1	H.233
2	Introduced by Representative Cordes of Lincoln
3	Referred to Committee on
4	Date:
5	Subject: Health; health insurance; prescription drugs; pharmacies; pharmacy
6	benefit managers
7	Statement of purpose of bill as introduced: This bill proposes to require
8	pharmacy benefit managers to obtain licensure from, rather than register with,
9	the Department of Financial Regulation. It would establish a detailed
10	regulatory framework for regulating pharmacy benefit managers and would
11	prohibit or restrict a number of pharmacy benefit management activities. The
12	bill would recodify most of the existing statutory provisions relating to
13	pharmacy benefit managers in a single chapter, with some revisions. It would
14	limit direct solicitation to consumers by pharmacies and pharmacy benefit
15	managers. The bill would also require the Agency of Human Services to
16	select a wholesale drug distributor through a competitive bidding process to be
17	the sole source to distribute prescription drugs to pharmacies for dispensing to
18	Medicaid beneficiaries.

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An act relating to licensure and regulation of pharmacy benefit managers

1	It is hereby enacted by the General Assembly of the State of Vermont:
2	Sec. 1. 18 VSA chapter 77 is added to read:
3	CHAPTER 77. PHARMACY BENEFIT MANAGERS
4	Subchapter 1. General Provisions
5	<u>§ 3601. PULPOSE</u>
6	The purpose of this chapter is to establish standards and criteria for the
7	licensure and regulation of pharmacy benefit managers providing claims
8	processing services or other prescription drug or device services for health
9	<u>benefit plans by:</u>
10	(1) promoting, preserving, and protecting the public health, safety, and
11	welfare through effective regulation and licensure of pharmacy benefit
12	managers;
13	(2) promoting the solvency of the commercial health insurance industry,
14	the regulation of which is reserved to the states by the McCarran-Ferguson
15	Act, 15 U.S.C. §§ 1011–1015, as well as providing for consumer savings and
16	for fairness in prescription drug benefits;
17	(3) providing for the powers and duties of the Commissioner of
18	Financial Regulation; and
19	(4) prescribing penalties and fines for violations of this chapter.
20	6.3602 DEPENDITIONS

1	<u>A cused in this chapter:</u>
2	(1) "Claims processing services" means the administrative services
3	performed in connection with the processing and adjudicating of claims
4	relating to pharmacist services that include receiving payments for pharmacist
5	services or making payments to pharmacists or pharmacies for pharmacy
6	services, or both.
7	(2) "Commissioner" means the Commissioner of Financial Regulation.
8	(3) "Covered person means a member, policyholder, subscriber,
9	enrollee, beneficiary, dependent, or other individual participating in a health
10	benefit plan.
11	(4) "Health benefit plan" means a policy, contract, certificate, or
12	agreement entered into, offered, or issued by a health insurer to provide,
13	deliver, arrange for, pay for, or reimburse any of the costs of physical, mental,
14	or behavioral health care services.
15	(5) "Health insurer" has the same meaning as in section 9402 of this
16	title and includes:
17	(A) health insurance companies, nonprofit hospital and medical
18	service corporations, and health maintenance organizations;
19	(B) employers, labor unions, and other group of persons organized in
20	Vermont that provide a health benefit plan to beneficiaries who are employed
21	or reside in Vermont, and

1	(C) the State of Vermont and any agent or instrumentality of the
2	State that offers, administers, or provides financial support to State
3	government.
4	(6) Maximum allowable cost" means the per unit drug product
5	reimbursement amount, excluding dispensing fees, for a group of equivalent
6	multisource prescription drugs.
7	(7) "Other prescription drug or device services" means services other
8	than claims processing services provided directly or indirectly, whether in
9	connection with or separate from claims processing services, and may include:
10	(A) negotiating rebates, plice concessions, discounts, or other
11	financial incentives and arrangements with drug companies;
12	(B) disbursing or distributing rebates or price concessions, or both;
13	(C) managing or participating in incentive programs or arrangements
14	for pharmacist services;
15	(D) negotiating or entering into contractual anangements with
16	pharmacists or pharmacies, or both;
17	(E) developing and maintaining formularies;
18	(F) designing prescription benefit programs; and
19	(G) advertising or promoting services.
20	(8) "Pharmacist" means an individual licensed as a pharmacist pursuant
21	to 20 v.S.A. chapter 50.

1	(0) "Pharmagist corvices" means products, goods, and corvices, or a
2	combination of these, provided as part of the practice of pharmacy.
3	(10) "Pharmacy" means a place licensed by the Vermont Board of
4	Pharmacy at which drugs, chemicals, medicines, prescriptions, and poisons are
5	compounded, a spensed, or sold at retail.
6	(11) "Pharmacy benefit management" means an arrangement for the
7	procurement of prescription drugs at a negotiated rate for dispensation within
8	this State to beneficiaries, the administration or management of prescription
9	drug benefits provided by a health benefit plan for the benefit of beneficiaries,
10	or any of the following services provided with regard to the administration of
11	pharmacy benefits:
12	(A) mail service pharmacy;
13	(B) claims processing, retail network management, and payment of
14	claims to pharmacies for prescription drugs dispensed to beneficiaries;
15	(C) clinical formulary development and management services;
16	(D) rebate contracting and administration;
17	(E) certain patient compliance, therapeutic intervention, and generic
18	substitution programs; and
19	(F) disease or chronic care management programs.
20	(12)(A) "Pharmacy benefit manager" means an individual, corporation,
21	or other entity, including a wholly or partially owned or controlled subsidiary

