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An act to amend Sections 14105.436 and 14105.86 of the Welfare and
Institutions Code, relating to Medi-Cal.



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THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14105.436 of the Welfare and Institutions Code is amended to read:

14105.436. (a) Effective July 1, 2002, all pharmaceutical manufacturers shall provide to the department a state rebate, in addition to rebates pursuant to other provisions of state or federal law, for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2 and reimbursed through the Medi-Cal outpatient fee-for-service drug program. The state rebate shall be negotiated as necessary between the department and the pharmaceutical manufacturer. The negotiations shall take into account offers such as rebates, discounts, disease management programs, and other cost savings offerings and shall be retroactive to July 1, 2002.

(b) The department may use existing administrative mechanisms for any drug for which the department does not obtain a rebate pursuant to subdivision (a). The department may only use those mechanisms in the event that, by February 1, 2003, the manufacturer refuses to provide the additional rebate. This subdivision shall become inoperative on January 1, 2010.

(c) For purposes of this section, "Medi-Cal utilization data" means the data used by the department to reimburse providers under all programs that qualify for federal drug rebates pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) or that otherwise qualify for federal funds under Title XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et seq.) pursuant to the Medicaid state plan or waivers. Medi-Cal utilization data excludes data from covered entities identified in



Section 256b(a)(4) of Title 42 of the United States Code in accordance with Sections 256b(a)(5)(A) and 1396r-8(a)(5)(C) of Title 42 of the United States Code, and those capitated plans that include a prescription drug benefit in the capitated rate and that have negotiated contracts for rebates or discounts with manufacturers.

(d) ~~Subdivision~~ Upon implementation of paragraphs (4) and (5) of subdivision (b) of Section 14105.33 for drugs pursuant to this section, subdivisions (a) and (c) shall become inoperative when the department implements paragraphs (4) and (5) of and “utilization data” shall be described pursuant to subdivision (b) of Section 14105.33. The department shall post on its Internet Web site a notice that it has implemented paragraphs (4) and (5) of subdivision (b) of Section ~~14105.33.~~ 14105.33 for drugs pursuant to this section.

(e) Effective July 1, 2009, all pharmaceutical manufacturers shall provide to the department a state rebate, in addition to rebates pursuant to other provisions of state or federal law, equal to an amount not less than 10 percent of the average manufacturer price based on Medi-Cal utilization data for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2.

(f) Pharmaceutical manufacturers shall, by January 1, 2010, enter into a supplemental rebate agreement for the rebate required in subdivision ~~(d)~~ (e) for drug products added to the Medi-Cal list of contract drugs on or before December 31, 2009.

(g) Effective January 1, 2010, all pharmaceutical manufacturers who have not entered into a supplemental rebate agreement pursuant to subdivisions ~~(d)~~ (e) and ~~(e)~~ (f) shall provide to the department a state rebate, in addition to rebates pursuant to other provisions of state or federal law, equal to an amount not less than 20 percent of



the average manufacturer price based on Medi-Cal utilization data for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2 prior to January 1, 2010. If the pharmaceutical manufacturer does not enter into a supplemental rebate agreement by March 1, 2010, the manufacturer's drug product shall be made available only through an approved treatment authorization request pursuant to subdivision ~~(h)~~: (i).

(h) For a drug product added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2 on or after January 1, 2010, a pharmaceutical manufacturer shall provide to the department a state rebate pursuant to subdivision ~~(d)~~: (e). If the pharmaceutical manufacturer does not enter into a supplemental rebate agreement within 60 days after the addition of the drug to the Medi-Cal list of contract drugs, the manufacturer shall provide to the department a state rebate equal to not less than 20 percent of the average manufacturers price based on Medi-Cal utilization data for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2. If the pharmaceutical manufacturer does not enter into a supplemental rebate agreement within 120 days after the addition of the drug to the Medi-Cal list of contract drugs, the pharmaceutical manufacturer's drug product shall be made available only through an approved treatment authorization request pursuant to subdivision ~~(h)~~: (i). For supplemental rebate agreements executed more than 120 days after the addition of the drug product to the Medi-Cal list of contract drugs, the state rebate shall equal an amount not less than 20 percent of the average manufacturers price based on Medi-Cal utilization data for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2.



14105.86. (a) For the purposes of this section, the following definitions apply:

(1) (A) "Average sales price" means the price reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. Sec. 1395w-3a).

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

(2) "Blood factors" means plasma protein therapies and their recombinant analogs. Blood factors include, but are not limited to, all of the following:

(A) Coagulation factors, including:

(i) Factor VIII, nonrecombinant.

(ii) Factor VIII, porcine.

(iii) Factor VIII, recombinant.

(iv) Factor IX, nonrecombinant.

(v) Factor IX, complex.

(vi) Factor IX, recombinant.

(vii) Antithrombin III.

(viii) Anti-inhibitor factor.

(ix) Von Willebrand factor.

