Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF INSURANCE

OFFICE OF THE COMMISSIONER

Statutory Authority: 18 Delaware Code, Sections 311 and Chapter 33A (18 **Del.C.** §311 & c. 33A)
18 **DE Admin. Code** 1411

FINAL

FINAL REGULATORY IMPLEMENTING ORDER

1411 Registration of Pharmacy Benefits Managers

I. SUMMARY OF THE EVIDENCE AND INFORMATION SUBMITTED

A. Publication Background

On October 1, 2022, the Delaware Department of Insurance (the Department) published in the *Register of Regulations* (see 26 **DE Reg.** 303 (10/01/22)) its proposal to amend Regulation 1411. The purpose of the proposed amendments is to implement House Bill 219 (151st General Assembly) (the Act), which includes additional requirements on PBMs that apply to "contracts between pharmacy benefit managers and pharmacies or pharmacists that are entered into, renewed, or extended on or after the effective date of this Act" (see Section 15 of the Act). The Department solicited comments for the requisite 30-day comment period and received one set of timely submitted comments, submitted by a group that represents the pharmacy benefit management (PBM) industry (the commenter).

B. Summary of timely submitted comments and Department responses

The commenter requested that the Department clarify the scope of the regulation to exclude any coverage administered by the Department of Health and Human Services in the performance of its duties for the Medicaid program (see 18 **Del.C.** § 3322A) and to exclude plans of health insurance or health benefits designed for issuance to persons eligible for Medicare, Medicaid, or any other similar coverage under a state or federal government health plan (see 18 **Del.C.** § 3352A). This suggestion is unnecessary because the statutes that provide the underlying authority for Regulation 1411 are sufficiently clear as to the exclusions.

The commenter objected to the network adequacy provisions in Sections 2.0 (Definitions) and 10.0 (Network Adequacy Annual Reporting Requirements), claiming that the provisions delineate new restrictions pertaining to networks. The commenter opined that these provisions exceed the Department's statutory authority because the statute only requires that PBMs provide a network with "convenient patient access to pharmacies within a reasonable distance from a patient's residence" (see 18 **Del.C.** § 3362A).

The Department disagrees with the commenter's characterization of Sections 2.0 and 10.0 as imposing new restrictions on PBM networks. As an initial matter, Section 2.0 is simply a definitional section defining terms used later in Regulation 1411. Section 10.0 sets forth the manner in which PBMs are to report on their network, including the information to be included in the report. Section 10.0 is the implementation of the reporting requirements of 18 **Del.C.** § 3363A and does not establish any minimum network requirements that PBMs must meet in order to demonstrate an adequate network under 18 **Del.C.** § 3362A. Through reporting, the Department will seek to gain a better understanding of PBM networks, which it intends to use to help it understand what constitutes an adequate pharmacy network in Delaware. As the Department gains a better understanding of pharmacy networks in and across Delaware, it may propose amendments to this regulation for public comment that will address through regulation metrics for demonstrating an adequate network.

Similarly, the commenter specifically objected to the definitions of "rural service area," "suburban service area," and "urban service area." The commenter objected to these definitions, which are based on numbers of residents within zip codes, as too granular, stating that creating a standard for reporting by zip code is problematic and not consistent with industry standard.

Again, the Department points out that Section 10.0, in which the defined terms "rural service area," "suburban service area," and "urban service area" are used, only contains reporting requirements. Moreover, Section 10.0 requires reporting by all rural, suburban, and urban service areas, not by zip code as the commenter suggests.

The commenter requested that the last sentence of the definition for "rebate" be stricken because it "is confusing" and "does not provide clarity" regarding the use of the term "reasonable estimates." The Department declines to take this

suggestion. This definition, which includes "incentives, disbursements, and reasonable estimates of a volume-based or category-based discount" is taken verbatim from the statute. Moreover, the listing of types of rebates contained in the statutory definition is not exclusive, and a PBM may include other types of rebates in the reports submitted to the Department.

The commenter requested that the proposed language in Section 3.0 be stricken as unnecessary, redundant, and unsupported by the underlying statute because insurers are already regulated by the Department and the underlying statute says nothing specific on subjecting insurers to PBM laws, nor was it the intent of the legislature to apply the law to insurers.

The Department disagrees with the commenter's characterization of Section 3.0. This section serves as a regulatory reminder to insurers, as potential purchasers under 18 **Del.C.** Ch. 33A, of their continued responsibilities under the Insurance Code as insurers.

