Chapter 319

(House Bill 838)

AN ACT concerning

Health Insurance – Pharmacy Benefits Managers – Audits and Reimbursement of Pharmacies or Pharmacists

FOR the purpose of altering certain requirements a pharmacy benefits manager must comply with when conducting an audit of a pharmacy or pharmacist; prohibiting a pharmacy benefits manager from disrupting the provision of services to the customers of a pharmacy during an audit; prohibiting a pharmacy benefits manager from taking certain actions relating to an audit of a pharmacy or pharmacist, with a certain exception; prohibiting a pharmacy benefits manager from recouping by setoff certain money until certain conditions are fulfilled; providing for a certain appeal, under certain circumstances; requiring authorizing the Maryland Insurance Commissioner to adopt regulations that standardize regarding certain documentation and a certain process; prohibiting a pharmacy benefits manager from retroactively denying or modifying reimbursement to a pharmacy or a pharmacist for a certain approved claim, with certain exceptions; requiring a pharmacy benefits manager to reimburse a pharmacy or pharmacist for a certain quantity of a prescription drug to meet a certain day's supply; limiting the amount of reimbursement that a pharmacy benefits manager may recoup, require to be repaid, or setoff under certain eircumstances; and generally relating to pharmacy benefits managers and audits and reimbursement of pharmacies and pharmacists.

BY repealing and reenacting, with amendments,

Article – Insurance Section 15–1629 Annotated Code of Maryland (2011 Replacement Volume)

BY adding to

Article – Insurance Section 15–1631 Annotated Code of Maryland (2011 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Insurance

15 - 1629.

- (a) This section does not apply to an audit that involves probable or potential fraud or willful misrepresentation by a pharmacy or pharmacist.
- (b) A pharmacy benefits manager shall conduct an audit of a pharmacy or pharmacist under contract with the pharmacy benefits manager in accordance with this section.
- (c) A pharmacy benefits manager may not schedule an onsite audit to begin during the first 5 calendar days of a month unless requested by the pharmacy or pharmacist.
 - (d) When conducting an audit, a pharmacy benefits manager shall:
- (1) if the audit is onsite, provide written notice to the pharmacy or pharmacist at least 2 weeks before conducting the initial onsite audit for each audit cycle;
- (2) employ the services of a pharmacist if the audit requires the clinical or professional judgment of a pharmacist;
- (3) PERMIT ITS AUDITORS TO ENTER THE PRESCRIPTION AREA OF A PHARMACY ONLY WHEN ACCOMPANIED BY OR AUTHORIZED BY A MEMBER OF THE PHARMACY STAFF;
- (4) ALLOW A PHARMACIST OR PHARMACY TO USE ANY PRESCRIPTION, OR AUTHORIZED CHANGE TO A PRESCRIPTION, THAT MEETS THE REQUIREMENTS OF COMAR 10.34.20.02 TO VALIDATE CLAIMS SUBMITTED FOR REIMBURSEMENT FOR DISPENSING OF ORIGINAL AND REFILL PRESCRIPTIONS;
- [(3)] (5) for purposes of validating the pharmacy record with respect to orders or refills of a drug [that is a controlled dangerous substance], allow the pharmacy or pharmacist to use [hospital or physician] records **OF A HOSPITAL OR A PHYSICIAN OR OTHER PRESCRIBER AUTHORIZED BY LAW** that are:
 - (i) written; or
- (ii) transmitted electronically **OR BY ANY OTHER MEANS OF COMMUNICATION** AUTHORIZED BY CONTRACT BETWEEN THE PHARMACY AND THE PHARMACY BENEFITS MANAGER:

- [(4)] (6) audit each pharmacy and pharmacist under the same standards and parameters as other similarly situated pharmacies or pharmacists audited by the pharmacy benefits manager;
- [(5)] (7) only audit claims submitted or adjudicated within the 2-year period immediately preceding the audit, unless a longer period is permitted under federal or State law;

(8) REQUEST ADDITIONAL INFORMATION ON PARTICULAR PRESCRIPTIONS ONLY IN PERSON OR BY CERTIFIED MAIL:

- [(6)] (8) deliver the preliminary audit report to the pharmacy or pharmacist within 120 calendar days after the completion of the audit, with reasonable extensions allowed;
- [(7)] (19) in accordance with subsection [(h)] (I) of this section, allow a pharmacy or pharmacist to produce documentation to address any discrepancy found during the audit; and
- [(8)] (11) (10) deliver the final audit report to the pharmacy or pharmacist:
- (i) within 6 months after delivery of the preliminary audit report if the pharmacy or pharmacist does not request an internal appeal under subsection [(h)] (I) of this section; or
- (ii) within 30 days after the conclusion of the internal appeals process under subsection **[(h)] (I)** of this section if the pharmacy or pharmacist requests an internal appeal.
- (E) DURING AN AUDIT, A PHARMACY BENEFITS MANAGER MAY NOT DISRUPT THE PROVISION OF SERVICES TO THE CUSTOMERS OF A PHARMACY.
 - [(e)] (F) (1) A pharmacy benefits manager may not:
- (1) (I) use the accounting practice of extrapolation to calculate overpayments or underpayments; OR

