Introduced by Representative Cordes of Lincoln

Referred to Committee on

Date:

Subject: Health; health insurance; prescription drugs; pharmacies; pharmacy benefit managers

Statement of purpose of bill as introduced: This bill proposes to require pharmacy benefit managers to obtain licensure from, rather than register with, the Department of Financial Regulation. It would establish a detailed regulatory framework for regulating pharmacy benefit managers and would prohibit or restrict a number of pharmacy benefit management activities. The bill would recodify most of the existing statutory provisions relating to pharmacy benefit managers in one chapter, with some revisions. It would allow health insurance plan beneficiaries to choose their own pharmacies, limit direct solicitation by pharmacies and pharmacy benefit managers, and provide pharmacies with additional rights during an audit. The bill would also require the Agency of Human Services to select a wholesale drug distributor through a competitive bidding process to be the sole source to distribute prescription drugs to pharmacies for dispensing to Medicaid beneficiaries.
It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. chapter 77 is added to read:

CHAPTER 77. PHARMACY BENEFIT MANAGERS


§ 3601. PURPOSE

The purpose of this chapter is to establish standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans by:

(1) promoting, preserving, and protecting the public health, safety, and welfare through effective regulation and licensure of pharmacy benefit managers;

(2) promoting the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act, 15 U.S.C. §§ 1011–1015, as well as providing for consumer savings and for fairness in prescription drug benefits;

(3) providing for the powers and duties of the Commissioner of Financial Regulation; and

(4) prescribing penalties and fines for violations of this chapter.

§ 3602. DEFINITIONS

As used in this chapter:
(1) “Claims processing services” means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include receiving payments for pharmacist services or making payments to pharmacists or pharmacies for pharmacy services, or both.

(2) “Commissioner” means the Commissioner of Financial Regulation.

(3) “Covered person” means a member, policyholder, subscriber, enrollee, beneficiary, dependent, or other individual participating in a health benefit plan.

(4) “Health benefit plan” means a policy, contract, certificate, or agreement entered into, offered, or issued by a health insurer to provide, deliver, arrange for, pay for, or reimburse any of the costs of physical, mental, or behavioral health care services.

(5) “Health insurer” has the same meaning as in section 9402 of this title and includes:

(A) health insurance companies, nonprofit hospital and medical service corporations, and health maintenance organizations; 

(B) employers, labor unions, and other group of persons organized in Vermont that provide a health benefit plan to beneficiaries who are employed or reside in Vermont.
(C) the State of Vermont and any agent or instrumentality of the State that offers, administers, or provides financial support to State government; and

(D) Medicaid and any other public health care assistance program.

(6) “Maximum allowable cost” means the per unit drug product reimbursement amount, excluding dispensing fees, for a group of equivalent multisource prescription drugs.

(7) “Other prescription drug or device services” means services other than claims processing services provided directly or indirectly, whether in connection with or separate from claims processing services, and may include:

(A) negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(B) disbursing or distributing rebates;

(C) managing or participating in incentive programs or arrangements for pharmacist services;

(D) negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(E) developing and maintaining formularies;

(F) designing prescription benefit programs; and

(G) advertising or promoting services.
(8) “Pharmacist” means an individual licensed as a pharmacist pursuant to 26 V.S.A. chapter 36.

(9) “Pharmacist services” means products, goods, and services, or a combination of these, provided as part of the practice of pharmacy.

(10) “Pharmacy” means a place licensed by the Vermont Board of Pharmacy at which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail.

(11) “Pharmacy benefit management” means an arrangement for the procurement of prescription drugs at a negotiated rate for dispensation within this State to beneficiaries, the administration or management of prescription drug benefits provided by a health benefit plan for the benefit of beneficiaries, or any of the following services provided with regard to the administration of pharmacy benefits:

(A) mail service pharmacy;

(B) claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

(C) clinical formulary development and management services;

(D) rebate contracting and administration;

(E) certain patient compliance, therapeutic intervention, and generic substitution programs; and

(F) disease or chronic care management programs.
(12)(A) “Pharmacy benefit manager” means an individual, corporation, or other entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides pharmacy benefit management services for health benefit plans.

(B) The term “pharmacy benefit manager” does not include:

(i) a health care facility licensed in this State;

(ii) a health care professional licensed in this State;

(iii) a consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or

(iv) a health insurer to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees.

§ 3603. RULEMAKING

The Commissioner of Financial Regulation may adopt rules in accordance with 3 V.S.A. chapter 25 to carry out the provisions of this chapter. The rules shall include, as appropriate, requirements that health insurers maintain the confidentiality of proprietary information.

§ 3604. REPORTING

Annually on or before January 15, the Department of Financial Regulation shall report to the House Committee on Health Care and the Senate
Committees on Health and Welfare and on Finance regarding pharmacy benefit managers’ compliance with the provisions of this chapter.

Subchapter 2. Pharmacy Benefit Manager Licensure and Regulation

§ 3611. LICENSURE

(a) A person shall not establish or operate as a pharmacy benefit manager for health benefit plans in this State without first obtaining a license from the Commissioner of Financial Regulation.

(b) A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the Commissioner and shall include with the application a nonrefundable application fee of $100.00 and a licensure fee of $500.00.

(c) The Commissioner may refuse to issue or renew a pharmacy benefit manager license if the Commissioner determines that the applicant or any individual responsible for the conduct of the applicant’s affairs is not competent, trustworthy, financially responsible, or of good personal and business reputation, or has been found to have violated the insurance laws of this State or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.

