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HOUSE BILL NO. 2561

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the House Committee on Commerce and Labor
on January 31, 2019)

(Patron Prior to Substitute—Delegate Pillion)

A BILL to amend and reenact § 38.2-3407.15:1 of the Code of Virginia, relating to carrier contracts with pharmacy providers; limitations on audits of pharmacy records.

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-3407.15:1 of the Code of Virginia is amended and reenacted as follows:

§ 38.2-3407.15:1. Carrier contracts with pharmacy providers; required provisions; limit on termination or nonrenewal.

A. As used in this section, unless the context requires a different meaning:

"Audit" includes any audit conducted or authorized by a carrier or its intermediary to determine whether the participating pharmacy provider has complied with the terms and conditions for reimbursement under the provider contract.

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

"Clerical error" means any clerical or recordkeeping error or omission, such as typographical errors, scrivener's errors, or computer errors, in the keeping, recording, handling, or transcribing of pharmacy records. "Clerical error" does not include any clerical or recordkeeping error or omission that results in an overpayment by a carrier or its intermediary or the dispensing of a prescription in breach of applicable law or regulation.

"Fraud" means a knowingly or willfully false act of misrepresentation or an act in deliberate ignorance of the truth or falsity of the information as evidenced by a review of claims data, evaluation of provider statements, physical review of pharmacy records, or use of similar investigative methods by the carrier or its intermediary.

"Onsite audit" means an audit conducted at the physical location of the pharmacy, the physical location of its corporate offices, or the physical location of its records.

"Overpayment" means a payment by the carrier or its intermediary to the pharmacy provider that is greater than the rate or amount the provider is entitled to under the provider contract or applicable fee schedule.

"Pharmacy record" means a patient record, signature or delivery log, or prescription, including written, phoned-in, faxed, or electronic prescriptions, whether original or substitute, that complies with applicable law and regulation.

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

B. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to conduct audits of participating pharmacy providers, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to conduct audits of participating pharmacy providers, shall contain specific provisions that prohibit the carrier or intermediary, in the absence of fraud, from recouping amounts calculated from or arising out of any of the following:

1. Probability sampling, extrapolation, or other mathematical or statistical methods that allegedly project an error;

2. Clerical errors by the participating pharmacy provider;

3. An act or omission of the participating pharmacy provider that was not specifically prohibited or required by the provider contract when the claim was adjudicated unless the act or omission was a violation of applicable law or regulation;

4. The refusal of a carrier or its intermediary to consider during an audit or audit appeal a pharmacy record in electronic form to validate a claim;

5. Dispensing fees or interest on the claim, except in the event of an overpayment, if the prescription was dispensed in accordance with applicable law or regulation;

6. Any claim authorized and dispensed more than 24 months prior to the date of the audit unless the claim is adjusted at the direction of the Commission, except that this time period shall be tolled while the denial of the claim is being appealed;

7. An alleged breach of auditing requirements if they are not the same as the requirements that the carrier or intermediary applies to other participating pharmacy providers in the same setting;

8. The refusal of the carrier or its intermediary to consider during an audit or audit appeal a pharmacy record, a prescriber or patient verification, or a prescriber record to validate a claim; or

9. The alleged failure of the participating pharmacy provider to supply during an audit or audit appeal a pharmacy record not specifically identified in the provider contract.

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60 C. Any (i) contract between a carrier and its intermediary pursuant to which the intermediary has
61 the right or obligation to conduct audits of participating pharmacy providers and (ii) provider contract
62 between a carrier and a participating pharmacy provider or its contracting agent pursuant to which the
63 carrier has the right or obligation to conduct audits of participating pharmacy providers, shall contain
64 the following terms and provisions relating to audits, which shall apply in the absence of fraud:

65 1. The initial onsite audit shall give the pharmacy written notice at least 14 days before conducting
66 the initial audit for each audit cycle and shall disclose the specific prescription numbers to be included
67 in the audit. The carrier or intermediary may mask the last two digits of such numbers. A pharmacy
68 shall have at least 72 hours after receiving the written notice of an onsite audit to request a five
69 business-day extension of the proposed audit date. A pharmacy making such a request shall be granted
70 at least five additional business days and shall cooperate with the auditor to establish an alternative
71 date.

72 2. Unless otherwise consented to by the pharmacy, an onsite audit shall not be initiated or scheduled
73 during the first five calendar days of any month, or on a Monday and shall not involve the auditing of
74 more than one location of the pharmacy at any particular time.

75 3. No onsite audit of a particular pharmacy location on behalf of a particular carrier shall occur
76 more than once in a 12-month period.

77 4. Each pharmacy shall be audited under the same standards and parameters as every other
78 similarly situated pharmacy. Any documentation and records required by an auditor during an audit
79 shall be of the same type as the documentation and records required for all other similarly situated
80 pharmacies.

81 5. Any audit issues that involve clinical or professional judgment shall be conducted by a pharmacist
82 who has available for consultation a pharmacist licensed by the Commonwealth.

