FINAL PROPOSED RULE # **25-P06**

Final Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Licensing Requirements for Pharmacy Benefit Managers

/s/ Sandy Bigglestone , on 4/3/2023

(signature) (date)

Printed Name and Title:
Sandy Bigglestone, Acting Commissioner

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

1. TITLE OF RULE FILING:
   Licensing Requirements for Pharmacy Benefit Managers
2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE
   25P006
3. ADOPTING AGENCY:
   Department of Financial Regulation
4. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: Susan Morris, Assistant General Counsel

   Agency: Department of Financial Regulation

   Mailing Address: 89 Main Street, Montpelier, VT 05620-3101

   Telephone: 802-798-6059 Fax:

   E-Mail: Susan.Morris@vermont.gov

   Web URL *(WHERE THE RULE WILL BE POSTED)*:
   https://dfr.vermont.gov/
5. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Dan Raddock, Assistant General Counsel

   Agency: Department of Financial Regulation

   Mailing Address: 89 Main Street, Montpelier, VT 05620-3101

   Telephone: 802-371-8980 Fax:

   E-Mail: Dan.Raddock@vermont.gov
6. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:
7. LEGAL AUTHORITY / ENABLING LEGISLATION:
   (THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

18 V.S.A. §3611(e), 18 V.S.A. §3603 and 18 V.S.A Chapter 77

8. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:
   Act 127 specifically assigned rulemaking under the statute (18 V.S.A. §3611(e))to the Commissioner of Financial Regulation to adopt rules to establish the licensing application, financial and reporting requirements for pharmacy benefit managers. 18 V.S.A. §3603 also directs the Commissioner to carry out the provisions of 18 V.S.A. Chapter 77 (Pharmacy Benefit Managers)and adopt rules to enforce this chapter.
9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.
10. THE AGENCY HAS INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
12. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
13. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
14. CONCISE SUMMARY (**150 WORDS OR LESS**):
    Following the passage of Act 127 in 2024, the Department of Financial Regulation was directed to adopt rules to establish the licensing application, financial and reporting requirements for PBMs. Pharmacy Benefit Managers (PBMs) are intermediaries between health insurance companies and drug manufacturers. They negotiate prescription drug prices with manufacturers and separately, they negotiate the reimbursement payable to pharmacies to dispense the drugs.
15. EXPLANATION OF WHY THE RULE IS NECESSARY:
    The rule is required by the enabling statute (18 V.S.A. §3611(e)), which directs the Commissioner of the Department of Financial Regulation to adopt rules to establish the licensing application, financial and reporting requirements for pharmacy benefit managers.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The rule is limited to setting forth the procedural process for obtaining a pharmacy benefit license in Vermont. The process detailed in the rule aligns with existing licensing procedures in place for other types of Department of Financial Regulation regulated entities operating in Vermont which have been found to be administratively effective for the Department and licensees in practice.

17. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Pharmacy benefit managers operating in Vermont that provide claim processing services, or other prescription drug services or device services for health benefit plans. Health insurance companies operating in Vermont that engage the services of a pharmacy benefit manager and who are licensed by the Insurance Division of the Department of Financial Regulation. Health plan members in Vermont with prescription drug coverage administered or managed by a pharmacy benefit manager.

18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

19. A HEARING WAS HELD.

20. HEARING INFORMATION
(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 2/27/2025

Time: 01:00 PM

Street Address: This hearing was held remotely via Microsoft Teams.

Zip Code:

URL for Virtual: https://teams.microsoft.com/l/meetup-join/19%3ameeting_YTNkZjgzZmItMzNiMi00Y2FlLWI3OGEtNjYxMDg1OGE0NTM1%40thread.v2/0?context=%7b%22Tid%22%3a%2220b4933b-baad-433c-9c02-70edcc7559c6%22%2c%22Oid%22%3a%22d2587d24-913a-4985-

921f-d30ba33292b8%22%7d

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
    3/6/2025

    KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

pharmacy benefit manager
health benefit plan
prescription drug
pharmacy
prescription

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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1. TITLE OF RULE FILING:
   Licensing Requirements for Pharmacy Benefit Managers
2. ADOPTING AGENCY:
   Department of Financial Regulation
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT -** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
   - **NEW RULE -** A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **A NEW RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE)*:

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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1. TITLE OF RULE FILING:

   Licensing Requirements for Pharmacy Benefit Managers

2. ADOPTING AGENCY:

   Department of Financial Regulation

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Parties potentially affected by the rule include: pharmacy benefit managers, health insurance companies licensed by the Department of Financial Regulation, and health plan members in Vermont with prescription drug coverage administered or managed by a pharmacy benefit manager.

This rule, in and of itself, does not impose any fees or costs on pharmacy benefit managers or health insurance companies operating in Vermont. Licensing and renewal license fees were established by the legislature under Act 127. This rule is limited to setting forth the procedural process by which pharmacy benefit managers may make an application for a pharmacy benefit manager license or renewal thereof.

The rule will benefit health plan members by establishing a pharmacy benefit manager licensing procedure aiding the Department of Financial Regulation's assessment pharmacy benefit managers to help ensure pharmacy benefit managers are competent, trustworthy, have a good business reputation and have not violated insurance laws in Vermont or any other states.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

The rule will not have an impact on public education, public schools, local school districts and/or taxpayers.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

In the absence of a pharmacy benefit manager licensing and reporting procedure as required by statute, the Department of Financial Regulation lacks an effective application process from which to provide oversight and enforcement into the conduct and practices of pharmacy benefit managers.

This rule will remedy this by providing the Department with a procedural process and subsequent visibility into the organizational structure, business practices and financial soundness of pharmacy benefit managers through the detailed application process.