1	of a pharmacy banafit managar, that provides pharmacy banafit management
2	services for health benefit plans.
3	(B) The term "pharmacy benefit manager" does not include:
4	(i) a health care facility licensed in this State;
5	(ii) a health care professional licensed in this State;
6	(iii) a consultant who only provides advice as to the selection or
7	performance of a pharmacy benefit manager;
8	(iv) a health in urer to the extent that it performs any claims
9	processing and other prescription drug or device services exclusively for its
10	enrollees; or
11	(v) an entity that provides pharmacy benefit management services
12	for Vermont Medicaid.
13	(13) "Pharmacy benefit manager affiliate" means a pharmacy or
14	pharmacist that, directly or indirectly, through one or more intermediaries, is
15	owned or controlled by, or is under common ownership or control with, a
16	pharmacy benefit manager.
17	<u>§ 3603. RULEMAKING</u>
18	The Commissioner of Financial Regulation shall adopt rules in accordance
19	with 3 V.S.A. chapter 25 to carry out the provisions of this chapter. The rules
20	shall include, as appropriate, requirements that health insurers maintain the
21	confidentiality of proprietary information and that pharmacy benefit managers

1	file their advertising and solicitation materials with the Commissioner for
2	approval prior to sending any such materials to patients or consumers.
3	<u>§ 3604. REPORTING</u>
4	Annually on or before January 15, the Department of Financial Regulation
5	shall report to the House Committee on Health Care and the Senate
6	Committees on Health and Welfare and on Finance regarding pharmacy
7	benefit managers' compliance with the provisions of this chapter.
8	Subchapter 2. Pharmacy Benefit Manager Licensure and Regulation
9	<u>§ 3611. LICENSURE</u>
10	(a) A person shall not establish or operate as a pharmacy benefit manager
11	for health benefit plans in this State without first obtaining a license from the
12	Commissioner of Financial Regulation.
13	(b) A person applying for a pharmacy benefit manager license shall submit
14	an application for licensure in the form and manner prescribed by the
15	Commissioner and shall include with the application a conrefundable
16	application fee of \$100.00 and a licensure fee of \$500.00.
17	(c) The Commissioner may refuse to issue or renew a pharmacy benefit
18	manager license if the Commissioner determines that the applicant or any
19	individual responsible for the conduct of the applicant's affairs is not
20	competent, trustworthy, financially responsible, or of good personal and
21	business reputation, or has been found to have violated the insurance laws of

1	this State or any other jurisdiction, or has had an insurance or other certificate
2	of authority or license denied or revoked for cause by any jurisdiction.
3	(d) Unless surrendered, suspended, or revoked by the Commissioner, a
4	license issued under this section shall remain valid, provided the pharmacy
5	benefit manage does all of the following:
6	(1) Continue to do business in this State.
7	(2) Complies with the provisions of this chapter and any applicable
8	<u>rules.</u>
9	(3) Submits a renewal application in the form and manner prescribed by
10	the Commissioner and pays the annual license renewal fee of \$500.00. The
11	renewal application and renewal fee shall be due to the Commissioner on or
12	before 90 days prior to the anniversary of the effective date of the pharmacy
13	benefit manager's initial or most recent license.
14	(e) The Commissioner shall adopt rules pursuant to 3 V.S.A. chapter 25 to
15	establish the licensing application, financial, and reporting requirements for
16	pharmacy benefit managers in accordance with this section.
17	<u>§ 3612. PROHIBITED PRACTICES</u>
18	(a) A participation contract between a pharmacy benefit manager and a
19	pharmacist shall not prohibit, restrict, or penalize a pharmacy or pharm cist in
20	any way from disclosing to any covered person any health care information
21	that the pharmacy of pharmacist deems appropriate, including.

1	(1) the nature of treatment risks or alternatives to treatment:
2	(2) the availability of alternate therapies, consultations, or tests;
3	(1) the decision of utilization reviewers or similar persons to authorize
4	or deny services;
5	(4) the process that is used to authorize or deny health care services; or
6	(5) information on finance incentives and structures used by the health
7	insurer.
8	(b) A pharmacy benefit manager shall not prohibit a pharmacy or
9	pharmacist from:
10	(1) discussing information regarding the total cost for pharmacist
11	services for a prescription drug;
12	(2) providing information to a covered person regarding the covered
13	person's cost-sharing amount for a prescription drug;
14	(3) disclosing to a covered person the cash plice for a prescription drug;
15	or
16	(4) selling a more affordable alternative to the covered person if a more
17	affordable alternative is available.
18	(c) A pharmacy benefit manager contract with a participating pharmacist or
19	pharmacy shall not prohibit, restrict, or limit disclosure of information to the
20	Commissioner, law enforcement, or State and federal government officials,
21	provided that.

1	(1) the recipient of the information represents that the recipient has the
2	authority, to the extent provided by State or federal law, to maintain
3	proprietary information as confidential; and
4	(2) prior to disclosure of information designated as confidential, the
5	<u>pharmacist or pharmacy:</u>
6	(A) marks as confidential any document in which the information
7	appears; and
8	(B) requests confidential treatment for any oral communication of
9	the information.
10	(d) A pharmacy benefit manager shall not terminate a contract with or
11	penalize a pharmacist or pharmacy due to the pharmacist or pharmacy:
12	(1) disclosing information about pharmacy benefit manager practices,
13	except for information determined to be a tradesecret under State law or by
14	the Commissioner, when disclosed in a manner other than in accordance with
15	subsection (c) of this section; or
16	(2) sharing any portion of the pharmacy benefit manager contract with
17	the Commissioner pursuant to a complaint or query regarding the contract's
18	compliance with the provisions of this chapter.
19	(e)(1) A pharmacy benefit manager shall not require a covered person
20	purchasing a covered prescription drug to pay an amount greater than the
21	lesser of.

