



### **Frequently Asked Questions**

**Version FY24 1.0 Updated: September 28, 2023**

#### **General FAQs**

##### ***Why am I Receiving this Assessment?***

[Section 21-2C-11 of the Health-General Article](#), Annotated Code of Maryland, directs the Maryland Prescription Drug Affordability Board to assess manufacturers, distributors, carriers and pharmacy benefits managers an annual assessment to fund the Prescription Drug Affordability Fund. By regulation, [COMAR 14.01.02](#), the assessment is \$1,000 per year.

##### ***What is the Maryland Prescription Drug Affordability Board?***

The Board is charged with protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products. The work of the Board is funded through the Prescription Drug Affordability Fund.

##### ***What is the Prescription Drug Affordability Fund?***

The Prescription Drug Affordability Fund is a special, non-lapsing fund administered by the Board to provide funding for its work. It is composed of revenue collected from this assessment, money appropriated in the State budget for the Fund, interest earnings, and any other money accepted for the benefit of the Fund.

##### ***Why are we being assessed for fiscal year 2024 (FY24) when we are in calendar year (CY) 2023?***

The State of Maryland's fiscal year runs from July 1 to June 30. State agencies, including the Maryland Prescription Drug Affordability Board, are currently in FY24 (ending June 30, 2024).

##### ***How do I pay the fee assessment?***

You may pay the assessment by ACH transfer, wire transfer, or check. Payment by ACH is encouraged. Please e-mail [payment.pdab@maryland.gov](mailto:payment.pdab@maryland.gov) for ACH and wire transfer instructions. Please note that if you pay the assessment by ACH or wire transfer, you will not be credited with payment unless you complete and submit the ACH/Wire Payment Voucher form.

To pay by check, please make the check payable to "Maryland Prescription Drug Affordability Board." For the payment to be credited to your entity, please **(1) enclose a copy of your invoice or (2) provide your PDAB vendor ID number and include "FY 2024 PDAB Fund."** All materials should be mailed to:

Maryland Prescription Drug Affordability Board  
16900 Science Drive, Suite 112-114  
Bowie, MD 20715

***When is payment due?***

Payment for the Prescription Drug Affordability Fund fee assessment is due by November 3, 2023. If you have not received an assessment by October 6, 2023, please contact Board staff by e-mail at [support.pdab@maryland.gov](mailto:support.pdab@maryland.gov).

***Is there a penalty if I don't pay the fee assessment by the November 3rd deadline?***

Any assessment not paid by the due date may be subject to an interest penalty. Repeated failure to pay may result in the account being declared delinquent and referred to the Central Collection Unit for an enforced collection action pursuant to State Finance and Procurement Article, Title 3, Subtitle 3, Annotated Code of Maryland, and COMAR 17.01.01. The Central Collection Unit charges the debtor a collection fee of 17 percent on all accounts referred for collection.

**Exemption FAQs**

***When is the Request for Exemption Due?***

All Requests for Exemption are due November 3, 2023.

***How do I submit a Request for Exemption?***

Please submit a completed Request for Exemption form, supporting documentation, Certificate of Business Record, and Affidavit (where applicable) by e-mail to [support.pdab@maryland.gov](mailto:support.pdab@maryland.gov) or by mail to:

Prescription Drug Affordability Board  
16900 Science Drive, Suite 112-114  
Bowie, MD 20715

***Can I submit the exception form by email/electronically?***

Yes. You may submit a scanned or electronic copy of your completed Request for Exemption form with a wet signature to [support.pdab@maryland.gov](mailto:support.pdab@maryland.gov). If you submit your Request for Exemption electronically, PDAB will respond electronically.

***What documentation do I submit in support of the Request for Exemption?***

Your organization bears the burden of demonstrating it qualifies for the exemption. The relevant supporting documentation necessarily depends on the reasons why you believe you are exempt from assessment.

Supporting documentation must be accompanied by an executed **Certificate of Business Record** (available on the Board's website) authenticating the business records.

Depending on the nature of the claimed exemption, supporting documentation may include but is not limited to:

**For carriers**, the NAIC "Annual Statement" including the cover page (signature page/jurat), Maryland State page, and Schedule T, acknowledgment from Maryland Insurance Administration of merger/change in subsidiary status, and SEC 10-K (any applicable exhibits).