6. IMPACT ON SMALL BUSINESSES:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

The rule will not have an impact on small businesses. Of note, pharmacy benefit managers themselves are not small businesses. Rather they are large, national, for organizations.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

An evaulation of the cost/burden impact is unnecessary as the rule will not impact small businesses.

8. COMPARISON:

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

The rule is required by the enabling statute (18 V.S.A. §3611(e)), which directs the Commissioner of the Department of Financial Regulation to adopt rules establish the licensing application, financial and reporting requirements for pharmacy benefit managers. Given this legistative mandate, no alternatives were considered.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

The rule, in and of itself, does not impose any fees or costs on pharmacy benefit managers or health insurance companies operating in Vermont. The rule sets forth the procedural process for obtaining an initial or renewal pharmacy benefit license in Vermont as required by the enabling statute. In establishing the application procedure, the Department of Financial Regulation looked to its other established licensing application procedures for other licensed entities as they have proven, over time, to be administratively effective for the Department and licensees. This rule's procedure closely aligns with licensing procedures utilized by the Department.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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1. TITLE OF RULE FILING:

   Licensing Requirements for Pharmacy Benefit Managers

2. ADOPTING AGENCY:

   Department of Financial Regulation

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No impact anticipated.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   No impact anticipated.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   No impact anticipated.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No impact anticipated.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No impact anticipated.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No impact anticipated.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The substance of this rule will have no anticipated impact on the environment. Therefore, no further analysis is warranted.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

   Licensing Requirements for Pharmacy Benefit Managers

2. ADOPTING AGENCY:

   Department of Financial Regulation

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   Prior to initiating formal rulemaking, the Department shared a copy of the proposed rule with the stakeholders listed in Section 4. to solict feedback prior to finalizing the rule. In conjunction with formal rulemaking, the Department will post the rule and related information on its website as well as make paper copies available. The Department will hold one public hearing that will be conducted remotely via Microsoft Teams. Call-in information for the meeting will be posted on the Department's website. The Department will also individually contact the stakeholders identified in Section 4, as well as anyone who inquires about the status of Act 127 rulemaking, to identify that the rule is available for public comment.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   - Vermont Retail Drug Association

- Vermont Pharmacists Association
- Vermont Medical Society
- Vermont Association of Hospitals and Health Systems
- MVP Health Care
- Cigna
- Blue Cross Blue Shield of Vermont
- Office of Professional Regulation
- Health Care Advocate’s Office
- Office of the Attorney General
- Pharmacy benefit managers - CVS Health, Express Scripts, Optum Rx
- Pharmaceutical Care Management Association

Incorporation by Reference

THIS FORM IS ONLY REQUIRED WHEN INCORPORATING MATERIALS BY REFERENCE. PLEASE REMOVE PRIOR TO DELIVERY IF IT DOES NOT APPLY TO THIS RULE FILING:

Instructions:

In completing the incorporation by reference statement, an agency describes any materials that are incorporated into the rule by reference and how to obtain copies.

This form is only required when a rule incorporates materials by referencing another source without reproducing the text within the rule itself (e.g., federal or national standards, or regulations).

Incorporated materials will be maintained and available for inspection by the Agency.

1. TITLE OF RULE FILING:

   Licensing Requirements for Pharmacy Benefit Managers

2. ADOPTING AGENCY:

   Department of Financial Regulation

3. DESCRIPTION (*DESCRIBE THE MATERIALS INCORPORATED BY REFERENCE)*:

   This rule incorporates the following Vermont laws and regulations by reference: Title 8 Section 2104.

4. FORMAL CITATION OF MATERIALS INCORPORATED BY REFERENCE:
   8 V.S.A §2104

5. OBTAINING COPIES: *(EXPLAIN WHERE THE PUBLIC MAY OBTAIN THE MATERIAL(S) IN WRITTEN OR ELECTRONIC FORM, AND AT WHAT COST)*:

   Cited materials are available online at the following links: Vermont Statutes Annotated: https://legislature.vermont.gov/statutes/

   Although all cited materials are readily available online, members of the public may obtain printed copies by contacting the Department by phone at 802-828-3301.

6. MODIFICATIONS (*PLEASE EXPLAIN ANY MODIFICATION TO THE INCORPORATED MATERIALS E.G., WHETHER ONLY PART OF THE MATERIAL IS ADOPTED AND IF SO, WHICH PART(S)ARE MODIFIED)*:

7. *E MODIFIED)*:

No modifications have been made to the cited material.

Run Spell Check

Vermont Department of Financial Regulation – Insurance Division

LICENSING REQUIREMENTS FOR PHARMACY BENEFIT MANAGERS

TABLE OF CONTENTS

SECTION 1. PURPOSE

The purpose of this rule is to set forth the requirements and standards for the licensing of persons or entities that establish or operate as a pharmacy benefit manager under 18 V.S.A. §3611 and 18 V.S.A. Chapter 77.

SECTION 2. AUTHORITY

This rule is adopted under the authority granted to the Commissioner by 18 V.S.A. §3611(e) and 18 V.S.A. §3603.

SECTION 3. DEFINITIONS

(a) "Commissioner" shall mean the Commissioner of Financial Regulation.

(b) "Health benefit plan" has the same meaning as in 18 V.S.A. §3602(4).

(c) "Pharmacy benefit manager" has the same meaning as in 18 V.S.A. §3602 (12).

(d) "Pharmacy benefit manager affiliate" has the same meaning as in 18 V.S.A. §3602(13).

(e) "Pharmacy benefit management" has the same meaning as in 18 V.S.A §3602(11).

