

16900 Science Drive Suites 112-114 Bowie, MD 20715 pdab.maryland.gov

General Frequently Asked Questions

Why am I Receiving this Assessment?

<u>Section 21-2C-11 of the Health-General Article</u>, 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, <u>COMAR 14.01.02</u>, 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 is this a fiscal year 2023 (FY23)Assessment? We have not completed calendar year (CY) 2022.

Because the State of Maryland's fiscal year runs from July 1 to June 30, state agencies are currently in FY23 (ending June 30, 2023).

How do I pay the fee assessment?

You may pay the assessment by ACH transfer, wire transfer or check. Payment by ACH is encouraged. To pay by ACH or Wire please follow the instructions posted on the Board's website (under "Fee Assessment" tab), complete the FY23 ACH/Wire Payment Voucher form and submit the completed voucher to payment.pdab@maryland.gov.

If paying by check, make checks payable to the "Maryland Prescription Drug Affordability Board." Please provide the PDAB vendor ID number and "FY 2023 PDAB Fund" or enclose a copy of the assessment, and mail to:

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

When is the payment for the fee assessment due?

Payment for the Prescription Drug Affordability Fund fee assessment is due by October 1. If you have not received an assessment by August 31 please contact Board staff by e-mail at support.pdab@maryland.gov.

Is there a penalty if I don't pay the fee assessment by the October 1 deadline?

Any assessment not paid within 30 days of the due date may be subject to an interest penalty. Additionally, the account may be declared delinquent and referred to the Central Collection Unit for 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.

Waiver and Exemptions Frequently Asked Questions

I don't do much business in Maryland. Can I get a waiver?

If the fee assessment (\$1000) exceeds 1% of your revenue earned in Maryland during your preceding fiscal year (you had less than \$100,000 in Maryland revenue), you may request that the Board waive your fee assessment. Supporting documentation for a waiver should be based on the entity's *most recently completed tax year*, which for most entities will be tax year 2021.

Supporting Documentation for Carrier

If you are an insurance carrier, you may request a waiver by submitting:

- (1) a completed and signed waiver request form; and
- (2) your company's 2021 NAIC "Annual Statement" including the cover page (signature page/jurat), Maryland state page, and Schedule T.

Supporting Documentation for Manufacturer, Distributor and Pharmacy Benefit Manager (PBM)

If you are a manufacturer, distributor, or pharmacy benefits manager (PBM), you may request a waiver by submitting:

- (1) a completed and signed waiver request form; and
- (2) your company's 2021 Maryland Tax return with all schedules.

If your company did not file a 2021 Maryland Tax return, indicate that on your request form and submit your company's 2021 Federal Tax return and all schedules and the following additional documentation:

(1) if you claim you had no Maryland revenue in tax year 2021, submit an affidavit from your chief financial officer or equivalent, or certified public accountant attesting to that statement; or

(2) if you claim you had less than \$100,000 in Maryland revenue in tax year 2021, submit an affidavit from your chief financial officer or equivalent, or certified public accountant attesting to that statement and submit business records reflecting your company's tax year 2021 Maryland revenue along with a business records certification. A sample business records certification is available on the PDAB website.

How do I submit a Request for Waiver or Request for Exemption?

Please submit your request, supporting documentation and Certificate of Business Record by e-mail to support.pdab@maryland.gov or by mail to:

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

When are Requests for Waiver and Requests for Exemption Due?

Requests for Waiver and Requests for Exemptions are due October 1.

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 <u>Request for Exemption</u> 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, etc.); and
- 3. Include an executed <u>Certificate of Business Record</u> (available on the Board's website) authenticating your business records submitted in support of your request for exemption.

What is the difference between a waiver and an exemption?

The waiver request is for entities that are subject to the fee assessment because they are a qualifying entity under Health General § 21-2C-11(b)(1), but earned less than \$100,000 in Maryland revenue for the entity's most recent completed tax year (for most entities, this will be tax year 2021). Because the waiver is based on the revenue from the most recent completed tax year, it is valid only for one year. If a waiver is granted, you will be assessed the following fiscal year.

Entities subject to assessment under Health General § 21-2C-11(b)(1) include:

- (i) Manufacturers that sell or offer for sale prescription drug products to persons in the State;
- (ii) Pharmacy benefits managers, as defined in § 15-1601 of the Insurance Article;
- (iii) Carriers, as defined in § 19-132 of Health General Article; and
- (iv) 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 the State.

The exemption request is for entities that may not be subject to the fee assessment because they are NOT a qualifying entity. For example, an entity may be exempt if the entity no longer does business in Maryland, manufactures only animal products or only distributes gases.

For the purpose of requesting the waiver, is Maryland revenue limited to prescription drug products (for manufacturers and wholesalers) or health insurance products (for carriers)?

No. The waiver is based on total Maryland revenue for the last completed tax year (for most entities, this will be tax year 2021), regardless of the source of that revenue.

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 can I submit as supporting documentation for the waiver? Can I send information on sales data?

Recommended supporting documentation includes the entity's Maryland tax return and schedule A (for pass through entities) for the last completed tax year or the entity's corporate federal income tax return with applicable schedules for the last completed tax year.

Please be advised that although you may submit other documentation in support of your waiver request such as internal sales documents, greater weight is given to the recommended tax documentation. Internal and unverified documentation may be insufficient, and your request may be denied or you may be directed to provide additional documentation.

Each entity seeking a waiver bears the burden of establishing the waiver by providing sufficient evidence that the entity's total Maryland revenue for the entity's most recent completed tax year was less than \$100,000 (*i.e.*, the fee assessment exceeds 1% of the entity's total Maryland revenue).

What if I am a new business or did not do business in Maryland in the previous year and I do not have Maryland tax forms to submit?

If you have not filed taxes in Maryland for the most recent closed tax year, but are otherwise a qualifying entity under <u>Health General § 21-2C-11(b)(1)</u>, you may submit a waiver request under oath stating:

- 1. The entity did not file a Maryland tax return for the most recent closed tax year;
- 2. The entity did not have any Maryland revenue in the most recent closed tax year; and,
- 3. The entity's corporate structure (Maryland corporation, Maryland pass through, out of state corporation, out of state pass through, etc).

What if I have filed taxes in Maryland in previous years because I had revenue in previous years, but I did not file taxes in the most recent year because I did not have any revenue in the most recent year?

If you have not filed taxes in Maryland for the most recent closed tax year and did not have any Maryland revenue, but are otherwise a qualifying entity under Health General § 21-2C-11(b)(1), and previously filed taxes, you may submit a waiver request under oath stating:

- 1. The entity did not file a Maryland tax return for the most recent closed tax year;
- 2. The entity did not have any Maryland revenue in the most recent closed tax year;
- 3. The entity's corporate structure (Maryland corporation, Maryland pass through, out-of-state corporation, out-of-state pass through, etc); and
- 4. The entity previously had revenue in Maryland.

What if I am licensed to do qualifying business in Maryland, but do not currently sell products in Maryland that meet the definitions in <u>Health-General § 21-2C-11</u> (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 <u>Health General</u> § 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 <u>Health General</u> § 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).

Can I submit the waiver or exception form by email/electronically?

Yes. You may submit a scanned or electronic copy of your completed Waiver/Exemption form with a wet signature to support.pdab@maryland.gov. If you submit your Waiver/Exemption electronically, PDAB will respond electronically.