(d) Unless surrendered, suspended, or revoked by the Commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager does all of the following.
(1) Continues to do business in this State.

(2) Complies with the provisions of this chapter and any applicable rules.

(3) Submits a renewal application in the form and manner prescribed by the Commissioner and pays the annual license renewal fee of $500.00. The renewal application and renewal fee shall be due to the Commissioner on or before 90 days prior to the anniversary of the effective date of the pharmacy benefit manager’s initial or most recent license.

(e) The Commissioner may adopt rules pursuant to 3 V.S.A. chapter 25 to establish the licensing application, financial, and reporting requirements for pharmacy benefit managers in accordance with this section.

§ 3612. PROHIBITED PRACTICES

(a) A participation contract between a pharmacy benefit manager and a pharmacist shall not prohibit, restrict, or penalize a pharmacy or pharmacist in any way from disclosing to any covered person any health care information that the pharmacy or pharmacist deems appropriate, including:

(1) the nature of treatment, risks, or alternatives to treatment;

(2) the availability of alternate therapies, consultations, or tests;

(3) the decision of utilization reviewers or similar persons to authorize or deny services;

(4) the process that is used to authorize or deny health care services, or
(5) information on finance incentives and structures used by the health insurer.

(b) A pharmacy benefit manager shall not prohibit a pharmacy or pharmacist from:

(1) discussing information regarding the total cost for pharmacist services for a prescription drug;

(2) providing information to a covered person regarding the covered person’s cost-sharing amount for a prescription drug;

(3) disclosing to a covered person the cash price for a prescription drug; or

(4) selling a more affordable alternative to the covered person if a more affordable alternative is available.

(c) A pharmacy benefit manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Commissioner, law enforcement, or State and federal government officials, provided that:

(1) the recipient of the information represents that the recipient has the authority, to the extent provided by State or federal law, to maintain proprietary information as confidential; and

(2) prior to disclosure of information designated as confidential, the pharmacist or pharmacy.
(A) marks as confidential any document in which the information appears; and

(B) requests confidential treatment for any oral communication of the information.

(d) A pharmacy benefit manager shall not terminate a contract with or penalize a pharmacist or pharmacy due to the pharmacist or pharmacy:

(1) disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret under State law or by the Commissioner, when disclosed in a manner other than in accordance with subsection (c) of this section; or

(2) sharing any portion of the pharmacy benefit manager contract with the Commissioner pursuant to a complaint or query regarding the contract’s compliance with the provisions of this chapter.

(e)(1) A pharmacy benefit manager shall not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of:

(A) the cost-sharing amount under the terms of the health benefit plan;

(B) the maximum allowable cost for the drug, or
(C) the amount the covered person would pay for the drug, after
application of any known discounts, if the covered person were paying the
cash price.

(2) Any amount paid by a covered person under subdivision (1) of this
subsection shall be attributed toward any deductible, to the extent consistent
with Sec. 2707 of the Public Health Service Act (42 U.S.C. § 300gg-6), the
annual out-of-pocket maximums under the covered person’s health benefit
plan.

(f) A pharmacy benefit manager shall not conduct or participate in spread
pricing in this State.

§ 3613. ENFORCEMENT

(a) The Commissioner of Financial Regulation shall enforce compliance
with the provisions of this chapter.

(b)(1) The Commissioner may examine or audit the books and records of a
pharmacy benefit manager providing claims processing services or other
prescription drug or device services for a health benefit plan to determine
compliance with this chapter.

(2) Information or data acquired in the course of an examination or
audit under subdivision (1) of this subsection shall be considered proprietary
and confidential, shall be exempt from public inspection and copying under the
Public Records Act, shall not be subject to subpoena, and shall not be subject
to discovery or admissible in evidence in any private civil action.

(c) The Commissioner may use any document or information provided
pursuant to subsection 3612 (c) or (d) of this chapter in the performance of the
Commissioner’s duties to determine compliance with this chapter.

(d) The Commissioner may impose a penalty on a pharmacy benefit
manager or the health insurer with which it is contracted, or both, for a
violation of this chapter. The penalty shall be not less than $25,000.00 nor
more than $50,000.00 for each violation of this chapter.

§ 3614. COMPLIANCE; CONSISTENCY WITH FEDERAL LAW

Nothing in this chapter is intended or should be construed to conflict with
applicable federal law.

§ 3615. CHARGES FOR EXAMINATIONS, APPLICATIONS, REVIEWS,
AND INVESTIGATIONS

(a) The Department of Financial Regulation may charge its reasonable
expenses in administering the provisions of this chapter to pharmacy benefit
managers in the manner provided for in 8 V.S.A. § 18. These expenses shall
be allocated in proportion to the lives of Vermonters covered by each
pharmacy benefit manager as reported annually to the Commissioner in a
manner and form prescribed by the Commissioner.
(b) The Department of Financial Regulation shall not charge its expenses to the pharmacy benefit manager contracting with the Department of Vermont Health Access if the Department of Vermont Health Access notifies the Department of Financial Regulation of the conditions contained in its contract with a pharmacy benefit manager.