SECTION 4. APPLICABILITY AND SCOPE

No person or entity meeting the definition of a pharmacy benefit manager shall engage in

pharmacy benefit management in this state without a valid and current pharmacy benefit manager license. Such license is not transferable or assignable and is valid only for the person or entity to whom issued.

SECTION 5. INITIAL LICENSE APPLICATION

(a) On or before January 1, 2026, and each year thereafter, each pharmacy benefit manager operating in Vermont shall complete a pharmacy benefit manager license application and submit to the Commissioner. The pharmacy benefit manager shall provide as part of the license application the following:

(1) Pharmacy benefit manager officer and business contact information including:

(A) The name and address of the pharmacy benefit manager;

(B) The names, business addresses, and job titles of the principal officers of the pharmacy benefit manager;

(C) The name, business address, business telephone number, business email address, and job title of the officer or employee who should be contacted regarding any pharmacy benefit manager regulatory compliance concerns; and

(D) The business telephone number and business email address where the pharmacy benefit manager personnel directly responsible for the processing of appeals from patients, providers and pharmacies may be contacted.

(2) Pharmacy benefit management organization documents:

(A) A copy of the pharmacy benefit manager's organizational documents, including Articles of Incorporation, Articles of Association, and partnership agreements;

(B) A copy of all by-laws or similar document(s), if any, regulating the conduct or the internal affairs of the pharmacy benefit manager or pharmacy benefit management affiliates; and

(C) The relevant documentation, such as policies and procedures, and a detailed explanation, that demonstrates the pharmacy benefit manager has adopted processes to ensure compliance with Act 127 of 2024 (18 V.S.A. §§ 9472-9473; 18 V.S.A. §3612, §3622 and §3631)

(3) Financial and Other Documents

(A) The most recent year-end financial statement for the pharmacy benefit manager;

(B) A listing of all health benefit plans the pharmacy benefit manager contracts with to provide pharmacy benefit management services for, in

Vermont, including any self-funded or governmental plans;

(C) The number of projected enrollees or beneficiaries in Vermont to be serviced by the applicant during the upcoming year for all contracted health benefit plans; and

(D) A listing of any delegated or contracted companies that perform part of the pharmacy benefit manager's pharmacy benefit management services.

(4) Required Responses

A certified statement indicating whether the pharmacy benefit manager:

(A) Has been refused or denied a registration, license, or certification to act as or provide the services of a pharmacy benefit manager in any state or federal entity, providing specific details separately for each such refusal or denial, if any, including the date, nature and disposition of the action;

(B) Has had any registration, license or certification to act as or provide the services of a pharmacy benefit manager suspended, revoked or nonrenewed for any reason by any state or federal entity, providing specific details separately for each such suspension, revocation or nonrenewal, if any, including the date, nature and disposition of the action;

(C) Has had a business relationship with a health plan terminated for cause, including for breach of contract or fiduciary duty, or anyfraudulent behavior in connection with the administration of a pharmacy benefits plan, providing specific details regarding the termination; and

(D) Has been the defendant or respondent in legal proceedings that have resulted in findings of fraudulent or illegal activities by a court of law or regulatory body, providing specific details of the case or matter.

(b) Application Fee

The applicant shall provide as part of the license application a nonrefundable application fee and an initial licensure fee, pursuant to 18 V.S.A. §3611(b).

(c) A pharmacy benefit manager providing services to less than 100 individuals in Vermont and unable to provide a required document in section 5 may submit to the Commissioner an exception request. The request must list the required document and provide a brief explanation.

(d) If the applicant asserts information submitted in connection with an initial license application is proprietary or otherwise exempt from public inspection and copying under the Vermont Public Records Act, the applicant must designate the specific section or document claimed as exempt and provide a detailed explanation supporting the claim for exemption, including reference to applicable sections of the Vermont Public Records Act and other applicable law.

SECTION 6. RENEWAL LICENSE APPLICATION

(a) Beginning on January 1, 2026, and each year thereafter, each pharmacy benefit manager operating in Vermont shall complete a renewal license application.

(b) The pharmacy benefit manager shall provide as part of the renewal application the information in section 5(a).

(c) The pharmacy benefit manager shall submit a non-refundable annual renewal license fee pursuant to 18 V.S.A. § 3611(d)(3).

(d) If the applicant asserts information submitted in connection with a renewal license application is proprietary or otherwise exempt from public inspection and copying under the Vermont Public Records Act, the applicant must designate the specific section or document claimed as exempt and provide a detailed explanation supporting the claim for exemption, including reference to applicable sections of the Vermont Public Records Act and other applicable law.

SECTION 7. APPLICATION REVIEW

(a) Upon receipt of a completed application for an initial or renewal pharmacy benefit manager license as required by section 5 and 6, the Commissioner shall review the application and may take the following actions:

(1) Approve the application;

(2) Notify the applicant, in writing, that the application is incomplete and request additional information to complete the review and, if the missing or requested information is not received, the Commissioner may deny the application; or

(3) Deny a license pursuant to the criteria set forth in 18 V.S.A §3611(c). If a pharmacy benefit manager license is denied, the Commissioner shall:

(A) Provide written notice to the applicant that the application has been denied and the grounds therefore; and

(B) Advise the applicant that they may request a reconsideration in accordance with 8 V.S.A §2104.

SECTION 8. SEVERABILITY

If any provision of this rule or the application of it to any person, entity or circumstance is for any reason held to be invalid, the remainder of this rule shall not be affected.

