

January 18, 2022

Director of Regulatory Affairs
The Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, Maryland 21202

Re: HDA Comments, Draft Proposed Regulations 31.10.49 and 31.10.50, Pharmacy Services Administrative Organizations – January 2022

Dear Director of Regulatory Affairs,

The Healthcare Distribution Alliance (HDA), the national trade association representing primary healthcare distributors, appreciates the opportunity to continue its dialogue with the Maryland Insurance Administration (MIA) involving proposed regulations impacting Pharmacy Services Administrative Organizations (PSAOs). HDA offers the following comments on the proposed draft regulations 31.10.49 and 31.10.50 and respectfully requests that the MIA take action to address the issues listed below.

In summary, HDA and its affiliated PSAO service providers are concerned that provisions included in the proposed regulations and empowering statutory provisions conflate the role of pharmacy benefit managers (PBMs) and PSAOs, hold PSAOs responsible for supply chain activities that are beyond their reasonable control, and impose unreasonable administrative burdens on PSAOs in providing timely notice to independent pharmacies in the normal course of business. HDA hopes to coordinate closely with MIA to address the following items and serve as a resource in any manner the MIA feels would be helpful.

Background

HDA members are the logistics experts within the healthcare supply chain, working around-the-clock to ship pharmaceutical and medical products safely and efficiently to pharmacies, hospitals, and other healthcare providers nationwide. Distributors are unlike any other supply chain entity – their core business is to ensure medicines and other critical medical supplies travel from manufacturers to dispensing locations safely and securely. Distributors do not manufacture, prescribe, or dispense medications to patients. Additionally, HDA members do not influence beneficiaries’ pharmacy benefit design.

Some HDA members may also provide an array of value-added financial and administrative focused services to their distribution customers. For community and small chain pharmacies specifically, some distributors offer voluntary PSAO services to help navigate and manage third-party payer and PBM relationships. These PSAO services are important to pharmacy partners, relieving administrative burdens and enabling them to focus on patient care instead of many of the other time consuming, “back-office” small businesses responsibilities.

PSAOs are not PBMs and do not function in the same manner. Unlike PBMs, PSAOs do not influence patient out-of-pocket costs, medication costs to health benefit plans, network design, formulary design, or other aspects within the pharmacy benefit network. PSAOs strictly support community and small chain pharmacies through administrative support and plan/PBM coordination.

With that in mind. HDA offers the following comments:

- *31.10.49 Section .03 – (E)* addresses the processes through which PSAOs may obtain affirmative consent from each independent pharmacy respecting the disclosures outlined in 31.10.49.03(A) – (C) which may be “delivered by electronic means” (as defined in 31.10.49.02(B)(3)). Unless and until such affirmative consent is provided, 31.10.49.03(E) makes clear that such disclosures may not be “delivered by electronic means,” thus suggesting that other physical means (e.g., FAX, U.S. Mail, etc.) must instead be utilized in each such case. Securing such consent from independent pharmacies prospectively seeking to join a PSAO, and from contracted pharmacies who have already agreed to receive notices electronically from their current PSAO in a manner not compliant with 31.10.49.03(E), while concurrently complying with each provision of 31.10.49.03 presents a significant challenge considering: (i) the large size of many PSAO networks’ membership; (ii) the significant costs associated with the use of physical notification means; (iii) the contents and frequency of the requisite disclosures; and (iv) the commonplace use of Email in today’s PSAO landscape.

For example, because PSAOs generally execute a high volume of contracts, amendments, payment schedules, and reimbursement rates on behalf of independent pharmacies throughout the year, administering disclosures pursuant to 31.10.49.03(A) would incur significant internal and environmental resources where physical disclosure must be provided. Conversely, disclosures pursuant to 31.10.49.03(B) and (C) would likely be infrequent yet far more informational in nature than their 31.10.49.03(A) counterparts, yet 31.10.49.03 fails to account for such inherent differences. In either case, the significant costs of administering physical disclosures outweigh the benefits independent pharmacies may receive in receiving such disclosures via non-electronic means and, consequently, create barriers around PSAOs’ timely disclosures to independent pharmacies in the normal course of business.

