

AMENDED IN SENATE MAY 1, 2012  
AMENDED IN SENATE MARCH 26, 2012

**SENATE BILL**

**No. 1195**

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**Introduced by Senator Price**

February 22, 2012

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An act to add Part 6.01 (commencing with Section 12665) to Division 2 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 1195, as amended, Price. Audits of pharmacy benefits.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. Existing law provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for specified benefits and requires contracts between plans or insurers and providers to contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism.

This bill would require a contract entered into between a pharmacy and a health insurer, health care service plan, or pharmacy benefit manager, as defined, for the provision of pharmacy services to beneficiaries of a health benefit plan, to include policies and procedures for any audits under the contract, and would impose specified requirements on those audits. Among other things, the bill would prohibit the entity conducting the audit from receiving payment on any basis tied to the amount claimed or recovered from the pharmacy and would require the entity to deliver a preliminary audit report to the pharmacy and to give the pharmacy an opportunity to respond to the

report. The bill would require the entity to deliver a final audit report to the pharmacy and to establish a process for appealing the findings of that report, as specified. The bill would ~~prohibit~~ *require that when the entity ~~from~~ is using extrapolation, as defined, in calculating penalties or amounts to be recouped from a pharmacy and, that the pharmacy be given an opportunity to provide evidence validating certain orders.* The bill also would prohibit a pharmacy from being subject to recoupment of funds for a clerical or recordkeeping error. The bill would enact other related provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.  
 State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Part 6.01 (commencing with Section 12665) is  
 2 added to Division 2 of the Insurance Code, to read:

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4 PART 6.01. AUDITS OF PHARMACY BENEFITS

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6 12665. For purposes of this article, the following definitions  
 7 shall apply:

8 (a) “Carrier” means a health care service plan, as defined in  
 9 Section 1345 of the Health and Safety Code, or a health insurer  
 10 that issues policies of health insurance, as defined in Section 106.

11 (b) “Clerical or recordkeeping error” includes, but is not limited  
 12 to, a typographical error, scrivener’s error, or computer error in a  
 13 required document or record.

14 (c) “Extrapolation” means the practice of inferring a frequency  
 15 or dollar amount of overpayments, underpayments, nonvalid  
 16 claims, or other errors on any portion of claims submitted, based  
 17 on the frequency or dollar amount of overpayments,  
 18 underpayments, nonvalid claims, or other errors actually measured  
 19 in a sample of claims.

20 (d) “Health benefit plan” means any plan or program that  
 21 provides, arranges, pays for, or reimburses the cost of health  
 22 benefits. “Health benefit plan” includes, but is not limited to, a  
 23 health care service plan contract issued by a health care service  
 24 plan, as defined in Section 1345 of the Health and Safety Code,  
 25 and a policy of health insurance, as defined in Section 106, issued  
 26 by a health insurer.

1 (e) “Pharmacy” has the same meaning *as* provided in Section  
2 4037 of the Business and Professions Code.

3 (f) “Pharmacy audit” means an audit, either onsite or remotely,  
4 of any records of a pharmacy conducted by or on behalf of a carrier  
5 or a pharmacy benefits manager, or a representative thereof, for  
6 prescription drugs that were dispensed by that pharmacy to  
7 beneficiaries of a health benefit plan pursuant to a contract with  
8 the health benefit plan or the issuer or administrator thereof.

9 (g) “Pharmacy benefit manager” means a person, business, or  
10 other entity that, pursuant to a contract or under an employment  
11 relationship with a carrier, health benefit plan sponsor, or other  
12 third-party payer, either directly or through an intermediary,  
13 manages the prescription drug coverage provided by the carrier,  
14 plan sponsor, or other third-party payer, including, but not limited  
15 to, the processing and payment of claims for prescription drugs,  
16 the performance of drug utilization review, the processing of drug  
17 prior authorization requests, the adjudication of appeals or  
18 grievances related to prescription drug coverage, contracting with  
19 network pharmacies, and controlling the cost of covered  
20 prescription drugs.

21 12665.1. (a) Nothing in this article shall apply to an audit  
22 conducted because a pharmacy benefit manager, carrier, health  
23 benefit plan sponsor, or other third-party payer has evidence or a  
24 significant suspicion that criminal wrongdoing, willful  
25 misrepresentation, or fraud has occurred.

26 (b) Nothing in this article shall apply to an audit conducted by  
27 the California State Board of Pharmacy, the State Department of  
28 Health Care Services, or the State Department of Public Health.