At subsection 9.1, the commenter objected to the requirement that a PBM list a single point of contact with whom the Department can correspond when is receives a maximum allowable cost pricing (MACP) appeal, stating that it is highly unlikely that one person would be handling a large number of appeals.

The Department understands that a PBM may have more than one person in its complaint handling division but points out that requiring a single point of contact prevents complaints from get lost in the morass of the company's general email.

The commenter also requested that appeals-related submissions should not be submitted by "electronic mail" as electronic mail is not a secure method. The commenter indicated that it prefers a system for submission that requires a password, at the very least, to access the data.

The Department appreciates this comment and maintains that, to the extent that a PBM uses a secure system on its end, the PBM may use that system when it submits appeals-related documentation to the Department. The Department is willing to work with PBMs to gain access to their secured systems.

The commenter requested that the entirety of subsection 9.3 be stricken because the commenter inferred that this subsection somehow applies a PBM's internal appeal processing procedure. The Department points out that subsection 9.1 makes it clear that Section 9.0 only applies to appeals filed with the Department under 18 **Del.C.** § 3324A(h).

The commenter also requested that subsection 9.4 be clarified to explicitly state that the appeals at issue are to the Department. However, as pointed out above, subsection 9.1 and the context of Section 9.0 in its entirety already indicates this, and therefore the Department maintains that this suggestion is unnecessary.

At subsection 9.5, the commenter suggested that requiring the use of a form when submitting information in connection with a MACP appeal would increase costs and burdens on a PBM and suggested that a PBM should be allowed to provide the necessary information on its own with a certain set of data elements included. The Department declines to accept this request. The use of standardized appeal and response forms provides for consistency in the appeals that are submitted to the Department and allows the staff who are in charge of processing the appeals to quickly access the pertinent information and efficiently process those appeals.

The commenter requested that the time limits set forth at subsection 9.5.2 be extended from "5 business days" to "14," opining that five days are not enough time for a PBM to file a response via the Department's form after receipt of the notice of appeal.

The Department points out that when a claim is at the stage that it is being appealed to the Department, the claim should have already gone through the PBM's internal appeals process, and therefore, all of the information needed to be submitted to the Department should already be compiled in the PBM's internal claims file. Therefore, the Department maintains that the 5-business day period reflected in the proposal is sufficient and declines to adopt the commenter's suggested revisions. The Department also notes that there is no language in the proposed regulation that prevents a PBM from making a reasonable request for a filing deadline extension if needed.

The commenter requested that all references to "covered" in subsection 10.2, concerning Network Adequacy Annual Reporting Requirements, be stricken in favor of the use of the phrase "individuals residing in." The Department declines this request because it is not interested in a report that includes people residing in a particular service area unless the people who reside in that service area are actually utilizing the services of the PBM. Again, this is only a reporting requirement.

The commenter also objected to the requirement that PBMs file information about their "preferred networks," citing to 18 **Del.C.** § 3362A as only requiring adequate networks "within a reasonable distance from a patient's residence." The Department directs the commenter to 18 **Del.C.** § 3363A(a), which requires a PBM's network adequacy report to describe both its network and its network's accessibility in the State. As a PBM's network may include preferred and non-preferred statuses for network pharmacies, it would be appropriate for the network adequacy report to include information on its preferred network.

The commenter requested that the reporting deadlines set forth in subsection 11.1 be extended to allow PBMs greater time to report the quarterly data and also requested that subsection 11.2 be amended to allow for PBMs to request an extension on the reporting deadline. The Department declines to extend the reporting deadlines and points out that the regulation does not prohibit a PBM from submitting a reasonable request for an extension, even though not expressly provided for in the regulation, which is consistent with Department practices.

The commenter requested that subsection 12.2.5, which requires a PBM to provide its "anticipated revenue from the fee" when the PBM applies to the Department to impose certain fees on pharmacies, be stricken because this information is confidential and proprietary financial information, and that this requirement is beyond the scope of the underlying statute. The underlying statute at 18 **Del.C.** § 3372A(3) requires the Commissioner to review and approve fees charged to pharmacies related to the adjudication of claims. In order to properly review a proposed fee, the Department needs the relevant information to evaluate the reasonableness of the proposed fee. The information requested under subsection 12.2 of the regulation will be used by the Department to make that determination. The PBM may identify any information as proprietary financial information and request that this information be kept confidential, subject to Delaware's Freedom of Information Act (FOIA).