**For manufacturers, distributors, and PBMs**, a discharge in bankruptcy, documentation of merger/change in corporate structure/subsidiary status (e.g., SEC 10-K and any applicable exhibits), acknowledgment from Board of Pharmacy of expiration of license/registration, expired license/registration, documentation that the business provides only non-covered products (e.g., provides gases only, product or inventory lists), and documentation that the entity does not do business in Maryland.

**If you are unable to provide any documentation supporting the claimed exemption**, you must provide an **Affidavit** (form on Board's website) from the chief operating officer, chief financial officer, or other authorized official attesting to the factual basis of the claimed exemption.

### ***What Can I Do If I Disagree with the Determination of my Request for Exemption?***

If you disagree with the determination of your Request for Exemption, you may seek reconsideration of that determination by submitting: (a) a one-time Request for Reconsideration on the form provided; and (b) additional information or documentation in support of the claimed exemption.

The Request for Reconsideration and supporting documentation (including a Certificate of Business Record) must be submitted within 15 days of the determination of the request for exemption.

Please submit additional information and documentation only. Do not resubmit the documentation submitted with the original request for exemption.

If you are unable to provide any documentation supporting the claimed exemption, you must provide an **Affidavit** (form on Board's website) from the chief operating officer, chief financial officer, or other authorized official attesting to the factual basis of the claimed exemption.

A request for reconsideration that does not include additional information or additional documentation will be denied. If the request for exemption is denied after reconsideration, the entity shall pay the assessment within 30 days of the issuance of the notice of denial. COMAR 14.01.02.02C.

### ***Last year I filed a Request for Waiver. Why Don't I See that Option this Year?***

After multiple opportunities for public comment, COMAR 14.01.02 was amended to remove the waiver process from the regulations.

### **Specific FAQs**

#### ***I am not an insurance carrier and I only sell medical devices. Am I subject to assessment?***

The Board does not issue advisory opinions in individual cases. If you believe that you are not subject to assessment, please:

1. Complete and submit the [Request for Exemption](#) form setting forth the basis of the exemption and why you believe you are exempt from the assessment (e.g., you only manufacture animal products, you no longer do business in Maryland, etc.);
2. Submit documentation that supports the basis of your exemption (e.g., filed suggestion of bankruptcy, acknowledgment from the Maryland Insurance Administration of merger, corporate documentation of merger (10-K exhibits), expired license/registration, product lists, advertising materials showing products, etc.); and
3. Submit an executed [Certificate of Business Record](#) (available on the Board's website) authenticating the business records submitted in support of your request for exemption.

#### ***What if I primarily sell non-prescription drugs, medical devices, or gases, but I happen to sell prescription drugs that make up a small percentage of my total revenue in Maryland?***

You are subject to assessment. An entity is subject to assessment if the entity is a qualifying entity under [Health General § 21-2C-11\(b\)\(1\)](#). This includes manufacturers that sell or offer for sale prescription drug products to persons in Maryland, and wholesale distributors, as defined in [§ 12-6C-01 of the Health Occupations Article](#), that sell or offer for sale prescription drug products to persons in Maryland. The assessment is not based on the volume of prescription drugs or the percentage of your revenue attributable to prescription drug products.

#### ***What if I am licensed to do qualifying business in Maryland, but do not currently sell products in Maryland that meet the definitions in [Health-General § 21-2C-11](#) (e.g., manufacturers or wholesalers that sell or offer for sale prescription drugs in the State or carriers that provides health insurance policies or contracts in the State)?***

If you are licensed to sell products that would make you a qualifying entity under [Health General § 21-2C-11\(b\)\(1\)](#), but do not currently sell those products, you may submit an exemption request stating under oath that you are not a qualifying entity under [Health General § 21-2C-11\(b\)\(1\)](#) and explaining how you do not meet the definition of a qualifying entity (e.g., I am licensed/have a certificate to sell prescription drugs/provide health insurance policies in Maryland, but do not offer to sell or sell prescription drugs/provide health insurance policies or contracts in Maryland).

You should support your request by providing documentation that demonstrates that you do not currently sell prescription drugs in Maryland. However, if you are unable to identify any documents that demonstrate this you may submit an Affidavit (form available on the Board's website) attesting to the factual basis of the claimed exemption (*e.g.*, no sales in Maryland). In most cases, a business should have documentation of the factual assertions underpinning the exemption request (*e.g.*, product lists, press announcement reflecting merger, SEC filings, annual reports, etc).