

DEPARTMENT OF INSURANCE

OFFICE OF THE COMMISSIONER

Statutory Authority: 18 Delaware Code, Sections 311 and 3373A(c) (18 **Del.C.** §§311 & 3373A(c))
18 **DE Admin. Code** 1411

FINAL

EXEMPT FINAL ORDER

1411 Registration of Pharmacy Benefits Managers

Pursuant to 18 **Del.C.** §§311 and 3359A(c) (redesignated to 3373A(c) in 83 Del. Laws, Ch. 245, Section 14), Regulation 1411, entitled Registration of Pharmacy Benefits Managers, requires all pharmacy benefits managers (PBMs) to:

- Register with the Commissioner before providing pharmacy benefits management services in Delaware to a "purchaser" (a "purchaser" is defined as an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity that: (1) provides prescription drug coverage or benefits in Delaware, and (2) enters into agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services); and
- To annually renew their registration on the May 1 after the initial date of registration and every May 1 thereafter.

On October 26, 2021, House Bill 219 (151st General Assembly) (the Act) became law. The Act, among other things, increases PBM registration fees at 18 **Del. C.** §§ 3353A and 3354A from \$150 to \$1000.

With this order, the Department is updating Section 8.0 of Regulation 1411 to conform the regulation with the Act. These updates are exempt from the requirement of public notice and comment because they include "amendments to existing regulations to make them consistent with changes in basic law but which do not otherwise alter the substance of the regulations," pursuant to 29 **Del.C.** §10113(b)(5).

This order shall be effective 10 days after publication in the *Register of Regulations*.

IS SO ORDERED.

The 15th day of December, 2021.

Trinidad Navarro
Commissioner, Delaware Department of Insurance

1411 Registration of Pharmacy Benefits Managers

1.0 Scope and Authority

- 1.1 This regulation is adopted by the Commissioner pursuant to the authority granted by 18 **Del.C.** §§311 and ~~3359A(c)~~ 3373A(c) and promulgated in accordance with the Delaware Administrative Procedures Act, 29 **Del.C.** Ch. 101.
- 1.2 This regulation does not apply to plans of health insurance or health benefits designed for issuance to persons eligible for coverage under Titles XVIII, XIX, and XXI of the Social Security Act, 42 U.S.C. §§1395 et seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state or federal government plan.

2.0 Definitions

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

“**Affiliate**” means an entity or person who directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, a specified entity or person.

“**Commissioner**” means the Insurance Commissioner of Delaware.

“**Control**” (including the terms “controlling”, “controlled by” and “under common control with”) means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or non-management services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing, ten percent (10%) or more of the

voting securities of any other person. This presumption may be rebutted by a showing made in the manner provided by 18 Del.C. Ch. 50 that control does not exist in fact. The Commissioner may determine, after furnishing all persons in interest notice and opportunity to be heard and making specific findings of fact to support the determination that control exists in fact, notwithstanding the absence of a presumption to that effect.

"Department" means the Delaware Department of Insurance.

"Insurer" means any entity that provides health insurance coverage in this State as defined in 18 Del.C. §903.

"Person" means an individual or a business entity.

"Pharmacy benefits management services" means all of the following:

- The procurement of prescription drugs at a negotiated rate for dispensation within this State to beneficiaries;
- The administration or management of prescription drug coverage provided by a purchaser for beneficiaries; and
- Any of the following services provided with regard to the administration of prescription drug coverage:
 1. Mail service pharmacy;
 2. Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;
 3. Clinical formulary development and management services;
 4. Rebate contracting and administration;
 5. Patient compliance, therapeutic intervention, and generic substitution programs; and
 6. Disease management programs.

"Pharmacy benefits manager" or **"PBM"** means an entity that contracts with pharmacists or pharmacies on behalf of an insurer or third-party administrator to:

- Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists;
- Pay pharmacies or pharmacists for prescription drugs or medical supplies; or
- Negotiate rebates with manufacturers for drugs paid for or procured as described in this chapter.

"Pharmacy services administrative organization" means a cooperative network of independent pharmacies.

"Purchaser" means an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity that does all of the following:

1. Provides prescription drug coverage or benefits in this State; and
2. Enters into agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services.

3.0 Requirement for Registration

No insurer may enter into a written agreement or contract with a pharmacy benefits manager unless the pharmacy benefits manager is registered with the Department in accordance with Section 4.0 of this regulation.