1	$(\Lambda)$ the cost sharing amount under the terms of the health henefit
2	plan as determined in accordance with subdivision (2) of this subsection (e);
3	(B) the maximum allowable cost for the drug; or
4	(C) the amount the covered person would pay for the drug, after
5	application of any known discounts, if the covered person were paying the
6	cash price.
7	(2) As used in subdivision (1)(A) of this subsection (e), the "cost-
8	sharing amount under the terms of the health benefit plan" shall be calculated
9	at the point of sale based on a price that has been reduced by an amount equal
10	to at least 100 percent of all rebates received, or to be received, in connection
11	with the dispensing or administration of the drug. The pharmacy benefit
12	manager shall pass on any remaining rebate amount in excess of the covered
13	person's cost-sharing amount to the health benefit plan to reduce premiums.
14	(3) A pharmacy benefit manager shall attribute any amount paid by or
15	on behalf of a covered person under subdivision (1) of this subsection,
16	including any third-party payment, financial assistance, discount, coupon, or
17	any other reduction in out-of-pocket expenses made by or on behalf of a
18	covered person for prescription drugs, toward any deductible and, it the extent
19	consistent with Sec. 2707 of the Public Health Service Act, 42 U.S.C.
20	§ 300gg-6, the annual out-of-pocket maximums under the covered person's
21	heaith benefit plan.

1	(f) A pharmacy honefit manager shall not conduct or participate in spread
2	pricing in this State.
3	<u>§ 3613. ENFORCEMENT; RIGHT OF ACTION</u>
4	(a) The Commissioner of Financial Regulation shall enforce compliance
5	with the provisions of this chapter.
6	(b)(1) The Commissioner may examine or audit the books and records of a
7	pharmacy benefit manager providing claims processing services or other
8	prescription drug or device vervices for a health benefit plan to determine
9	compliance with this chapter.
10	(2) Information or data acquired in the course of an examination or
11	audit under subdivision (1) of this subsection shall be considered proprietary
12	and confidential, shall be exempt from public inspection and copying under the
13	Public Records Act, shall not be subject to subpoena, and shall not be subject
14	to discovery or admissible in evidence in any private civil action.
15	(3) The Office of the Health Care Advocate shall have the right to
16	receive or review copies of all materials provided to or reviewed by the
17	Commissioner under this chapter in order to protect and promote patients' and
18	consumers' interests in accordance with the Office's duties under chapter 229
19	of this title. The Office of the Health Care Advocate shall not further asclose
20	any confidential or proprietary information provided to this Office pursuant to
21	this subdivision.

1	(c) The Commissioner may use any document or information provided
2	pur uant to subsection 3612(c) or (d) of this chapter in the performance of the
3	Commissioner's duties to determine compliance with this chapter.
4	(d) The Commissioner may impose a penalty on a pharmacy benefit
5	manager or the health insurer with which it is contracted, or both, for a
6	violation of this chapter. The penalty shall be not less than \$25,000.00 nor
7	more than \$50,000.00 for each violation of this chapter.
8	(e) A pharmacy, pharmacist, or other person injured by a pharmacy benefit
9	manager's violation of this charter may bring an action in Superior Court
10	against the pharmacy benefit manager for injunctive relief, compensatory and
11	punitive damages, costs and reasonable attorney's fees, and other appropriate
12	<u>relief.</u>
13	<u>§ 3614. COMPLIANCE; CONSISTENCY WITH FEDERAL LAW</u>
14	Nothing in this chapter is intended or should be construed to conflict with
15	applicable federal law.
16	<u>§ 3615. CHARGES FOR EXAMINATIONS, APPLICATIONS, REVIEWS,</u>
17	AND INVESTIGATIONS
18	(a) The Department of Financial Regulation may charge its reasonable
19	expenses in administering the provisions of this chapter to pharmacy benefit
20	managers in the manner provided for in 8 V.S.A. § 18. These expenses shall
21	be anotated in proportion to the lives of vermonters covered by each

1	pharmacy benefit manager as reported annually to the Commissioner in a
2	manner and form prescribed by the Commissioner.
3	(b) The Department of Financial Regulation shall not charge its expenses to
4	the pharmacy benefit manager contracting with the Department of Vermont
5	Health Access in the Department of Vermont Health Access notifies the
6	Department of Financial Regulation of the conditions contained in its contract
7	with a pharmacy benefit manager.
8	Subchapter 3. Pharmacy Renefit Manager Relations with Health Insurers
9	<u>§ 3621. INSURER AUDIT OF NHARMACY BENEFIT MANAGER</u>
10	<u>ACTIVITIES</u>
11	In order to enable periodic verification of pricing arrangements in
12	administrative-services-only contracts, pharm cy benefit managers shall allow
13	access, in accordance with rules adopted by the Commissioner, by the health
14	insurer who is a party to the administrative-services-only contract to financial
15	and contractual information necessary to conduct a complete and independent
16	audit designed to verify the following:
17	(1) full pass through of negotiated drug prices and fees associated with
18	all drugs dispensed to beneficiaries of the health benefit plan in both regail and
19	mail order settings or resulting from any of the pharmacy benefit management
20	functions defined in the contract.

1	(2) full pass through of all financial remuneration associated with all
2	drugs dispensed to beneficiaries of the health benefit plan in both retail and
3	mail order settings or resulting from any of the pharmacy benefit management
4	functions defined in the contract; and
5	(3) any other verifications relating to the pricing arrangements and
6	activities of the pharmacy benefit manager required by the contract if required
7	by the Commissioner.
8	§ 3622. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES
9	WITH RESPECT TO HEALTH INSURERS
10	(a) A pharmacy benefit manage, that provides pharmacy benefit
11	management for a health benefit plan has a fiduciary duty to its health insurer
12	client that includes a duty to be fair and truthful toward the health insurer; to
13	act in the health insurer's best interests; and to perform its duties with care,
14	skill, prudence, and diligence. In the case of a health benefit plan offered by a
15	health insurer as defined by subdivision 3602(5)(A) of this title, the health
16	insurer shall remain responsible for administering the health benefit plan in
17	accordance with the health insurance policy or subscriber contract or plan and
18	in compliance with all applicable provisions of Title 8 and this title.
19	(b) A pharmacy benefit manager shall provide notice to the health insurer
20	that the terms contained in subsection (c) of this section may be included in the
21	contract between the pharmacy benefit manager and the health insurer.

