned problem and provides direct and immediate benefit to patients. **CSRO strongly supports its implementation.**

CSRO also strongly supports policy that establishes guidelines for the creation of mechanisms to calculate patient coinsurance amounts consistent with the provisions of §114-99-5.15. CSRO is aware that in some circumstances the total rebate amount owed to a PBM or health plan may not be received at or around the time of claim administration, which may create an additional opportunity for PBMs and health plans to circumvent their obligations to reduce patient coinsurance amounts under §114-99-5.15. PBMs may be incentivized to delay receipt of rebate amounts in order to obscure their connection to the dispensing of a particular prescription for a particular patient. **To that end, CSRO strongly supports the Office's proposal to require the patient's coinsurance reduction must fully reflect the amount of** "rebate received, ***or to be received***[6]." The requirement to account for future amounts to be received when calculating a patient's coinsurance amount should be finalized in some form.

CSRO is sympathetic to the possibility that there may be an inability to predict the total amount of a rebate with pinpoint accuracy at the time of claim administration due to contractual incentives that may be based on broader utilization beyond a single claim. As a result, there may be some discrepancy between cost-sharing reduction at the time of claim administration and total rebate received. **In order to ensure that coinsurance amounts are being calculated in good faith, the Office should consider implementing additional reporting requirements that allow the department to appropriately monitor compliance with this section.**

[6] Emphasis added.

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Thank you for your consideration of these comments. If you require additional information, please do not hesitate to contact us.

Sincerely,

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Madelaine Feldman, MD, FACR
President – Coalition of State Rheumatology Organizations
MFeldmanCSRO@gmail.com