TO THE HOUSE OF REPRESENTATIVES:

The Committee on Health Care to which was referred House Bill No. 353 entitled "An act relating to pharmacy benefit management" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. 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~~ 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;

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

(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.

(h) 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.

§ 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.

~~(b)~~(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~~ more

affordable alternative to the covered person if a more affordable alternative 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.

~~(c)~~(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 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.

(i) 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.

(j) 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.

(k) 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.

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

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~~ 30 days following the ~~conclusion of the audit~~ pharmacy's preliminary response.

* * *

(21) To have a final audit report delivered to the pharmacy within ~~120~~ 30 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.

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

Sec. 4. APPLICABILITY

(a) The provisions of Sec. 1 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, 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 221, subchapter 9, pharmacy benefit managers).

Sec. 5. 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.

Sec. 6. EFFECTIVE DATE

This act shall take effect on July 1, 2022.

(Committee vote: _____)

_____

Representative _____

FOR THE COMMITTEE