

HOUSE BILL 374

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3lr0476
CF SB 565

By: ~~Delegate Kipke~~ Delegates Kipke, Alston, Bagnall, Bhandari, Chisholm, Cullison, Guzzone, Hill, Hutchinson, S. Johnson, Kaiser, Kerr, R. Lewis, Lopez, Martinez, M. Morgan, Pena-Melnyk, Reilly, Rosenberg, Szeliga, Taveras, White, and Woods

Introduced and read first time: January 26, 2023

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 10, 2023

CHAPTER _____

1 AN ACT concerning

2 **Health Insurance – Pharmacy Benefits Managers – Audits of Pharmacies and**
3 **Pharmacists**

4 FOR the purpose of expanding the applicability of the provisions regarding audits of a
5 pharmacy or pharmacist to all pharmacy benefits managers; ~~authorizing a pharmacy~~
6 ~~benefits manager to conduct an audit through an auditing entity that is registered~~
7 ~~with the Maryland Insurance Commissioner;~~ requiring the Secretary of Health to
8 adopt certain regulations for pharmacy benefits managers that contract with
9 managed care organizations that establish requirements for conducting audits of
10 pharmacies or pharmacists; establishing requirements and prohibitions regarding
11 audits by pharmacy benefits managers, including provisions related to audit limits,
12 the acceptance of certain documents as ~~validation or~~ proof, the recoupment of funds
13 or charging and payment of fees for prescriptions of unbreakable package sizes,
14 access to financial documentation, and audit documentation; ~~requiring that a final~~
15 ~~audit report include certain information if applicable;~~ ~~authorizing a pharmacy or~~
16 ~~pharmacist to confirm with a pharmacy customer or purchaser that the pharmacy~~
17 ~~customer or purchaser received a certain refund;~~ and generally relating to audits by
18 pharmacy benefits managers.

19 BY adding to

20 Article – Health – General

21 Section ~~15-102.3(k)~~ 15-103(b)(33)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Annotated Code of Maryland
2 (2019 Replacement Volume and 2022 Supplement)

3 BY repealing and reenacting, with amendments,
4 Article – Insurance
5 Section 15–1629
6 Annotated Code of Maryland
7 (2017 Replacement Volume and 2022 Supplement)

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

10 **Article – Health – General**

11 ~~15–102.3.~~

12 ~~(K) THE PROVISIONS OF § 15–1629 OF THE INSURANCE ARTICLE APPLY TO~~
13 ~~PHARMACY BENEFITS MANAGERS THAT CONTRACT WITH MANAGED CARE~~
14 ~~ORGANIZATIONS.~~

15 15–103.

16 (b) (33) THE SECRETARY SHALL ADOPT REGULATIONS FOR PHARMACY
17 BENEFITS MANAGERS THAT CONTRACT WITH MANAGED CARE ORGANIZATIONS THAT
18 ESTABLISH REQUIREMENTS FOR CONDUCTING AUDITS OF PHARMACIES OR
19 PHARMACISTS THAT ARE:

20 (I) TO THE EXTENT PRACTICABLE, SUBSTANTIVELY SIMILAR
21 TO THE AUDIT PROVISIONS UNDER § 15–1629 OF THE INSURANCE ARTICLE; AND

22 (II) CONSISTENT WITH FEDERAL LAW.

23 **Article – Insurance**

24 15–1629.

25 [(a) This section applies only to a pharmacy benefits manager that provides
26 pharmacy benefits management services on behalf of a carrier.]

27 [(b)] (A) This section does not apply to an audit that involves probable or
28 potential fraud or willful misrepresentation by a pharmacy or pharmacist.

29 [(c)] (B) A pharmacy benefits manager shall conduct an audit of a pharmacy or
30 pharmacist under contract with the pharmacy benefits manager in accordance with this
31 section.

1 (C) (1) A PHARMACY BENEFITS MANAGER MAY CONDUCT AN AUDIT
2 THROUGH AN AUDITING ENTITY.