SECTION 9. ENFORCEMENT

(a) The Commissioner shall deny, suspend or revoke the license of a pharmacy benefit manager, or shall issue a cease and desist order should the pharmacy benefit manager not have a license if, after notice and opportunity for hearing, the Commissioner finds that the pharmacy benefit manager:

(1) Is in an unsound financial condition;

(2) Is not competent, trustworthy, or of good personal and business reputation;

(3) Has been found to have violated the insurance laws of this State or any other jurisdiction or has had an insurance license, registration or other certification or license denied, suspended, nonrenewed or revoked for cause by any jurisdiction.

(4) Is using such methods or practices in the conduct of its business so as to render its further transaction of business in this state hazardous or injurious to insured persons or the public;

(5) Has failed to pay any judgment rendered against it in this state within sixty (60) days after the judgment has become final;

(6) Has refused to have its books and records examined or audited as it relates to its provision of pharmacy benefit management;

(7) Is required under this rule to have a pharmacy benefit manager license and fails at any time to meet any qualification for which issuance of a license could have been refused had the failure then existed and been known to the Commissioner, unless the Commissioner issued a license with knowledge of the ground for disqualification and had the authority to waive it; or

(8) Has failed to provide the required documents required under this rule.

(b) The Commissioner may, without advance notice, and before a hearing may issue an order immediately suspending the license of a pharmacy benefit manager, or may issue a cease and desist order should the pharmacy benefit manager not have a license, if the Commissioner finds that one or more of the following circumstances exist:

(1) The pharmacy benefit manager is insolvent or impaired;

(2) A proceeding for receivership, conservatorship, rehabilitation, or other delinquency proceeding regarding the pharmacy benefit manager has been commenced in any state; or

(3) The financial condition or business practices of the pharmacy benefit manager otherwise pose an imminent threat to the public health, safety, or welfare of Vermont residents.

(c) At the time an order has been issued by the Commissioner in accordance with subsection b of this section, the Commissioner shall serve notice to the pharmacy benefit manager that the pharmacy benefit manager may request a hearing within ten business days after the receipt of the order. If a hearing is requested, the Commissioner shall schedule a hearing within ten business days after receipt of the request. If a hearing is not requested and the Commissioner orders none, the order shall remain in effect until modified or vacated by the Commissioner.

If the Commissioner finds that one or more grounds exist for the suspension or revocation of a license issued under this part, or for a cease and desist order, the Commissioner may, in lieu of or in addition to the suspension, revocation or cease and desist order, impose a fine upon the pharmacy benefit manager.

SECTION 10. EFFECTIVE DATE

This rule shall take effect upon adoption.

Vermont Department of Financial Regulation

LICENSING REQUIREMENTS FOR PHARMACY BENEFIT MANAGERS

TABLE OF CONTENTS

SECTION 1. PURPOSE

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SECTION 2. AUTHORITY

This rule is adopted under the authority granted to the Commissioner by 18 V.S.A. § 3611(e) and 18 V.S.A. §3603.

SECTION 3. DEFINITIONS

(a) "Commissioner" shall mean the Commissioner of Financial Regulation.

(b) "Health benefit plan" has the same meaning as in 18 V.S.A. § 3602(4).

(c) "Pharmacy benefit manager" has the same meaning as in 18 V.S.A § 3602 (12~~((A~~).

(d) "Pharmacy benefit manager affiliate" has the same meaning as in 18 V.S.A. § 3602(13).

(e) "Pharmacy benefit management" has the same meaning as in 18 V.S.A § 3602(11).

SECTION 4. APPLICABILITY AND SCOPE

No person or entity meeting the definition of a pharmacy benefit manager shall engage in

pharmacy benefit management~~provide claims processing services, prescription drug or device services for health benefit plans~~ in this state without a valid and current pharmacy benefit manager license. Such license is not transferable or assignable and is valid only for the person or entity to whom issued.

SECTION 5. INITIAL LICENSE APPLICATION

(a) On or before January 1, 2026, and each year thereafter, each pharmacy benefit manager operating in Vermont shall complete a pharmacy benefit manager license application and submit to the Commissioner. The pharmacy benefit manager shall provide as part of the license application the following:

(1) Pharmacy benefit manager officer and business contact information including:

(A) The name and address of the pharmacy benefit manager;

(B) The names, business addresses, and job titles of the principal officers of the pharmacy benefit manager;

(C) The name, business address, business telephone number, business email address, and job title of the officer or employee who should be contacted regarding any pharmacy benefit manager regulatory compliance concerns; and

(D) The business telephone number and business email address where the pharmacy benefit manager personnel directly responsible for the processing of appeals from patients, providers and pharmacies may be contacted.

(2) Pharmacy benefit management organization documents:

(A) A copy of the pharmacy benefit manager's organizational documents, including Articles of Incorporation, Articles of Association, and partnership agreements;

(B) A copy of all by-laws or similar document(s), if any, regulating the conduct or the internal affairs of the pharmacy benefit manager or pharmacy benefit management affiliates; and

(C) The relevant documentation, such as policies and procedures, and a detailed explanation, that demonstrates the pharmacy benefit manager has adopted processes to ensure compliance ~~with 18 V.S.A §§ 9472-9473 including any written policies or procedures describing the appeals or dispute resolution processes between the pharmacy benefit manager and a pharmacy benefit manager-affiliated pharmacy, as applicable.~~Act 127 of 2024.

(3) Financial and Other Documents

(A) The most recent year-end financial statement for the pharmacy benefit

manager;

(B) A listing of all health benefit plans the pharmacy benefit manager contracts with to provide pharmacy benefit management services for, in Vermont, including any ~~non-ERISA~~ self-funded or governmental plans;

(C) The number of projected enrollees or beneficiaries in Vermont to be serviced by the applicant during the upcoming year for all contracted health benefit plans; and

(D) A listing of any delegated or contracted companies that perform part of the pharmacy benefit manager's pharmacy benefit management services.