Subchapter 3. Pharmacy Benefit Manager Relations with Health Insurers

§ 3621. INSURER AUDIT OF PHARMACY BENEFIT MANAGER ACTIVITIES

In order to enable periodic verification of pricing arrangements in administrative-services-only contracts, pharmacy benefit managers shall allow access, in accordance with rules adopted by the Commissioner, by the health insurer who is a party to the administrative-services-only contract to financial and contractual information necessary to conduct a complete and independent audit designed to verify the following:

(1) full pass through of negotiated drug prices and fees associated with all drugs dispensed to beneficiaries of the health benefit plan in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract;

(2) full pass through of all financial remuneration associated with all drugs dispensed to beneficiaries of the health benefit plan in both retail and
mail order settings or resulting from any of the pharmacy benefit management
functions defined in the contract; and

(2) any other verifications relating to the pricing arrangements and
activities of the pharmacy benefit manager required by the contract if required
by the Commissioner.

§ 3622. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES
WITH RESPECT TO HEALTH INSURERS

(a) A pharmacy benefit manager that provides pharmacy benefit
management for a health benefit plan has a fiduciary duty to its health insurer
client that includes a duty to be fair and truthful toward the health insurer, to
act in the health insurer’s best interests, and to perform its duties with care,
skill, prudence, and diligence. In the case of a health benefit plan offered by a
health insurer as defined by subdivision 3602(3)/(A) of this title, the health
insurer shall remain responsible for administering the health benefit plan in
accordance with the health insurance policy or subscriber contract or plan and
in compliance with all applicable provisions of Title 8 and this title.

(b) A pharmacy benefit manager shall provide notice to the health insurer
that the terms contained in subsection (c) of this section may be included in the
contract between the pharmacy benefit manager and the health insurer.

(c) A pharmacy benefit manager that provides pharmacy benefit
management for a health plan shall do all of the following:
(1) Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer’s health benefit plan and all financial and utilization information relating to services to that health insurer. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection shall not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer protection provisions of 9 V.S.A. chapter 63, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) to State and federal government officials;

(C) when authorized by 9 V.S.A. chapter 63;

(D) when ordered by a court for good cause shown; or

(E) when ordered by the Commissioner as to a health insurer as defined in subdivision 3602(5)(A) of this chapter pursuant to the provisions of Title 8 and this title.
(2) Notify a health insurer in writing of any proposed or ongoing activity, policy, or practice of the pharmacy benefit manager that presents, directly or indirectly, any conflict of interest with the requirements of this section.

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

(4) If the pharmacy benefit manager derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State, pass that payment or benefit on in full to the health insurer.

(5) Disclose to the health insurer all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer’s health benefit plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees. A pharmacy benefit manager providing
information under this subsection may designate that material as confidential.

Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection shall not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer protection provisions of 9 V.S.A. chapter 63, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) when authorized by 9 V.S.A. chapter 63;

(C) when ordered by a court for good cause shown; or

(D) when ordered by the Commissioner as to a health insurer as defined in subdivision 3602(5)(A) of this title pursuant to the provisions of Title 8 and this title.

(d) A pharmacy benefit manager contract with a health insurer shall not contain any provision purporting to reserve discretion to the pharmacy benefit manager to move a drug to a higher tier or remove a drug from its drug formulary any more frequently than two times per year.

(e) At least annually, a pharmacy benefit manager that provides pharmacy benefit management for a health benefit plan shall disclose to the health
insurer, the Department of Financial Regulation, and the Green Mountain Care Board the aggregate amount the pharmacy benefit manager retained on all claims charged to the health insurer for prescriptions filled during the preceding calendar year in excess of the amount the pharmacy benefit manager reimbursed pharmacies.

(f) Compliance with the requirements of this section is required for pharmacy benefit managers entering into contracts with a health insurer in this State for pharmacy benefit management in this State.

Subchapter 4. Pharmacy Benefit Manager Relations with Pharmacies

§ 3631. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES WITH RESPECT TO PHARMACIES

(a) Within 14 calendar days following receipt of a pharmacy claim, a pharmacy benefit manager or other entity paying pharmacy claims shall do one of the following:

(1) Pay or reimburse the claim.

(2) Notify the pharmacy in writing that the claim is contested or denied. The notice shall include specific reasons supporting the contest or denial and a description of any additional information required for the pharmacy benefit manager or other payer to determine liability for the claim.

(b) In addition to the practices prohibited by section 3612 of this chapter, a pharmacy benefit manager or other entity paying pharmacy claims shall not
require a pharmacy to pass through any portion of the insured’s co-payment, or
patient responsibility, to the pharmacy benefit manager or other payer.

(c) For each drug for which a pharmacy benefit manager establishes a
maximum allowable cost in order to determine the reimbursement rate, the
pharmacy benefit manager shall do all of the following:

(1) Make available, in a format that is readily accessible and
understandable by a pharmacist, the actual maximum allowable cost for each
drug and the source used to determine the maximum allowable cost, which
shall not be dependent upon individual beneficiary identification or benefit
stage.

(2) Update the maximum allowable cost at least once every seven
calendar days. In order to be subject to maximum allowable cost, a drug must
be widely available for purchase by all pharmacies in the State, without
limitations, from national or regional wholesalers and must not be obsolete or
temporarily unavailable.

(3) Establish or maintain a reasonable administrative appeals process to
allow a dispensing pharmacy provider to contest a listed maximum allowable
cost.

(4)(A) Respond in writing to any appealing pharmacy provider within
10 calendar days after receipt of an appeal, provided that, except as provided
in subdivision (D) of this subdivision (4), a dispensing pharmacy provider
shall file any appeal within 10 calendar days from the date its claim for reimbursement is adjudicated.

(B) A pharmacy benefit manager shall allow a dispensing pharmacy provider to appeal after the 10-calendar-day appeal period set forth in subdivision (A) of this subdivision (4) if the prescription claim is subject to an audit initiated by the pharmacy benefit manager or its auditing agent.