3 ~~(2) AN AUDITING ENTITY MUST REGISTER WITH THE COMMISSIONER~~
4 ~~AS AN AUDITING ENTITY BEFORE CONDUCTING AN AUDIT IN THE STATE.~~

5 ~~(3) (2)~~ THE COMMISSIONER MAY ADOPT REGULATIONS TO CARRY
6 OUT THIS SUBSECTION.

7 (d) A pharmacy benefits manager may not schedule an onsite audit to begin
8 during the first 5 calendar days of a month unless requested by the pharmacy or
9 pharmacist.

10 (e) When conducting an audit, a pharmacy benefits manager shall:

11 (1) if the audit is onsite, provide written notice to the pharmacy or
12 pharmacist at least 2 weeks before conducting the initial onsite audit for each audit cycle;

13 (2) employ the services of a pharmacist if the audit requires the clinical or
14 professional judgment of a pharmacist;

15 (3) [permit] ALLOW its auditors to enter the prescription area of a
16 pharmacy only when accompanied by or authorized by a member of the pharmacy staff;

17 (4) allow a pharmacist or pharmacy to use any prescription, or authorized
18 change to a prescription, that meets the requirements of COMAR 10.34.20.02 to validate
19 claims submitted for reimbursement for dispensing of original and refill prescriptions;

20 (5) for purposes of validating the pharmacy record with respect to orders
21 or refills of a drug, allow the pharmacy or pharmacist to use records of a hospital or a
22 physician or other prescriber authorized by law that are:

23 (i) written; or

24 (ii) transmitted electronically or by any other means of
25 communication authorized by contract between the pharmacy and the pharmacy benefits
26 manager;

27 ~~(6) FOR PURPOSES OF AN INVOICE AUDIT, ACCEPT AS VALIDATION~~
28 ~~INVOICES ISSUED BEFORE THE DATE OF DISPENSING FROM:~~

29 ~~(1) A WHOLESALE DISTRIBUTOR:~~

30 ~~1. THAT HAS BEEN ISSUED A PERMIT BY THE STATE~~
31 ~~BOARD OF PHARMACY UNDER TITLE 12, SUBTITLE 6C OF THE HEALTH~~
32 ~~OCCUPATIONS ARTICLE; AND~~

1 ~~2. FROM WHICH THE PHARMACY OR PHARMACIST HAS~~
 2 ~~PURCHASED PRESCRIPTION DRUGS; OR~~

3 ~~(H) FOR INVOICES FOR DURABLE MEDICAL EQUIPMENT OR~~
 4 ~~SICKROOM SUPPLIES, A DISTRIBUTOR THAT HAS THE APPROPRIATE~~
 5 ~~AUTHORIZATION TO DO BUSINESS IN THE STATE;~~

6 ~~(7) (6) ALLOW ACCEPT A COMPLETED CASH REGISTER~~
 7 ~~TRANSACTION TO SERVE AS PROOF OF DELIVERY OR PICKUP FOR A PHARMACY~~
 8 ~~CUSTOMER UNLESS THERE IS CONTRADICTORY INFORMATION;~~

9 [(6) ~~(8) (7)~~ audit each pharmacy and pharmacist under the same standards
 10 and parameters as other similarly situated pharmacies or pharmacists audited by the
 11 pharmacy benefits manager;

12 [(7) ~~(9) (8)~~ only audit claims submitted or adjudicated within the 2-year
 13 period immediately preceding the audit, unless a longer period is authorized under federal
 14 or State law;

15 [(8) ~~(10) (9)~~ deliver the preliminary audit report to the pharmacy or
 16 pharmacist within 120 calendar days after the completion of the audit, with reasonable
 17 extensions allowed;

18 [(9) ~~(11) (10)~~ in accordance with subsection [(k)] ~~(M) (L)~~ of this section,
 19 allow a pharmacy or pharmacist to produce documentation to address any discrepancy
 20 found during the audit; and

21 [(10)] ~~(12) (11)~~ deliver the final audit report to the pharmacy or
 22 pharmacist:

23 (i) within 6 months after delivery of the preliminary audit report if
 24 the pharmacy or pharmacist does not request an internal appeal under subsection [(k)] ~~(M)~~
 25 ~~(L)~~ of this section; or

26 (ii) within 30 days after the conclusion of the internal appeals
 27 process under subsection [(k)] ~~(M) (L)~~ of this section if the pharmacy or pharmacist
 28 requests an internal appeal.