The commenter expressed concerns with subsection 12.4 concerning information that is collected by the Department and is then forwarded to the Board of Pharmacy. The commenter pointed out that the Board membership includes licensed pharmacists who would be considered market actors and competitors that may be in many PBMs' networks and as such, may have a vested personal interest in the outcome of the process. Additionally, the commenter suggests that such information should not be disclosed to the public in any setting, especially the Board of Pharmacy public meetings, due to the competitive nature of the information. Lastly, the commenter noted that the Board should not be permitted to request information independent of the Commissioner as the statute does not authorize this, "likely due to the potential for a conflict of interest and the competitive nature of the information."

The Department declines to accept any of the proposed changes to subsection 12.4, as the proposed changes operate to circumvent the PBM statute and FOIA. The underlying statute requires that the Commissioner work "in coordination" with the Board of Pharmacy in reviewing and approving additional accreditation standards or certification requirements. As a public body with multiple members, the Board of Pharmacy conducts business in accordance with the open meeting requirements of FOIA. If a PBM believes certain information submitted for purposes of review under subsection 12.3 does not meet the definition of "public record" under 29 **Del.C.** § 10002, it can identify those documents in its submission and provide a reasoned explanation justifying its position so that the Board of Pharmacy can determine whether review of the information during an executive session is warranted. The Department also rejects the notion that a conflict of interest may exist because of the makeup of the Board of Pharmacy given that licensing boards always have professional members. If Board member has a conflict of interest related to a specific filing/PBM, that issue can be addressed at the time the Board considers the filing.

As its final comment, the commenter requested that the effective date of the Proposed Regulation be pushed out to allow PBMs to put new implementation processes in place, including new processes and/or systems for fee approvals and accreditation requirements. The Department declines this request. The effective date of the regulation has already been extended beyond the Department's anticipated timeframe and the Department is not receptive to any further extension of the effective date.

II. FINDINGS

1. The proposed amendments to Regulation 1411 effectively implement the Act.
2. The Department declines to make the edits to the proposed language for the reasons set forth in Section I.B of this order.
3. The Department met the public notice requirements of the Administrative Procedures Act.

III. DECISION TO ADOPT PROPOSED AMENDMENTS TO REGULATION 1411

For the foregoing reasons, the Commissioner concludes that it is appropriate to adopt the amendments to 18 **DE**

Admin. Code 1411 as proposed.

IV. EFFECTIVE DATE OF ORDER

The actions referred to hereinabove were taken by the Commissioner pursuant to 18 **Del.C.** §311 and Chapter 33A on the date indicated below. The effective date of this Order and of the amendments to this regulation shall be January11, 2023.

IT IS SO ORDERED.

The15th day of December 2022.

Trinidad Navarro
Commissioner, Delaware Department of Insurance

1411 Registration and Regulation 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 3373A(c)~~ §311 and Chapter 33A 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.

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

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%)~~ 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.

"**Health benefit plan**" means any hospital or medical policy or certificate, major medical expense insurance, health service corporation subscriber contract, or health maintenance organization subscriber contract. Health benefit plan does not include accident-only, credit, dental, vision, Medicaid plans, long-term care or disability income insurance, coverage issued as a supplement to liability insurance, worker's compensation or similar insurance, or automobile medical payment insurance.

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

"**Maximum allowable cost pricing**" or "**MACP**" means drug pricing that meets the requirements of 18 **Del.C.** §3323A.

"**Network provider**" means a pharmacist or pharmacy who provides covered health-care services or supplies to an insured or a member pursuant to a contract with an insurer or pharmacy benefits manager.

"**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~~ a person to do any of the following:

- 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 benefits manager network**" means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacy goods and services.

"**Pharmacy services administrative organization**" or "**PSAO**" 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.

"**Rebate**" means a discount or other price concession, or a payment, that is based on utilization of a prescription drug and that is paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy. "Rebate" includes incentives, disbursements, and reasonable estimates of a volume-based or category-based discount.

"**Rural service area**" means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

"**Suburban service area**" means a five-digit ZIP code in which the population density is between 1,000 and 2,500 individuals per square mile.

"**Third party**" means a person, business, or entity other than a pharmacy benefits manager that is not an enrollee or insured in a health benefit plan.

"**Urban service area**" means a five-digit ZIP code in which the population density is greater than 2,500 individuals per square mile.

3.0 Requirement for Registration; Insurer Responsibilities

3.1 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.