(4) Required Responses

A certified statement indicating whether the pharmacy benefit manager:

(A) Has been refused or denied a registration, license, or certification to act as or provide the services of a pharmacy benefit manager in any state or federal entity, providing specific details separately for each such refusal or denial, if any, including the date, nature and disposition of the action;

(B) Has had any registration, license or certification to act as or provide the services of a pharmacy benefit manager suspended, revoked or nonrenewed for any reason by any state or federal entity, providing specific details separately for each such suspension, revocation or nonrenewal, if any, including the date, nature and disposition of the action; ~~and~~

(C) Has had a business relationship with a health plan terminated for cause, including for breach of contract or fiduciary duty, or ~~any finding by a court of law of~~any fraudulent behavior ~~or illegal activities~~ in connection with the administration of a pharmacy benefits plan, providing specific details regarding the termination; and~~.~~

~~(C)~~(D) Has been the defendant or respondent in legal proceedings that have resulted in findings of fraudulent or illegal activities by a court of law or regulatory body, providing specific details of the case or matter.

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(b) Application Fee

The applicant shall provide as part of the license application a nonrefundable application fee of and an initial licensure fee, pursuant to 18 V.S.A. §3611(b).

(c) A pharmacy benefit manager providing services to less than 100 individuals in Vermont and unable to provide a required document in section 5 may submit to the Commissioner an exception request. The request must list the required document and provide a brief explanation.

(d) If the applicant asserts information submitted in connection with an initial license application is proprietary or otherwise exempt from public inspection and copying under the Vermont Public Records Act, the applicant must designate the specific section or document claimed as exempt and provide a detailed explanation supporting the claim for exemption, including reference to applicable sections of the Vermont Public Records Act and other applicable law.

SECTION 6. RENEWAL LICENSE APPLICATION

(a) Beginning on January 1, 2026, and each year thereafter, each pharmacy benefit manager operating in Vermont shall complete a renewal license application.

(b) The pharmacy benefit manager shall provide as part of the renewal application the information in section 5(a).

(c) The pharmacy benefit manager shall submit a non-refundable annual renewal license fee pursuant to 18 V.S.A. § 3611(d)(3).

(d) If the applicant asserts information submitted in connection with a renewal license application is proprietary or otherwise exempt from public inspection and copying under the Vermont Public Records Act, the applicant must designate the specific section or document claimed as exempt and provide a detailed explanation supporting the claim for exemption, including reference to applicable sections of the Vermont Public Records Act and other applicable law.

SECTION 7. APPLICATION REVIEW

(a) Upon receipt of a completed application for an initial or renewal pharmacy benefit manager license as required by section 5~~6~~ and ~~7~~6, the Commissioner shall review the application and may take the following actions:

(1) Approve the application;

(2) Notify the applicant, in writing, that the application is incomplete and request additional information to complete the review and, if the missing or requested information is not received, the Commissioner may deny the application; or

(3) Deny a license~~registration~~ pursuant to the criteria set forth in 18 V.S.A § 3611(c). If a pharmacy benefit manager license is denied, the Commissioner shall:

(A) Provide written notice to the applicant that the application has been denied and the grounds therefor; and

(B) Advise the applicant that they may request a reconsideration in accordance with 8 V.S.A § 2104.

SECTION 8. SEVERABILITY

If any provision of this rule or the application of it to any person, entity or circumstance is for any reason held to be invalid, the remainder of this rule shall not be affected.

SECTION 9. ENFORCEMENT

(a) The Commissioner shall deny, suspend or revoke the license of a pharmacy benefit manager, or shall issue a cease and desist order should the pharmacy benefit manager not have a license if, after notice and opportunity for hearing, the Commissioner finds that the pharmacy benefit manager:

(1) Is in an unsound financial condition;

(2) Is not competent, trustworthy, or of good personal and business reputation;

(3) Has been found to have violated the insurance laws of this State or any other jurisdiction or has had an insurance license, registration or other certification or license denied, suspended, nonrenewed or revoked for cause by any jurisdiction.

(4) Is using such methods or practices in the conduct of its business so as to render its further transaction of business in this state hazardous or injurious to insured persons or the public;

(5) Has failed to pay any judgment rendered against it in this state within sixty (60) days after the judgment has become final;

(6) Has refused to have its books and records examined or audited as it relates to its provision of pharmacy benefit management~~claim processing services or other prescription drug or device services for a health plan~~;

(7) Is required under this rule to have a pharmacy benefit manager license and fails at any time to meet any qualification for which issuance of a license could have been refused had the failure then existed and been known to the Commissioner, unless the Commissioner issued a license with knowledge of the ground for disqualification and had the authority to waive it; or

(8) Has failed to provide the required documents required under this rule.

(b) The Commissioner may, without advance notice, and before a hearing may issue an order immediately suspending the license of a pharmacy benefit manager, or may issue a cease and desist order should the pharmacy benefit manager not have a license, if the Commissioner finds that one or more of the following circumstances exist:

(1) The pharmacy benefit manager is insolvent or impaired;

(2) A proceeding for receivership, conservatorship, rehabilitation, or other delinquency proceeding regarding the pharmacy benefit manager has been commenced in any state; or

(3) The financial condition or business practices of the pharmacy benefit manager otherwise pose an imminent threat to the public health, safety, or welfare of Vermont residents.

(c) At the time an order has been issued by the Commissioner in accordance with subsection b

of this section, the Commissioner shall serve notice to the pharmacy benefit manager that the pharmacy benefit manager may request a hearing within ten business days after the receipt of the order. If a hearing is requested, the Commissioner shall schedule a hearing within ten business days after receipt of the request. If a hearing is not requested and the Commissioner orders none, the order shall remain in effect until modified or vacated by the Commissioner.

