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September 30, 2020

By email to lisa.larson@maryland.gov and by First Class Mail

Ms. Lisa M. Larson
Administrator, Regulatory Affairs
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, Maryland 21202

**Re: Pharmacy Services Administrative Organizations regulations and
EPIC Pharmacy Network, Inc.**

Dear Ms. Larson,

This law firm represents EPIC Pharmacy Network, Inc. ("EPIC"), a Pharmacy Services Administrative Organization ("PSAO"). EPIC's sole shareholder is Maryland-based EPIC Pharmacies, Inc., a group purchasing organization that is owned solely by approximately 1,500 independent U.S. pharmacies. We hereby submit on EPIC's behalf comments regarding the regulations that your agency has proposed to add to Title 31, Subtitle 10 of the Code of Maryland Regulations, and to request additional guidance regarding the requirements of new Maryland Code Insurance Article §15-2015.

Comments on Proposed Regulations

Chapter 49

The beginning of Subpart .03.B. is unclear. You could revise it as follows:

"A PSAO shall provide written notice to an independent pharmacy of any ownership interest or control . . ."

Chapter 50, Filing of PSAO Contracts and Amendments

1. Subpart .03.A. requires a PSAO to submit to the Commissioner various materials, "except as provided in §E of this regulation". Subsection E. does

not disclose any exceptions, but rather a variety of types of amendments that the PSAO must file. Are there any exceptions to the filing requirement?

2. Subpart .03.A.(1) requires submission of "all pharmacy service administrative contracts and amendments [thereto]". Must the PSAO submit its signed contract with each independent pharmacy, or may the PSAO submit the current form of agreement that it has with each pharmacy?
3. Is the PSAO required to submit each contract that it has entered into with a PBM, or just currently effective contracts including amendments thereto?
4. Is the PSAO required to submit amendments that a PBM demands that the PSAO sign, on behalf of the PSAO's member pharmacies, if the PBM-demanded change deals with any of the categories specified in subpart .03.E.?
5. Does the Commissioner propose an electronic submission by the PSAO of the contracts and amendments, or submission solely in paper form?
6. In subpart .03.E.(1)(a), the words "to disclosure" should be "to disclose".
7. Subpart .03.E. should not have a part (1), followed by subparts (a) through (n), but rather just parts (1) – (14).

Clarification Requested Regarding Maryland Code Insurance Article §15-2015

This section of the new law requires the PSAO to pass all remittances for claims that the PSAO receives due to a pharmacy's claims to that pharmacy "within a reasonable period of time." Unfortunately, circumstances that large PBM organizations have imposed on PSAOs necessitate that EPIC seek clarification on the effect of this law.

Specifically, in recent years Maryland and many other states enacted legislation regulating PBMs administration of Maximum Allowable Cost ("MAC") payment programs, including rights to appeal below-cost reimbursements. In calendar year 2018 both Caremark, LLC (the subsidiary of CVS Health, Inc.) and OptumRx, Inc. (the subsidiary of United Healthcare) each compelled EPIC and most other PSAOs to amend pre-existing agreements to add effective rate ("ER") requirements for its pharmacies' claims for private insurance reimbursement and for Medicaid reimbursement. What this means is that the PBM compares the amount that it initially pays on each claim to the amount that it would have paid if it had adjudicated the claim at a fixed pricing formula, through a reconciliation.

For example, a generic effective rate ("GER") for ingredients costs reimbursement might be 15% of the Average Wholesale Price ("AWP"), or "AWP - 85%" under the terminology in PBM contracts. What this means is that, if the PBM originally adjudicated the drug outside of the MAC list and under a pricing metric of AWP - 25%, then the reconciliation to the GER results in a large deficiency as compared to what Caremark originally paid on the claim. Some pharmacies dispense significant amounts of less common generic drugs that are not on a MAC list and therefore end up causing large aggregate deficiencies when those claims are reconciled to a GER.

GER programs were not new to PBMs' reimbursements of pharmacies in 2018. Medicare Part D program sponsors have had such programs in place for several years prior to 2018, under the misnomer "direct and indirect remuneration" or performance programs, and Express Scripts, Inc. has had a GER for non-Medicare claims as part of its reimbursement program since at least 2014. However, each of those programs measure the GER of each pharmacy separately. If the PBM's overall reimbursement of a pharmacy for generics were more favorable than the GER during the calendar year, then that particular pharmacy would have the amount of the "overpayments" withheld from its claim payments in the subsequent year. By contrast, the programs Caremark and OptumRx required in 2018 required measurement of the overall reimbursement to all of a PSAO's pharmacies taken together and sought to hold the PSAOs financially responsible if there was an "overpayment" after aggregating all of that data.

Caremark and OptumRx reconciled claims many months after initial adjudication, and for calendar year 2018 that ER reconciliation resulted in a substantial deficiency by the overall EPIC network of pharmacies (and the networks of other PSAOs).¹ Since EPIC is owned by its independent pharmacy members, the economic effect of such a large deficiency largely has been borne by all EPIC shareholders - regardless of whether their dispensing practices caused large ER deficiencies.