(5) For a denied appeal, provide the reason for the denial and identify the national drug code and a Vermont-licensed wholesaler of an equivalent drug product that may be purchased by contracted pharmacies at or below the maximum allowable cost.

(6) For an appeal in which the appealing pharmacy is successful:

(A) make the change in the maximum allowable cost within 30 business days after the redetermination; and

(B) allow the appealing pharmacy or pharmacist to reverse and rebill the claim in question.

(d) If a pharmacy benefit manager denies a pharmacy’s or pharmacist’s appeal in whole or in part and the reimbursement amount is less than the pharmacy’s reasonable acquisition cost plus a dispensing fee, the pharmacy or pharmacist may submit a claim to the health insurer for the balance and the health insurer shall reimburse the pharmacy or pharmacist that amount.
(e) A pharmacy benefit manager shall not reimburse a pharmacy or pharmacist in this State an amount less than the amount the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmacist services. The reimbursement amount shall be calculated on a per unit basis based on the generic product identifier or generic code number and shall include a professional dispensing fee that shall be not less than the professional dispensing fee established for the Vermont Medicaid program by the Department of Vermont Health Access in accordance with 42 C.F.R. Part 447.

(f) A pharmacy benefit manager shall not restrict, limit, or impose requirements on a licensed pharmacy in excess of those set forth by the Vermont Board of Pharmacy or by other State or federal law, nor shall it withhold reimbursement for services on the basis of noncompliance with participation requirements.

(g) A pharmacy benefit manager shall provide notice to all participating pharmacies prior to changing its drug formulary.

(h)(1) A pharmacy benefit manager or other third party that reimburses a 340B covered entity for drugs that are subject to an agreement under 42 U.S.C. § 256b through the 340B drug pricing program shall not reimburse the 340B covered entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies that are not 340B covered entities, and the
pharmacy benefit manager shall not assess any fee, charge-back, or other adjustment on the 340B covered entity on the basis that the covered entity participates in the 340B program as set forth in 42 U.S.C. § 256b.

(2) With respect to a patient who is eligible to receive drugs that are subject to an agreement under 42 U.S.C. § 256b through the 340B drug pricing program, a pharmacy benefit manager or other third party that makes payment for the drugs shall not discriminate against a 340B covered entity in a manner that prevents or interferes with the patient’s choice to receive the drugs from the 340B covered entity.

Sec. 2. 18 V.S.A. § 3802 is amended to read:

§ 3802. PHARMACY RIGHTS DURING AN AUDIT

Notwithstanding any provision of law to the contrary, whenever a health insurer, a third-party payer, or an entity representing a responsible party conducts an audit of the records of a pharmacy, the pharmacy shall have a right to all of the following:

* * *

(2) If an audit is to be conducted on-site at a pharmacy, the entity conducting the audit:

(A) shall give the pharmacy at least 14 days’ advance written notice of the audit and the specific prescriptions to be included in the audit, and
(B), may shall not audit a pharmacy on Mondays or on weeks containing a federal holiday, unless the pharmacy agrees to alternative timing for the audit; and

(3) Not to have an entity

(C), shall not audit claims that:

(A)(i) were submitted to the pharmacy benefit manager more than 18 months prior to the date of the audit, unless:

(i)(I) required by federal law; or

(ii)(II) the originating prescription was dated within the 24-month period preceding the date of the audit; or

(B)(ii) exceed 200 selected prescription claims.

(3) If any audit is to be conducted remotely, the entity conducting the audit:

(A) shall give the pharmacy at least seven business days following the pharmacy’s confirmation of receipt of the notice of the audit to respond to the audit; and

(B) shall not audit claims that:

(i) were submitted to the pharmacy benefit manager more than three months prior to the date of the audit or on a date earlier than that for which the pharmacy could electronically retransmit a corrected claim; or

(ii) exceed five selected prescription claims.
(19) To have the preliminary audit report delivered to the pharmacy within 60 days following the conclusion of the pharmacy’s preliminary response.

(21) To have a final audit report delivered to the pharmacy within 120 days after the end of the appeals period, as required by section 3803 of this title.

(24) To have all payment data related to audited claims, including:

(A) payment amount;

(B) any direct and indirect remuneration (DIR) or generic effective rate (GER) fees assessed or other financial offsets;

(C) date of electronic payment or check date and number;

(D) the specific contracted reimbursement basis for each claim, including its basis, such as maximum allowable cost (MAC), wholesale acquisition cost (WAC), average wholesale price (AWP), or average manufacturer price (AMP); and

(E) the respective values used to calculate each claim payment.
Sec. 3. 8 V.S.A. § 4089j is amended to read:

§ 4089j. RETAIL PHARMACIES; FILLING OF PRESCRIPTIONS

(a) As used in this section:

   * * *

(4) “Direct solicitation” means direct contact, including telephone, computer, e-mail, instant messaging, or in-person contact, by a pharmacy provider or its agent to a beneficiary of a plan offered by a health insurer without the beneficiary’s consent for the purpose of marketing the pharmacy provider’s services.

   * * *

(d)(1) A health insurer or pharmacy benefit manager shall permit a beneficiary of a plan offered by the health insurer to fill a prescription at the pharmacy of the beneficiary’s choice and shall not impose differential cost-sharing requirements based on the choice of pharmacy or otherwise promote the use of one pharmacy over another.

(2) A health insurer or pharmacy benefit manager shall permit a participating network pharmacy to perform all pharmacy services within the lawful scope of the profession of pharmacy as set forth in 26 V.S.A. chapter 36.