1	(c) <u>A pharmacy benefit manager that provides pharmacy benefit</u>
2	management for a health plan shall do all of the following:
3	(1) Provide all financial and utilization information requested by a
4	health insurve relating to the provision of benefits to beneficiaries through that
5	health insurer's realth benefit plan and all financial and utilization information
6	relating to services to that health insurer. A pharmacy benefit manager
7	providing information under this subsection may designate that material as
8	confidential. Information designated as confidential by a pharmacy benefit
9	manager and provided to a health insurer under this subsection shall not be
10	disclosed by the health insurer to any person without the consent of the
11	pharmacy benefit manager, except that disclosure may be made by the health
12	insurer:
13	(A) in a court filing under the consumer protection provisions of
14	9 V.S.A. chapter 63, provided that the information shall be filed under seal and
15	that prior to the information being unsealed, the court shan give notice and an
16	opportunity to be heard to the pharmacy benefit manager on why the
17	information should remain confidential;
18	(B) to State and federal government officials;
19	(C) when authorized by 9 V.S.A. chapter 63;
20	(D) when ordered by a court for good cause shown, or

1	(E) when ordered by the Commissioner as to a health insurer as
2	defined in subdivision 3602(5)(A) of this chapter pursuant to the provisions of
3	Title 8 and this title.
4	(2) Notify a health insurer in writing of any proposed or ongoing
5	activity, policy, or practice of the pharmacy benefit manager that presents,
6	directly or indirectly, any conflict of interest with the requirements of this
7	section.
8	(3) With regard to the dispensation of a substitute prescription drug for a
9	prescribed drug to a beneficiary in which the substitute drug costs more than
10	the prescribed drug and the pharmacy benefit manager receives a benefit or
11	payment directly or indirectly, disclose to the health insurer the cost of both
12	drugs and the benefit or payment directly or indirectly accruing to the
13	pharmacy benefit manager as a result of the substitution.
14	(4) If the pharmacy benefit manager derives any payment or benefit for
15	the dispensation of prescription drugs within the State cased on volume of
16	sales for certain prescription drugs or classes or brands of drugs within the
17	State, pass that payment or benefit on in full to the health insurer.
18	(5) Disclose to the health insurer all financial terms and arrangements
19	for remuneration of any kind that apply between the pharmacy benefit
20	manager and any prescription drug manufacturer that relate to benefits
21	provided to beneficiaries under or services to the health insurer's health benefit

1	plan, including formulary management and drug switch programs, educational
2	support, claims processing, and pharmacy network fees charged from retail
3	pharmaties and data sales fees. A pharmacy benefit manager providing
4	information under this subsection may designate that material as confidential.
5	Information designated as confidential by a pharmacy benefit manager and
6	provided to a health insurer under this subsection shall not be disclosed by the
7	health insurer to any person without the consent of the pharmacy benefit
8	manager, except that disclosure may be made by the health insurer:
9	(A) in a court filing under the consumer protection provisions of
10	9 V.S.A. chapter 63, provided that the information shall be filed under seal and
11	that prior to the information being unsealed, the court shall give notice and an
12	opportunity to be heard to the pharmacy benefit manager on why the
13	information should remain confidential;
14	(B) when authorized by 9 V.S.A. chapter 63,
15	(C) when ordered by a court for good cause shown; or
16	(D) when ordered by the Commissioner as to a health insurer as
17	defined in subdivision 3602(5)(A) of this title pursuant to the provisions of
18	Title 8 and this title.
19	(d) A pharmacy benefit manager contract with a health insurer shall not
20	contain any provision purporting to reserve discretion to the pharmacy benefit

1	manager to move a drug to a higher tier or remove a drug from its drug
2	formulary any more frequently than two times per year.
3	(e) At least annually, a pharmacy benefit manager that provides pharmacy
4	benefit management for a health benefit plan shall disclose to the health
5	insurer, the Department of Financial Regulation, the Green Mountain Care
6	Board, and the Office of the Health Care Advocate the aggregate amount the
7	pharmacy benefit manager retained on all claims charged to the health insurer
8	for prescriptions filled during the preceding calendar year in excess of the
9	amount the pharmacy benefit manager reimbursed pharmacies.
10	(f) Compliance with the requirements of this section is required for
11	pharmacy benefit managers entering into contracts with a health insurer in this
12	State for pharmacy benefit management in this State.
13	Subchapter 4. Pharmacy Benefit Manager Relations with Pharmacies
14	<u>§ 3631. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES</u>
15	WITH RESPECT TO PHARMACIES
16	(a) Within 14 calendar days following receipt of a pharmacy claim, a
17	pharmacy benefit manager or other entity paying pharmacy claims shall do one
18	of the following:
19	(1) Pay or reimburse the claim.
20	(2) Notify the pharmacy in writing that the claim is contested or denied.
21	The notice shall include specific reasons supporting the contest or denial and a

1	description of any additional information required for the pharmacy benefit
2	manager or other payer to determine liability for the claim.
3	(b) In addition to the practices prohibited by section 3612 of this chapter, a
4	pharmacy benefit manager or other entity paying pharmacy claims shall not
5	require a pharmaty to pass through any portion of the insured's co-payment, or
6	patient responsibility, to the pharmacy benefit manager or other payer.
7	(c) For each drug for which a pharmacy benefit manager establishes a
8	maximum allowable cost in order to determine the reimbursement rate, the
9	pharmacy benefit manager shall do all of the following:
10	(1) Make available, in a format that is readily accessible and
11	understandable by a pharmacist, the actual maximum allowable cost for each
12	drug and the source used to determine the maximum allowable cost, which
13	shall not be dependent upon individual beneficiary identification or benefit
14	stage.
15	(2) Update the maximum allowable cost at least once every seven
16	calendar days. In order to be subject to maximum allowable cost, a drug must
17	be widely available for purchase by all pharmacies in the State, without
18	limitations, from national or regional wholesalers and must not be obsolete or
19	temporarily unavailable.