4.0 Pharmacy Benefits Manager Registration Requirements

- 4.1 A pharmacy benefits manager shall register with the Commissioner in accordance with this Section before providing pharmacy benefits management services in this State to a purchaser.
- 4.2 An applicant who wishes to apply to be a pharmacy benefits manager in Delaware shall submit a Pharmacy Benefits Manager Registration Application to the Department, on which the applicant includes all of the following:
 - 4.2.1 Applicant Information:
 - 4.2.1.1 Name, address, telephone number;
 - 4.2.1.2 Name and address of applicant's agent for service of process in this State;
 - 4.2.1.3 Name and address of each person beneficially interested in the applicant's business (e.g. ownership of 10% or more);
 - 4.2.1.4 Name and address of each officer and director; and
 - 4.2.1.5 The non-renewable registration fee set forth in Section 8.0 of this regulation;
 - 4.2.2 Organization and Background Information:
 - 4.2.2.1 All basic organizational documents of the applicant, including any articles of incorporation, articles of association, partnership agreement, trade name certificate, trust agreement, shareholder agreement and other applicable documents and all amendments to such documents;

- 4.2.2.2 The bylaws, rules, regulations or similar documents regulating the internal affairs of the applicant;
- 4.2.2.3 A biographical affidavit of each individual who is responsible for the conduct of affairs of the applicant, including:
 - 4.2.2.3.1 All members of the board of directors, board of trustees, executive committee or other governing board or committee;
 - 4.2.2.3.2 The principal officers in the case of a corporation or the partners or members in the case of a partnership, association or limited liability company;
 - 4.2.2.3.3 Any shareholders or members holding directly or indirectly ten percent (10%) or more of the voting stock, voting securities or voting interest of the applicant; and
 - 4.2.2.3.4 Any other person who exercises control or influence over the affairs of the applicant; and
- 4.2.3 A statement describing the applicant's business plan, that includes the following information:
 - 4.2.3.1 Staffing levels and activities proposed in Delaware and nationwide;
 - 4.2.3.2 Details concerning the applicant's capability for providing a sufficient number of experienced and qualified personnel in the areas of claims processing and record keeping; and
 - 4.2.3.3 A list of all insurers for whom applicant provides pharmacy benefits management services in this State; and
- 4.2.4 Information on the applicant's compliance with Chapter 33A requirements, including:
 - 4.2.4.1 A copy of the PBM's standard, generic contract template, provider manual or other appropriate items incorporated by reference that the PBM uses for contracts entered into by the PBM with pharmacists, pharmacies or pharmacy services administrative organizations in this State in administration of pharmacy benefits for insurers, for the purpose only of the Department's review that such contracts comply with 18 **Del.C.** Ch. 33A;
 - 4.2.4.2 A copy of the written policies and procedures which demonstrate that the applicant has compliant processes established to adhere to all of the following:
 - 4.2.4.2.1 The appeals and dispute resolution process as required by 18 **Del.C.** §3324A;
 - 4.2.4.2.2 The requirements for maximum allowable cost pricing set forth in 18 **Del.C.** §3323A; and
 - 4.2.4.2.3 The Audit Integrity Program set forth in 18 **Del.C.** §§3301A-3310A; and
- 4.2.5 Such other pertinent information as may be required by the Commissioner to verify the information in the application.
- 4.3 A registration certificate issued under this section shall remain valid, unless surrendered, suspended or revoked by the Commissioner, until May 1 following the effective date of the initial registration and the May 1 following the date of the registration renewal, as provided in subsection 4.4 of this regulation.
- 4.4 No pharmacy benefits manager may continue to do business in Delaware unless it has registered annually with the Commissioner on or before May 1 following the effective date of the initial registration and on or before the May 1 following the date of any subsequent registration renewal. A pharmacy benefits manager may renew a certificate of registration for an additional one-year term by timely submitting:
 - 4.4.1 All of the information required in subsection 4.2 of this regulation, updated as necessary to reflect the most current information concerning the pharmacy benefits manager's operations; and
 - 4.4.2 The non-refundable renewal application fee set forth in Section 8.0 of this regulation.
- 4.5 A pharmacy benefits manager who is registered or who is applying for registration under Section 4.0 of this regulation shall, within 15 days after the end of the calendar month in which any of the foregoing transactions occur, notify the Commissioner of any material change in its ownership, control, or other fact or circumstance affecting its qualification for a registration certificate in this state.
- 4.6 A pharmacy benefits manager who is applying for registration or who is registered under this Section shall make available for inspection by the Commissioner copies of each permit issued to each nonresident pharmacy under 24 **Del.C.** §2535 that the pharmacy benefits manager uses to ship, mail, or deliver prescription drugs or devices in this state.

