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HOUSE BILL NO. 2561

Offered January 9, 2019
Prefiled January 9, 2019

A BILL to amend the Code of Virginia by adding a section numbered 38.2-3407.15:5, relating to health plans; limitations on audits of pharmacy records.

Patrons—Pillion, O'Quinn and Peace

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.15:5 as follows:

§ 38.2-3407.15:5. Limitations on audits of pharmacy records.

A. As used in this section:

"Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15.

"Copayment" means an amount an enrollee is required to pay at the point of sale in order to receive a covered prescription drug.

"Enrollee" means a policyholder, subscriber, participant, or other individual covered by a health plan.

"Health plan" means any health benefit plan, as defined in § 38.2-3438, that provides coverage for prescription drugs.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of enrollees.

"Pharmacy benefits manager" or "PBM" means an entity that performs pharmacy benefits management. The term includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier.

"Provider contract" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15.

B. Every provider contract between a carrier or its pharmacy benefits manager and a pharmacy or its contracting agent under a health plan shall include the following contract terms and provisions:

1. The initial audit shall give the pharmacy written notice at least 30 days before conducting the initial audit for each audit cycle and shall disclose the specific prescriptions to be included in the audit.

2. Unless otherwise consented to by the pharmacy, an audit shall not be initiated or scheduled during the first five calendar days of any month, on the day before or after a federal holiday, or on a Monday due to the high volume of prescriptions filled during that time and shall not involve the auditing of more than one location of the pharmacy at any particular time.

3. A pharmacy shall have seven days after receiving the written notice of an audit to request a seven-day extension of the audit date. A pharmacy making such a request shall be granted at least seven additional business days and shall cooperate with the auditor to establish an alternative date.

4. No audit of a particular pharmacy location shall occur more than once in a one-year period.

5. The period covered by an audit shall not exceed two years from the date the initial prescription claim was submitted to or adjudicated under a health plan.

6. Each pharmacy shall be audited under the same standards and parameters as every other pharmacy. Any documentation and records required by an auditor during an audit shall be of the same type as the documentation and records required for all other pharmacies.

7. Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist licensed by the Commonwealth.

8. Each audit shall be conducted by a field agent who possesses the requisite expertise in pharmacy practice.

9. Any unintentional clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not necessarily constitute fraud. Such claims may be subject to recoupment, but such claims shall not be referred for criminal penalties without proof of intent to commit fraud. In the case of errors that do not harm an enrollee, carrier, or health plan financially, the auditor shall not assess any chargebacks.

10. All audits shall be conducted in accordance with generally accepted accounting principles, standards, and procedures and generally accepted auditing principles, standards, and procedures and shall use standards and parameters established by regulation adopted by the Commission that are identical for all audits conducted.

11. Prescriptions shall be considered valid prescriptions if they are compliant with the then-current

Board of Pharmacy rules and regulations and have been positively adjudicated upon claim submission by the PBM. Plan restrictions shall be addressed during the claims adjudication process either through the rejection of the claim or a rejection of the claim with direction to obtain a prior authorization and shall not be the basis for a retrospective recoupment of a paid claim.

12. With the exception of overpayments, if a PBM approves a claim through adjudication, the PBM may not retroactively deny or modify reimbursement based on information accompanying the original claim or information available to the PBM at the time of adjudication, unless the claim was fraudulent, the pharmacy or pharmacist had been reimbursed for the claim previously, or the services reimbursed were not rendered by the pharmacy or pharmacist.

13. The pharmacy shall not be subject to the recoupment on any portion of the reimbursement for the dispensed product of a prescription, except that:

a. Recoupment of reimbursement, or a portion of reimbursement, for the dispensed product of a prescription may be had in the case of:

(1) Fraud or other intentional and willful misrepresentation evidenced by a review of the claims data, statements, physical review, or other investigative methods;

(2) Dispensing of excess of the benefit design as established by the plan sponsor;

(3) Prescriptions not filled in accordance with the prescriber's order; or

(4) Actual overpayment to the pharmacy;

b. Recoupment of claims in cases set out in subdivision a shall be based on the actual financial harm to the entity or the actual underpayment or overpayment. Calculations of overpayments shall not include dispensing fees unless:

(1) A prescription was not actually dispensed;

(2) The prescriber denied authorization;

(3) The prescription dispensed was a medication error by the pharmacy. For purposes of this subdivision, "medication error" means dispensing of the wrong drug, dispensing to the wrong patient, or dispensing with the wrong directions;

(4) The identified overpayment was based solely on an extra dispensing fee;

(5) There was insufficient documentation, including electronically stored information, as described in this subsection; or

(6) There was fraud or other intentional and willful misrepresentation by the pharmacy.

14. A PBM may not require more information to be written on a prescription than is required by state or federal law. A PBM may not require more stringent records to validate a prescription order than is required by state or federal law.

15. Electronic records, including electronic beneficiary signature logs, electronic tracking of prescriptions, electronic prescriber prescription transmissions and imagery of hard copy prescriptions, electronically scanned store and patient records maintained at or accessible to the offices of an audited pharmacy's central operations, and any other reasonably clear and accurate electronic documentation shall be acceptable for auditing under the same terms and conditions and for the same purposes as their paper analogs, provided that:

a. If paper logs are used, auditors shall look at least 14 days past the dispense date to check for patient pickup; and

b. Point of sale electronic register data shall qualify as proof of delivery to the patient.

16. A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

17. Validation of appropriate days' supply and drug dosing shall be based on manufacturer guidelines and definitions or, in the case of topical products or titrated products, the professional judgment of the pharmacist based upon communication with the patient or prescriber.

18. A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless an alternate price is published in the provider contract and signed by both parties.

19. A PBM may not require a pharmacy to agree to recoupments deducted against future remittances and shall invoice the pharmacy for payment if the pharmacy elects. Recoupment may be deducted against future remittances without mutual consent when the pharmacy is delinquent in payment of the invoice per the contractual arrangement.

20. Notwithstanding any other provision in this section, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. A finding of overpayment or underpayment shall be based on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

21. The preliminary audit report shall be delivered to the pharmacy and pharmacy corporate office

within 30 days, with reasonable extensions allowed, after conclusion of the audit, and shall contain claim level information for any discrepancy found and total dollar amount of claims subject to recovery.

22. A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit or to file an appeal.

23. A final audit report containing claim level information for any discrepancy found and total dollar amount of claims subject to recovery shall be delivered to the pharmacy and pharmacy corporate office (i) within 45 days after the audited pharmacy's receipt of the preliminary audit report, if the audited pharmacy does not file an appeal or offers no documentation to address a discrepancy found during an audit, or (ii) within 60 days after the auditing entity receives the audited pharmacy's appeal or documentation to address a discrepancy. The final audit results shall be reflected in the 835 EDI remittance advice, or equivalent electronic version of a paper health care claim payment advice used to make a payment or send an explanation of benefits from a health care insurer to a health care provider, at the claim level.

24. A PBM may not recover from the pharmacy payment of claims that is identified through the audit process to be the responsibility of another payer. The PBM shall reconcile directly with the other payer for any moneys owed without requiring the pharmacy to reverse and rebill the original claim in the retail setting.

25. The PBM, auditor, third party contractor, or agency conducting the audit or agent may not receive payment based on a percentage of the amount claimed for recovery. This subdivision shall not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both:

a. The carrier and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the carrier; and

b. A commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

C. This section does not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or abuse.