



First Supplement to Frequently Asked Questions

NEW: Why is this a FY22 Assessment? We have not completed CY21.

Because the State of Maryland's fiscal year runs from July 1 to June 30, state agencies are currently in FY 22 (ending June 30, 2022). Thus, the invoice issued by PDAB in September 2021 is for State FY 22. Supporting documentation for a waiver request should be based on the entity's *most recently completed tax year*, which for most entities will be tax year 2020 (an entity's tax year may be based on a fiscal year, calendar year, etc.).

NEW: Can I pay the assessment by wire transfer or credit card?

No. We can only accept checks for the FY22 Maryland Prescription Drug Affordability Fund Fee Assessment at this time. Please contact the Maryland PDAB staff at support.pdab@maryland.gov if you need additional information.

NEW: 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 COMAR 14.01.01 and Health General § 21-2C-11(b)(1), but the fee assessment exceeds 1% of the entity's total Maryland revenue (*i.e.*, the entity 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 2020). 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 for the following fiscal year.

Entities subject to assessment under Health General § 21-2C-11(b)(1) and COMAR 14.01.01 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 received an invoice, but may not be subject to the fee assessment because they are NOT a qualifying entity under COMAR 14.01.01 and Health General § 21-2C-11(b)(1). An entity may be exempt if the entity does not provide "health insurance policies or contracts" in Maryland, no longer does business in Maryland, or manufactures only animal products or only distributes gases.

NEW: 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)?

The PDAF fee assessment waiver is based on total Maryland revenue for the last completed tax year (for most entities, this will be tax year 2020). If the entity qualifies for the fee assessment under COMAR 14.01.01 and Health General § 21-2C-11(b)(1), the waiver is based on your total revenue in Maryland, regardless of the source of that revenue.

NEW: 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?

An entity is subject to the fee assessment if the entity is a qualifying entity under COMAR 14.01.01 and 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. If you are a qualifying entity under these definitions, you may request a waiver of the assessment based on your total Maryland revenue for the last completed tax year (for most entities, this will be tax year 2020).

NEW: 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 (the fee assessment exceeds 1% of the entity's total Maryland revenue).

NEW: 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 COMAR 14.01.01 and Health General § 21-2C-11(b)(1), 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).

NEW: 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 COMAR 14.01.01 and 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.

NEW: 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 COMAR 14.01.01 and 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 COMAR 14.01.01 and 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).

NEW: Can the assessment waiver or exception forms be emailed/submitted 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, then we will respond electronically.