

DEPARTMENT OF INSURANCE
OFFICE OF THE COMMISSIONER

Statutory Authority: 18 Delaware Code, Sections 311 and 3359A(c) (18 **Del.C.** §§311 & 3359A(c))

FINAL

REGULATORY IMPLEMENTING ORDER

1411 Registration of Pharmacy Benefits Managers

I. SUMMARY OF THE EVIDENCE AND INFORMATION SUBMITTED

In the April 1, 2020 edition of the *Register of Regulations* at 23 **DE Reg.** 834, the Commissioner of the Delaware Department of Insurance (Commissioner), published a notice of intent to propose new Regulation 1411. The proposed new regulation 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.

The Delaware Code authority for the regulation is 18 **Del.C.** §§311 and 3359A(c).

The Department solicited written comments from the public for thirty (30) days as mandated by the Administrative Procedures Act at 29 **Del.C.** §10118(a). The Department published a written notice of a thirty-day comment period extension in the May 1, 2020 *Register of Regulations* (see 23 **DE Reg.** 947). The Department did not hold a public hearing on the proposal.

The Department received comments from five commenters which are on file with the Department.

Two commenters voiced strong support of the legislative and regulatory efforts to promote transparency in drug pricing and in the drug distribution system. However, one of the commenters believes that increased transparency and registration requirements are not enough. The commenter requested that the Commissioner and Delaware legislators consider legislation similar to that passed in Nevada that specifies that PBMs have a fiduciary duty to a third party with which the PBM has entered into a contract to manage that party's pharmacy benefits plan, opining that such legislation would require the PBM to act in the best interest of the pharmacies or consumers it serves and would further protect the citizens of Delaware.

Two commenters requested that definitions of the terms "affiliate," and "GAAP" be stricken from subsection 2.0 of the proposed regulation, opining that these terms are not used in the text of the regulation.

Several commenters opined that the requirement of subsection 4.2.3 that PBMs file a business plan statement including staffing levels and 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 is not a statutory condition for registration and lacks a clear standard for measurement of sufficiency.

Two commenters objected to the requirement at subsection 4.2.4 that PBM applicants file a copy of a standard, generic contract template used with pharmacists, pharmacies or pharmacy services administrative organizations. The commenters opined that the statute does not require contracts to be filed and stated that it is unclear to the commenters how this requirement assists the Department in processing registrations of PBMs or what is the connection between filing a template and a claims handling requirement, concluding that the requirement should be stricken as, in the commenter's opinion, the requirement falls outside the scope of the law.

Two commenters pointed out that subsection 4.2.4.2 requires the filing of several policies and procedures within the scope of registration, stating that the commenters understand that if the Department should have a compliance issue, information related to such an issue can be requested. However, the commenters expressed that they did not understand why the requirement would be necessary for registration purposes and requested that it be stricken, or, in the alternative, that specifically subsection 4.2.4.2.2, regarding maximum allowable cost (MAC) pricing, be stricken because 18 **Del.C.** §3323A relates to specific requirements for a MAC list as opposed to policies and procedures.

Commenters also objected to the requirements in subsections 4.2.4.3 and 4.2.4.4 concerning reporting of the number of projected enrollees or beneficiaries in Delaware on an annual basis, and network service areas by county for an insurer, including the pharmacy directory list, because the commenters believe that this mandate is part of an insurer's network adequacy filing already required and maintained by the Department, and because the commenters believe that the requirement falls outside the scope of the statute.

Two commenters requested additional flexibility be added to the requirement at subsection 4.5 that PBM applicants notify the Commissioner of any material change in ownership within 10 days.

Several commenters objected to the requirement at subsection 4.6 that a PBM applicant make available for inspection

by the Commissioner copies of all contracts with insurers, opining that the enabling statute does not require PBM-client contracts to be submitted, nor are PBM-client relationships the subject of this law.

Several commenters requested a clarification of the term "financially hazardous condition" as used in Section 5.0, which outlines application or renewal denials. These commenters opined that PBMs operate under the regulatory umbrella of a health insurance provider who accepts risk and follows the financial requirements for insurers. Two commenters raised concerns about subsection 5.3.1, as the standards used of "competent, trustworthy, financially responsible or of good personal and business reputation" are, in the commenters' opinion, vague and unsupported by the statute.