(x) Factor VIIa, recombinant.

(B) Immune Globulin Intravenous.

(C) Alpha-1 Proteinase Inhibitor.



(b) The reimbursement for blood factors shall be by national drug code number and shall not exceed 120 percent of the average sales price of the last quarter reported.

(c) The average sales price for blood factors of manufacturers or distributors that do not report an average sales price pursuant to subdivision (a) shall be identical to the average manufacturer price. The average sales price for new products that do not have a calculable average sales price or average manufacturer price shall be equal to a projected sales price, as reported by the manufacturer to the department. Manufacturers reporting a projected sales price for a new product shall report the first monthly average manufacturer price reported to the federal Centers for Medicare and Medicaid Services. The reporting of an average sales price that does not meet the requirement of this subdivision shall result in that blood factor no longer being considered a covered benefit.

(d) The average sales price shall be reported at the national drug code level to the department on a quarterly basis.

(e) (1) Effective July 1, 2008, the department shall collect a state rebate, in addition to rebates pursuant to other provisions of state or federal law, for blood factors reimbursed pursuant to this section by programs that qualify for federal drug rebates pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) or otherwise qualify for federal funds under Title XIX of the federal Social Security Act (42 U.S.C. Sec. 1396 et seq.) pursuant to the Medicaid state plan or waivers and the programs authorized by Article 5 (commencing with Section 123800) of Chapter 3 of Part 2 of, and Article 1 (commencing with Section 125125) of Chapter 2 of Part 5 of, Division 106 of the Health and Safety Code.



(2) ~~Paragraph (1) shall become inoperative when the department implements~~
Upon implementation of paragraphs (4) and (5) of subdivision (b) of Section 14105.33,
14105.33 for blood factors pursuant to this section, “utilization data” used to determine
the state rebate shall be described pursuant to subdivision (b) of Section 14105.33. The
department shall post on its Internet Web site a notice that it has implemented
paragraphs (4) and (5) of subdivision (b) of Section ~~14105.33.~~ 14105.33 for blood
factors pursuant to this section.

(3) The state rebate shall be negotiated as necessary between the department and
the manufacturer. Manufacturers who do not execute an agreement to pay additional
rebates pursuant to this section shall have their blood factors available only through
an approved treatment or service authorization request. All blood factors that meet the
definition of a covered outpatient drug pursuant to Section 1927 of the federal Social
Security Act (42 U.S.C. Sec. 1396r-8) shall remain a benefit subject to the utilization
controls provided for in this section.

(4) In reviewing authorization requests, the department shall approve the lowest
net cost product that meets the beneficiary’s medical need. The review of medical need
shall take into account a beneficiary’s clinical history or the use of the blood factor
pursuant to payment by another third party, or both.

(f) A beneficiary may obtain blood factors that require a treatment or service
authorization request pursuant to subdivision (e) if the beneficiary qualifies for
continuing care status. To be eligible for continuing care status, a beneficiary must be
taking the blood factor and the department has reimbursed a claim for the blood factor
with a date of service that is within 100 days prior to the date the blood factor was



placed on treatment authorization request status. A beneficiary may remain eligible for continuing care status, provided that a claim is submitted for the blood factor in question at least every 100 days and the date of service of the claim is within 100 days of the date of service of the last claim submitted for the same blood factor.

(g) Changes made to the list of covered blood factors under this or any other section shall be exempt from the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), and shall not be subject to the review and approval of the Office of Administrative Law.



LEGISLATIVE COUNSEL'S DIGEST

Bill No.

as introduced, _____.

General Subject: Medi-Cal: supplemental drug rebates.

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.

Existing law provides for a schedule of benefits under the Medi-Cal program, which includes prescribed drugs subject to the Medi-Cal list of contract drugs. Existing law authorizes the State Department of Health Care Services to enter into contracts with manufacturers of single-source and multiple-source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category. Existing law requires these contracts to provide for a state rebate to be remitted to the department quarterly. Existing law also requires pharmaceutical manufacturers to provide to the department a state rebate for any drug products that have been added to the Medi-Cal list of contract drugs



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related to drugs used to treat AIDS and cancer. Existing law similarly requires the department to collect a state rebate for blood factors reimbursed by specified programs.

Existing law requires that the utilization data to determine these rebates exclude data from specified entities and certain capitated plans. The data exclusions became inoperative after the department took prescribed actions, and commencing July 1, 2014, utilization data used to determine the state rebates included data from all health plans, with specified exceptions. Existing law requires the department to develop coverage policies, in consultation with clinical experts, Medi-Cal managed care plans, and other stakeholders, for prescription drugs that the department reimburses managed care plans through separate capitated rate payments or other supplemental payments.

This bill would make inoperative specified provisions that set forth procedures for determining state rebates based on the obsolete data exclusions described above. The bill would correct erroneous cross-references and make other technical, nonsubstantive changes.

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

