

Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter 02 Prescription Drug Affordability Fund

.02 Fee Assessment, Exemption, [Waiver,] and Collection.

A. Annual Assessment.

(1) In each State fiscal year, the Board shall issue a fee assessment to each entity identified in Health-General Article, §21-2C-11, Annotated Code of Maryland, and Regulation .03 of this chapter and collect the assessment.

(2) *Unless the entity requests and is granted an exemption from the assessment, the entity shall pay the assessment by October 1.*

(3) *An entity may pay the assessment by ACH transfer, wire transfer, or check.*

B. Exemption from Assessment.

(1) An entity may request an exemption from the annual assessment by submitting a completed exemption form to the Board within 30 days of the Board transmitting the fee assessment.

(2) The exemption form shall be executed under oath and attest that:

(a) The entity is not a qualifying entity as defined in COMAR 14.01.01 and Health-General Article, §21-2C-11(b)(1), Annotated Code of Maryland;

(b) The entity no longer does business in Maryland; or

(c) The entity is not subject to assessment for another reason with an explanation of that reason.

(3) The entity bears the burden of demonstrating it qualifies for the claimed exemption and shall submit documentation in support of the exemption request:

(a) *The entity shall provide an executed certificate of business record (available on the Board's website) authenticating any business record the entity submits in support of the request for exemption.*

(b) *For carriers supporting documentation may include but is not limited to: 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).*

(c) For manufacturers, distributors, and PBMs supporting documentation may include but is not limited to: 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 manufacturer/distributor 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.

(d) If the entity is unable to provide any documentation supporting the claimed exemption, the entity shall 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.

(4) While the exemption request is pending, payment of the assessment is deferred.

(5) The Board shall determine all requests for exemption promptly [and may require additional documentation or information from the entity requesting an exemption].

C. Reconsideration.

(1) Within 15 days of the notice denying the exemption, an entity may file for reconsideration of the denial of a request for exemption by submitting:

(a) A request for reconsideration on the form provided; and

(b) Additional information or documentation in support of the claimed exemption.

(2) A request for reconsideration that does not include additional information or additional documentation will be denied.

(3) 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.

[C. Waiver of Assessment.

(1) An entity that is otherwise subject to assessment because it meets the definition of a qualifying entity under COMAR 14.01.01 and Health-General Article, §21-2C-11(b)(1), Annotated Code of Maryland, may request a waiver of the annual assessment by submitting a completed waiver form to the Board within 30 days of the Board transmitting the assessment.

(2) The waiver form shall be executed under oath and:

- (a) Attest that the Prescription Drug Affordability Fund assessment exceeds 1 percent of the entity's Maryland revenue in a specified year; and
- (b) Be accompanied by supporting documentation for the specified year.
- (3) The entity's Maryland revenue is based on:
 - (a) The entity's most recent completed tax year; and
 - (b) The entity's total Maryland revenue.
- (4) Recommended supporting documentation includes verifiable evidence of the entity's Maryland revenue for the entity's most recent completed tax year, including, but not limited to, the entity's Maryland income tax return and supporting schedules.
- (5) The entity bears the burden of demonstrating it qualifies for the claimed waiver and shall submit additional documentation in support of the exemption request as required by the Board.
- (6) While the waiver request is pending, payment of the assessment is deferred.
- (7) The Board shall determine all requests for waiver promptly and may require additional documentation or information from the entity requesting a waiver.]

D. Collection and Penalties.

- (1) Any fee assessment not paid within 30 days of the payment due date may be subject to an interest penalty to be determined and collected by the Board.
- (2) In addition to any penalties the Board may impose on an entity that fails to pay the fee assessed by the Board in a timely manner, the Board may also refer an entity's delinquent account to the Department of Budget and Management's Central Collection Unit, pursuant to the procedures in State Finance and Procurement Article, Title 3, Subtitle 3, Annotated Code of Maryland, and COMAR 17.01.01.

E. Maintenance of Assessment List.

(1) The Board shall maintain a list of entities that are subject to assessment as identified in Health-General Article, §21-2C-11, Annotated Code of Maryland.

(2) Board staff shall:

- (a) Review the list on an annual basis;*
- (b) Add additional entities when reported by or obtained from other agencies; and*
- (c) Remove entities when the entity:*

(i) Is no longer a going concern; or

(ii) Has not been required to pay the assessment for three consecutive years.

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.03 Amount of Assessment.

A. Entities identified in Health-General Article, §21-2C-11, Annotated Code of Maryland, shall be subject to the following fee schedule:

(1) Manufacturers engaged in wholesale distribution, as defined in Health Occupations Article, §12-6C-01, Annotated Code of Maryland, shall pay an assessment of \$1,000;

(2) Wholesale distributors, as defined in Health Occupations Article, §12-6C-01, Annotated Code of Maryland, that distribute prescription drugs shall pay an assessment of \$1,000;

(3) Pharmacy benefits managers, as defined in Insurance Article, §15-1601, Annotated Code of Maryland, shall pay an assessment of \$1,000; and

(4) Carriers[,]*that provide health benefit plans*, as defined in Health-General Article, §19-132(e), Annotated Code of Maryland, shall pay an assessment of \$1,000.

B. An entity may request to pay the annual assessment in installments by submitting a letter to the Board demonstrating significant financial hardship in paying the assessment in a single payment.