ASSEMBLY BILL No. 804

Introduced by Assembly Member Lowenthal

February 21, 2013

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

LEGISLATIVE COUNSEL'S DIGEST

AB 804, as introduced, Lowenthal. Medi-Cal: pharmacy providers: invoices.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid Program provisions. Existing law requires reimbursement to Medi-Cal pharmacy providers for drugs, as prescribed, and authorizes the department to establish a new reimbursement methodology based on average acquisition cost, as defined. Under existing law, Medi-Cal pharmacy providers are required to submit drug price information, including invoice prices, to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. Under existing law, drug pricing information is confidential and exempt from public disclosure, as specified.

This bill would provide that pharmacy invoice information is confidential and exempt from public disclosure, as specified.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the

interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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

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

SECTION 1. Section 14105.45 of the Welfare and Institutions Code is amended to read:

14105.45. (a) For purposes of this section, the following definitions shall apply:

(1) "Average acquisition cost" means the average weighted cost determined by the department to represent the actual acquisition cost paid for drugs by Medi-Cal pharmacy providers, including those that provide specialty drugs. The average acquisition cost shall not be considered confidential and shall be subject to disclosure pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(2) "Average manufacturers price" means the price reported to the department by the federal Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).

(3) "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.

(4) "Estimated acquisition cost" means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the federal Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength and dosage form, and of the same generic drug name, as determined by the United States Adopted Names ~~(USAN)~~ *Council (USANC)*

and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) "Nonlegend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) "Pharmacy warehouse," as defined in Section 4163 of the Business and Professions Code, means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

(12) "Specialty drugs" means drugs determined by the department pursuant to subdivision (f) of Section 14105.3 to generally require special handling, complex dosing regimens, specialized self-administration at home by a beneficiary or caregiver, or specialized nursing facility services, or may include extended patient education, counseling, monitoring, or clinical support.

(13) "Volume weighted average" means the aggregated average volume for a group of legend or nonlegend drugs, weighted by each drug's percentage of the group's total volume in the Medi-Cal fee-for-service program during the previous six months. For purposes of this paragraph, volume is based on the standard billing unit used for the legend or nonlegend drugs.

(14) "Wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail pharmacies in California.

(15) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall not exceed the lowest of either of the following:

(A) The estimated acquisition cost of the drug plus a professional fee for dispensing.

(B) The pharmacy's usual and customary charge as defined in Section 14105.455.

(2) The professional fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph "skilled nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations. If the department determines that a change in dispensing fee is necessary pursuant to this section, the department shall establish the new dispensing fee through the budget process and implement the new dispensing fee pursuant to subdivision (d).

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

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

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

(C) Average wholesale price shall not be used to establish the estimated acquisition cost once the department has determined that the average acquisition cost methodology has been fully implemented.

(4) For purposes of paragraph (3), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California. The department shall

update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall 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.

(B) If average manufacturer prices are unavailable, the department shall establish the MAIC in one of the following ways:

(i) Based on the volume weighted average of wholesaler acquisition costs 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.

(ii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

(iii) Based on the volume weighted average acquisition cost of drugs generically equivalent to the particular innovator drug adjusted by the department to represent the average purchase price paid by Medi-Cal pharmacy providers.

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

(D) The department shall establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying providers.

(E) In determining the average purchase price, the department shall consider the provider-related costs of the products that include, but are not limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(5) (A) The department may establish the average acquisition cost in one of the following ways:

(i) Based on the volume weighted average acquisition cost adjusted by the department to ensure that the average acquisition

cost represents the average purchase price paid by retail pharmacies in California.

(ii) Based on the proposed average acquisition cost as calculated by the vendor pursuant to subparagraph (B).

(iii) Based on a national pricing benchmark obtained from the federal Centers for Medicare and Medicaid Services or on a similar benchmark listed in the department's primary price reference source adjusted by the department to ensure that the average acquisition cost represents the average purchase price paid by retail pharmacies in California.

(B) For the purposes of paragraph (3), the department may contract with a vendor for the purposes of surveying drug price information, collecting data from providers, wholesalers, or drug manufacturers, and calculating a proposed average acquisition cost.