To prevent such a situation from occurring again, beginning January 1, 2019 EPIC began a system of real-time reconciliation of each claim adjudicated by Caremark and by OptumRx against the applicable effective rate, and if the initial amount that the PBM paid on the claim was higher than the ER reimbursement then EPIC holds the "over-payment" in an escrow account. Claims paid at lower than ER reimbursement result in "under-payment" credits to the pharmacy's escrow account balance.² Through

¹ The PBMs also require Brand Effective Rates (as to reimbursement for branded drug ingredients cost) and Dispensing Fee Effective Rates. The latter is often quite low, such as \$0.10 per claim, and the dispensing fee paid at claims adjudication is often much higher (such as \$0.50 per claim), which has resulted in the PBMs asserting substantial deficiencies on Dispensing Fees many months after adjudication.

² These escrows are for private insurance and Medicaid claims only. Prior to 2019, EPIC had administered the same type of reconciliation and escrowing system for the "DIR" programs for Medicare Part D plans, to prevent individual pharmacies from accruing large annual reconciliation balances that they cannot afford to pay.

a members-only computer interface, EPIC member pharmacies monitor the reconciliation of each claim to the ER when EPIC receives the remittance advice from the PBM. Other than amounts that EPIC escrows due to a pharmacy's negative ER reconciliation balance, EPIC's practice is to remit promptly all claims receipts to Maryland pharmacies, net of periodic fees pharmacies agree to pay for EPIC's services.

Maryland Insurance Code Section 15-1628.3, as effective from May 13, 2019 to present, is entitled "Fee or performance-based reimbursement related to claim adjudication" and states:

A pharmacy benefits manager or a purchaser may not directly or indirectly charge a contracted pharmacy, or hold a contracted pharmacy responsible for, a fee or performance-based reimbursement related to the adjudication of a claim or an incentive program that is not:

- (1) specifically enumerated by the pharmacy benefits manager or purchaser at the time of claim processing; or
- (2) reported on the initial remittance advice of an adjudicated claim.

Even after enactment of that statute, Caremark, OptumRx and Express Scripts have continued to reconcile to an ER claims submitted by EPIC members that operate in Maryland, and they have not reported the effect of the ER reconciliation to EPIC or the pharmacy with the initial remittance advice. EPIC's reconciliation and reporting system for Caremark and OptumRx claims has disclosed to its members the economic effect of ER reconciliation on that pharmacy's compensation on each adjudicated claim.

To date, neither OptumRx, Caremark nor Express Scripts has stated that it will exclude the claims of Maryland pharmacies made during 2020 from its reconciliation of ER claims submitted by all EPIC members. Those PBMs typically reconcile on an annual basis, and payments made as a result thereof typically are made several months after the end of the measured calendar year. For calendar year 2019, Caremark and OptumRx did not complete reconciliation with EPIC until after June 30, 2020.

Question Presented: EPIC's real-time reconciliation of claims payments to the ER reimbursement results in EPIC holding in escrow some of the amounts that Caremark and OptumRx pay due to private insurance and Medicaid claims submitted by Maryland pharmacies. Given the PBM requirements described above, and Maryland Insurance Code Section 15-1628.3 as effective, does the Insurance Commissioner consider EPIC to be in compliance with Maryland Code Insurance Article §15-2015 if it continues the escrowing system on claims for the remainder of 2020?

Clarification Requested Regarding Maryland Code Insurance Article §15-1628.3, as amended effective January 1, 2021

Through enactment of 2020 House Bill 1307, this provision in the PBM law will be as follows effective January 1, 2021:

(A) A pharmacy benefits manager or a purchaser may not directly or indirectly charge a contracted pharmacy, or hold a contracted pharmacy responsible for, a fee or performance-based reimbursement related to the adjudication of a claim or an incentive program.

(B) A pharmacy benefits manager or purchaser may not make or allow any reduction in payment for pharmacy services by a pharmacy benefits manager or purchaser or directly or indirectly reduce a payment for a pharmacy service under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payments.

Questions Presented:

1. Does this new law prohibit all PBMs from requiring ER reconciliation with regard to Maryland independent pharmacies, whether directly or through a PBM's agreement with a PSAO?
2. As a result of this law, is EPIC permitted to continue its ER escrowing system with regard to claims submitted by Maryland pharmacies for private insurance or Medicaid reimbursement?

Thank you for your attention to these comments, and for your consideration of and response to the questions presented regarding Maryland Code Insurance Article Sections 15-2015 and 15-1628.3.

Sincerely,



David L. Cahn

Cc: Mr. David Cooney, Associate Commissioner, Life and Health Insurance
Mr. Lee Jay Romero, III, President of EPIC Pharmacy Network, Inc. (by email)
Mr. Dennis Rasmussen (by email)