1	(3) Establish or maintain a reasonable administrative appeals process to
2	allow a dispensing pharmacy provider to contest a listed maximum allowable
3	<u>cost.</u>
4	(4)(A) Respond in writing to any appealing pharmacy provider within
5	10 calendar days after receipt of an appeal, provided that, except as provided
6	in subdivision (B) of this subdivision (4), a dispensing pharmacy provider
7	shall file any appeal within 10 calendar days from the date its claim for
8	reimbursement is adjudicated.
9	(B) A pharmacy benefit manager shall allow a dispensing pharmacy
10	provider to appeal after the 10-cale dar-day appeal period set forth in
11	subdivision (A) of this subdivision (4) If the prescription claim is subject to an
12	audit initiated by the pharmacy benefit manager or its auditing agent.
13	(5) For a denied appeal, provide the reason for the denial and identify
14	the national drug code and a Vermont-licensed wholesaler of an equivalent
15	drug product that may be purchased by contracted pharmacies at or below the
16	maximum allowable cost.
17	(6) For an appeal in which the appealing pharmacy is successful:
18	(A) make the change in the maximum allowable cost within 30
19	business days after the redetermination; and
20	(B) allow the appealing pharmacy or pharmacist to reverse and reail
21	the claim in question.

1	(d). If a pharmacy hanafit manager denies a pharmacy's or pharmacist's
2	appeal in whole or in part without identifying the national drug code and a
3	Vermont-licensed wholesaler of an equivalent drug product that may be
4	purchased by contracted pharmacies at or below the maximum allowable cost,
5	and the reimbul sement amount is less than the pharmacy's actual acquisition
6	cost plus a dispensing fee, the pharmacy or pharmacist may submit a claim to
7	the health insurer for the balance and the health insurer shall reimburse the
8	pharmacy or pharmacist that amount.
9	(e) A pharmacy benefit manager shall not reimburse a pharmacy or
10	pharmacist in this State an amount cess than the amount the pharmacy benefit
11	manager reimburses a pharmacy benefit manager affiliate for providing the
12	same pharmacist services. The reimbursement amount shall be calculated on a
13	per-unit basis based on the pharmacy's actual acquisition cost and shall include
14	a professional dispensing fee that shall be not less than the professional
15	dispensing fee established for the Vermont Medicaid program by the
16	Department of Vermont Health Access in accordance with 2 C.F.R. Part 447.
17	(f) A pharmacy benefit manager shall not restrict, limit, or hppose
18	requirements on a licensed pharmacy in excess of those set forth by the
19	Vermont Board of Pharmacy or by other State or federal law, nor shall t
20	withhold reimbursement for services on the basis of noncompliance with
21	participation requirements.

1	(g) A pharmacy herefit manager shall provide notice to all participating
2	pharmacies prior to changing its drug formulary.
3	(h)(1) A pharmacy benefit manager or other third party that reimburses a
4	340B covered entity for drugs that are subject to an agreement under 42 U.S.C.
5	§ 256b through the 340B drug pricing program shall not reimburse the 340B
6	covered entity for pharmacy-dispensed drugs at a rate lower than that paid for
7	the same drug to pharmanies that are not 340B covered entities, and the
8	pharmacy benefit manager shall not assess any fee, charge-back, or other
9	adjustment on the 340B covered untity on the basis that the covered entity
10	participates in the 340B program as set forth in 42 U.S.C. § 256b.
11	(2) With respect to a patient who is eligible to receive drugs that are
12	subject to an agreement under 42 U.S.C. § 25(b through the 340B drug pricing
13	program, a pharmacy benefit manager or other third party that makes payment
14	for the drugs shall not discriminate against a 340B covered entity in a manner
15	that prevents or interferes with the patient's choice to receive the drugs from
16	the 340B covered entity.
17	(i) A pharmacy benefit manager shall not:
18	(1) require a claim for a drug to include a modifier or supplemental
19	transmission, or both, to indicate that the drug is a 340B drug unless the claim
20	is for payment, directly or indirectly, by Medicaid, or

1	(2) restrict access to a pharmacy network or adjust raimbursement rates
2	based on a pharmacy's participation in a 340B contract pharmacy
3	arrangement.
4	Sec. 2. 8 VS.A. § 4084 is amended to read:
5	§ 4084. ADVERTISING PRACTICES
6	(a) No company doing business in this State, and no insurance agent or
7	broker, shall use in conjection with the solicitation of health insurance or
8	pharmacy benefit management any advertising copy or advertising practice or
9	any plan of solicitation which that is materially misleading or deceptive. An
10	advertising copy or advertising practice or plan of solicitation shall be
11	considered to be materially misleading or deceptive if by implication or
12	otherwise it transmits information in such manner or of such substance that a
13	prospective applicant for health insurance may be misled thereby to his or her
14	by it to the applicant's material damage.
15	(b)(1) If the Commissioner finds that any such advertising copy or $(b)(1)$
16	advertising practice or plan of solicitation is materially misreading or
17	deceptive <u>, he or she the Commissioner</u> shall order the company or the agent or
18	broker using such copy or practice or plan to cease and desist from uch use.
19	(2) Before making any such finding and order, the Commissioner shall
20	give notice, not less than 10 days in advance, and a hearing to the company,
21	agent, or broker affected.