5.0 Standard of Review

- 5.1 The Commissioner shall deny an initial application or renewal application made under this regulation if the pharmacy benefits manager:
 - 5.1.1 Has been determined by the Commissioner to be in violation or non-compliance with the requirements of this regulation or 18 **Del.C.** Ch. 33A; or
 - 5.1.2 Has failed to timely submit information to complete review of the application or has failed to submit a renewal application and information under Section 4.0 of this regulation.

- 5.2 In lieu of a denial for an initial registration or renewal application under subsection 5.1 of this regulation, the Commissioner may permit the pharmacy benefits manager to submit to the Commissioner a corrective action plan to cure or correct deficiencies identified under subsection 5.1 of this regulation.
- 5.3 The Commissioner may refuse to issue a certificate of registration if the Commissioner determines that the pharmacy benefits manager, or any individual responsible for the conduct of affairs of the pharmacy benefits manager:
 - 5.3.1 Has had an insurance or a pharmacy benefits manager certificate or license denied or revoked for cause by any jurisdiction; or
 - 5.3.2 If the Commissioner determines that any of the grounds set forth in Section 6.0 of this regulation exists.

6.0 Grounds for Denial, Suspension or Revocation of Registration Certificate

- 6.1 The Commissioner may deny, suspend or revoke the certificate of registration of a pharmacy benefits manager if the Commissioner finds that the pharmacy benefits manager or an officer, director, or employee of the pharmacy benefits manager has engaged in any of the following:
 - 6.1.1 A material misstatement, misrepresentation, or omission in a registration or registration renewal application, including but not limited to:
 - 6.1.1.1 Failure to meet any qualification for which issuance of the certificate could have been refused had the failure then existed and been known to the Commissioner;
 - 6.1.1.2 Failure to timely file an annual registration pursuant to Section 4.0 of this regulation and filing fee pursuant to Section 8.0 this regulation;
 - 6.1.1.3 Failure to disclose that its license, registration or certification is under suspension or revocation in another state; or
 - 6.1.1.4 Failure to disclose that individuals who are responsible for the conduct of the affairs of the pharmacy benefit manager have been convicted of, or have entered a plea of guilty or nolo contendere to a felony without regard to whether adjudication was withheld;
 - 6.1.2 Fraudulently or deceptively obtaining or attempting to obtain a registration or renewal of a registration;
 - 6.1.3 In connection with the administration of pharmacy benefits management services, fraud or illegal or dishonest activities, including but not limited to:
 - 6.1.3.1 Using such methods or practices in the conduct of its business that render its further transaction of business in Delaware hazardous or injurious to insured persons or the public;
 - 6.1.3.2 Violating any lawful rule or order of the Commissioner or any applicable law of this state;
 - 6.1.3.3 Failing to pay any judgment rendered against it in this state within sixty days after the judgment has become final; or
 - 6.1.3.4 Without just cause, refusing to make reimbursements in compliance with its contracts and as required by law; or
 - 6.1.4 A violation of any provision of 18 **Del.C.** Ch. 33A or this regulation, including but not limited to:
 - 6.1.4.1 In connection with the affairs of the pharmacy benefits manager, refusing to be examined or to produce pharmacy benefits manager-related accounts, records and files for examination, of any individual responsible for the conduct of affairs of the pharmacy benefits manager, including:
 - 6.1.4.1.1 Members of the board of directors, board of trustees, executive committee or other governing board or committee;
 - 6.1.4.1.2 The principal officers in the case of a corporation or the partners or members in the case of a partnership, association or limited liability company;
 - 6.1.4.1.3 Any shareholder or member holding directly or indirectly ten percent (10%) or more of the voting stock, voting securities or voting interest of the pharmacy benefits manager; and
 - 6.1.4.1.4 Any other person who exercises control or influence over the affairs of the pharmacy benefits manager; or
 - 6.1.4.2 Refusing to give information with respect to its affairs or refusing to perform any other legal obligation as to an examination, when required by the Commissioner.
- 6.2 In addition to any other remedies set forth in this regulation, the Commissioner may issue a cease and desist order to a pharmacy benefits manager that is registered or is seeking renewal of a registration if the pharmacy benefits manager, or an officer, director, or employee of the pharmacy benefits manager commits any of the acts set forth in subsection 6.1 of this regulation.