(2) REQUEST INFORMATION ON PRESCRIPTIONS THAT:

(I) HAVE BEEN AUDITED PREVIOUSLY; OR

(H) HAVE BEEN APPROVED BY PRIOR AUTHORIZATION, UNLESS THE PRESCRIPTION HAS BEEN CHANGED;

- (3) AUDIT MORE THAN 250 PRESCRIPTIONS AT A SINGLE PHARMACY DURING ANY 6 MONTH PERIOD:
- (4) (II) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION:
- $\underline{\mathbf{1}}$. SHARE INFORMATION FROM AN AUDIT WITH ANOTHER PHARMACY BENEFITS MANAGER; $\underline{\mathbf{OR}}$
- (5) 2. USE INFORMATION FROM AN AUDIT CONDUCTED BY ANOTHER PHARMACY BENEFITS MANAGER; OR.
- (2) PARAGRAPH (1)(II) OF THIS SUBSECTION DOES NOT APPLY TO THE SHARING OF INFORMATION:
 - (I) REQUIRED BY FEDERAL OR STATE LAW;
- (II) IN CONNECTION WITH AN ACQUISITION OR MERGER INVOLVING THE PHARMACY BENEFITS MANAGER; OR
- (III) AT THE PAYOR'S REQUEST OR UNDER THE TERMS OF THE AGREEMENT BETWEEN THE PHARMACY BENEFITS MANAGER AND THE PAYOR.
- (6) PAY FOR AUDITING SERVICES BASED ON A PERCENTAGE OF THE AMOUNT RECOVERED IN AN AUDIT.
- [(f)] (G) The recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits manager shall be based on an actual overpayment or denial of an audited claim unless the projected overpayment or denial is part of a settlement agreed to by the pharmacy or pharmacist.
- [(g)] (H) (1) In this subsection, "overpayment" means a payment by the pharmacy benefits manager to a pharmacy or pharmacist that is greater than the rate or terms specified in the contract between the pharmacy or pharmacist and the pharmacy benefits manager at the time that the payment is made.
- (2) A clerical error, record–keeping error, typographical error, or scrivener's error in a required document or record may not constitute fraud or grounds for recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits manager if the prescription was otherwise legally dispensed and the claim was otherwise materially correct.

- (3) Notwithstanding paragraph (2) of this subsection, claims remain subject to recoupment of overpayment or payment of any discovered underpayment by the pharmacy benefits manager.
- [(h)] (I) (1) A pharmacy benefits manager shall establish an internal appeals process under which a pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report.
- (2) Under the internal appeals process, a pharmacy benefits manager shall allow a pharmacy or pharmacist to request an internal appeal within 30 working days after receipt of the preliminary audit report, with reasonable extensions allowed.
- (3) The pharmacy benefits manager shall include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person to whom an internal appeal should be addressed.
- (4) The decision of the pharmacy benefits manager on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist shall be reflected in the final audit report.
- (5) The pharmacy benefits manager shall deliver the final audit report to the pharmacy or pharmacist within 30 calendar days after conclusion of the internal appeals process.
- [(i)] (J) (1) A pharmacy benefits manager may not recoup by setoff any moneys for an overpayment or denial of a claim until:
- (I) THE PHARMACY OR PHARMACIST HAS AN OPPORTUNITY TO REVIEW THE PHARMACY BENEFITS MANAGER'S FINDINGS; AND
- (II) IF THE PHARMACY OR PHARMACIST CONCURS WITH THE PHARMACY BENEFITS MANAGER'S FINDINGS OF OVERPAYMENT OR DENIAL, 30 working days HAVE ELAPSED after the date the final audit report has been delivered to the pharmacy or pharmacist.
- (2) IF THE PHARMACY OR PHARMACIST DOES NOT CONCUR WITH THE PHARMACY BENEFITS MANAGER'S FINDINGS OF OVERPAYMENT OR DENIAL.
- (I) THE PHARMACY OR PHARMACIST MAY APPEAL THE FINDINGS: AND

(H), THE PHARMACY BENEFITS MANAGER MAY NOT RECOUP BY SETOFF ANY MONEY PENDING THE OUTCOME OF THE AN APPEAL UNDER SUBSECTION (I) OF THIS SECTION.