(3) A health insurer or pharmacy benefit manager shall adhere to the definitions of prescription drugs and the requirements and guidance regarding
the pharmacy profession established by State and federal law and the Vermont Board of Pharmacy and shall not establish classifications of or distinctions between prescription drugs, impose penalties on prescription drug claims, attempt to dictate the behavior of pharmacies or pharmacists, or place restrictions on pharmacies or pharmacists that are more restrictive than or inconsistent with State or federal law or with rules adopted or guidance provided by the Board of Pharmacy.

(4) A pharmacy benefit manager or licensed pharmacy shall not make a direct solicitation to the beneficiary of a plan offered by a health insurer unless one or more of the following applies:

(A) the beneficiary has given written permission to the supplier or the ordering health care professional to contact the beneficiary regarding the furnishing of a prescription item that is to be rented or purchased;

(B) the supplier has furnished a prescription item to the beneficiary and is contacting the beneficiary to coordinate delivery of the item; or

(C) if the contact relates to the furnishing of a prescription item other than a prescription item already furnished to the beneficiary, the supplier has furnished at least one prescription item to the beneficiary within the 15-month period preceding the date on which the supplier attempts to make the contact.
§ 2011. WHOLESALE DRUG DISTRIBUTOR CONTRACT

(a) As used in this section:

(1) “Dead net cost” means the wholesale acquisition cost of a prescription drug, less any applicable discounts and all vendor rebates, fees, and incentives, including inventory management agreement fees, fee-for-service agreements, volume incentives, rebates, and reporting fees.

(2) “Wholesale drug distributor” has the same meaning as “wholesale distributor” in 26 V.S.A. § 202.

(b) The Agency of Human Services shall establish a competitive bidding process for a wholesale drug distributor or for several wholesale drug distributors through a group purchasing organization, through which the selected wholesaler or group purchasing organization shall be the sole source to distribute prescription drugs to the community and outpatient pharmacies with which the wholesaler or group purchasing organization enters into contracts for prescription drugs dispensed to beneficiaries of Medicaid and other State health assistance programs for which the Department of Vermont Health Access pays pharmaceutical claims. The Agency of Human Services shall convene a group comprising one representative each from the Green Mountain Care Board, the Department of Vermont Health Access, the Vermont Board of Pharmacy, the Vermont Association of Chain Drug Stores, and the
Vermont Community Pharmacy Network to conduct the competitive bidding process and to select the wholesale drug distributor or group purchasing organization that the group determines:

1. will offer the greatest cost savings to the Department of Vermont Health Access;
2. will provide complete transparency; and
3. demonstrates a willingness to facilitate additional savings throughout the State by expanding the program to additional public and private purchasers.

(c) The wholesale drug distributor or group purchasing organization selected pursuant to subsection (b) of this section shall:

1. establish contracts with all Medicaid-participating community and outpatient pharmacies operating in this State;
2. maintain compliance with all applicable federal and State statutes, rules, and regulations relating to the operation of a wholesale drug distributor or group purchasing organization;
3. segregate the commercial portion of its pharmacy business from the Vermont Medicaid portion;
4. match the Department of Vermont Health Access’s reports of claims paid per pharmacy with the pharmacies’ invoices.
(5) invoice the Department of Vermont Health Access in an amount equal to the aggregate sum of the wholesaler’s or group purchasing organization’s dead net costs for all claims dispensed during a given period across all participating pharmacies;

(6) collaborate with the Department of Vermont Health Access to maximize the amount of direct manufacturer rebates and minimize the costs of the Medicaid formulary, and

(7) create a financial mechanism through which pharmacies shall be relieved of drug unit costs dispensed to Vermont Medicaid during the relevant period identified pursuant to subdivision (5) of this subsection.

(d) Only those community and outpatient pharmacies that agree to purchase their entire Vermont Medicaid inventory from the wholesaler or group purchasing organization selected pursuant to this section shall be eligible to establish or maintain enrollment as Medicaid-participating pharmacy providers.

(e) The Department of Vermont Health Access shall limit reimbursements to participating pharmacies to an amount equal to the established dispensing fee for prescription claims dispensed; provided, however, that this provision shall not be construed to prohibit the Department from reimbursing a participating pharmacy for recognized ancillary services provided in connection with these claims.
Sec. 5. REPEALS

The following are repealed on July 1, 2021:

(1) 18 V.S.A. § 9421 (pharmacy benefit management; registration; insurer audit of pharmacy benefit manager activities); and

(2) 18 V.S.A. chapter 221, subchapter 9 (§§ 9471–9474; pharmacy benefit managers).

Sec. 6. APPLICABILITY

(a) The provisions of Sec. 1 of this act (18 V.S.A. chapter 77, pharmacy benefit managers) shall apply to a contract or health benefit plan issued, offered, renewed, recredentialed, amended, or extended on or after the effective date of this act, including any health insurer that performs claims processing or other prescription drug or device services through a third party.

(b) A person doing business in this State as a pharmacy benefit manager on or before the effective date of this act shall have six months following the effective date of this act to come into compliance with the provisions of Sec. 1 of this act (18 V.S.A. chapter 77, pharmacy benefit manager licensure and regulation).

Sec. 7. EFFECTIVE DATE

This act shall take effect on July 1, 2021.

Sec. 1. INTENT
It is the intent of the General Assembly to increase access to needed medications by making prescription drugs more affordable and accessible to Vermonters by increasing State regulation of pharmacy benefit managers and pharmacy benefit management. It is also the intent of the General Assembly to stabilize and safeguard against the loss of more independent and community pharmacies, where pharmacists provide personalized care to Vermonters and help them with their health care needs, including medication management, medication adherence, and health screenings.