29 12665.2. Notwithstanding any other provision of law, a contract  
30 that is issued, amended, or renewed on or after January 1, 2013,  
31 between a pharmacy and a carrier or a pharmacy benefit manager  
32 to provide pharmacy services to beneficiaries of a health benefit  
33 plan shall include policies and procedures for any audits performed  
34 under the contract. The policies and procedures shall be consistent  
35 with generally accepted auditing practices and shall comply with  
36 the provisions of this part.

37 12665.3. (a) An entity conducting a pharmacy audit shall not  
38 receive payment or any other consideration on any basis that is  
39 tied to the amount claimed or actual amount recovered from the  
40 pharmacy that is the subject of the audit.

1 ~~(b) An entity conducting a pharmacy audit shall not use~~  
 2 ~~extrapolation in calculating penalties or amounts to be recouped~~  
 3 ~~from a pharmacy. Any findings of overpayment or underpayment~~  
 4 ~~to a pharmacy shall be based solely on documented instances of~~  
 5 ~~overpayment or underpayment to the pharmacy and shall not be~~  
 6 ~~based on an estimate or projection based on the number of patients~~  
 7 ~~served having a similar diagnosis or on the number of similar~~  
 8 ~~orders or refills for similar drugs.~~

9 ~~(e) Any calculation of overpayment to a pharmacy determined~~  
 10 ~~pursuant to a pharmacy audit shall not include the portion of any~~  
 11 ~~payment that constitutes dispensing fees.~~

12 ~~(d)~~

13 (b) A pharmacy shall not be subject to recoupment of funds for  
 14 a clerical or recordkeeping error, unless there is proof of intent to  
 15 commit fraud or that the error resulted in actual financial harm to  
 16 the pharmacy benefit manager, the carrier, or the beneficiary of a  
 17 health benefit plan.

18 12665.4. (a) Except as otherwise prohibited by state or federal  
 19 law, an entity conducting a pharmacy audit shall keep confidential  
 20 any information collected during the course of the audit and shall  
 21 not share any information with any person other than the carrier,  
 22 pharmacy benefit manager, or third-party payer for which the audit  
 23 is being performed. An entity conducting a pharmacy audit shall  
 24 have access only to previous audit reports relating to a particular  
 25 pharmacy conducted by or on behalf of the same entity. Nothing  
 26 in this subdivision shall be construed to authorize access to  
 27 information that is otherwise prohibited by law.

28 (b) An entity that is not a carrier or pharmacy benefit manager  
 29 and that is conducting a pharmacy audit on behalf of a carrier or  
 30 pharmacy benefit manager shall, prior to conducting the audit,  
 31 provide the pharmacy with an attestation that the entity and the  
 32 carrier or pharmacy benefit manager have executed a business  
 33 associate agreement or other agreement as required under state  
 34 and federal privacy laws.

35 (c) An entity conducting a pharmacy audit shall, prior to leaving  
 36 a pharmacy at the end of an onsite portion of the audit, provide  
 37 the pharmacist in charge with a complete list of records reviewed  
 38 to allow the pharmacy to account for disclosures as required by  
 39 state and federal privacy laws.

1 12665.5. (a) An entity conducting a pharmacy audit shall not  
2 initiate or schedule a pharmacy audit during the first five business  
3 days of any calendar month, unless it is expressly agreed to by the  
4 pharmacy being audited.

5 (b) An entity conducting an onsite pharmacy audit shall provide  
6 the pharmacy at least one week's prior written notice before  
7 conducting an initial audit.

8 12665.6. (a) A pharmacy audit that involves clinical judgment  
9 shall be conducted by a pharmacist licensed pursuant to Chapter  
10 9 (commencing with Section 4000) of Division 2 of the Business  
11 and Professions Code.

12 (b) An entity conducting a pharmacy audit shall make all  
13 determinations regarding the legal validity of a prescription or  
14 other record consistent with determinations made pursuant to  
15 Article 4 (commencing with Section 4070) of Chapter 9 of Division  
16 2 of the Business and Professions Code ~~and shall accept as valid.~~  
17 *A pharmacy may submit to an entity conducting a pharmacy audit*  
18 *electronically stored images of prescriptions, electronically created*  
19 *annotations, and other related supporting documentation as valid*  
20 *proof of the pharmacy record with respect to orders or refills of*  
21 *a dangerous drug or device.*

22 ~~(c) An entity conducting a pharmacy audit shall accept A~~  
23 ~~*pharmacy may submit to an entity conducting a pharmacy audit*~~  
24 ~~paper or electronic signature logs that indicate the delivery of~~  
25 ~~pharmacy services as valid proof of receipt of those services by a~~  
26 ~~health benefit plan beneficiary.~~

27 12665.7. The time period covered by a pharmacy audit shall  
28 not exceed a 24-month period beginning no more than 24 months  
29 prior to the initial date of the onsite portion of the audit, and the  
30 audit shall encompass only claims that were submitted to or  
31 adjudicated by the carrier or pharmacy benefit manager during  
32 that 24-month period.