Subsection 6.1.3.4 authorizes the Commissioner to deny, suspend or revoke the certificate of registration of a PBM if the Commissioner finds the PBM has refused to pay clean claims or perform services arising under its contracts. Commenters objected to this provision, stating that compliance and enforcement of prompt pay laws are outside the scope of the enabling statute. Additionally, two commenters pointed out that contracts between PBMs and pharmacies set forth dispute resolution remedies in accordance with Delaware law, that those contract terms determine the rights and obligations of the parties, and that the parties to the contract are responsible for enforcing the terms if there has been a breach or another issue with the contract, such that this is not part of the Commissioner's enforcement authority.

Commenters also commented on subsection 6.1.4, which states that a PBM certificate of registration may be revoked if a PBM refuses to produce or allow examination of accounts, records and files of any individual responsible for the conduct of affairs of the PBM. The commenters opined that this provision appears to require examination of the individual's personal accounts and information, which is unnecessary and is outside the scope of the law, and requested that it be stricken, or in the alternative, that the section be limited to examination of records and files at issue to those relevant to the PBM's affairs.

Several commenters recommended that subsections 7.4 and 7.5 should be amended to include protection of proprietary and confidential information. Two commenters suggested that the language in subsection 7.5 be reconciled with the language in subsection 7.4 by amending subsection 7.5 to recognize that any information reported must not include proprietary/confidential information and is instead protected under the confidentiality provisions referenced in 18 **Del.C.** §321(g).

Two commenters opined that subsection 7.6 grants the insurer or purchaser "ownership" of the records generated by the PBM pertaining to the insurer or purchaser, as applicable, and objected to this provision because the statute does not address a transfer of ownership of such information and therefore, goes beyond the statute and would interfere in existing contract terms with regard to client access to relevant records.

Finally, subsection 7.8 requires that a PBM who is applying for registration or is registered in the state to produce its accounts, records, and files for examination and make its officer available to give information as often as reasonably required by the Commissioner. Two commenters expressed concern about this provision because "as often as reasonably required" is, in their opinion, overly broad. These commenters recommended that subsection 7.8 be amended to tie frequency to an annual exam, official business, etc. Additionally, rather than broadly referencing "officers," the commenters suggested that this section be amended to be limited to a designated officer for simplifying such a request for information from the Commissioner.

II. FINDINGS OF FACTS

1. Proposed new Regulation 1411 Registration of Pharmacy Benefits Managers implements the registration requirements of HB 194/HA 1 (82 Del. Laws, c. 115 (2019)), promulgated at 18 **Del.C.** §3353A.

2. The Department acknowledges the comments in support of the regulation.

3. The Department agrees that the term "GAAP" is not used in the regulation and is therefore superfluous. The Department will delete this term and its definition upon adoption. However, the Department declines to delete the term "affiliate" from the definitions section as this term is used in the regulation at subsection 7.5.

4. The Department declines to delete subsection 4.2.3. The Department interprets the comment as a challenge to the Department's authority to include within the application a statement describing the applicant's business plans, including staffing levels and proposed activities, capability to handle claims processing and record keeping.

The Department has broad authority under 18 **Del.C.** §3355A(a) to determine whether a registration should be denied, suspended or revoked, and the information requested will inform the grounds for which the Department makes such a determination. Information regarding the applicant's business plans will help the Department in its analysis of whether the PBM can comply with the requirements of Chapter 33A in the first instance. Accordingly, the Department necessarily needs to request enough information or documentation with the initial and renewal applications to make an informed determination on registration.

5. The Department declines to delete the requirement at subsection 4.2.4 that an applicant must supply a copy of the generic contract. Allowing the Department to review a template contract will help the Department ensure that the contract does not include Chapter 33A-proscribed contract provisions. Additionally, since violations of any provision of Chapter 33A and the commission of illegal activities constitute grounds for denial of registration, the contract is relevant in making that determination. However, the Department will revise the heading at subsection 4.2.4 to "information on the applicant's compliance with Chapter 33A requirements, including . . ." for clarity. This change is not substantive in nature and, therefore, may be made upon adoption.