1	(3) If the Commissioner finds, after due notice and hearing, that any
2	authorized insurer, licensed pharmacy benefit manager, licensed insurance
3	agent, or licensed insurance broker has wilfully intentionally violated any such
4	order to cease and desist, he or she the Commissioner may suspend or revoke
5	the license of such insurer, pharmacy benefit manager, agent, or broker.
6	Sec. 3. 8 V.S.A. § 1089j is amended to read:
7	§ 4089j. RETAIL PHARMACIES; FILLING OF PRESCRIPTIONS
8	(a) As used in this section:
9	* * *
10	(6) "Direct solicitation" means direct contact, including telephone,
11	computer, e-mail, instant messaging, or in-person contact, by a pharmacy
12	provider or its agent to a beneficiary of a plan offered by a health insurer
13	without the beneficiary's consent for the purpose of marketing the pharmacy
14	provider's services.
15	* * *
16	(d)(1) A health insurer or pharmacy benefit manager shall permit a
17	participating network pharmacy to perform all pharmacy services within the
18	lawful scope of the profession of pharmacy as set forth in 26 V.S.A. chapter
19	36.
20	(2) A health insurer or pharmacy benefit manager shall not do any or
21	the following.

1	* * *
2	(F) Exclude any amount paid by or on behalf of a covered person,
3	including any third-party payment, financial assistance, discount, coupon, or
4	other reduction, when calculating a covered individual's contribution to any
5	deductible or, to the extent not inconsistent with Sec. 2707 of the Public
6	Health Service Act, 12 U.S.C. § 300gg-6, out-of-pocket maximums applicable
7	to the covered individual's health insurance plan.
8	* * *
9	(5) A health insurer or pharmacy benefit manager shall adhere to the
10	definitions of prescription drugs and the requirements and guidance regarding
11	the pharmacy profession established by State and federal law and the Vermont
12	Board of Pharmacy and shall not establish classifications of or distinctions
13	between prescription drugs, impose penalties on prescription drug claims,
14	attempt to dictate the behavior of pharmacies or pharmacists, or place
15	restrictions on pharmacies or pharmacists that are more restrictive than or
16	inconsistent with State or federal law or with rules adopted or suidance
17	provided by the Board of Pharmacy.
18	(6) A pharmacy benefit manager or licensed pharmacy shall not make a
19	direct solicitation to the beneficiary of a plan offered by a health insurer uness
20	one or more of the following applies.

1	$(\Lambda)$ the beneficiary has given written permission to the supplier or
2	the ordering health care professional to contact the beneficiary regarding the
3	furnishing of a prescription item that is to be rented or purchased;
4	(B) the supplier has furnished a prescription item to the beneficiary
5	and is contacting the beneficiary to coordinate delivery of the item; or
6	(C) if the contact relates to the furnishing of a prescription item other
7	than a prescription item dready furnished to the beneficiary, the supplier has
8	furnished at least one prescription item to the beneficiary within the 15-month
9	period preceding the date on which the supplier attempts to make the contact.
10	(8) The provisions of this subsection shall not apply to Medicaid.
11	(e) A health insurer or pharmacy benefit manager shall not alter a patient's
12	prescription drug order or the pharmacy chosen by the patient without the
13	patient's consent.
14	Sec. 4. 33 V.S.A. § 2011 is added to read:
15	<u>§ 2011. WHOLESALE DRUG DISTRIBUTOR CONTRACT</u>
16	(a) As used in this section:
17	(1) "Dead net cost" means the wholesale acquisition cost of
18	prescription drug, less any applicable discounts and all vendor rebates, fees,
19	and incentives, including inventory management agreement fees, fee-for-
20	service agreements, volume incentives, rebates, and reporting fees.

1	(2) "Wholesale drug distributor" has the same meaning as "wholesale
2	<u>distributor" in 26 V.S.A. § 2022.</u>
3	(b) The Agency of Human Services shall establish a competitive bidding
4	process for a wholesale drug distributor, or for several wholesale drug
5	distributors through a group purchasing organization, through which the
6	selected wholesaler or group purchasing organization shall be the sole source
7	to distribute prescription drugs to the community and outpatient pharmacies
8	with which the wholesaler or group purchasing organization enters into
9	contracts for prescription drugs dispensed to beneficiaries of Medicaid and
10	other State health assistance programs for which the Department of Vermont
11	Health Access pays pharmaceutical claim. The Agency of Human Services
12	shall convene a group comprising one representative each from the Green
13	Mountain Care Board, the Department of Vermon Health Access, the Vermont
14	Board of Pharmacy, the Vermont Association of Chain Drug Stores, and the
15	Vermont Community Pharmacy Network to conduct the competitive bidding
16	process and to select the wholesale drug distributor or group purchasing
17	organization that the group determines:
18	(1) will offer the greatest cost savings to the Department of Vern ont
19	Health Access;
20	(2) will provide complete transparency, and

1	(3) demonstrates a willingness to facilitate additional savings
2	throughout the State by expanding the program to additional public and private
3	purchasers.
4	(c) The wholesale drug distributor or group purchasing organization
5	selected pursuant to subsection (b) of this section shall:
6	(1) establish contracts with all Medicaid-participating community and
7	outpatient pharmacies operating in this State;
8	(2) maintain compliance with all applicable federal and State statutes,
9	rules, and regulations relating to the operation of a wholesale drug distributor
10	or group purchasing organization;
11	(3) segregate the commercial polyion of its pharmacy business from the
12	Vermont Medicaid portion;
13	(4) match the Department of Vermont Health Access's reports of claims
14	paid per pharmacy with the pharmacies' invoices;
15	(5) invoice the Department of Vermont Health Access in an amount
16	equal to the aggregate sum of the wholesaler's or group purchasing
17	organization's dead net costs for all claims dispensed during a given period
18	across all participating pharmacies;
19	(6) collaborate with the Department of Vermont Health Access to
20	maximize the amount of direct manufacturer rebates and minimize the costs of
21	the Wedicaid formulary, and

1	(7) create a financial machanism through which pharmacies shall be
2	relayed of drug unit costs dispensed to Vermont Medicaid during the relevant
3	period elentified pursuant to subdivision (5) of this subsection.
4	(d) Only those community and outpatient pharmacies that agree to
5	purchase their entire Vermont Medicaid inventory from the wholesaler or
6	group purchasing organization selected pursuant to this section shall be eligible
7	to establish or maintain enrollment as Medicaid-participating pharmacy
8	providers.
9	(e) The Department of Vermont Health Access shall limit reimbursements
10	to participating pharmacies to an amount equal to the established dispensing
11	fee for prescription claims dispensed; provided, however, that this provision
12	shall not be construed to prohibit the Department from reimbursing a
13	participating pharmacy for recognized ancillary services provided in
14	connection with these claims.
15	Sec. 5. REPEALS
16	The following are repealed on July 1, 2023:
17	(1) 18 V.S.A. § 9421 (pharmacy benefit management; registration;
18	insurer audit of pharmacy benefit manager activities); and
19	(2) 18 V.S.A. chapter 221, subchapter 9 (§§ 9471–9474; pharmacy
20	benefit managers).