Given that both PSAOs and independent pharmacies are accustomed to using Email as the primary means of communication, HDA recommends that 31.10.49.03(E) be modified to: (1) eliminate the affirmative consent requirement for contracted pharmacies who have already consented to receive notices from their PSAO electronically; (2) simplify the preliminary disclosure and affirmative consent requirements for independent pharmacies seeking to join a PSAO in order to mitigate the administrative burden on PSAOs in issuing notices in both electronic and physical formats; and (3) more precisely account for the inherent differences between disclosures delivered pursuant to 31.10.49.03(A) – (C). Conversely, HDA recommends that Email be removed from the definition of “delivered by electronic means” (as defined in 31.10.49.02(B)(3)) or otherwise excepted from the affirmative consent requirements under 31.10.49.03(E).

- *31.10.49 Section .04 and .05* – These sections are mostly irrelevant to a PSAO contract because such ‘appealable’ activity do not exist and are not in the purview of a PSAO; a possible exception that may be considered appealable is when a PSAO is acting in its administrative capacity facilitating central pay. Reimbursement appeals are made to PBMs, and are often a service a pharmacy services administrative organizations assists its pharmacy customers with. PBMs are the entities who set prices/reimbursement for the independent pharmacies and the entity that must be appealed to. HDA recommends that these sections be struck from the proposed regulation. If the section is to remain, HDA respectfully requests for the MIA to clarify what specific types of appeals the MIA would foresee a pharmacy making directly against a PSAO.
- *31.10.50 Section .03 – A(2)* addresses forms and amendments to contract forms between PSAOs and PBMs. Such documents originate with and are exclusively controlled by the PBMs and not the PSAOs.

While the regulation attempts to be consistent with the statute, HDA strongly believes that as presented, there is a fundamental statutory and regulatory impossibility to require a PSAO to file contract forms and amendments to contracts forms for an entity for which the PSAOs does not exercise any control.

Furthermore, in subsection C. of the same section, the regulation further confuses the issue through the use of the word *'its'* when referencing

'A PSAO that receives written notice from the Commissioner that *its (emphasis added)* contract forms or amendments to a contract form contains defects...'

The use of *'its'* appears to refer back to the PSAO's contract forms and amendments to contract forms – the ones that originate with the PSAOs. This creates an internal inconsistency within the entirety of the section.

Subsection E creates submission requirements to the MIA for *'a PSAO that amends any of the following...'*. The subsection also creates uncertainty due to the fact that PSAOs do not amend contracts that they do not originate. The PSAOs may request that the PBMs make amendments to the PBM originated contract forms, but the regulatory language only speaks to when a PSAO controls the amendment process. Such a situation would only exist for a PSAO contract as defined in .02(6) of this section.

Finally, because the PBMs are in control of the contract forms and amendments to contract forms that originate with them and because they already have an affirmative duty to report to the MIA such contracts under 31.10.48, we believe that the MIA could assist in a regulatory manner by inserting language that allows any submissions that a PBM makes pursuant to 31.10.48 to also fulfill the requirement for the submission of such contract forms and amendments to contract forms that originated with the PBMs that exists in 31.10.50.

As MIA is aware, HDA has appreciated the opportunity to engage in these discussions, and we believe that statutory clarity may ultimately be necessary to address the above concerns. Generally speaking, HDA believes that the proposed regulations and empowering statute "Blur the lines" between the PSAO and PBM industry and hold PSAOs responsible for the actions and activities of PBMs.

Conclusion

HDA appreciates the opportunity to provide these comments and hopes our perspective is taken under consideration as MIA moves forward with rulemaking. We look forward to continuing discussions with MIA. If you have any questions or require additional information, please do not hesitate to contact Kelly Memphis at kmemphis@hda.org.

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance (HDA)