6. The Department declines to delete the requirement at subsection 4.2.4.2 concerning the filing of several policies and procedures. The Department has the right to request information to confirm that the PBM is not in violation of any laws before a PBM is registered and it can be considered a conservation of regulatory resources and a matter of consumer protection to so confirm before, rather than waiting until after, any compliance issues arise. Moreover, to the extent that 18 **Del.C.** §3323A requires a PBMs to "maintain a procedure to eliminate products" from the MAC list, the Department is within its statutory authority to request procedures concerning the updating of an applicant's MAC lists.

7. Upon review and consideration of the comments received, the Department has determined to strike subsections 4.2.4.3 and 4.2.4.4 as being beyond the scope of the statute, as the statute does not give the Department the authority to regulate network adequacy standards for PBMs. A bill has recently been introduced in the General Assembly that would give the Department authority in this area and, therefore, the Department will revisit the inclusion of these provision into Regulation 1411 should those provisions become law. The Department will strike these subsections on adoption to conform the regulation to the statute.

8. The Department accepts the request to expand the 10-day timeframe within which a PBM must notify the Commissioner of any material change in ownership at subsection 4.5 and will expand the timeframe to within 15 days after the end of the calendar month in which any of the foregoing transactions occur. This change is procedural in nature and, therefore, the Department finds it is not a substantive change and it can therefore be made upon adoption.

9. The Department will strike that portion of subsection 4.6 that requires PBMs to make available for inspection all contracts with insurers. The Department finds that this requirement is superfluous since 18 **Del.C.** § 3357A(a), as further reflected in subsection 7.3 of the regulation, authorizes the Commissioner to examine the affairs, books and records of a registered PBM. This change is not substantive in nature and, therefore, may be made upon adoption.

10. The Department agrees to strike the requirement at subsection 5.1.1 concerning the standard of review of an application regarding whether the PBM is operating in a financially hazardous condition. Since the Department is not requiring the submission of financial information in the application process, it would not be able to know that the PBM is operating in a financially hazardous condition. Striking this provision adds consistency to the regulation and is therefore non-substantive and technical in nature and may be made upon adoption.

11. The Department will strike the phrase "competent, trustworthy, financially responsible or of good personal and business reputation" at subsection 5.3.1. The Department finds that this requirement is superfluous since the grounds for denial, suspension or revocation of registration certificate are set forth with specificity at subsection 6.0. The Department is also striking the superfluous phrase "with respect to the pharmacy benefits manager" from the end of subsection 5.3.3. These changes are non-substantive and technical in nature and, therefore, may be made upon adoption. The Department is also striking the phrase "with respect to the pharmacy benefits manager" from the end of subsection 5.3.3. because it inadvertently restricts the scope of the authorizing statute and subsection 6.0.

12. At subsection 6.1.3.4., the Department recognizes that it did not define the term "clean claims" in the published draft of the regulation. The Department has determined to revise subsection 6.1.3.4 to clarify what it intended by its use of the term "clean claims" with respect to pharmacy reimbursements. The Department will clarify that instead of "clean claims," the statutorily relevant information is information concerning reimbursements in compliance with the PBM's contracts. Chapter 33A not only requires registration but also requires compliance with statutory mandates that dictate how PBMs may operate in the state. Moreover, the statute at 18 **Del.C.** §3355A(a)(3) specifically states that the Department may suspend or revoke a certificate if it finds that the PBM, "in connection with the administration of pharmacy benefits manager services, commits fraud or illegal or dishonest activities." The Department views this change as clarifying and therefore non-substantive in nature.

13. The Department agrees that subsection 6.1.4 could be further clarified to ensure that examination of accounts, records and files of any individual responsible for the conduct of affairs of the PBM do not require examination of the individual's personal accounts and information. The Department will add a clarifying phrase at the beginning of this subsection.

14. The Department declines to make the suggested change to subsections 7.4 and 7.5 concerning confidentiality. The Insurance Code at 18 **Del.C.** §321(g) relates to work papers and documents underlying a final order or report of the Department. Subsection 7.5 of the proposed regulation relates to a final adjudication itself (i.e. the final order or examination report), which is generally public pursuant to the Delaware Freedom of Information Act ("FOIA") and 29 **Del.C.** § 10112(a)(1). In addition, the language in subsection 7.5 is already qualified by the language "that are open to public inspection" under FOIA. The Department retains the ability to determine whether any document is subject to FOIA's disclosure requirements or constitutes a nonpublic document.