3.2 An insurer who uses one or more PBMs for administration of the pharmacy benefits provided under its health benefit plans remains responsible for:

3.2.1 Ensuring that its pharmacy benefits comply with coverage requirements mandated under Title 18 of the Delaware Code; and

3.2.2 The insurer's compliance with the requirements under 18 **Del.C.** Ch. 73.

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%)~~ 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

4.2.2.4 For each individual who is required to submit a biographical affidavit pursuant to subsection 4.2.2.3 of this regulation, a background check that has been performed by an independent third-party within six months of the date of the signature on the relevant biographical affidavit, chosen by the affiant from the list of approved vendors located on the NAIC website under the Uniform Certificate of Authority Application which may be downloaded from naic.org.

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~~ §§3301A-3310A.

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 <u>of Initial and Renewal Registration Applications</u>

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~~ <u>refuse to renew, suspend,</u> 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~~ <u>Making a</u> 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~~ <u>benefits</u> 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, <u>committing</u> fraud or <u>engaging in</u> 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~~ <u>Violating</u> 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%)~~ 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 Reimbursing a pharmacy or pharmacist in this State in an amount less than the amount that the PBM reimburses a PBM affiliate for providing the same pharmacy goods or services;

6.1.4.3 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.~~ Commissioner; or

6.1.4.4 Engaging in any of the prohibited practices identified in 18 **Del.C.** §3372A.

6.2 In addition to any other remedies set forth in this regulation, the Commissioner may issue a ~~cease and desist~~ 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~~ 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~~ §3373A.

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	$1,000.00
Renewal registration application	$1,000.00
Amendment of certificate	$1,000.00
Duplicate or replacement certificate	$1,000.00

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

9.0 Pharmacy Provider Appeals Related to Maximum Allowable Cost Pricing (MACP) Reimbursements

9.1 A PBM shall designate the name, address, phone number, and electronic mail address of the person within the PBM organization who shall be the point of contact for responding to appeals received by the Department from a pharmacy provider or PSAO under 18 **Del.C.** §3324A(h).

9.2 All filings submitted to the Department, including the notice of appeal and any subsequent responses by either party shall be made by electronic mail to the electronic mail address designated by the Department on the Department's website.

9.3 Notice and Manner of Service

9.3.1 Notice and manner of service, except service of the notice of appeal, is sufficient and complete if properly addressed, upon mailing the same with prepaid first-class U.S. Postage.

9.3.2 Service of the initial notice of appeal shall be made by the pharmacy or PSAO on the PBM by Certified U.S. Postage and return receipt requested or hand delivery to the respondent and is complete upon receipt by addressee or an employee in respondent's place of business.

9.3.3 The parties must provide a brief statement verifying the service of all filed papers with the manner, date and address of service.

9.4 When an Appeal May Be Commenced

9.4.1 An appeal may be commenced after the pharmacy provider or PSAO and a PBM have attempted to resolve the matter in accordance with the PBM's internal appeal process required by 18 **Del.C.** §3324A(a).

9.4.2 A PBM's failure to communicate and process an internal appeal, as required under 18 **Del.C.** §3324A, or its failure to abide by its MACP appeal processes as described to the Department in the PBM's submission under subsection 4.2.4.2.1 of this regulation, shall constitute a denial under the internal appeal process for purposes of allowing the pharmacy provider or PSAO on its behalf to file an appeal with the Department.

9.4.3 The Commissioner may dismiss the appeal without prejudice if the Commissioner finds that the parties have not exhausted the PBM's internal appeals process.

9.4.4 A PBM shall not be held responsible for failure to timely process an internal appeal in the event that a pharmacy provider or PSAO acting on its behalf has not submitted sufficient information for the PBM to process the appeal.

9.4.5 All pricing information and data collected by the Department for purposes of processing an appeal under Section 9.0 of this regulation is confidential and is not subject to subpoena or the Freedom of Information Act, 29 **Del.C.** Ch. 100.

9.5 Commencement of Appeal

9.5.1 A pharmacy provider or PSAO may commence an appeal by filing a notice of appeal on a form provided by the Department and as specified at subsection 9.2 of this regulation, with the supporting documents or other evidence attached thereto. The pharmacy provider or PSAO shall at the same time serve a copy of the same notice of appeal and supporting documents to the PBM or PBM's representative and a statement verifying service in accordance with subsection 9.3 of this regulation. The Department may return any non-conforming notice of appeal.