33 12665.8. (a) (1) An entity conducting a pharmacy audit shall  
34 deliver a preliminary audit report to the pharmacy before issuing  
35 a final audit report. This preliminary report shall be issued no later  
36 than 60 days after conclusion of the audit.

37 (2) A pharmacy shall be provided a time period of no less than  
38 30 days following receipt of the preliminary audit report under  
39 paragraph (1) to respond to the findings in the report, including

1 addressing any alleged mistakes or discrepancies and producing  
2 documentation to that effect.

3 (3) A pharmacy may use the records of a health facility,  
4 physician and surgeon, or other authorized practitioner of the  
5 healing arts involving drugs, medicinal supplies, or medical devices  
6 written or transmitted by any means of communication for purposes  
7 of validating the pharmacy record with respect to orders or refills  
8 of a dangerous drug or device.

9 (4) *If an entity conducting a pharmacy audit uses extrapolation*  
10 *to calculate penalties or amounts to be recouped, the pharmacy*  
11 *may present evidence to validate orders for dangerous drugs or*  
12 *devices that are subject to invalidation due to extrapolation.*

13 ~~(4)~~

14 (5) Prior to issuing a final audit report, an entity conducting a  
15 pharmacy audit shall take into consideration any response by the  
16 pharmacy to the preliminary audit report.

17 (b) (1) An entity conducting a pharmacy audit shall deliver a  
18 final audit report to the pharmacy no later than 90 days after the  
19 conclusion of the audit or 30 days after receipt of a pharmacy's  
20 response to the preliminary audit report, as applicable.

21 (2) An entity conducting a pharmacy audit shall establish a  
22 process for appealing the findings in a final audit report that  
23 complies with the following requirements:

24 (A) A pharmacy shall be provided a time period of no less than  
25 60 days following receipt of the final audit report to file an appeal  
26 with the entity identified in the appeal process.

27 (B) A pharmacy may use the records of a hospital, physician  
28 and surgeon, or other authorized practitioner of the healing arts  
29 involving drugs, medicinal supplies, or medical devices written  
30 or transmitted by any means of communication for purposes of  
31 validating the pharmacy record with respect to orders or refills of  
32 a dangerous drug or device.

33 (C) An entity conducting a pharmacy audit shall provide the  
34 pharmacy with a written determination of appeal issued by the  
35 entity identified in the appeal process, which shall be appended to  
36 the final audit report, and a copy of the determination shall be sent  
37 to the carrier, health benefit plan sponsor, or other third-party  
38 payer.

1 (D) The appeals process may include a dispute resolution option  
2 as long as the pharmacy retains the right to file a written appeal  
3 and obtain a written determination pursuant to this subdivision.

4 (c) An entity conducting a pharmacy audit, a carrier, a health  
5 benefit plan sponsor, or other third-party payer, or any person  
6 acting on behalf of those entities, shall not attempt to make  
7 chargebacks or seek recoupment from a pharmacy, or assess or  
8 collect penalties from a pharmacy, until the time period for filing  
9 an appeal to a final audit report has passed, or until the appeal  
10 process has been exhausted, whichever is later.

11 (d) An entity conducting a pharmacy audit, a carrier, a health  
12 benefit plan sponsor, or other third-party payer, or any person  
13 acting on behalf of those entities, shall not charge interest during  
14 the audit or appeal period.

15 (e) If, following final disposition of a pharmacy audit pursuant  
16 to this section, an entity conducting a pharmacy audit, a carrier, a  
17 health benefit plan sponsor, or other third-party payer, or any  
18 person acting on behalf of those entities, finds that an audit report  
19 or any portion thereof is unsubstantiated, the entity shall dismiss  
20 the audit report or the unsubstantiated portion thereof without the  
21 necessity of any further proceedings ~~and shall return any moneys~~  
22 ~~recouped as a result of the lack of substantiation, as applicable.~~