

AMENDED IN ASSEMBLY APRIL 10, 2008

AMENDED IN ASSEMBLY MARCH 24, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

**ASSEMBLY BILL**

**No. 2535**

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**Introduced by Assembly Member Hernandez**

February 21, 2008

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An act to amend Section 14105.45 of, and to add Section 14105.455 to, the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 2535, as amended, Hernandez. Medi-Cal: prescription drugs.

Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income persons receive health care services, including prescription drugs.

Existing law requires the reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs, as defined, to consist of the estimated acquisition cost of the drug, as defined, plus a professional fee for dispensing. Under existing law, the professional fee is \$7.50 per dispensed prescription, except for legend drugs that are dispensed to a beneficiary residing in specified types of facilities, for which the professional fee is \$8 per dispensed prescription.

This bill would revise the method by which the professional fee is calculated, and would require the department to review and, commencing July 1, 2009, recalculate the professional fee every 2 years, pursuant to a prescribed formula and in accordance with specified objectives. The bill would require the professional fee for legend and nonlegend drugs dispensed to a beneficiary residing in specified types

of facilities to include an additional reimbursement for certain costs incurred by pharmacies in servicing these beneficiaries, would authorize the department to set a professional fee for multiple source drugs, as defined, and would authorize the department to create additional incentives designed to encourage the utilization of lower cost multiple source prescription drugs.

Existing law defines “direct price” to mean the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department’s primary reference source.

This bill would revise this definition to mean the price of a drug product generally available to pharmacies in California if purchased directly from a manufacturer listed in the department’s primary reference source.

Under existing law, the department is required to base the selling price of a drug product on the average manufacturer’s price plus a percent markup determined by the department to be necessary for the selling price to represent the average purchase price paid by retail pharmacies in California.

This bill would revise the amount by which the department determines the percent markup to, instead, require the selling price to represent ~~100%~~ of the *average* purchase paid by ~~at least 90% of the community~~ retail pharmacies in California.

Existing law requires the department to establish a list of maximum allowable ingredient costs (MAIC) for drugs provided under the Medi-Cal program, and for purposes of establishing the acquisition cost for legend and nonlegend drugs, requires the department to establish a list of MAICs for generically equivalent drugs, as provided. Existing law requires the department to update the list of, and establish new, MAICs, and to base the MAIC on the mean of the average manufacturer’s price of drugs generically equivalent to the particular innovator drug, plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

This bill would revise the amount by which the department calculates the percent markup to, instead, require the selling price to represent ~~100%~~ of the *average* purchasing price paid by ~~at least 90% of community~~ retail pharmacies in California and be sufficient to result in the utilization of innovator multiple source drugs, as defined, that is consistent with utilization targets established by the department and approved by the Legislature.

Existing law requires the department to update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 30 days after receiving the average manufacturer’s price.

This bill would, instead, require the department to update the claims processing system to reflect changes in the estimated acquisition cost of drugs not later than 3 days after receiving notice of any change.

Existing law requires the department to make a one-time adjustment to the dispensing fees paid to pharmacy providers if certain conditions are met.

This bill would delete this provision.

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

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

- 1 SECTION 1. Section 14105.45 of the Welfare and Institutions
- 2 Code is amended to read:
- 3 14105.45. (a) For purposes of this section, the following
- 4 definitions shall apply:
- 5 (1) “Average ~~manufacturers~~ *manufacturer’s price*” means the
- 6 price reported to the department by the Centers for Medicare and
- 7 Medicaid Services pursuant to Section 1927 of the Social Security
- 8 Act (42 U.S.C. Sec. 1396r-8). In the event an average
- 9 manufacturer’s price is not available, the department shall use the
- 10 direct price as the average manufacturer’s price.
- 11 (2) “Average wholesale price” means the price for a drug
- 12 product listed in the department’s primary price reference source.
- 13 (3) “Direct price” means the price for a drug product generally
- 14 available to pharmacies in California if purchased directly from a
- 15 drug manufacturer listed in the department’s primary reference
- 16 source.
- 17 (4) “Estimated acquisition cost” means the department’s best
- 18 estimate of the price generally and currently paid by providers for
- 19 a drug product sold by a particular manufacturer or principal labeler
- 20 in a standard package.
- 21 (5) “Federal upper limit” means the maximum per unit
- 22 reimbursement when established by the Centers for Medicare and
- 23 Medicaid Services and published by the department in Medi-Cal
- 24 pharmacy provider bulletins and manuals.