9.5.2 Within 5 business days of receipt of the notice of appeal, the responding PBM ("Respondent") shall file a response on a form provided by the Department and as specified at subsection 9.2 of this regulation, that shall include a copy of the contract between the PBM and the appealing pharmacy provider or PSAO, along with any other documentation necessary for the Department to review the PBM's compensation program to determine whether the reimbursement underlying the appeal complies with 18 **Del.C.** §§3323A-3324A and the terms of the contract. The PBM shall at the same time serve a copy of the same response to the pharmacy provider or PSAO and a statement verifying service in accordance with subsection 9.3 of this regulation. The Department may return any non-conforming response.

9.5.3 If the Respondent fails to file a response in a timely fashion, the Department, after verifying proper service and notice to the parties, may enter a summary disposition. The Department may determine the matter in the nature of a default judgment after establishing that the appeal is properly supported and was properly served on Respondent. The Department may allow the re-opening of the matter to prevent a manifest injustice. A request for re-opening must be made no later than 5 business days after notice of the default judgment.

9.6 Consideration of Appeal

9.6.1 The Department shall consider the matter based on the submissions of the parties and information otherwise requested from the parties by the Department. The Department shall not consider any matter not contained in the original or supplemental submissions of the parties which has not been provided to the opposing party with at least 5 business days' notice, except claims of a continuing nature which are set out in the filed papers.

9.6.2 The Department shall review the pharmacy benefits manager's compensation program to ensure that the reimbursement for pharmacy benefits management services paid to the pharmacist or a pharmacy complies with 18 **Del.C.** §§3323A-3324A and the terms of the contract between the PBM and the appealing pharmacy or PSAO and shall either:

9.6.2.1 Dismiss the appeal; or

9.6.2.2 Grant the appeal and order the pharmacy benefits manager to pay the claim in accordance with the Department's findings.

10.0 Network Adequacy Annual Reporting Requirements

10.1 Annually, no later than May 1, a pharmacy benefits manager shall submit to the Department a pharmacy benefits manager network adequacy report describing the pharmacy benefits manager network and the pharmacy benefits manager network's accessibility in this State, subject to the following:

10.1.1 The report is to address network adequacy in terms of patient access to physical pharmacy locations. The report may include a notation that mail-order pharmacy services are available, if applicable, but the report should not include mail-order pharmacies in calculations used to demonstrate the PBM's network adequacy.

10.2 The PBM's network adequacy report shall include at a minimum:

10.2.1 A hotspot map that shows density of network pharmacies;

10.2.2 A list identifying the number of lives within 5 miles, 10 miles, and 15 miles of a network pharmacy;

10.2.3 The percentage of covered individuals residing in urban, suburban, and rural service areas and their proximity to network retail pharmacies as follows:

10.2.3.1 The percentage of covered individuals residing in an urban service area who live within 2 miles of a retail pharmacy participating in the PBM's retail pharmacy network;

10.2.3.2 The percentage of covered individuals residing in an urban service area who live within 5 miles of a retail pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network;

10.2.3.3 The percentage of covered individuals residing in a suburban service area who live within 5 miles of a retail pharmacy participating in the PBM's retail pharmacy network;

10.2.3.4 The percentage of covered individuals residing in a suburban service area who live within 7 miles of a retain pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network;

10.2.3.5 The percentage of covered individuals residing in a rural service area who live within 15 miles of a retail pharmacy participating in the PBM's retail pharmacy network; and

10.2.3.6 The percentage of covered individuals residing in a rural service area who live within 18 miles of a retail pharmacy designated as a preferred participating pharmacy in the PBM's retail pharmacy network;

10.2.4 A description of how network adequacy is monitored to ensure a reasonably adequate and accessible network;

10.2.5 The percentage change in the number of pharmacies in the pharmacy network from the previous year; and

10.2.6 Any other information that the PBM may wish to provide to demonstrate network adequacy.

11.0 Quarterly Reporting by PBMs

11.1 By January 15, April 15, July 15, October 15 of each year, a PBM shall provide a report of its rebating practices for the calendar quarter immediately preceding the report on a form provided by the Department (the "Rebate Report"), and shall include the following information for each insurer with which it contracts:

11.1.1 The name and Delaware registration number of the PBM;

11.1.2 The name and contact information of the person responsible for completing and filing the report with the Department;

11.1.3 The itemized amount of pharmacy benefits manager revenue sources, including professional fees, administrative fees, processing fees, audits, direct and indirect renumeration fees, or any other fees;

11.1.4 The aggregate dollar amount of rebates distributed to the appropriate insurer;

11.1.5 The aggregate dollar amount of rebates passed on to insureds of each insurer at the point of sale that reduced the insureds' applicable deductible, copayment, coinsurance, or other cost-sharing amount;

