Submitted on behalf of the Vermont Retail Druggists, Inc. (VRD) by its lobbyist, Theo Kennedy, Esq., JD/MPH of Otis & Kennedy, LLC

Proposed Statutory "Fixes" Document

Today we find PBMs exploiting the lack of definition of "desk audits" or "remote audits"

2020 Session

I) Chapter 79 "Pharmacy Audits"

http://legislature.vermont.gov/statutes/chapter/18/079

Today we find PBMs exploiting the lack of definition of "desk audits" or "remote audits" which are carried out by facsimile. Historically, these types of audits were reserved for one claim to address a particular concern (i.e., high dose, high cost, and such). What we see today is PBMs, or their auditing partners, sending desk audits with a list of 150 or so prescriptions on them (< 200 as required under statute). They request a pharmacy provider fax their responses in the amount of several hundred pages before the deadline. No other communication is given and if a pharmacy fails to comply, all revenue for those prescriptions is recouped. In one such event by way of example, a pharmacy did comply and confirmed on the phone that the fax was received by the auditing agent, only to learn 3 months later when audited for many of the same prescriptions, that the auditing agents informed the PBM to recoup on funds for lack of compliance. It took another 4 months for the pharmacy to receive its money back, a total in excess of $168,000.00.

Below is or suggested edits which aim to enhance pharmacy audit protections:

18 V.S.A.§ 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:

(1) To have an audit involving clinical or professional judgment be conducted by a pharmacist licensed to practice pharmacy in one or more states, who has at least a familiarity with Vermont pharmacy statutes and rules and who is employed by or working with an auditing entity.

(2) To have all payment data related to audited claims, including payment amount, any DIR/GER fees assessed, date of electronic payment or check date and number, the specific contracted payment metrics for each claim including cost basis, such as MAC, WAC, AWP or AMP, and the respective values used to calculate each claim payment.

~~(2)~~ (3) 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 not audit a pharmacy on Mondays or on weeks containing a federal holiday, unless the pharmacy agrees to alternative timing for the audit.

(C) ~~Not to have an~~ may not audit claims that:

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

(a) required by federal law; or

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

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

(4) If an audit is to be performed remotely, "desk-audit", the entity conducting the audit:

(A) shall give the pharmacy at least 7 business days to respond to the audit provided receipt is confirmed by pharmacy; and

(B) may not audit claims that:

(i) were submitted to the pharmacy benefit manager more than 3 months prior to the date of the audit or more than a date to which the pharmacy could electronically retransmit a corrected claim; and

(ii) exceed 5 selected prescription claims.

***(continued renumbering) ***

~~(19)~~ (20) To have the preliminary audit report delivered to the pharmacy within ~~60~~ 30 days following the ~~conclusion of the audit~~ preliminary response by the pharmacy.

~~(20)~~ (21) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during the audit.

~~(21)~~ (22) To have a final audit repot delivered to the pharmacy within ~~120~~ 30 days after the end of the appeals period, as required by section 3803 of this title.

II) "MAC Transparency" (S.139) 2015-2016 Session

http://legislature.vermont.gov/statues/section/18/221/09473

With the exception of DVHA and a worker's compensation plan, called Tmesys, no PBM actually makes MAC prices "readily" available to pharmacies

The lack of compliance with current statutes, which aims at transparency and improved patient choices, can not be understated, and when coupled with other facts, leads many to question these behaviors under both the consumer fraud and antitrust statutes.

Below are a few suggested edits for your consideration that begin to address the issues:

18 V.S.A. § 9473 PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES WITH RESPECT TO PHARMACIES

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

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

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

(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. *shall not be dependent on 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 (need something) administrative appeals process to allow a dispensing pharmacy provider to contest a listed maximum allowable cost.

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

(5) Pharmacies shall be given rights to appeal beyond the 10 calendar days in the event the prescription claim is subject to an audit initiated by the PBM or its auditing agent.

(6) If the appeal is denied, the pharmacy benefit manager shall:

(A) Provide the reason for the denial; and

(B) Identify the national drug code and regional distributor of an equivalent drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost; and, if the appeal is granted, the pharmacy benefit

manager shall within 30 business days after granting the appeal, make the change in the maximum allowable cost.

III) Patient Access

http://legislature.vermont.gov/statues/section/08/107/04089j

8 VSA 4089(j) Retail pharmacies; filling of prescriptions amended to include:

Today we find insurance companies and PBMs dictating to patients which pharmacy they MUST utilize, typically the mail-order pharmacy owned by the PBM itself. There is no definition of "Specialty Drugs" in any statute or regulation. These drugs are simply HIGH COST BRANDS. The special handling associated with them typically amounts to refrigeration, much like insulin, which ironically, meets all commonly used definitions of "Specialty". If a manufacturer has concerns that a particular product requires additional oversight, then the product is placed on the "Limited Distribution" list and only certain pharmacies have access to the medication and ensure that adverse effects are properly reported back to the manufacturer. If a pharmacy can get the drug than they should be allowed to dispense it.

The language suggested below (1) and (2) was drafted initially back in 2015 under H97. This language was deemed unnecessary in the final omnibus bill that came out after crossover because of the testimony of representatives from both BCBSVT and MVP who stated the current law was sufficient. Apparently, they have changed their minds.
The proposed language below was adopted from CMS who requires open networks for Part D plans and recently ruled that restrictive "Specialty networks" violate that principle.

45 CFR 156.122
http://www.ncpa.co/pdf/member-analysis-2019-part-d-final-rule.pdf

(d) CHOICE OF PHARMACY

(1) A health insurer or pharmacy benefit manager shall permit a plan beneficiary to fill a prescription at the pharmacy of his or her 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 networked pharmacy to perform all pharmacy services within the lawful scope of practice of the profession of pharmacy as defined under 26 VSA §2022-2023;
(3) ***A pharmacy benefit manager, or licensed pharmacy agree not to make a direct solicitation (as defined in) of a covered beneficiary unless one or more of the following applies: (i) The individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them concerning the furnishing of a prescription item that is to be

rented or purchased. (ii) The supplier has furnished prescription item to the individual and the supplier is contacting the individual to coordinate the delivery of the item. (iii) If the contact concerns the furnishing of a prescription item other than a prescription item already furnished to the individual, the supplier has furnished at least one prescription item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

Definitions:

1. "Direct solicitation" means direct contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, by a Pharmacy Provider or its agents to a beneficiary without his or her consent for the purpose of marketing the Pharmacy Provider's services.

*** Adopted from 42 CFR §424.57