6.3 If a pharmacy benefits manager that is registered or seeking renewal of a registration does not comply with a cease and desist order issued by the Commissioner under subsection 6.2 of this regulation, the Commissioner may deny, refuse to renew, suspend, or revoke its registration.

6.4 Hearings

6.4.1 If the action by the Commissioner is to deny or not renew a registration, the Commissioner shall notify the pharmacy benefits manager of the decision, in writing, including the reason for the denial or nonrenewal of the registration. The pharmacy benefits manager may, within 10 days after the Commissioner provides notice under this subsection, make written demand on the Commissioner for a hearing before the Commissioner to determine the reasonableness of the Commissioner's action.

6.4.2 If the Commissioner determines that a pharmacy benefits manager has violated any provision of 18 Del.C. Ch. 33A or this regulation, the Commissioner may, after notice and a hearing, issue an order in accordance with 18 Del.C. §3359A.

6.4.3 All hearings under this regulation must be held under 18 Del.C. §§323 through 328 and this regulation.

7.0 Maintenance of Information – Examination by Commissioner

7.1 A pharmacy benefits manager shall maintain adequate books and records about each purchaser for which the pharmacy benefits manager provides pharmacy benefits management services.

7.2 The pharmacy benefits manager shall maintain all books and records in accordance with prudent standards of record keeping and shall retain all records referred to in subsection 7.1 of this regulation:

7.2.1 For the duration of the agreement between the pharmacy benefits manager and the purchaser; and

7.2.2 For three years after the pharmacy benefits manager ceases to provide pharmacy benefits management services for the purchaser.

7.3 The Commissioner shall have access to books and records maintained by a pharmacy benefits manager for the purposes of examining the affairs of the pharmacy benefits manager.

7.4 The conduct of an examination of any pharmacy benefits manager shall be in accordance with 18 Del.C. §§320 and 321, including the confidentiality provisions contained therein.

7.5 Nothing in this regulation shall prohibit the Commissioner from releasing final, adjudicated actions that are open to public inspection pursuant to 29 Del.C. Ch. 100 to a database or other clearinghouse service maintained by the National Association of Insurance Commissioners, its affiliates or subsidiaries.

7.6 In the event the insurer or purchaser, as applicable, and the pharmacy benefits manager cancel their agreement, notwithstanding the provisions of subsection 7.1 of this regulation, the pharmacy benefits manager may, by written agreement with the insurer or purchaser, as applicable, transfer all records to a new pharmacy benefits manager rather than retain them as is required under subsection 7.1 of this regulation. In such cases, the new pharmacy benefits manager shall acknowledge, in writing, that it is responsible for retaining the records of the prior pharmacy benefits manager as required in subsection 7.1 of this regulation.

7.7 A pharmacy benefits manager who is applying for registration or who is registered under this Section shall produce its accounts, records and files for examination, and make its officers available to give information with respect to its affairs, as often as considered advisable by the Commissioner.

7.8 A pharmacy benefits manager shall be subject to assessment for all fees, costs, experts and related expenditures with respect to any examination or enforcement action undertaken by the Commissioner pursuant to 18 Del.C. Ch. 33A and this regulation.

8.0 Fees

The following fees shall be applicable for filings and matters arising under this regulation:

Initial registration application	\$150.00 <u>\$1,000.00</u>
Renewal registration application	\$150.00 <u>\$1,000.00</u>
Amendment of certificate	\$150.00 <u>\$1,000.00</u>
Duplicate or replacement certificate	\$150.00 <u>\$1,000.00</u>

9.0 Severability

If any section or portion of a section of this regulation or its applicability to any person or circumstance is held invalid by a court, the remainder of this regulation or the applicability of the provision to other persons or circumstances shall not be affected.

10.0 Effective Date

This Regulation shall become effective August 11, 2020. The effective date of the revisions to Section 8.0 is January 11, 2022.

24 DE Reg. 167 (08/01/20)

25 DE Reg. 715 (01/01/22) (Final)