

August 20, 2021

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

Dear Director of Regulatory Affairs,

The Healthcare Distribution Alliance (HDA), the national trade association representing primary healthcare distributors, submits these public comments on the proposed draft regulations on Pharmacy Services Administrative Organizations (PSAOs), [31.10.49 and 31.10.50](#).

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 not manufacturing, and they do not prescribe or dispense medications to patients. Their primary role is to ensure medicines and other critical medical supplies travel from manufacturers to dispensing locations safely and securely.

In addition to their role as distributors, HDA members provide an array of financial and administrative services to their customers. Pharmacy Services Administrative Organizations (PSAOs) are one of the many ways some distributors support their pharmacy customers, enabling them to focus on patient care and their business. Independent pharmacies rely on PSAOs to interact with third-party payers and Pharmacy Benefit Managers (PBMs). PSAOs provide valuable services to independent pharmacies in their relationship with third-party payers and PBMs. These organizations also relieve administrative burdens for these small business owners and enable them to focus on patient care.

Comments

COMAR 31.10.49.02 Definitions:

For clarity purposes, we recommend that the definition of “Contracted pharmacy” include a cross reference to Insurance Article §15-2001(b) when referring to independent pharmacy in Chapters 49 and 50.

COMAR 31.10.49.03 Disclosures to an Independent Pharmacy

E(1) MIA should further clarify what would constitute affirmative consent of pharmacy to delivery by electronic means; or make clear that no additional consent is required if contracted pharmacy and PSAO have agreed by contract that electronic delivery is acceptable.

E(2)-(4) The requirements related to electronic delivery and consent are overly broad and places an undue burden and impacts the operational efficiencies of PSAOs that in turn could have a negative impact on contracted pharmacies. The COVID-19 pandemic has required organizations to streamline and develop efficient processes to communicate with their customers. The ability to communicate electronically with contracted independent pharmacies is cost efficient for the PSAO and pharmacies and critical to ensuring that contracted independent pharmacies receive critical and vital information in a timely manner.

The requirements which allow a pharmacy to withdraw consent from receiving electronic notice would require PSAOs to manage different processes to communicate with contracted pharmacies. If enough contracted pharmacies withdraw consent to electronic delivery, PSAOs will need to engage in large mailing campaigns to send documents in a short period of time (i.e., 5 days of signing a PBM contract or amendment). In addition, this requirement will also place a financial burden on pharmacies. PSAOs will have to pass on the cost of sending copies of documents to contracted pharmacies, specifically as it relates to copies of PBM contracts where such agreements including applicable rate schedules could exceed a hundred pages. At a minimum, the MIA should exclude electronic mail from the consent requirements. Electronic mail is a standard mode of communication, and one that is often preferred by pharmacies. (Electronic mail is a very common communications tool used by many pharmacy benefits managers and other payers to communicate with pharmacies)

COMAR 31.10.49.04 Internal Appeal Procedures

We believe that any requirements related to the establishment of an internal appeals process as outlined COMAR 31.10.49.04 be further clarified or removed. Most pharmacy complaints are typically related to a claims issue or audit by a PBM. PSAOs have no hand in the claim's submission and claim adjudication/audit process as such provisions.

COMAR 31.10.50.02 Definition

For clarity purposes, we recommend that the definition of "Contracted pharmacy" include a cross reference to Insurance Article §15-2001(b) when referring to independent pharmacy in Chapters 49 and 50.

COMAR 31.10.50.03 Submission Requirements

(A)(2) – MIA should provide additional clarification regarding the responsibility of a PSAO to file a form agreement that does not originate with or is not drafted by the PSAO. PSAOs typically contract with PBMs on the PBM contract form and would not have access to the PBMs form agreement.

(C)MIA should provide additional clarification that only the documents that were disapproved are required to be refiled if for example several form agreements are included in a form filing and only one agreement is disapproved.

(E) Overall, the detail here is not needed due to the broad obligation to file amendments under .03A(1).

(J) Strike existing language and replace with: *Nothing shall prohibit a PSAO from signing a pharmacy services administrative contract with a PBM on a form provided by the PBM. Such form is not required to be filed by the PSAO but shall be filed by the PBM in accordance with its obligation.*

COMAR 31.10.50.04 Noncompliant Contract Terms

(A)(1)-(6)- These provisions appear to apply to and relate primarily to the PBM and not the PSAO. Such requirements are more appropriate for regulations that apply to PBMs. PSAO typically do not include such provisions in their agreements with independent pharmacies, except for (6) which appears to apply to a PSAO contract with an independent pharmacy. Please note, there are two different contract agreements in place, contracts between the PSAO and the pharmacy as well as contracts between the PBM and the PSAO. Certain elements being sought by MIA may be within PBM contracts and not within the PSAO contracts.

Since Sections (A)(1)-(5) apply to the PBM-PSAO contract, which originates with the PBM, and do not apply to the PSAO-Pharmacy contracts, we suggest striking these sections.

In addition to the details provided above, HDA members have some general questions and comments about the draft rules:

- Under the interim guidance from MIA, PSAOs provided form contracts and templates, where applicable. Please confirm that this approach remains appropriate under the final regulations.
- Should a PSAO file a template agreement applicable to PSAO-PBM contracts even if most of the contracts between the PSAO and PBMs are based upon the PBMs' network agreements that are generated from a PBM base form? It would be more appropriate for the MIA to request the form contracts from the PBM since they are the originators of the contracts within the PBM-PSAO relationship.

Many of the PSAO requirements included in these draft regulations are controlled by PBMs and make more sense if included in a PBM regulation. The items that MIA may not want included in a PSAO contract should instead prohibit PBMs from including those items in the contracts. Regulating upstream to the point where contracts are first created would be the most prudent way to achieve the goals and requirements outlined in these draft rules. Furthermore, the goal should be fair reimbursement to independent pharmacies. This would be best achieved by requiring National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee.

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 Roxi Kozyckj at rkozyckj@hda.org.

Sincerely,



Roxolana Kozyckj
Director, State Government Affairs
Healthcare Distribution Alliance