- 1 (6) “Generically equivalent drugs” means drug products with  
 2 the same active chemical ingredients of the same strength, quantity,  
 3 and dosage form, and of the same generic drug name, as determined  
 4 by the United States Adopted Names (USAN) and accepted by the  
 5 federal Food and Drug Administration (FDA), as those drug  
 6 products having the same chemical ingredients.
- 7 (7) “Legend drug” means any drug whose labeling states  
 8 “Caution: Federal law prohibits dispensing without prescription,”  
 9 “Rx only,” or words of similar import.
- 10 (8) “Maximum allowable ingredient cost” (MAIC) means the  
 11 maximum amount the department will reimburse Medi-Cal  
 12 pharmacy providers for generically equivalent drugs.
- 13 (9) “Innovator multiple source drug,” “noninnovator multiple  
 14 source drug,” and “single source drug” have the same meaning as  
 15 those terms are defined in Section 1396r-8(k)(7) of Title 42 of the  
 16 United States Code.
- 17 (10) “Nonlegend drug” means any drug whose labeling does  
 18 not contain the statement referenced in paragraph (7).
- 19 (11) “Operational costs” means those pharmacy costs associated  
 20 with ensuring that possession of the appropriate covered outpatient  
 21 drug is transferred to the patient. Operational costs may include,  
 22 but need not be limited to, costs incurred in both of the following:
- 23 (A) Preparing and dispensing the prescription through all of the  
 24 following:
- 25 (i) Point-of-sale verification of patient eligibility and coverage.
  - 26 (ii) Prescription packaging and labeling.
  - 27 (iii) Compounding the prescription, if necessary.
  - 28 (iv) Delivery to the beneficiary at the pharmacy site.
  - 29 (v) Maintaining compliance with federal and state program laws  
 30 and regulations, including those for the Medi-Cal and federal  
 31 Health Insurance Portability and Accountability Act (HIPAA)  
 32 programs.
  - 33 (vi) Overhead expenses, including salaries, utilities, and rent.
  - 34 (vii) Pharmacist continuing education and training.
  - 35 (viii) Pharmacy equipment maintenance.
- 36 (B) Ensuring the patient’s proper use of the medication  
 37 prescribed through all of the following:
- 38 (i) Drug utilization review.
  - 39 (ii) Preferred drug list compliance.
  - 40 (iii) Counseling the patient as required by federal and state law.

1 (iv) Consulting with the physician.

2 (12) “Selling price” means the price used in the establishment  
3 of the estimated acquisition cost. The department shall base the  
4 selling price on the average manufacturer’s price plus a percent  
5 markup determined by the department to be necessary for the  
6 selling price to represent ~~100 percent of the~~ *the average* purchase  
7 price paid by ~~at least 90 percent of community~~ retail pharmacies  
8 in California. The selling price shall not be considered confidential  
9 and shall be subject to disclosure under the California Public  
10 Records Act (Chapter 3.5 (commencing with Section 6250) of  
11 Division 7 of Title 1 of the Government Code).

12 (b) (1) (A) Reimbursement to Medi-Cal pharmacy providers  
13 for legend and nonlegend drugs shall consist of the estimated  
14 acquisition cost of the drug plus a professional fee for dispensing.  
15 Until July 1, 2009, the professional fee shall be seven dollars and  
16 twenty-five cents (\$7.25) per dispensed prescription, except that  
17 the professional fee for legend drugs dispensed to a beneficiary  
18 residing in a skilled nursing facility or intermediate care facility  
19 shall be eight dollars (\$8) per dispensed prescription. For purposes  
20 of this subparagraph, “skilled nursing facility” and “intermediate  
21 care facility” shall have the same meaning as defined in Division  
22 5 (commencing with Section 70001) of Title 22 of the California  
23 Code of Regulations.

24 (B) Commencing July 1, 2009, and every two years thereafter,  
25 the professional fee described in subparagraph (A) shall be  
26 determined in accordance with Section 14105.455.

27 (2) The department shall establish the estimated acquisition cost  
28 of legend and nonlegend drugs as follows:

29 (A) For single source and innovator multiple source drugs, the  
30 estimated acquisition cost shall be equal to the lowest of the  
31 average wholesale price minus 17 percent, the selling price, the  
32 federal upper limit, or the MAIC.

33 (B) For noninnovator multiple source drugs, the estimated  
34 acquisition cost shall be equal to the lowest of the average  
35 wholesale price minus 17 percent, the selling price, the federal  
36 upper limit, or the MAIC.

37 (3) For purposes of paragraph (2), the department shall establish  
38 a list of MAICs for generically equivalent drugs, which shall be  
39 published in pharmacy provider bulletins and manuals. The

1 department shall update the list of MAICs and establish additional  
2 MAICs in accordance with all of the following:

3 (A) The department shall base the MAIC on the mean of the  
4 average manufacturer's price of drugs generically equivalent to  
5 the particular innovator drug plus a percent markup determined  
6 by the department to be necessary for the MAIC to represent ~~100~~  
7 ~~percent of the~~ *the average* purchase price paid by ~~at least 90 percent~~  
8 ~~of community~~ retail pharmacies in California and be sufficient to  
9 result in utilization of innovator multiple source drugs consistent  
10 with targets established by the department and approved by the  
11 Legislature.