29 (f) If a contract between a pharmacy or pharmacist and a pharmacy benefits
 30 manager specifies a period of time in which a pharmacy or pharmacist is allowed to
 31 withdraw and resubmit a claim and that period of time expires before the pharmacy
 32 benefits manager delivers a preliminary audit report that identifies discrepancies, the
 33 pharmacy benefits manager shall allow the pharmacy or pharmacist to withdraw and
 34 resubmit a claim within 30 days after:

1 (1) the preliminary audit report is delivered if the pharmacy or pharmacist
2 does not request an internal appeal under subsection [(k)] ~~(M)~~ (L) of this section; or

3 (2) the conclusion of the internal appeals process under subsection [(k)]
4 ~~(M)~~ (L) of this section if the pharmacy or pharmacist requests an internal appeal.

5 (g) During an audit, a pharmacy benefits manager may not disrupt the provision
6 of services to the customers of a pharmacy.

7 (h) (1) A pharmacy benefits manager may not:

8 (i) use the accounting practice of extrapolation to calculate
9 overpayments or underpayments; [or]

10 (ii) [Except] EXCEPT as provided in paragraph (2) of this subsection:

11 1. share information from an audit with another pharmacy
12 benefits manager; or

13 2. use information from an audit conducted by another
14 pharmacy benefits manager;

15 ~~(III) CHARGE A PHARMACY OR PHARMACIST A FEE UNLESS AN~~
16 ~~AUDIT FINDS THERE WAS A FINANCIAL DETRIMENT TO THE PHARMACY CUSTOMER~~
17 ~~OR PURCHASER;~~

18 ~~(IV) CHARGE A PHARMACY OR PHARMACIST A FEE WITH REGARD~~
19 ~~TO AN INCORRECT DAYS OF SUPPLY CALCULATION IF THE PHARMACY BENEFITS~~
20 ~~MANAGER IS UNABLE TO ACCEPT THE CORRECT DAYS OF SUPPLY WITHOUT HELP~~
21 ~~DESK INTERVENTION;~~

22 (III) RECOUP ANY FUNDS FROM OR CHARGE ANY FEES TO A
23 PHARMACY OR PHARMACIST FOR A PRESCRIPTION WITH REGARD TO AN INCORRECT
24 DAYS OF SUPPLY CALCULATION IF THE PACKAGE SIZE OF THE MEDICATION IS
25 UNBREAKABLE AND THE PHARMACY BENEFITS MANAGER CANNOT ACCEPT THE
26 CORRECT MATHEMATICALLY CALCULABLE DAYS' SUPPLY DURING PRESCRIPTION
27 ADJUDICATION;

28 ~~(V)~~ (IV) HAVE OR REQUEST ACCESS TO A PHARMACY'S OR
29 PHARMACIST'S BANK, CREDIT CARD, OR DEPOSITORY STATEMENTS OR DATA AS IT
30 RELATES TO COST-SHARING; OR

31 ~~(VI)~~ (V) AUDIT CLAIMS THAT WERE REVERSED OR FOR WHICH
32 THERE WAS NO REMUNERATION BY THE PURCHASER OR COST TO THE PHARMACY
33 CUSTOMER EXCEPT IF NECESSARY TO EVALUATE COMPLIANCE TO A CONTRACT.

1 (2) Paragraph (1)(ii) of this subsection does not apply to the sharing of
2 information:

3 (i) required by federal or State law;

4 (ii) in connection with an acquisition or merger involving the
5 pharmacy benefits manager; or

6 (iii) at the payor's request or under the terms of the agreement
7 between the pharmacy benefits manager and the payor.