15. The Department agrees to delete subsection 7.6 regarding ownership of documents as outside the scope of the PBM registration statute. Title 18 **Del.C.** §3356A governs record retention requirements for PBMs. However, the statute does not discuss who owns the documents. Striking this provision comports the regulation to the statute. Therefore, this change is non-substantive and technical in nature and may be made upon adoption.

16. The Department declines to make the edits to subsection 7.8 suggested by the commenters. However, the Department is substituting the promulgated phrase "considered advisable" for the phrase "reasonably required" to track verbatim the statutory language establishing the frequency with which the Commissioner may conduct examinations under the statute. This is a change that is non-substantive and technical in nature and may be made upon adoption.

17. The Department is also addressing typographical errors as permitted under the Administrative Procedures Act at 29 **Del.C.** §10113(b)(4).

18. The Department met the public notice requirements of the Administrative Procedures Act.

19. The Commissioner finds that it is appropriate to adopt new 18 **DE Admin. Code** 1411 as proposed in the April 1, 2020 *Register of Regulations* with further amendments in accordance with this Final Order, for the reasons set forth in this Final Order and in the proposal.

III. DECISION TO ADOPT PROPOSED NEW REGULATION 1411

For the foregoing reasons, the Commissioner concludes that it is appropriate to adopt proposed new 18 **DE Admin. Code** 1411 as further amended by this order.

IV. EFFECTIVE DATE OF ORDER

The actions referred to hereinabove were taken by the Commissioner pursuant to 18 **Del.C.** §§311 and 3359A(c) on the date indicated below. The effective date of this Order and of the regulation shall be August 11, 2020.

IT IS SO ORDERED.

The 15th day of July, 2020.

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) 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.

~~"GAAP" means United States generally accepted accounting principles consistently applied.]~~

"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 ~~[claims handling expertise 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;
 - ~~4.2.4.3 The number of projected enrollees or beneficiaries in Delaware to be serviced by the applicant on an annual basis for all contracted insurers. If applicable, provide the number of enrollees or beneficiaries administered by the applicant for each insurer during the previous year;~~
 - ~~4.2.4.4 A copy of the applicant's network service areas by county in this State for an insurer and the applicant's pharmacy directory list. Please list mail order pharmacies separately, because they may not be included in determining the adequacy of a retail pharmacy network;~~ 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 ~~[10 business days~~ **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 all contracts with insurers, and]~~ 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 Operates, or proposes to operate, in a financially hazardous condition relative to its financial condition and the services it administers, or proposes to administer for purchasers in Delaware;~~
 - ~~5.1.2~~ 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
 - ~~5.1.3~~ 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 Is not competent, trustworthy, financially responsible or of good personal and business reputation; or~~
- ~~5.3.2-5.3.1] Has had an insurance or a pharmacy benefits manager certificate or license denied or revoked for cause by any jurisdiction; or~~
- ~~[5.3.3-5.3.2]If the Commissioner determines that any of the grounds set forth in Section 6.0 of this regulation [exists with respect to the pharmacy benefits manager 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 [has have] entered a plea of guilty or *nolo contendere* [to, 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 [manager 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 [pay clean claims or perform services arising under make reimbursements in compliance with] its contracts [or, without just cause, causing covered individuals to accept less than the amount due them or causing covered individuals to employ attorneys or bring suit against the pharmacy benefits manager to secure full payment or settlement of such claims 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 [Refusing 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~~ **The insurer or purchaser, as applicable, shall own the records generated by the pharmacy benefits manager pertaining to the insurer or purchaser, as applicable; however, the pharmacy benefits manager shall retain the right to continuing access to books and records to permit the pharmacy benefits manager to fulfill all of its contractual obligations to insured parties, claimants, and the insurer or purchaser, as applicable.**

~~7.7~~ 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.

~~7.8~~ 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 ~~reasonably required~~ **considered advisable** by the Commissioner.

~~7.9~~ 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:

<u>Initial registration application</u>	<u>\$150.00</u>
<u>Renewal registration application</u>	<u>\$150.00</u>
<u>Amendment of certificate</u>	<u>\$150.00</u>

Duplicate or replacement certificate

\$150.00

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 [~~June~~ August] 11, 2020.

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