An act to amend Sections 14105.45 and 14105.456 of the Welfare and Institutions Code, relating to Medi-Cal.

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~~ "Actual acquisition cost" has the same meaning as that term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations. The actual 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.~~

(4) "Blood factors" has the same meaning as that term is defined in Section 14105.86.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the federal Centers for Medicare and Medicaid Services.

(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 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,~~ warehouse" 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) "Professional dispensing fee" has the same meaning as that term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations.

(13) "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.

(14) "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.

~~(15) "Wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail pharmacies in California.~~

(15) "Wholesaler" has the same meaning as that term is defined in Section 4043 of the Business and Professions Code.

(16) "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~~ drug ingredient cost plus a professional dispensing fee.

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

(2) (A) ~~Until April 1, 2017,~~ Effective for dates of service on or before March 31, 2017, the professional dispensing fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription, and the professional dispensing 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" have the same meaning as those terms are defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

~~(B) Commencing April 1, 2017, the department shall implement a new professional dispensing fee or fees.~~

(B) Effective for dates of service on or after April 1, 2017, the professional dispensing fee shall be based upon a pharmacy's total, both Medicaid and non-Medicaid, annual claim volume of the previous year as follows:

(i) Less than 90,000 claims per year, the professional dispensing fee shall be thirteen dollars and twenty cents ($13.20).

(ii) Ninety thousand or more claims per year, the professional dispensing fee shall be ten dollars and five cents ($10.05).

(C) If the department determines that a change in the amount of the professional dispensing fee is necessary pursuant to this section in order to meet federal Medicaid requirements, the department shall establish a new professional dispensing fee through the state budget process.

(i) When establishing the new professional dispensing fee or fees, the department shall establish the professional dispensing fee or fees consistent with ~~subsection (d) of~~ Section ~~447.518~~ 447.518(d) of Title 42 of the Code of Federal Regulations.

(ii) The department shall consult with interested parties and appropriate stakeholders in implementing this subparagraph.

~~(C) If the department determines that a change in the amount of a professional dispensing fee is necessary pursuant to this section in order to meet federal Medicaid requirements, the department shall establish the new professional dispensing fee through the state budget process.~~

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

(A) ~~For single source and innovator multiple source drugs, the estimated acquisition~~ Effective for dates of service on or before March 31, 2017, the drug ingredient cost shall be equal to the lowest of the average wholesale price minus 17 percent, the ~~average~~ actual acquisition cost, the federal upper limit, or the MAIC.

(B) ~~For noninnovator multiple source drugs, the estimated acquisition~~ Effective for dates of service on or after April 1, 2017, the drug ingredient cost shall be equal to the lowest of the ~~average wholesale price minus 17 percent, the average~~ actual acquisition cost, the federal upper limit, or the MAIC.

(C) For blood factors, the drug ingredient cost shall be established pursuant to Section 14105.86.

~~(C)~~

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

(4) For purposes of paragraph (3), the department ~~shall~~ may 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~~ drugs. If the department establishes a list of MAICs for generically equivalent drugs, the department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) 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.

~~(A)~~

(B) 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)~~

(C) 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~~ actual 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)~~

(D) The department shall publish the list of MAICs in pharmacy provider bulletins and manuals, update the MAICs at least ~~every three months~~ annually, and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

~~(D)~~

(E) 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)~~

(F) 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.~~ and storage. 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~~ actual acquisition cost in one of the following ways:

(i) Based on the volume weighted ~~average~~ actual acquisition cost adjusted by the department to ~~ensure~~ verify that the ~~average~~ actual acquisition cost represents the average purchase price paid by retail pharmacies in California.

(ii) Based on the proposed ~~average~~ actual 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~~ verify that the ~~average~~ actual 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~~ actual 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~~ actual 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.

(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, 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~~ actual 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 shall not be a reimbursable benefit of the Medi-Cal program for those manufacturers and wholesalers until the department has established the ~~average~~ actual 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~~ actual 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~~ actual acquisition cost methodology, the department shall collect data through a survey of pharmacy providers for purposes of establishing a professional dispensing fee or fees 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~~ actual acquisition costs and professional dispensing costs.

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

(H) Notwithstanding any other law, if the department implements ~~average~~ actual 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~~ make available a process for providers to seek a change to a specific ~~average~~ actual acquisition cost when the providers believe the ~~average~~ actual acquisition cost does not reflect current available market prices. If the

department determines an ~~average~~ actual acquisition cost change is warranted, the department may update a specific ~~average~~ actual 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~~ Effective for dates of service on or after April 1, 2017, adjustments to pharmacy drug product ~~payment~~ payments 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.~~ apply.

(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~~ actual acquisition cost methodology pursuant to this section.