12 (B) The department shall update MAICs at least every three  
13 months and notify Medi-Cal providers at least 30 days prior to the  
14 effective date of a MAIC.

15 (c) The department shall update the Medi-Cal claims processing  
16 system to reflect changes in the estimated acquisition cost of drugs  
17 not later than three days after receiving notice of any change.

18 (d) The director shall implement this section in a manner that  
19 is consistent with federal Medicaid law and regulations. The  
20 director shall seek any necessary federal approvals for the  
21 implementation of this section. This section shall be implemented  
22 only to the extent that federal approval is obtained.

23 (e) Notwithstanding Chapter 3.5 (commencing with Section  
24 11340) of Part 1 of Division 3 of Title 2 of the Government Code,  
25 the department may take the actions specified in this section by  
26 means of a provider bulletin or notice, policy letter, or other similar  
27 instructions, without taking regulatory action.

28 (f) The department shall issue a Medi-Cal pharmacy  
29 reimbursement fact sheet to the chairperson of the committee in  
30 each house of the Legislature that considers appropriations no later  
31 than March 1, 2008. The reimbursement fact sheet shall contain,  
32 but not be limited to, available data and information regarding the  
33 change in reimbursement due to the federal Deficit Reduction Act  
34 of 2005 implementation of average manufacturer's price based  
35 federal upper limits, the implementation of selling price, change  
36 in the average wholesale price reported to the department by the  
37 primary price reference source, change in pharmacy dispensing  
38 fees, prescription drug volume trends, and the number of active  
39 Medi-Cal pharmacy providers. The fact sheet shall also contain  
40 general information and definitions regarding drug pricing

1 terminology and a description of pharmacy claims processing in  
2 Medi-Cal.

3 SEC. 2. Section 14105.455 is added to the Welfare and  
4 Institutions Code, to read:

5 14105.455. (a) (1) Commencing July 1, 2009, and every two  
6 years thereafter, the department shall recalculate the professional  
7 fee described in Section 14105.45 in accordance with this section.

8 (2) In implementing this section, the department shall ensure  
9 that the professional fee is all of the following:

10 (A) Fair, transparent, reasonable, and designed to approximate  
11 a pharmacy's actual dispensing cost and allow for a reasonable  
12 profit.

13 (B) Adequate to ensure that an individual covered under the  
14 Medi-Cal program has access to prescription drugs and pharmacy  
15 services at the same level as those services are available for  
16 California residents who are not enrolled in the Medi-Cal program.

17 (C) Consistent with the principles of efficiency, economy, and  
18 quality of care.

19 (b) (1) The initial professional fee established pursuant to this  
20 section, which shall be in effect as of July 1, 2009, shall be an  
21 amount that is equal to the cost of dispensing a prescription, as  
22 determined in the national cost of dispensing survey conducted by  
23 a nationally respected auditing firm in 2006, or similar cost of  
24 dispensing survey authorized by the Legislature, adjusted by the  
25 annual inflation in the health care cost inflation rate, plus a  
26 reasonable profit, as determined by the department.

27 (2) For the professional fee established for the 2011–12 fiscal  
28 year, and each professional fee established by the department  
29 thereafter, the department shall calculate the fee by utilizing  
30 information on the cost of dispensing a prescription in California  
31 derived from all of the following:

32 (A) Compilations and data regarding professional salaries and  
33 fees.

34 (B) Audits and surveys of operational costs.

35 (C) Analyses of compiled data regarding overhead costs, profits,  
36 and related information.

37 (c) Notwithstanding Section 14105.45, the department may set  
38 a reasonable professional rate for innovator multiple source drugs,  
39 as defined in paragraph (9) of subdivision (a) of Section 14105.45,  
40 and may, as part of the rate, create additional incentives designed

1 to encourage the utilization of lower cost innovator multiple source  
2 prescription drugs.  
3 (d) The professional fee for legend and nonlegend drugs  
4 dispensed to a beneficiary residing in a skilled nursing facility,  
5 intermediate care facility, or assisted living facility shall include  
6 additional reimbursement for the costs associated with special  
7 packaging and delivery by pharmacies servicing these beneficiaries.  
8 For purposes of this subdivision, “skilled nursing facility” and  
9 “intermediate care facility” shall have the same meaning as defined  
10 in Division 5 (commencing with Section 70001) of Title 22 of the  
11 California Code of Regulations.

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