If the Commissioner finds that one or more grounds exist for the suspension or revocation of a license issued under this part, or for a cease and desist order, the Commissioner may, in lieu of or in addition to the suspension, revocation or cease and desist order, impose a fine upon the pharmacy benefit manager.

SECTION 10. EFFECTIVE DATE

This rule shall take effect upon adoption.

State of Vermont
Agency of Administration
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322

Sarah Clark, Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: January 13, 2025, virtually via Microsoft Teams
Members Present: Chair Sean Brown, Diane Sherman, Jennifer Mojo, John Kessler, Michael Obuchowski, Natalie Weill, and Nicole Dubuque
Members Absent: Jared Adler
Minutes By: Melissa Mazza-Paquette

- 3:01 p.m. meeting called to order, welcome and introductions.
  - Announcement made that Nick Kramer, Chief Operating Officer for the Agency of Administration will become the new Chair of ICAR effective February 24, 2025.
- Review and approval of minutes from the December 9, 2024 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- Note: the following emergency rule was supported by ICAR Chair Brown on 12/23/24:
  1) 'General Assistance Emergency Housing Assistance Emergency Rules' by the Agency of Human Services, Department for Children and Families
- No public comments made.
- Presentation of Proposed Rule on page 2 to follow.
  1. Licensing Requirements for Pharmacy Benefit Managers, Department of Financial Regulation
- Next scheduled meeting is February 10, 2025 at 2:00 p.m.
- 3:21 p.m. meeting adjourned.

Proposed Rule: Licensing Requirements for Pharmacy Benefit Managers, Department of Financial Regulation

Presented By: Susan Morris, Sebastian Arduengo, Dan Raddock

Motion made to accept the rule by , seconded by, and passed unanimously except for Diane Sherman who abstained, with the following recommendations:

1. Proposed Filing – Coversheet, #9: Review for omission as this section appears to be missing a word or comma.
2. Economic Impact Analysis, #6: Add the word 'profit' before the last word 'organizations'.
3. Public Input Maximization Plan, #3: Change 'was' to 'as' in the 6th line between "…its website" and "well as…".

VERMONT LEGAL AID

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264 North Winooski Ave., Burlington VT 05401
Toll Free Hotline: 800-917-7787
www.vtlawhelp.org/health ▪ Fax: 802-863-7152

March 6, 2025

Susan Morris, Esq.
Assistant General Counsel
Vermont Department of Financial Regulation
89 Main Street
Montpelier, VT 05602

RE: Office of the Health Care Advocate Comments regarding the Proposed Rule: Licensing Requirements for Pharmacy Benefit Managers

Dear Attorney Morris:

The Office of the Health Care Advocate respectfully submits the following comments regarding the Department of Financial Regulation's Proposed Rule: Licensing Requirements for Pharmacy Benefit Managers.

Section 3: Definitions

- The statutory definition of "pharmacy benefit manager" at 18 V.S.A. § 3602(12) includes two elements: an affirmative definition of what a pharmacy benefit manager is, and an exclusionary definition of what a pharmacy benefit manager is not. Since the rule states that the definition of pharmacy benefit manager "has the same meaning" as in statute, we recommend changing the rule text to read: "'Pharmacy benefit manager' has the same meaning as in 18 V.S.A. § 3602(12)."
- If the Department elects to keep the reference to subparagraph (A), it should correct the typographical error in the citation, i.e. "(12)(A)" instead of "(12((A)".

Section 4: Applicability and Scope

- We recommend changing the first sentence under this heading to "No person or entity meeting the definition of a pharmacy benefit manager shall engage in pharmacy benefit management in this state without a valid and current pharmacy benefit manager license." The term "pharmacy

benefit management" is defined in the rule, whereas the terms "claims processing services" and "prescription drug or device services" are not defined. Furthermore, the definition of "pharmacy benefit management" encompasses more than claims processing and prescription drug and device services, e.g. formulary management and care management. See 18 V.S.A. § 3602(11).

Section 5: Initial License Application

- In subparagraph (a)(2)(C), we think it is incorrect to refer to compliance with 18 V.S.A. §§ 9472-9473. Those sections are due to sunset on July 1, 2029. Further, those sections were recodified at 18 V.S.A. §§ 3612, 3622, and 3631.[1] At the same time, new language was added, such as the copay accumulator adjustment ban at 3612(e)(2) and the ban on spread pricing at 3612(f). Finally, per Section 4 of Act 127, any conflicts between the old and new sections are to be controlled by the new sections. For these reasons, we think the rule text should be changed to require PBMs to prove "compliance with 18 V.S.A. §§ 3612, 3622, and 3631".
- In subparagraph (a)(3)(B), we think the Department should strike "non-ERISA" such that the final clause reads, "including any self-funded or governmental plans". Broadening the language as such would provide the Department with a fuller picture of PBM operations in the state. Further, requiring PBMs to list all health plans they provide services to in the state, including ERISA plans, would not violate ERISA, since the requirement would not be a regulation of an ERISA health plan. If a court were to construe that portion of the rule to be preempted by ERISA, the offending language could be stricken via the severability clause in the rule.
- In subparagraph (a)(4)(C), we are concerned that a PBM could interpret the language as written to avoid disclosure. We also think it is confusing to tie reporting of terminated business relationships to court findings. We recommend separating these elements into two subparagraphs:
    - "Has a had a business relationship with a health plan terminated for cause, including for breach of contract or fiduciary duty, or fraudulent behavior in connection with the administration of a pharmacy benefits plan, providing specific details regarding the termination."

