AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 627

Introduced by Assembly Member Gomez

February 24, 2015

An act to amend Section 4431 of 4430 of, and to add Section 4440 to, the Business and Professions Code, relating to audits of pharmacy benefits benefit managers.

LEGISLATIVE COUNSEL'S DIGEST

AB 627, as amended, Gomez. Audits of pharmacy benefits. Pharmacy benefit managers: contracting pharmacies.

Existing law imposes specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan, and defines certain terms for its purposes, including, among others, pharmacy benefit manager.

The bill would require a pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis to include in a contract, renewed on or after January 1, 2016, information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list and to provide for an appeal process for the contracting pharmacy, as specified. The bill would also require a pharmacy benefit manager to make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the pharmacy benefit manager for patients served by the pharmacy in a readily accessible, secure, and usable Web-based format or other comparable format. The bill would prohibit a drug from being included on a maximum allowable cost list or from being

AB 627 — 2 —

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reimbursed on a maximum allowable cost basis unless certain requirements are met, including, but not limited to, that the drug is not obsolete.

Existing law imposes specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan. Existing law provides that those requirements do not apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other 3rd-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation, fraud, or abuse has occurred, or to an audit conducted by, or at the direction of, the California State Board of Pharmacy, the State Department of Health Care Services, the State Department of Public Health, or the Medicare program.

This bill would make nonsubstantive changes to that provision.

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. Section 4430 of the Business and Professions 2 Code is amended to read:
- 3 4430. For purposes of this chapter, the following definitions 4 shall apply:
 - (a) "Carrier" means a health care service plan, as defined in Section 1345 of the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106 of the Insurance Code.
 - (b) "Clerical or recordkeeping error" includes a typographical error, scrivener's error, or computer error in a required document or record.
 - (c) "Extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.
- 18 (d) "Health benefit plan" means any plan or program that 19 provides, arranges, pays for, or reimburses the cost of health 20 benefits. "Health benefit plan" includes, but is not limited to, a 21 health care service plan contract issued by a health care service

3 AB 627

plan, as defined in Section 1345 of the Health and Safety Code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

- (e) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.
- (f) "Maximum allowable cost list" means a list of drugs for which a maximum allowable cost has been established by a pharmacy benefit manager.
- (g) "Obsolete" means a drug that may be listed in national drug pricing compendia but is no longer available to be dispensed based on the expiration date of the last lot manufactured.

(e)

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14 (h) "Pharmacy" has the same meaning as provided in Section 15 4037.

(f)

(i) "Pharmacy audit" means an audit, either onsite or remotely, of any records of a pharmacy conducted by or on behalf of a carrier or a pharmacy benefits manager, or a representative thereof, for prescription drugs that were dispensed by that pharmacy to beneficiaries of a health benefit plan pursuant to a contract with the health benefit plan or the issuer or administrator thereof. "Pharmacy audit" does not include a concurrent review or desk audit that occurs within three business days of transmission of a claim, or a concurrent review or desk audit where no chargeback or recoupment is demanded.

(g)

(*j*) "Pharmacy benefit manager" means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

AB 627 —4—

SEC. 2. Section 4440 is added to the Business and Professions Code, immediately following Section 4439, to read:

- 4440. (a) A pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis shall comply with this section.
- (b) A pharmacy benefit manager shall include in a contract, entered into or renewed on or after January 1, 2016, with the contracting pharmacy information identifying any national drug pricing compendia or other data sources used to determine the maximum allowable cost for the drugs on a maximum allowable cost list.
- (c) A pharmacy benefit manager shall make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost list or lists used by the pharmacy benefit manager for patients served by that pharmacy in a readily accessible, secure, and usable Web-based format or other comparable format.
- (d) A drug shall not be included on a maximum allowable cost list or reimbursed on a maximum allowable cost basis unless all of the following apply:
- (1) The drug is listed as "A" or "B" rated in the most recent version of the federal Food and Drug Administration's (FDA) approved drug products with therapeutic equivalent evaluations, also known as the Orange Book or has an "NA" or "NR" rating or a similar rating by a nationally recognized pricing reference, such as Medi-Span or First DataBank.
- (2) The drug is generally available for purchase in the state from a national or regional wholesaler.
 - (3) The drug is not obsolete.
- (e) For contracts entered into or renewed on or after January 1, 2016, a pharmacy benefit manager shall review and shall make necessary adjustments to the maximum allowable cost of each drug on a maximum allowable cost list using the most recent data sources available at least once every seven days.
- (f) For contracts entered into or renewed on or after January 1, 2016, a pharmacy benefit manager shall have a clearly defined process for a contracting pharmacy to appeal the maximum allowable cost for a drug on a maximum allowable cost list that includes all of the following:
- 39 (1) A contracting pharmacy may base its appeal on either of 40 the following:

5 AB 627

(A) The maximum allowable cost for a drug is below the cost at which the drug is available for purchase by similarly situated pharmacies in the state from a national or regional wholesaler.

- (B) The drug does not meet the requirements of subdivision (d).
- (2) A contracting pharmacy shall be provided no less than 14 business days following receipt of payment for the claim upon which the appeal is based to file an appeal with a pharmacy benefit manager. The pharmacy benefit manager shall make a final determination regarding a contracting pharmacy's appeal within seven business days of the pharmacy benefit manager's receipt of the appeal.
- (3) If an appeal is denied by a pharmacy benefit manager, the pharmacy benefit manager shall provide to the contracting pharmacy the reason for the denial and the national drug code (NDC) of an equivalent drug that may be purchased by a similarly situated pharmacy at the price that is equal to or less than the maximum allowable cost of the appealed drug.
- (4) If an appeal is upheld by a pharmacy benefit manager, the pharmacy benefit manager shall adjust the maximum allowable cost of the appealed drug for the appealing contracting pharmacy and all similarly situated contracting pharmacies in the state within one calendar day of the date of determination. The pharmacy benefit manager shall permit the appealing pharmacy to reverse and resubmit the claim upon which the appeal was based in order to receive the corrected reimbursement.
- (g) A contracting pharmacy shall not disclose to any third party the maximum allowable cost list and any related information it receives either directly from a pharmacy benefit manager or through a pharmacy services administrative organization or similar entity with which the contracting pharmacy has a contract to provide administrative services for that pharmacy.
- SECTION 1. Section 4431 of the Business and Professions Code is amended to read:
- 4431. (a) This chapter shall not apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other third-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation, fraud, or abuse has occurred.
- (b) This chapter shall not apply to an audit conducted by, or at the direction of, the California State Board of Pharmacy, the State

AB 627 — 6—

- 1 Department of Health Care Services, the State Department of
- 2 Public Health, or the Medicare program.