Sec. 2. 18 V.S.A. chapter 221, subchapter 9 is amended to read:

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

* * *

(2) “Health insurer” is defined by section 9402 of this title and shall include:

(A) a health insurance company, a nonprofit hospital and medical service corporation, and health maintenance organizations;

(B) an employer, labor union, or other group of persons organized in Vermont that provides a health plan to beneficiaries who are employed or reside in Vermont; and
(C) the State of Vermont and any agent or instrumentality of the State
that offers, administers, or provides financial support to State government; and
(D) Medicaid, and any other public health care assistance program.

* * *

§ 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES
WITH RESPECT TO HEALTH INSURERS AND COVERED
PERSONS

(a) A pharmacy benefit manager that provides pharmacy benefit
management for a health plan shall discharge its duties with reasonable care
and diligence and be fair and truthful under the circumstances then prevailing
that a pharmacy benefit manager acting in like capacity and familiar with such
matters would use in the conduct of an enterprise of a like character and with
like aims has a fiduciary duty to its health insurer client that includes a duty to
be fair and truthful toward the health insurer to act in the health insurer’s best
interests, and to perform its duties with care, skill, prudence, and diligence. In
the case of a health benefit plan offered by a health insurer as defined by
subdivision 9471(2)(A) of this title, the health insurer shall remain responsible
for administering the health benefit plan in accordance with the health
insurance policy or subscriber contract or plan and in compliance with all
applicable provisions of Title 8 and this title.
(b) A pharmacy benefit manager shall provide notice to the health insurer that the terms contained in subsection (c) of this section may be included in the contract between the pharmacy benefit manager and the health insurer.

(c) A pharmacy benefit manager that provides pharmacy benefit management for a health plan shall do all of the following:

(1) Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer’s health plan and all financial and utilization information relating to services to that health insurer. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer protection provisions of 9 V.S.A. chapter 63, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) to State and federal government officials;
(C) when authorized by 9 V.S.A. chapter 63;

(C)(D) when ordered by a court for good cause shown; or

(D)(E) when ordered by the Commissioner as to a health insurer as defined in subdivision 9471(2)(A) of this title pursuant to the provisions of Title 8 and this title.

(2) Notify a health insurer in writing of any proposed or ongoing activity, policy, or practice of the pharmacy benefit manager that presents, directly or indirectly, any conflict of interest with the requirements of this section.

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

(4) Unless the contract provides otherwise, if the pharmacy benefit manager derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State, pass that payment or benefit on in full to the health insurer.
(5) Disclose to the health insurer all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer’s health plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

(A) in a court filing under the consumer protection provisions of 9 V.S.A. chapter 63, provided that the information shall be filed under seal and that prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

(B) when authorized by 9 V.S.A. chapter 63;

(C) when ordered by a court for good cause shown; or
(D) when ordered by the Commissioner as to a health insurer as defined in subdivision 9471(2)(A) of this title pursuant to the provisions of Title 8 and this title.

(d) At least annually, a pharmacy benefit manager that provides pharmacy benefit management for a health plan shall disclose to the health insurer, the Department of Financial Regulation, and the Green Mountain Care Board the aggregate amount the pharmacy benefit manager retained on all claims charged to the health insurer for prescriptions filled during the preceding calendar year in excess of the amount the pharmacy benefit manager reimbursed pharmacies.

(e) A pharmacy benefit manager contract with a health insurer shall not contain any provision purporting to reserve discretion to the pharmacy benefit manager to move a drug to a higher tier or remove a drug from its drug formulary any more frequently than two times per year.

(f)(1) A pharmacy benefit manager shall not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of:

(A) the cost-sharing amount under the terms of the health benefit plan;

(B) the maximum allowable cost for the drug; or
(C) the amount the covered person would pay for the drug, after application of any known discounts, if the covered person were paying the cash price.

(2) Any amount paid by a covered person under subdivision (1) of this subsection shall be attributed toward any deductible and, to the extent consistent with Sec. 2707 of the Public Health Service Act (42 U.S.C. § 300gg-6), the annual out-of-pocket maximums under the covered person’s health benefit plan.

(g) Compliance with the requirements of this section is required for pharmacy benefit managers entering into contracts with a health insurer in this State for pharmacy benefit management in this State.

§ 9473. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES WITH RESPECT TO PHARMACIES

(a) Within 14 calendar days following receipt of a pharmacy claim, a pharmacy benefit manager or other entity paying pharmacy claims shall do one of the following:

(1) Pay or reimburse the claim.

(2) Notify the pharmacy in writing that the claim is contested or denied. The notice shall include specific reasons supporting the contest or denial and a description of any additional information required for the pharmacy benefit manager or other payer to determine liability for the claim.
(b) A participation contract between a pharmacy benefit manager and a pharmacist shall not prohibit, restrict, or penalize a pharmacy or pharmacist in any way from disclosing to any covered person any health care information that the pharmacy or pharmacist deems appropriate, including:

(1) the nature of treatment, risks, or alternatives to treatment;

(2) the availability of alternate therapies, consultations, or tests;

(3) the decision of utilization reviewers or similar persons to authorize or deny services;

(4) the process that is used to authorize or deny health care services; or

(5) information on finance incentives and structures used by the health insurer.