(C) (i) Medi-Cal pharmacy providers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. The information submitted by pharmacy providers shall include, but not be limited to, invoice prices and all discounts, rebates, and refunds known to the provider that would apply to the acquisition cost of the drug products purchased during the calendar quarter. Pharmacy warehouses shall be exempt from the survey process, but shall provide drug cost information upon audit by the department for the purposes of validating individual pharmacy provider acquisition costs. *Pharmacy invoice information shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).*

(ii) Pharmacy providers that fail to submit drug price information to the department or the vendor as required by this subparagraph shall receive notice that if they do not provide the required information within five working days, they shall be subject to suspension under subdivisions (a) and (c) of Section 14123.

(D) (i) For new drugs or new formulations of existing drugs, ~~where~~ *if* drug price information is unavailable pursuant to clause (i) of subparagraph (C), drug manufacturers and wholesalers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost. Drug price information shall include, but

not be limited to, net unit sales of a drug product sold to retail pharmacies in California divided by the total number of units of the drug sold by the manufacturer or wholesaler in a specified period of time determined by the department.

(ii) Drug products from manufacturers and wholesalers that fail to submit drug price information to the department or the vendor as required by this subparagraph may not be a reimbursable benefit of the Medi-Cal program for those manufacturers and wholesalers until the department has established the average acquisition cost for those drug products.

(E) Drug pricing information provided to the department or a vendor designated by the department for the purposes of establishing the average acquisition cost pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(F) Prior to the implementation of an average acquisition cost methodology, the department shall collect data through a survey of pharmacy providers for purposes of establishing a professional fee for dispensing in compliance with federal Medicaid requirements.

(i) The department shall seek stakeholder input on the retail pharmacy factors and elements used for the pharmacy survey relative to both average acquisition costs and dispensing costs. Any adjustment to the dispensing fee shall not exceed the aggregate savings associated with the implementation of the average acquisition cost methodology.

(ii) For drug products provided by pharmacy providers pursuant to subdivision (f) of Section 14105.3, a differential professional fee or payment for services to provide specialized care may be considered as part of the contracts established pursuant to that section.

(G) When the department implements the average acquisition cost methodology, the department shall update the Medi-Cal claims processing system to reflect the average acquisition cost of drugs not later than 30 days after the department has established average acquisition cost pursuant to subparagraph (A).

(H) Notwithstanding any other provision of law, if the department implements average acquisition cost pursuant to clause (i) or (ii) of subparagraph (A), the department shall update actual

acquisition costs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of any change in an actual acquisition cost.

(I) The department shall establish a process for providers to seek a change to a specific average acquisition cost when the providers believe the average acquisition cost does not reflect current available market prices. If the department determines an average acquisition cost change is warranted, the department may update a specific average acquisition cost prior to notifying providers.

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

(d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(e) The department may enter into contracts with a vendor for the purposes of implementing this section on a bid or nonbid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into to implement this section, and all contract amendments and change orders, shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(f) (1) The rates provided for in this section shall be implemented only if the director determines that the rates will comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(2) In determining whether federal financial participation is available, the director shall determine whether the rates comply with applicable federal Medicaid requirements, including those set forth in Section 1396a(a)(30)(A) of Title 42 of the United States Code.

(3) To the extent that the director determines that the rates do not comply with applicable federal Medicaid requirements or that federal financial participation is not available with respect to any

rate of reimbursement described in this section, the director retains the discretion not to implement that rate and may revise the rate as necessary to comply with federal Medicaid requirements.

(g) The director shall seek any necessary federal approvals for the implementation of this section.

(h) This section shall not be construed to require the department to collect cost data, to conduct cost studies, or to set or adjust a rate of reimbursement based on cost data that has been collected.

(i) Adjustments to pharmacy drug product payment pursuant to Section 14105.192 shall no longer apply when the department determines that the average acquisition cost methodology has been fully implemented and the department's pharmacy budget reduction targets, consistent with payment reduction levels pursuant to Section 14105.192, have been met.

(j) Prior to implementation of this section, the department shall provide the appropriate fiscal and policy committees of the Legislature with information on the department's plan for implementation of the average acquisition cost methodology pursuant to this section.

SEC. 2. The Legislature finds and declares that Section 1 of this act imposes a limitation on the public's right of access to meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following finding to demonstrate the interest protected by this limitation and the need for protecting that interest: the Legislature finds and declares that in order to protect the privacy of pharmacy providers who disclose sensitive information, it is necessary to treat that information as confidential.

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