[1] We think this a complete list of the new sections where 18 V.S.A. §§ 9472-9473 were recodified, but there should be a thorough review before enactment of the rule.

    - "Has been the defendant or respondent in legal proceedings that have resulted in findings of fraudulent or illegal activities by a court of law or regulatory body, providing specific details of the case or matter."
- In subparagraph (b), we recommend deleting the word "of" following the first use of the word "fee", so the sentence reads: "The applicant shall provide as part of the license application a nonrefundable application fee and an initial licensure fee, pursuant to 18 V.S.A. § 3611(b)."

Section 7: Application Review

- The section references in paragraph (a) should be to sections 5 and 6, and the word "manager" should be inserted after "benefit", so the sentence reads "Upon receipt of a completed application for an initial or renewal pharmacy benefit manager license as required by sections 5 and 6, the Commissioner shall …"
- In subparagraph (a)(3) we recommend changing "registration" in the first line to "license" so the sentence reads: "Deny a license pursuant to …"

Section 9: Enforcement

- In subparagraph (a)(6), we recommend replacing the phrase "claim processing services or other prescription drug or device services" with "pharmacy benefit management". As stated previously, "pharmacy benefit management" is defined by the rule, and the definition is broader than encompassed by the current language.

Thank you for the opportunity to submit these comments regarding the proposed rule. Please do not hesitate to contact me with any questions at cbecker@vtlegalaid.org.

Sincerely,

/s/ Charles Becker
Staff Attorney
Office of the Health Care Advocate

601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

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March 6, 2025

Acting Commissioner Sandy Bigglestone
Of the Department of Financial Regulation
89 Main Street
Montpelier, VT 05620-3101

RE: AHIP Comments on Proposed Licensing Requirements for Pharmacy Benefits Managers

To Acting Commissioner Bigglestone,

AHIP appreciates the opportunity to comment on the proposed rule "Licensing Requirements for Pharmacy Benefit Managers" to reiterate our concern that the proposed regulation implementing Act 127 of 2024 (H.233) does not include an exemption for self-funded plans under the Employee Retirement Income Security Act of 1974 (ERISA) **and** Medicare Part D coverage.

During the legislative process for Act 127 of 2024 (H.233), AHIP requested policymakers to include explicit exemption language for ERISA self-funded and Medicare Part D coverage. We were particularly concerned that Act 127 of 2024 / H.233's broad definition of "health insurer" might be interpreted to apply to ERISA self-funded plans as well as Medicare Part D plans.

Charles Becker, staff attorney at the Office of the Health Care Advocate, has indicated the language is not intended to apply to federally preempted plans.[1] Mr. Becker noted that while the definition could be interpreted to apply to ERISA plans, the Department of Financial Regulation (DFR) has previously released bulletins, such as the Division of Health Care Administration's Bulletin 114, dated May 12, 2005,[2] that support the general position that ***the state does not have regulatory authority over plans that are exempt from state regulation by virtue of federal law, ultimately concluding Act 127 of 2024 / H.233 would not apply to plans regulated under federal law***.

While we greatly appreciate this on-the-record statement, an explicit exemption for both ERISA self-funded plans and Medicare Part D coverage – plans that are exempt from state legislation by virtue of federal law – would most clearly and accurately reflect the state's intent on applicability.

AHIP remains strongly opposed to <u>any</u> attempt to regulate ERISA self-funded plans and Medicare Part D plans that may move beyond the limits allowed under current federal preemption law and jurisprudence.

Should the state act contrary to such federal limits, it may jeopardize the cost-saving, uniform standards your state's ERISA self-insured employers rely upon to provide affordable health insurance coverage and it will increase costs for seniors and other individuals served under the Medicare Part D program. These

[1] https://www.youtube.com/live/o-mbhBeUZPM?si=ovrX-HRtAJkY77NJ (at the 1 hour and 27-minute mark)
[2] https://dfr.vermont.gov/sites/finreg/files/regbul/dfr-bulletin-health-114.pdf.

potential impacts would be significant as over 185,614 Vermonters take part in employer sponsored coverage, with [3][4]

AHIP's Recommendation*:* To protect Vermont seniors and employers from increased health care costs**,** AHIP urges you to codify the Office of Health Care Advocate's current regulatory position by including specific language clearly exempting ERISA self-funded plans and Medicare Part D plans.

Thank you for your consideration of this important request. AHIP and our member plans stand ready to work with you on this issue. Together, we can advance market-based innovative policy solutions that ensure Americans have access to high-quality and affordable care choices that deliver financial protection and peace of mind – now and for the future.

Sincerely,

Sarah Lynn Geiger, MPA
Regional Director, State Affairs

AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

[3] AHIP, Health Coverage: State-to-State – February 2023.
[4] Medicare Beneficiaries Enrolled in Part D Coverage | KFF

VERMONT

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[Securities] 877-550-3907
www.dfr.vermont.gov

April 3, 2025

Office of the Secretary of State
128 State Street
Montpelier, VT 056933

To whom it may concern,

The Department of Financial Regulation ("Department") submits its Final Proposed Rule titled "Licensing Requirements for Pharmacy Benefit Managers" (the "Rule") which includes changes from the Proposed Filing to the Vermont Secretary of State and the Legislative Committee on Administrative Rules (LCAR).

In response to comments received by a representative from Vermont Legal Aid, Office of Health Care Advocate, during the public comment period, the Department made the following changes to the Rule as shown:

Section 3. DEFINITIONS

(c) "Pharmacy benefit manager" has the same meaning as in 18 V.S.A. §3602 (12~~((A~~).