1	See 6 ADDI ICADII ITV
2	(a) The provisions of Sec. 1 of this act (18 V.S.A. chapter 77, pharmacy
3	benefit managers) shall apply to a contract or health benefit plan issued,
4	offered, renewed, recredentialed, amended, or extended on or after January 1,
5	2024, including any health insurer that performs claims processing or other
6	prescription drug or device services through a third party.
7	(b) A person doing business in this State as a pharmacy benefit manager on
8	or before January 1, 2024 shall have six months following that date to come
9	into compliance with the provisions of Sec. 1 of this act (18 V.S.A. chapter 77,
10	pharmacy benefit managers).
11	Sec. 7. EFFECTIVE DATE
12	This act shall take effect on July 1, 2023.

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

CHAPTER 77. PHARMACY BENEFIT MANAGERS

#### Subchapter 1. General Provisions

<u>§ 3601. PURPOSE</u>

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; and

(C) the State of Vermont and any agent or instrumentality of the State that offers, administers, or provides financial support to State government.

(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, price concessions, discounts, or other financial incentives and arrangements with drug companies; (B) disbursing or distributing rebates or price concessions, or both;

(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;

(iv) a health insurer to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees; or (v) an entity that provides pharmacy benefit management services for Vermont Medicaid.

(13) "Pharmacy benefit manager affiliate" means a pharmacy or pharmacist that, directly or indirectly, through one or more intermediaries, is owned or controlled by, or is under common ownership or control with, a pharmacy benefit manager.

§ 3603. RULEMAKING

The Commissioner of Financial Regulation shall 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 and that pharmacy benefit managers file their advertising and solicitation materials with the Commissioner for approval prior to sending any such materials to patients or consumers.

§ 3604. REPORTING

<u>Annually on or before January 15, the Department of Financial Regulation</u> <u>shall report to the House Committee on Health Care and the Senate</u> <u>Committees on Health and Welfare and on Finance regarding pharmacy</u> <u>benefit managers' compliance with the provisions of this chapter.</u> 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 (2,500,00) \$1,600.00 and an initial licensure fee of (1,000,00) \$10,000.00.

(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, provided 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 £1,000.00 \$12,000.00. 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 shall 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 financial 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, as determined in accordance with subdivision (2) of this subsection (e);

(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)(A) A pharmacy benefit manager shall attribute any amount paid by or on behalf of a covered person under subdivision (1) of this subsection (e), including any third-party payment, financial assistance, discount, coupon, or any other reduction in out-of-pocket expenses made by or on behalf of a covered person for prescription drugs, toward:

(i) the out-of-pocket limits for prescription drug costs under 8 V.S.A. § 4089i;

(ii) the covered person's deductible, if any; and

(iii) to the extent not inconsistent with Sec. 2707 of the Public Health Service Act, 42 U.S.C. § 300gg-6, the annual out-of-pocket maximums applicable to the covered person's health benefit plan.

(B) The provisions of subdivision (A) of this subdivision (2) relating to a third-party payment, financial assistance, discount, coupon, or other reduction in out-of-pocket expenses made on behalf of a covered person shall only apply to a prescription drug:

(i) for which there is no generic drug or interchangeable biological product, as those terms are defined in section 4601 of this title; or (ii) for which there is a generic drug or interchangeable biological product, as those terms are defined in section 4601 of this title, but for which the covered person has obtained access through prior authorization, a step therapy protocol, or the pharmacy benefit manager's or health benefit plan's exceptions and appeals process.

(C) The provisions of subdivision (A) of this subdivision (2) shall apply to a high-deductible health plan only to the extent that it would not disqualify the plan from eligibility for a health savings account pursuant to 26 U.S.C. § 223.

(f) A pharmacy benefit manager shall not conduct or participate in spread pricing in this State, which means that a pharmacy benefit manager must ensure that the total amount required to be paid by a health benefit plan and a covered person for a prescription drug covered under the plan does not exceed the amount paid to the pharmacy for dispensing the drug.

§ 3613. ENFORCEMENT; RIGHT OF ACTION

(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.

(3) The Office of the Health Care Advocate shall have the right to receive or review copies of all materials provided to or reviewed by the Commissioner under this chapter in order to protect and promote patients' and consumers' interests in accordance with the Office's duties under chapter 229 of this title. The Office of the Health Care Advocate shall not further disclose any confidential or proprietary information provided to the Office pursuant to this subdivision. Information provided to the Office pursuant to this subdivision 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 an administrative penalty on a pharmacy benefit manager or the health insurer with which it is contracted, or both, for a violation of this chapter in accordance with 8 V.S.A. § 3661.

(e) A pharmacy, pharmacist, or other person injured by a pharmacy benefit manager's violation of this chapter may bring an action in Superior Court against the pharmacy benefit manager for injunctive relief, compensatory and punitive damages, costs and reasonable attorney's fees, and other appropriate relief.

§ 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

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.

Subchapter 3. Pharmacy Benefit Manager Relations with Health Insurers § 3621. INSURER AUDIT OF PHARMACY BENEFIT MANAGER

<u>ACTIVITIES</u>

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

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

<u>§ 3622. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES</u> 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(5)(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) 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 (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) 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.