- [(2)] (3) A pharmacy benefits manager shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 30 working days after the final audit report has been delivered to the pharmacy or pharmacist.
- [(3)] (4) Notwithstanding the provisions of paragraph (1) of this subsection, a pharmacy benefits manager may withhold future payments before the date the final audit report has been delivered to the pharmacy or pharmacist if the identified discrepancy for all disputed claims in a preliminary audit report for an individual audit exceeds \$25,000.
- [(j)] (K) (1) THE COMMISSIONER SHALL MAY ADOPT REGULATIONS THAT STANDARDIZE REGARDING:
- (I) THE DOCUMENTATION THAT MAY BE REQUESTED DURING AN AUDIT; AND
- (II) THE PROCESS A PHARMACY BENEFITS MANAGER MAY USE TO CONDUCT AN AUDIT.
- (2) On request of the Commissioner or the Commissioner's designee, a pharmacy benefits manager shall provide a copy of its audit procedures or internal appeals process.

15-1631.

- (A) EXCEPT FOR AN OVERPAYMENT AS DEFINED IN § 15–1629(H) OF THIS SUBTITLE, IF A CLAIM HAS BEEN APPROVED BY A PHARMACY BENEFITS MANAGER THROUGH ADJUDICATION, THE PHARMACY BENEFITS MANAGER MAY NOT RETROACTIVELY DENY OR MODIFY REIMBURSEMENT TO A PHARMACY OR PHARMACIST FOR THE APPROVED CLAIM UNLESS:
 - (1) THE CLAIM WAS FRAUDULENT;
- (2) THE PHARMACY OR PHARMACIST HAD BEEN REIMBURSED FOR THE CLAIM PREVIOUSLY; Θ R
- (3) THE SERVICES REIMBURSED WERE NOT RENDERED BY THE PHARMACY OR PHARMACIST ; OR
- (4) SUBJECT TO § 15–1629(H)(2) OF THIS PART, THE CLAIM OTHERWISE CAUSED MONETARY LOSS TO THE PHARMACY BENEFITS MANAGER, PROVIDED THAT THE PHARMACY BENEFITS MANAGER ALLOWED THE

PHARMACY A REASONABLE OPPORTUNITY TO REMEDY THE CAUSE OF THE MONETARY LOSS.

- (B) (1) A PHARMACY BENEFITS MANAGER SHALL REIMBURSE A PHARMACY OR PHARMACIST FOR THE FULL QUANTITY OF THE SMALLEST AVAILABLE COMMERCIAL PACKAGE OF A PRESCRIPTION DRUG THAT CONTAINS THE TOTAL AMOUNT OF THE PRESCRIPTION DRUG REQUIRED TO BE DISPENSED TO MEET THE DAY'S SUPPLY ORDERED BY THE PRESCRIBER, EVEN IF THE FULL QUANTITY OF THE COMMERCIALLY PACKAGED PRESCRIPTION DRUG EXCEEDS THE MAXIMUM DAY'S SUPPLY ALLOWED UNDER THE CONTRACT BETWEEN THE PHARMACY BENEFITS MANAGER AND THE PHARMACY OR PHARMACIST.
- (2) (I) A PHARMACY BENEFITS MANAGER SHALL DETERMINE A DAY'S SUPPLY ACCORDING TO THE HIGHEST DAILY TOTAL DOSE THAT MAY BE UTILIZED BY A PATIENT ACCORDING TO THE PRESCRIPTION.
- (II) FOR PRESCRIPTIONS HAVING A TITRATED DOSE SCHEDULE, THE SCHEDULE SHALL BE USED TO DETERMINE THE DAY'S SUPPLY.
- (3) IF THE ACTUAL QUANTITY OF A PRESCRIPTION DRUG DISPENSED ON A VALID PRESCRIPTION EXCEEDS THE ALLOWABLE MAXIMUM DAY'S SUPPLY SPECIFIED IN THE CONTRACT BETWEEN A PHARMACY BENEFITS MANAGER AND A PHARMACY OR PHARMACIST, THE AMOUNT ALLOWED TO BE RECOUPED, REPAID, OR SETOFF AGAINST FUTURE REIMBURSEMENT BY THE PHARMACY BENEFITS MANAGER SHALL BE LIMITED TO AN AMOUNT THAT IS CALCULATED BASED ON:
- (I) THE QUANTITY OF THE PRESCRIPTION DRUG DISPENSED THAT EXCEEDS THE ALLOWED DAY'S SUPPLY QUANTITY; AND
 - (H) THE COST OF THE PRESCRIPTION DRUG ON THE CLAIM.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2012.

Approved by the Governor, May 2, 2012.