11.1.6 The individual and aggregate amount the insurer paid to the pharmacy benefits manager for pharmacy goods or services, itemized by all of the following:

11.1.6.1 Pharmacy;

11.1.6.2 Product; and

11.1.6.3 Goods and services; and

11.1.7 The individual and aggregate amount a pharmacy benefits manager paid for pharmacy goods or services, itemized by each of the following:

11.1.7.1 Pharmacy;

11.1.7.2 Product; and

11.1.7.3 Goods and services.

11.2 Failure to timely file a report as required under Section 11.0 of this regulation may result in the nonrenewal, suspension or revocation of the PBM's registration as set forth in 18 **Del.C.** Ch. 33A.

12.0 Review and Approval of Claim Adjudication Fees and Pharmacy Standards

12.1 Unless approved in advance by the Commissioner as provided in this Section 12.0, no PBM may do either of the following:

12.1.1 Charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including a fee for any of the following:

12.1.1.1 The receipt and processing of a pharmacy claim;

12.1.1.2 The development or management of claims processing services in a pharmacy benefits manager network; or

12.1.1.3 Participation in a pharmacy benefits manager network; or

12.1.2 Require a pharmacy accreditation standard or certification requirement that is inconsistent with, more stringent than, or in addition to any requirements of the Board of Pharmacy.

12.2 To seek Commissioner approval of a fee as required under subsection 12.1.1 of this regulation, a PBM shall provide the following minimum information:

12.2.1 The name, registration number and contact information of the PBM;

12.2.2 The fee for which the PBM seeks approval;

12.2.3 A statement regarding how the fee is to be charged, the need for the fee, and whether the fee represents a new fee, or an increase or decrease in a previously-charged fee;

12.2.4 A statement as to whether the requested fee applies to all contracted pharmacies within its complete network or a subset of contracted pharmacies. If the fee applies only to a subset of contracted pharmacies and/or the amount of the fee varies among contracted pharmacies, the statement should include the reason for the differential treatment among contracted pharmacies;

12.2.5 The PBM's anticipated revenue from the fee; and

12.2.6 Any other information the PBM wants the Department to consider as justification for the proposed fee.

12.3 To seek Commissioner approval of a pharmacy accreditation standard or certification requirement as required under subsection 12.1.2 of this regulation, a PBM shall provide the following minimum information on a form provided by the Department for such purposes:

12.3.1 The name, registration number and contact information of the PBM;

12.3.2 The accreditation standard or certification requirement sought to be implemented;

12.3.3 A statement of how the accreditation standard or certification requirement deviates from the requirements of the Board of Pharmacy;

12.3.4 Detailed justification for the necessity of an accreditation standard or certification requirement that is inconsistent with, more stringent than, or in addition to the requirements of the Board of Pharmacy, including the risk it is intended to mitigate and why the Board of Pharmacy standards are not sufficient for those purposes;

12.3.5 A statement whether the accreditation standard or certification requirement applies to all contracted pharmacies or a subset of contracted pharmacies. If the standard or requirement applies only to a subset of contracted pharmacies, the statement should include the reason for the differential treatment among contracted pharmacies;

12.3.6 A statement describing how application of the accreditation standard or certification requirement may impact patient access to pharmacy services or the PBM's network;

12.4 Upon receipt by the Department of a submission pursuant to subsection 12.3 of this regulation, the Department shall forward a copy of the submission to the Executive Director of the Board of Pharmacy to be placed on the agenda for the Board of Pharmacy's next available public meeting.

12.4.1 The PBM shall supplement its filing under subsection 12.3 of this regulation with any additional information requested by either the Department or the Board of Pharmacy.

12.4.2 Following consideration of the submission by the Board of Pharmacy, the Department shall take under advisement any recommendation provided or position taken by the Board of Pharmacy regarding the additional accreditation standard or certification requirement when rendering a final decision on the PBM's sub-mission under subsection 12.3 of this regulation.

~~9.0~~ 13.0Severability

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~~ 14.0Effective Date

This Regulation shall become effective August 11, 2020. The effective date of the revisions to Section 8.0 is January 11, 2022. The amendments implementing House Bill 219 (151st General Assembly) shall become effective 11 days after the publication of a final order adopting those subsections and sections.

24 DE Reg. 167 (08/01/20)
25 DE Reg. 715 (01/01/22)
26 DE Reg. 594 (01/01/23) (Final)