(c) A pharmacy benefit manager or other entity paying pharmacy claims shall not:

(1) impose a higher co-payment for a prescription drug than the co-payment applicable to the type of drug purchased under the insured’s health plan;

(2) impose a higher co-payment for a prescription drug than the maximum allowable cost for the drug;

(3) require a pharmacy to pass through any portion of the insured’s co-payment, or patient responsibility, to the pharmacy benefit manager or other payer;
(2) prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug;

(4)(3) prohibit or penalize a pharmacy or pharmacist for providing information to an insured regarding the insured’s cost-sharing amount for a prescription drug; or

(5)(4) prohibit or penalize a pharmacy or pharmacist for the pharmacist or other pharmacy employee disclosing to an insured the cash price for a prescription drug or selling a lower cost drug to the insured if one is available.

(d) A pharmacy benefit manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Commissioner, law enforcement, or State and federal government officials, provided that:

(1) the recipient of the information represents that the recipient has the authority, to the extent provided by State or federal law, to maintain proprietary information as confidential; and

(2) prior to disclosure of information designated as confidential, the pharmacist or pharmacy:

(A) marks as confidential any document in which the information appears; and

(B) requests confidential treatment for any oral communication of the information.
(e) A pharmacy benefit manager shall not terminate a contract with or penalize a pharmacist or pharmacy due to the pharmacist or pharmacy:

(1) disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret under State law or by the Commissioner, when disclosed in a manner other than in accordance with subsection (d) of this section; or

(2) sharing any portion of the pharmacy benefit manager contract with the Commissioner pursuant to a complaint or query regarding the contract’s compliance with the provisions of this chapter.

(f) For each drug for which a pharmacy benefit manager establishes a maximum allowable cost in order to determine the reimbursement rate, the pharmacy benefit manager shall do all of the following:

(1) Make available, in a format that is readily accessible and understandable by a pharmacist, the actual maximum allowable cost for each drug and the source used to determine the maximum allowable cost, which shall not be dependent upon individual beneficiary identification or benefit stage.

(2) Update the maximum allowable cost at least once every seven calendar days. In order to be subject to maximum allowable cost, a drug must be widely available for purchase by all pharmacies in the State, without
limitations, from national or regional wholesalers and must not be obsolete or temporarily unavailable.

(3) Establish or maintain a reasonable administrative appeals process to allow a dispensing pharmacy provider to contest a listed maximum allowable cost.

(4)(A) Respond in writing to any appealing pharmacy provider within 10 calendar days after receipt of an appeal, provided that, except as provided in subdivision (B) of this subdivision (4), a dispensing pharmacy provider shall file any appeal within 10 calendar days from the date its claim for reimbursement is adjudicated.

(B) A pharmacy benefit manager shall allow a dispensing pharmacy provider to appeal after the 10-calendar-day appeal period set forth in subdivision (A) of this subdivision (4) if the prescription claim is subject to an audit initiated by the pharmacy benefit manager or its auditing agent.

(5) For a denied appeal, provide the reason for the denial and identify the national drug code and a Vermont-licensed wholesaler of an equivalent drug product that may be purchased by contracted pharmacies at or below the maximum allowable cost.

(6) For an appeal in which the appealing pharmacy is successful:

(A) make the change in the maximum allowable cost within 30 business days after the redetermination; and
(B) allow the appealing pharmacy or pharmacist to reverse and rebill
the claim in question.

(d)(g) A pharmacy benefit manager shall not:

(1) require a claim for a drug to include a modifier or supplemental
transmission, or both, to indicate that the drug is a 340B drug unless the claim
is for payment, directly or indirectly, by Medicaid; or

(2) restrict access to a pharmacy network or adjust reimbursement rates
based on a pharmacy’s participation in a 340B contract pharmacy
arrangement.

(h)(1) A pharmacy benefit manager or other third party that reimburses a
340B covered entity for drugs that are subject to an agreement under 42
U.S.C. § 256b through the 340B drug pricing program shall not reimburse the
340B covered entity for pharmacy-dispensed drugs at a rate lower than that
paid for the same drug to pharmacies that are not 340B covered entities, and
the pharmacy benefit manager shall not assess any fee, charge-back, or other
adjustment on the 340B covered entity on the basis that the covered entity

(2) With respect to a patient who is eligible to receive drugs that are
subject to an agreement under 42 U.S.C. § 256b through the 340B drug
pricing program, a pharmacy benefit manager or other third party that makes
payment for the drugs shall not discriminate against a 340B covered entity in a
manner that prevents or interferes with the patient’s choice to receive the drugs from the 340B covered entity.

(i) A pharmacy benefit manager shall not reimburse a pharmacy or pharmacist in this State an amount less than the amount the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmacist services.

(j) A pharmacy benefit manager shall not restrict, limit, or impose requirements on a licensed pharmacy in excess of those set forth by the Vermont Board of Pharmacy or by other State or federal law, nor shall it withhold reimbursement for services on the basis of noncompliance with participation requirements.

(k) A pharmacy benefit manager shall provide notice to all participating pharmacies prior to changing its drug formulary.

Sec. 3. 18 V.S.A. § 3802 is amended to read:

§ 3802. PHARMACY RIGHTS DURING AN AUDIT

Notwithstanding any provision of law to the contrary, whenever a health insurer, a third-party payer, or an entity representing a responsible party conducts an audit of the records of a pharmacy, the pharmacy shall have a right to all of the following:

* * *
(2) If an audit is to be conducted on-site at a pharmacy, the entity conducting the audit:

(A) shall give the pharmacy at least 14 days’ advance written notice of the audit and the specific prescriptions to be included in the audit; and

(B) may shall not audit a pharmacy on Mondays or on weeks containing a federal holiday, unless the pharmacy agrees to alternative timing for the audit.; and

(3) Not to have an entity

(C) shall not audit claims that:

(A)(i) were submitted to the pharmacy benefit manager more than 18 months prior to the date of the audit, unless:

(i)(I) required by federal law; or

(ii)(II) the originating prescription was dated within the 24-month period preceding the date of the audit; or

(B)(ii) exceed 200 selected prescription claims.