(e) 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.

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

(g)(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.

(3) As used in this section, "other third party" does not include Vermont Medicaid.

(h) 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.

Sec. 2. 8 V.S.A. § 4084 is amended to read:

§ 4084. ADVERTISING PRACTICES

(a) No company doing business in this State, and no insurance agent or broker, shall use in connection with the solicitation of health insurance or pharmacy benefit management any advertising copy or advertising practice or any plan of solicitation which that is materially misleading or deceptive. An advertising copy or advertising practice or plan of solicitation shall be considered to be materially misleading or deceptive if by implication or otherwise it transmits information in such manner or of such substance that a prospective applicant for health insurance may be misled thereby to his or her by it to the applicant's material damage.

(b)(1) If the Commissioner finds that any such advertising copy or advertising practice or plan of solicitation is materially misleading or deceptive he or she, the Commissioner shall order the company or the agent or broker using such copy or practice or plan to cease and desist from such use.

(2) Before making any such finding and order, the Commissioner shall give notice, not less than 10 days in advance, and a hearing to the company, agent, or broker affected.

(3) If the Commissioner finds, after due notice and hearing, that any authorized insurer, <u>licensed pharmacy benefit manager</u>, licensed insurance agent, or licensed insurance broker has wilfully intentionally violated any such order to cease and desist he or she, the Commissioner may suspend or revoke the license of such insurer, <u>pharmacy benefit manager</u>, agent, or broker. Sec. 3. 8 V.S.A. § 4089j is amended to read:

§ 4089j. RETAIL PHARMACIES; FILLING OF PRESCRIPTIONS

(a) As used in this section:

\* \* \*

(6) "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 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.

(2) A health insurer or pharmacy benefit manager shall not do any of the following:

\* \* \*

(F)(i) Exclude any amount paid by or on behalf of a covered individual, including any third-party payment, financial assistance, discount, coupon, or other reduction, when calculating a covered individual's contribution toward:

(1) the out-of-pocket limits for prescription drug costs under section 4089i of this title;

(II) the covered individual's deductible, if any; or

(III) to the extent not inconsistent with Sec. 2707 of the Public Health Service Act, 42 U.S.C. § 300gg-6, the annual out-of-pocket maximums applicable to the covered individual's health benefit plan. (ii) The provisions of subdivision (i) of this subdivision (F) relating to a third-party payment, financial assistance, discount, coupon, or other reduction in out-of-pocket expenses made on behalf of a covered person shall only apply to a prescription drug:

(I) for which there is no generic drug or interchangeable biological product, as those terms are defined in 18 V.S.A. § 4601; or

(II) for which there is a generic drug or interchangeable biological product, as those terms are defined in 18 V.S.A. § 4601, but for which the covered person has obtained access through prior authorization, a step therapy protocol, or the pharmacy benefit manager's or health benefit plan's exceptions and appeals process.

(iii) The provisions of subdivision (i) of this subdivision (F) shall apply to a high-deductible health plan only to the extent that it would not disqualify the plan from eligibility for a health savings account pursuant to 26 U.S.C. § 223.

\* \* \*

(5) <u>A health insurer or pharmacy benefit manager shall adhere to the</u> definitions of prescription drugs and the requirements and guidance regarding the pharmacy profession established by State and federal law and the Vermont <u>Board of Pharmacy and shall not establish classifications of or distinctions</u> 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.

(6) 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.

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

(e) A health insurer or pharmacy benefit manager shall not alter a patient's prescription drug order or the pharmacy chosen by the patient without the patient's consent; provided, however, that nothing in this subsection shall be construed to affect the duty of a pharmacist to substitute a lower-cost drug or biological product in accordance with the provisions of 18

<u>V.S.A. § 4605.</u>

Sec. 4. REPEALS; CONTROLLING LAWS

(a) The following are repealed on July 1, 2029:

(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).

(b) To the extent that any provision of 18 V.S.A. § 9421 or 18 V.S.A. chapter 221, subchapter 9 is found to conflict with one or more provisions of 18 V.S.A. chapter 77 prior to July 1, 2029, the provisions of 18 V.S.A. chapter 77, as enacted in this act and as may be further amended, shall control. Sec. 5. APPLICABILITY

(a)(1) The provisions of Sec. 1 of this act (18 V.S.A. chapter 77, pharmacy benefit managers) relating to contracting and to benefit design shall apply to a contract or health benefit plan issued, offered, renewed, or recredentialed on or after January 1, 2025, including any health insurer that performs claims processing or other prescription drug or device services through a third party, but in no event later than July 1, 2029.

(2) At least annually through 2029, a pharmacy benefit manager that provides pharmacy benefit management for a health benefit plan and uses spread pricing shall disclose to the health insurer, the Department of Financial Regulation, the Green Mountain Care Board, and the Office of the Health Care Advocate 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.

(b) A person doing business in this State as a pharmacy benefit manager on or before January 1, 2025 shall have 12 months following that date to come into compliance with the licensure provisions of Sec. 1 of this act (18 V.S.A. chapter 77, pharmacy benefit managers).

Sec. 6. PHARMACY BENEFIT MANAGER REGULATION; POSITIONS; APPROPRIATION

(a) The following permanent positions are created in the Department of Financial Regulation:

(1) one exempt Enforcement Attorney;

(2) one classified Pharmacy Benefit Manager (PBM) Investigator; and

(3) one classified Pharmacy Benefit Manager (PBM) Licensing/Consumer Services Investigator.

(b) The sum of \$405,000.00 is appropriated to the Department of Financial Regulation from the Insurance Regulatory and Supervision Fund in fiscal year 2025 to support the Department's pharmacy benefit manager regulation

activities as set forth in this act.

Sec. 7. EFFECTIVE DATE

This act shall take effect on July 1, 2024.