83 6. Each audit shall be conducted by a field agent who possesses the requisite knowledge and
84 experience in pharmacy practice.

85 7. Audits shall be conducted in the Commonwealth in compliance with federal and state laws, rules
86 and regulations, including regulations adopted by the Board of Pharmacy.

87 8. Prescriptions shall be considered valid prescriptions if they are compliant with the then-current
88 Board of Pharmacy rules and regulations and have been successfully adjudicated upon a clean claim
89 submission. Carrier restrictions shall be addressed during the claims adjudication process either
90 through the rejection of the clean claim or a rejection of the clean claim with direction to obtain a
91 prior authorization and shall not be the basis for a retrospective recoupment of a paid claim.

92 9. Electronic records, including electronic beneficiary signature logs, electronic tracking of
93 prescriptions, electronic prescriber prescription transmissions and imagery of hard copy prescriptions,
94 electronically scanned store and patient records maintained at or accessible to the offices of an audited
95 pharmacy's central operations, and any other reasonably clear and accurate electronic documentation
96 shall be acceptable for auditing under the same terms, conditions, and validation and for the same
97 purposes as their paper analogs. Point of sale electronic register data shall qualify as proof of delivery
98 to the patient, provided that the auditor can validate the receipt on the basis of the patient data
99 included.

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

104 11. Validation and documentation at the time of dispensing of appropriate days' supply and drug
105 dosing shall be based on manufacturer guidelines and definitions or, in the case of topical products or
106 titrated products, based on the professional judgment of the pharmacist in communication with the
107 patient or prescriber.

108 12. A pharmacy's usual and customary price for compounded medications is considered the
109 reimbursable cost unless the pricing methodology is published in the provider contract and signed by
110 both parties or their agents.

111 13. A carrier or its intermediary shall not make charge backs or seek recoupment from a pharmacy,
112 or assess or collect penalties from a pharmacy, until the time period for filing an appeal to an initial
113 audit report has passed or until the appeals process has been exhausted, whichever is later. If the
114 identified discrepancy for a single audit exceeds \$25,000, future payments in excess of that amount may
115 be withheld pending adjudication of an appeal.

116 14. The preliminary audit report shall (i) be delivered to the pharmacy or its pharmacy corporate
117 office within 60 calendar days, with reasonable extensions allowed, after conclusion of the audit and (ii)
118 contain claim level information for any discrepancy found and total dollar amount of claims subject to
119 recovery.

120 15. A pharmacy shall be allowed at least 60 calendar days following receipt of the preliminary audit
121 report in which to produce documentation to address any discrepancy found during an audit or to file

122 *an appeal.*

123 *16. A final audit report containing claim level information for any discrepancy found and total dollar*
124 *amount of claims subject to recovery shall be delivered to the pharmacy or its pharmacy corporate*
125 *office (i) within 90 calendar days after the audited pharmacy's receipt of the preliminary audit report, if*
126 *the audited pharmacy does not file an appeal or offers no documentation to address a discrepancy*
127 *found during an audit, or (ii) within 60 calendar days after the auditing entity receives the audited*
128 *pharmacy's appeal or documentation to address a discrepancy.*

129 *17. A carrier or its intermediary may not recover from the pharmacy payment of claims that is*
130 *identified through the audit process to be the responsibility of another payer.*

131 *18. No recoupment of amounts paid to a pharmacy for any claim shall be made solely on the basis*
132 *of a prescriber's or patient's lack of response to a request made by a carrier or its intermediary.*

133 *19. A carrier or its intermediary shall issue its initial audit findings in conformity with the laws of*
134 *the Commonwealth.*

135 *20. A carrier or its intermediary may not retroactively deny a claim (i) more than one year after the*
136 *date of payment of the claim if the reason for denial would be patient ineligibility or (ii) at any time if*
137 *the carrier or its intermediary verified the patient's eligibility at the time of dispensing and provided an*
138 *authentication number to the pharmacy.*

139 *D. Any contract between a carrier and its intermediary, pursuant to which the intermediary has the*
140 *right or obligation to conduct audits of participating pharmacy providers, and any provider contract*
141 *between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the*
142 *carrier has the right or obligation to conduct audits of participating pharmacy providers, shall contain*
143 *specific provisions that prohibit the carrier or intermediary, in the absence of fraud by the participating*
144 *pharmacy provider, from terminating or failing to renew the contractual relationship with a participating*
145 *pharmacy provider for invoking its rights under any contractual provision required to be contained in the*
146 *contract pursuant to subsection B or C.*

147 *Ð. E. The Commission shall have no jurisdiction to adjudicate individual controversies arising out of*
148 *this section.*

149 *Ë. F. This section shall apply with respect to contracts described in subsection B or Æ D entered*
150 *into, amended, extended, or renewed on or after January 1, 2015, except that the provisions of*
151 *subsection C shall apply with respect to contracts described in subsection B or D entered into,*
152 *amended, extended, or renewed on or after January 1, 2020.*