SEC. 2. Section 14105.456 of the Welfare and Institutions Code is amended to read:

14105.456. (a) For purposes of this section, the following definitions shall apply:

~~(1) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names Council (USANC) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.~~

~~(2) "Legend drug" means any drug with a label that states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.~~

(1) "Blood factors" has the same meaning as that term is defined in Section 14105.86.

(2) "Generically equivalent drugs" has the same meaning as that term is defined in Section 14105.45.

(3) "Legend drug" has the same meaning as that term is defined in Section 14105.45.

~~(3)~~

(4) "Medicare rate" means the rate of reimbursement established by the Centers for Medicare and Medicaid Services for the Medicare Program.

~~(4) "Nonlegend drug" means any drug with a label that does not contain a statement referenced in paragraph (2).~~

(5) "Nonlegend drug" has the same meaning as that term is defined in Section 14105.45.

~~(5)~~

(6) "Pharmacy rate of reimbursement" means the reimbursement to a Medi-Cal pharmacy provider pursuant to the provisions of paragraph (3) of subdivision (b) of Section 14105.45.

~~(6)~~

(7) "Physician-administered drug" means any legend drug, nonlegend drug, or vaccine administered or dispensed to a beneficiary by a Medi-Cal provider other than a pharmacy provider and billed to the department on a fee-for-service basis.

~~(7)~~

(8) "Volume-weighted average" means the aggregated average volume for generically equivalent drugs, weighted by each drug's percentage of the 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 generically equivalent drugs.

(b) The department may reimburse providers for a physician-administered drug using either a Healthcare Common Procedure Coding System code or a National Drug Code.

(c) The Healthcare Common Procedure Coding System code rate of reimbursement for a physician-administered drug shall be equal to the volume-weighted average of the pharmacy rate of reimbursement for generically equivalent drugs. The

department shall publish the Healthcare Common Procedure Coding System code rates of reimbursement.

(d) The National Drug Code rate of reimbursement shall equal the pharmacy rate of reimbursement.

(e) Notwithstanding subdivisions (c) and (d), the department may reimburse providers for physician-administered ~~drugs~~ drugs, with the exception of blood factors, at a rate not less than the Medicare rate.

(f) Physician-administered drugs that are blood factors shall be reimbursed pursuant to the provisions of subdivision (b) of Section 14105.86.

~~(f)~~

(g) 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 this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

~~(g)~~

(h) (1) The rates provided for in this section shall be implemented commencing January 1, 2011, but only if the director determines that the rates comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(2) In assessing whether federal financial participation is available, the director shall determine whether the rates comply with the federal Medicaid requirements, including those set forth in Section 1396a(a)(30)(A) of Title 42 of the United States Code. To the extent that the director determines that a rate of reimbursement described in this section does not comply with the federal Medicaid requirements, the director

retains the discretion not to implement that rate and may revise the rate as necessary to comply with the federal Medicaid requirements.

~~(h)~~

(i) The director shall seek any necessary federal approval for the implementation of this section. To the extent that federal financial participation is not available with respect to a 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 the federal Medicaid requirements.

LEGISLATIVE COUNSEL'S DIGEST

Bill No.

as introduced, _____.

General Subject: Medi-Cal: pharmacy providers: drug reimbursement.

Existing law establishes 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 prohibits the reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs, as defined, from exceeding the lowest of either the estimated acquisition cost of the drug plus a professional dispensing fee or the pharmacy's usual and customary charge, as defined. Existing law, commencing April 1, 2017, requires the department to implement a new professional dispensing fee or fees consistent with a specified provision of federal law. Existing law requires the department to establish a list of maximum allowable ingredient costs (MAIC), as defined, for generically equivalent drugs, and requires these MAICs to be updated at least every 3 months.

This bill would modify the way in which reimbursement to Medi-Cal pharmacy providers is calculated by, in part, requiring the department to implement a drug ingredient cost reimbursement methodology based on actual acquisition cost, as defined, and, effective for dates of service on or after April 1, 2017, a dispensing fee that is based upon a pharmacy's total annual claim volume of the previous year, as specified. The bill would instead authorize the department to establish a list of MAICs for generically equivalent drugs, and would instead require the department to update the MAICs at least annually. The bill, effective for dates of service on or after April 1, 2017, would require existing adjustments to pharmacy drug product payments to no longer apply. The bill would revise the definition of "pharmacy wholesaler" and "wholesaler" for purposes of these provisions, and would correct an erroneous cross-reference. The bill would make conforming changes.

The bill would require the department to reimburse physician-administered drugs that are blood factors, as defined, at an amount that does not exceed 120% of the average sales prices of the last quarter reported.

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