(3) If any audit is to be conducted remotely, the entity conducting the audit:

(A) shall give the pharmacy at least seven business days following the pharmacy’s confirmation of receipt of the notice of the audit to respond to the audit; and

(B) shall not audit claims that:
(i) were submitted to the pharmacy benefit manager more than three months prior to the date of the audit or on a date earlier than that for which the pharmacy could electronically retransmit a corrected claim; or

(ii) exceed five selected prescription claims.

* * *

(19) To have the preliminary audit report delivered to the pharmacy within 30 days following the conclusion of the audit pharmacy’s preliminary response.

* * *

(21) To have a final audit report delivered to the pharmacy within 420 days after the end of the appeals period, as required by section 3803 of this title.

* * *

(24) To have all payment data related to audited claims, including:

(A) payment amount;

(B) any direct and indirect remuneration (DIR) or generic effective rate (GER) fees assessed or other financial offsets;

(C) date of electronic payment or check date and number;

(D) the specific contracted reimbursement basis for each claim, including its basis, such as maximum allowable cost (MAC), wholesale
acquisition cost (WAC), average wholesale price (AWP), or average manufacturer price (AMP); and

(E) the respective values used to calculate each claim payment.

Sec. 4. 8 V.S.A. § 4089j is amended to read:

§ 4089j. RETAIL PHARMACIES; FILLING OF PRESCRIPTIONS

* * *

(d)(1) A health insurer or pharmacy benefit manager shall permit a beneficiary of a plan offered by the health insurer to fill a prescription at the in-network pharmacy of the beneficiary’s choice and, except with respect to pharmacies owned or operated, or both, by a health care facility, as defined in 18 V.S.A. § 9432, shall not impose differential cost-sharing requirements based on the choice of pharmacy or otherwise promote the use of one pharmacy over another.

(2) A health insurer or pharmacy benefit manager shall permit a participating network pharmacy to perform all pharmacy services within the lawful scope of the profession of pharmacy as set forth in 26 V.S.A. chapter 36.

(3) A health insurer or pharmacy benefit manager shall adhere to the definitions of prescription drugs and the requirements and guidance regarding the pharmacy profession established by State and federal law and the Vermont Board of Pharmacy and shall not establish classifications of or distinctions between prescription drugs, impose penalties on prescription drug claims,
attempt to dictate the behavior of pharmacies or pharmacists, or place restrictions on pharmacies or pharmacists that are more restrictive than or inconsistent with State or federal law or with rules adopted or guidance provided by the Board of Pharmacy.

(4) The provisions of this subsection shall not apply to Medicaid.

Sec. 5. DEPARTMENT OF FINANCIAL REGULATION; PHARMACY BENEFIT MANAGEMENT; REPORT

(a) The Department of Financial Regulation, in consultation with interested stakeholders, shall consider:

(1) whether pharmacy benefit managers should be required to be licensed to operate in this State;

(2) whether pharmacy benefit managers should be prohibited from conducting or participating in spread pricing;

(3) in collaboration with the Board of Pharmacy, whether any amendments to the Board’s rules are needed to reflect necessary distinctions or appropriate limitations on pharmacist scope of practice;

(4) whether there should be a minimum dispensing fee that pharmacy benefit managers and health insurers must pay to pharmacies and pharmacists for dispensing prescription drugs;

(5) how a pharmacy should be reimbursed for a claim if a pharmacy benefit manager denies a pharmacy’s appeal in whole or in part, including
whether the pharmacy should be allowed to submit a claim to the health insurer for the balance between the pharmacy benefit manager’s reimbursement and the pharmacy’s reasonable acquisition cost plus a dispensing fee;

(6) whether there is a problem in Vermont of pharmacies soliciting health insurance plan beneficiaries directly to market the pharmacy’s services and, if so, how best to address the problem; and

(7) other issues relating to pharmacy benefit management and its effects on Vermonters, on pharmacies and pharmacists, and on health insurance in this State.

(b) On or before January 15, 2023, the Department of Financial Regulation shall provide its findings and recommendations regarding the issues described in subsection (a) of this section to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance.

Sec. 6. APPLICABILITY

(a) The provisions of Sec. 2 of this act (18 V.S.A. chapter 221, subchapter 9, pharmacy benefit managers) shall apply to a contract or health plan issued, offered, renewed, recredentialled, amended, or extended on or after the effective date of this act, including any health insurer that performs claims processing or other prescription drug or device services through a third party.
(b) A person doing business in this State as a pharmacy benefit manager on or before the effective date of this act shall have six months following the effective date of this act to come into compliance with the provisions of Sec. 2 of this act (18 V.S.A. chapter 221, subchapter 9, pharmacy benefit managers).

Sec. 7. 2021 Acts and Resolves No. 74, Sec. E.227.2 is amended to read:

Sec. E.227.2 REPEAL

18 V.S.A. § 9473(d)(g) (pharmacy benefit managers; 340B entities) is repealed on January 1, 2023 April 1, 2024.

Sec. 8. EFFECTIVE DATE

This act shall take effect on July 1, 2022.