8 ~~(3) FOR CLAIMS THAT WERE AUDITED IN VIOLATION OF PARAGRAPH~~
9 ~~(1)(VI) OF THIS SUBSECTION, THE PHARMACY BENEFITS MANAGER OR PURCHASER~~
10 ~~SHALL PAY THE PHARMACY OR PHARMACIST \$20 PER CLAIM FOUND TO BE IN~~
11 ~~VIOLATION.~~

12 (I) ~~(1)~~ A PHARMACY BENEFITS MANAGER OR PURCHASER MAY NOT
13 AUDIT MORE THAN ~~50~~ 125 PRESCRIPTIONS DURING A DESK OR SITE AUDIT ~~UNLESS~~
14 ~~THE PHARMACY BENEFITS MANAGER OR PURCHASER REQUESTING THE AUDIT PAYS~~
15 ~~THE PHARMACY OR PHARMACIST \$20 PER ADDITIONAL PRESCRIPTION OR PROOF~~
16 ~~OF DELIVERY OR PICKUP REQUEST.~~

17 ~~(2) THE FEE REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION~~
18 ~~IS IN ADDITION TO THE FEE REQUIRED UNDER SUBSECTION (J)(1) OF THIS SECTION.~~

19 ~~(J) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, A PHARMACY~~
20 ~~BENEFITS MANAGER OR PURCHASER SHALL PAY A PHARMACY OR PHARMACIST \$250~~
21 ~~PER HOUR OF AUDIT OR \$10 PER PRESCRIPTION AUDITED, WHICHEVER IS GREATER.~~

22 ~~(2) THE FEE REQUIRED UNDER THIS SUBSECTION SHALL BE~~
23 ~~ADJUSTED ON JULY 1 EACH YEAR FOR INFLATION IN ACCORDANCE WITH THE~~
24 ~~CONSUMER PRICE INDEX.~~

25 [(i)] ~~(H)~~ (J) The recoupment of a claims payment from a pharmacy or pharmacist
26 by a pharmacy benefits manager shall be based on an actual overpayment or denial of an
27 audited claim unless the projected overpayment or denial is part of a settlement agreed to
28 by the pharmacy or pharmacist.

29 [(j)] ~~(H)~~ (K) (1) In this subsection, "overpayment" means a payment by the
30 pharmacy benefits manager to a pharmacy or pharmacist that is greater than the rate or
31 terms specified in the contract between the pharmacy or pharmacist and the pharmacy
32 benefits manager at the time that the payment is made.

1 (2) A clerical error, record-keeping error, typographical error, or
2 scrivener's error in a required document or record may not constitute fraud or grounds for
3 recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits
4 manager if the prescription was otherwise legally dispensed and the claim was otherwise
5 materially correct.

6 (3) Notwithstanding paragraph (2) of this subsection, claims remain
7 subject to recoupment of overpayment or payment of any discovered underpayment by the
8 pharmacy benefits manager.

9 [(k)] ~~(M)~~ (L) (1) A pharmacy benefits manager shall establish an internal appeals
10 process under which a pharmacy or pharmacist may appeal any disputed claim in a
11 preliminary audit report.

12 (2) Under the internal appeals process, a pharmacy benefits manager shall
13 allow a pharmacy or pharmacist to request an internal appeal within 30 working days after
14 receipt of the preliminary audit report, with reasonable extensions allowed.

15 (3) The pharmacy benefits manager shall include in its preliminary audit
16 report a written explanation of the internal appeals process, including the name, address,
17 and telephone number of the person to whom an internal appeal should be addressed.

18 (4) The decision of the pharmacy benefits manager on an appeal of a
19 disputed claim in a preliminary audit report by a pharmacy or pharmacist shall be reflected
20 in the final audit report.

21 (5) The pharmacy benefits manager shall deliver the final audit report to
22 the pharmacy or pharmacist within 30 calendar days after conclusion of the internal
23 appeals process.

24 [(l)] ~~(N)~~ (M) (1) A pharmacy benefits manager may not recoup by setoff any
25 money for an overpayment or denial of a claim until:

26 (i) the pharmacy or pharmacist has an opportunity to review the
27 pharmacy benefits manager's findings; and

28 (ii) if the pharmacy or pharmacist concurs with the pharmacy
29 benefits manager's findings of overpayment or denial, 30 working days have elapsed after
30 the date the final audit report has been delivered to the pharmacy or pharmacist.