The statutory definition of "pharmacy benefit manager" at 18 V.S.A. §3602 (12)(A) included the definition of what a pharmacy benefit manager is but omitted the broader definition of what a pharmacy benefit manager is not as provided in 18 V.S.A. §3602 (12)(B). The Department determined inclusion of both components was consistent with the full statutory definition.

Section 4: APPLICABILITY AND SCOPE

No person or entity meeting the definition of a pharmacy benefit manager shall engage in pharmacy benefit management ~~provide claims processing services, prescription drug or device services for health benefit plans~~ in this state without a valid and current pharmacy benefit manager license. Such license is not transferable or assignable and is valid only for the person or entity to whom issued.

The Department determined that the term "pharmacy benefit management" as defined in statute (18 V.S.A § 3602(11)) is the more inclusive term to reference in the Rule as it encompasses more activities than those originally listed.

Section 5: INITIAL LICENSE APPLICATION

Subparagraph (a)(2)(C) Pharmacy benefit management organization documents:

> The relevant documentation, such as policies and procedures, and a detailed explanation, that demonstrates the pharmacy benefit manager has adopted processes to ensure compliance with Act 127 of 2024 (18 V.S.A. §§ 9472-9473; 18 V.S.A. §3612, §3622 and §3631) (A) ~~including any written policies or procedures describing the appeals or dispute resolution processes between the pharmacy benefit manager and a pharmacy benefit manager-affiliated pharmacy, as applicable~~.

After careful review, the Department determined that more statutory references were necessary beyond 18 V.S.A. §§ 9472-9473 given those sections, while still applicable until they sunset on July 1, 2029, had been recodified at 18 V.S.A. §§3612, §3622, and §3631. To remove any doubt as to what statutory provisions apply in the Rule, the Department revised the citations to reference Act 127 of 2024 and the applicable citations thereunder as recodified.

Subparagraph (a)(3)(B) Financial and Other Documents:

> A listing of all health benefit plans the pharmacy benefit manager contracts with to provide pharmacy benefit management services for, in Vermont, including any ~~Non-ERISA~~ self-funded or governmental plans;

The enabling statute and by extension this Rule are intended to promote, preserve and protect the public health, safety and welfare of Vermonters through the effective regulation and licensure of pharmacy benefit managers. As such, the Department needs to broadly examine the financial activities, operations and business practices of applicants to determine their fitness for a license to operate in the State of Vermont. Removal of the term "Non-ERISA" broadens the Department's view into an applicant during the licensing process with an increased understanding of the scope of health plans serviced by a pharmacy benefit manager operating in Vermont versus limiting the review to only insured health plans (a likely much smaller number).

Subparagraph (a)(4)(B), (C) and (D) Required Responses:

> (A) Has been refused or denied a registration, license, or certification to act as or provide the services of a pharmacy benefit manager in any state or federal entity, providing specific details separately for each such refusal or denial, if any, including the date, nature and disposition of the action;
>
> (B) Has had any registration, license or certification to act as or provide the services of a pharmacy benefit manager suspended, revoked or nonrenewed for any reason by any state or federal entity, providing specific details separately for each such suspension, revocation or nonrenewal, if any, including the date, nature and disposition of the action; ~~and~~
>
> (C) Has had a business relationship with a health plan terminated for cause, including for breach of contract or fiduciary duty or any ~~finding by a court of law of~~ fraudulent behavior ~~or illegal activities~~ in connection with the administration of a pharmacy benefits plan, providing specific details regarding the termination~~.~~; and

(D) Has been the defendant or respondent in legal proceedings that have resulted in findings of fraudulent or illegal activities by a court of law or regulatory body, providing specific details of the case or matter.

The Department determined that as originally drafted, subsections (C) could be interpreted by a pharmacy benefit manager licensee applicant in a manner that could avoid the disclosures sought by the language. As such, revisions were made to clarify what data points are required to be shared as part of the application process to help ensure the Department has what it needs to perform a thorough review of an applicant.

Section 7: Application Review:

Subparagraph (a):

(a) Upon receipt of a completed application for an initial or renewal pharmacy benefit manager license as required by section 5~~6~~ and 6~~7~~, the Commissioner shall review the application and may take the following actions:

The Department added a missing word and corrected the section references.

Subparagraph (a)(3):

(1) Deny a license ~~registration~~ pursuant to the criteria set forth in 18 V.S.A § 3611(c). If a pharmacy benefit manager license is denied, the Commissioner shall:

The Department changed "registration" to "license" to align with the terminology within the Rule.

Section 9: Enforcement

Subparagraph (a)(6):

(6) Has refused to have its books and records examined or audited as it relates to its provision of pharmacy benefit management ~~claim processing services or other prescription drug or device services for a health plan~~;

Consistent with the response to Section 4, The Department determined that the term "pharmacy benefit management" as defined in statute (18 V.S.A § 3602(11)) is the more inclusive term to reference in the Rule as it encompasses more activities than those originally listed.

Error Corrections

The Department also corrected the following typographical, or grammatical errors:
Section 3(c) removed an extra parenthetical; and Section 5 (b) removed the word "of".

Additionally, the Department received comments from an AHIP representative related to concerns that the enabling statute (and by extension this Rule) do not include a specific exemption from application to self-funded ERISA plans and Medicare under applicable federal law.

While concerns about statutory language are best addressed with the Vermont Legislature, regarding the Rule, the Department is of the opinion that 18 V.S.A. §3614 addresses the legislative intent that the enabling statute (and this Rule) must be consistent with federal law including any applicable exemption.

> § 3614. Compliance; consistency with federal law
> Nothing in this chapter is intended or should be construed to conflict with applicable federal law.

No other changes have been made to the Rule since the Proposed Filing.

Sincerely,

Susan F. Morris

Susan F. Morris
Assistant General Counsel