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## **BULLETIN 21-07**

Date: March 4, 2021

To: All Pharmacy Services Administrative Organizations Providing Services in Maryland to Independent Pharmacies

Re: Regulation of Pharmacy Services Administrative Organizations – House Bill 978, Chapter 399, Acts of 2020

House Bill 978, Chapter 399, Acts of 2020 was passed by the General Assembly during the 2020 Session and became effective on October 1, 2020. This bill establishes a framework for the Maryland Insurance Administration (MIA) to regulate Pharmacy Services Administrative Organizations (PSAOs) under Title 15, Subtitle 20 of the Maryland Insurance Article, Annotated Code of Maryland,<sup>1</sup> which includes a registration requirement, a form filing requirement, and various recordkeeping and disclosure requirements.

The MIA is in the process of promulgating regulations to implement Title 15, Subtitle 20, which will include provisions addressing the PSAO contract filing requirements under § 15-2010 and the complaint process for addressing disputes and appeals brought to the MIA in accordance with § 15-2019. Draft PSAO regulations were posted for public comment on the MIA website on September 14, 2020. The purpose of this Bulletin is to establish the application process and fee for PSAO registration, and to provide interim guidance with respect to the form filing requirements for PSAOs that provide services in Maryland to independent pharmacies. The interim form filing guidance will remain effective until the PSAO regulations are finalized.

### Registration Requirements:

Beginning July 1, 2021, § 15-2002 provides that each PSAO shall register with the MIA before providing PSAO services to independent pharmacies. Beginning April 1, 2021, the MIA will begin accepting initial applications for registration from PSAOs. In order to register, an applicant shall submit the following:

- PSAO Application (available at: <https://insurance.maryland.gov/Pages/default.aspx>)

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<sup>1</sup> Unless otherwise noted all statutory references are to the Insurance Article, Annotated Code of Maryland.

- Initial application fee of \$500 (non-refundable) made payable to the Maryland Insurance Administration

The criteria for review of the application by a PSAO can be found in § 15-2005. A PSAO that has not registered with the Commissioner may not enter into an agreement or contract with an independent pharmacy or pharmacy benefit manager and may be subject to other sanctions by the Commissioner.

Once registered, the PSAO is required to apply bi-annually to renew its registration by September 30. The renewal process will include the submission of an application and payment of the \$500 renewal fee.

#### Form Filing and Other Requirements:

Under § 15-2010, a form filing is required for contracts and amendments a PSAO makes with independent pharmacies and with pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) on behalf of independent pharmacies.<sup>2</sup> Section 15-210 requires certain contract and amendment forms to be filed with the MIA at least 60 days before the contract or amendment is to become effective. If the MIA does not disapprove the forms within 60 days after the filing date, the contracts become effective upon expiration of the 60-day period. The contracts may become effective sooner if the MIA provides notice to the PSAO within the 60-day period that the filed forms may be used in Maryland. While the filing requirements under § 15-2010 became effective on October 1, 2020, Section 2 of House Bill 978 provides that a PSAO contract that is in effect on the effective date of the bill may remain in effect as long as the contract is filed with the MIA on or before July 1, 2021 and is administered in accordance with all applicable provisions of Title 15, Subtitle 20.

Until such time that the MIA adopts PSAO regulations, the MIA intends to enforce the provisions of § 15-2010 as follows:

- A contractual agreement between:
  - a PSAO and an independent pharmacy;
  - a PSAO and a PBM; or
  - a PSAO and a GPOmust be filed with the MIA if the agreement relates to services the PSAO will provide on behalf of an independent pharmacy, with respect to services the independent pharmacy will provide to beneficiaries of a “purchaser,” as defined in § 15-2001(f).
- A PSAO is only required to file the form of agreement for the contracts listed above. In other words, a PSAO must file the contract “template” that provides the basis for the various contract types the PSAO negotiates with independent pharmacies, PBMs, and GPOs. When the same template is used for multiple entity-specific agreements, the PSAO is not required to file copies of the separate contracts it makes with each individual independent pharmacy, PBM, and GPO.

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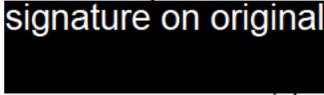
<sup>2</sup> These requirements apply to contracts under which the PSAO negotiates with purchasers on behalf of independent pharmacies per § 15-2001(d) and (f).

- Templates for any new contracts entered into on or after October 1, 2020 must be filed with the MIA at least 60 days before the contracts become effective.
- Upon receipt of a contract or amendment filing, the MIA will provide written acknowledgement to the PSAO that the filing has been received, and that the forms may become effective 60 days after the date of acknowledgement, unless the MIA provides notice of disapproval prior to the expiration of the 60-day period.
- For contracts that were already in effect prior to October 1, 2020, the PSAO must file the applicable templates on or before July 1, 2021, and must administer the in-force contracts in accordance with Title 15, Subtitle 20. Failure to comply with this requirement will result in administrative action from the MIA’s Compliance and Enforcement Unit.
- An amendment to a previously filed contract template must be filed with the MIA if the amendment implicates any issue that is expressly addressed by a Maryland insurance law related to PSAOs, PBMs, or pharmacies. Refer, for example, to Title 15, Subtitles 16 and 20.
- The MIA may disapprove a contract if the contract contains a clause or provision that violates any section of the Insurance Article, including Title 15, Subtitles 16 and 20. If the MIA discovers a violation of the Insurance Article, written notice of the violation will be provided to the PSAO, and the PSAO will be given the opportunity to correct the deficiency. In this case, a contract template does not become effective until the MIA has provided to the PSAO notice that the deficiency has been corrected.
- Contract and amendment templates required to be filed under § 15-2010 may be submitted to the MIA electronically or as paper filings. All filings must include a cover letter that contains a list of the contract forms and amendments being submitted, along with a brief description of the purpose of each form.
  - Electronic filings should be submitted in PDF format using the following dedicated mailbox for PBM and PSAO contract filings: [pbmcontractfilings.mia@maryland.gov](mailto:pbmcontractfilings.mia@maryland.gov). PSAOs are encouraged to send any emailed form filings in an encrypted or other secure format to protect confidentiality. However, PDFs should not be submitted with security features that block the “Compare Documents” tool in Adobe Acrobat, unless the PSAO provides a password to disable those features.
  - Paper filings should be mailed to: Maryland Insurance Administration, Life and Health/Rates and Forms, 200 St. Paul Place, Suite 2700, Baltimore, Maryland 21202

PSAOs are reminded that they are required to comply with each requirement of Title 15, Subtitle 20 as of the applicable effective date specified in House Bill 978. Until such time that the MIA adopts PSAO regulations, the MIA intends to exercise enforcement discretion when evaluating a PSAO’s compliance with a provision of Title 15, Subtitle 20.

Questions about the registration requirements described in this Bulletin may be directed to the MIA’s Company Licensing Unit at 410-468-2104. Other questions about this Bulletin may be directed to the Life/Health Section of the MIA at 410-468-2170.

KATHLEEN A. BIRrane  
Commissioner

By:  signature on original

David Cooney   
Associate Commissioner  
Life and Health