31 (2) If the pharmacy or pharmacist does not concur with the pharmacy
32 benefits manager's findings of overpayment or denial, the pharmacy benefits manager may
33 not recoup by setoff any money pending the outcome of an appeal under subsection [(k)]
34 ~~(M)~~ (L) of this section.

(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.

(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.

~~(O) THE FINAL AUDIT REPORT SHALL, IF APPLICABLE:~~

~~(1) IDENTIFY EACH PHARMACY CUSTOMER OR PURCHASER RECEIVING A REFUND; AND~~

~~(2) SPECIFY THE AMOUNT BEING REFUNDED TO EACH PHARMACY CUSTOMER OR PURCHASER.~~

~~(P) A PHARMACY OR PHARMACIST MAY CONFIRM WITH THE PHARMACY CUSTOMER OR PURCHASER THAT THE PHARMACY CUSTOMER OR PURCHASER RECEIVED THE REFUND AMOUNT FROM THE PHARMACY BENEFITS MANAGER.~~

~~(O)~~ (N) (1) A PHARMACY BENEFITS MANAGER SHALL PROVIDE A PHARMACY OR PHARMACIST BEING AUDITED WITH A PHONE NUMBER AND, IF AVAILABLE, ACCESS TO A SECURE PORTAL THAT THE PHARMACY OR PHARMACIST MAY USE TO ASK QUESTIONS REGARDING THE AUDIT.

(2) AN INDIVIDUAL WHO IS FAMILIAR WITH THE AUDIT SHALL RESPOND TO ALL ~~TELEPHONE~~ INQUIRIES MADE THROUGH A PHONE NUMBER OR SECURE PORTAL PROVIDED UNDER PARAGRAPH (1) OF THIS SUBSECTION WITHIN 72 HOURS 3 BUSINESS DAYS AFTER THE ~~CALL~~ INQUIRY WAS MADE.

~~(R)~~ (O) (1) THE PHARMACY BENEFITS MANAGER SHALL GIVE THE PHARMACY OR PHARMACIST THE OPTION TO PROVIDE REQUESTED AUDIT DOCUMENTATION BY POSTAL MAIL, E-MAIL, OR FACSIMILE.

(2) IF A DOCUMENT IS REQUESTED REGARDING AN AUDIT, THE PHARMACY BENEFITS MANAGER SHALL PROVIDE A SECURE FACSIMILE NUMBER AND A MECHANISM FOR RECEIVING SECURE E-MAILS.

(3) ON OR BEFORE OCTOBER 1, 2025, A PHARMACY BENEFITS MANAGER SHALL PROVIDE A MECHANISM FOR SECURE ELECTRONIC COMMUNICATION FOR PHARMACIES AND PHARMACISTS TO COMMUNICATE WITH AND SUBMIT DOCUMENTS TO THE AUDITING ENTITY.

[(m)] ~~(S)~~ (P) (1) The Commissioner may adopt regulations regarding:

1 (i) the documentation that may be requested during an audit; and

2 (ii) the process a pharmacy benefits manager may use to conduct an
3 audit.

4 (2) On request of the Commissioner or the Commissioner’s designee, a
5 pharmacy benefits manager shall provide a copy of its audit procedures or internal appeals
6 process.

7 SECTION 2. AND BE IT FURTHER ENACTED, That:

8 (a) Except as provided in subsection (b) of this section, for an audit of a pharmacy
9 or pharmacist under contract with a pharmacy benefits manager, this Act shall apply only
10 to an audit performed on or after January 1, 2024.

11 (b) For a pharmacy benefits manager that contracts with the State or a local
12 government, this Act shall apply only to audits that occur on the first day of the first plan
13 year beginning on or after January 1, 2024, or the first time a contract between a pharmacy
14 benefits manager with the State or a local government is amended or renewed on or after
15 January 1, 2024.

16 SECTION 2. 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
17 October 1, 2023 January 1, 2024.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.