

California Department of Health Care Services
Proposed May Revision Trailer Bill Language

**Mandatory Rebates on Drugs Used to Treat AIDS/AIDS-related Conditions and
Cancer Drugs**
Version: 5-22-09

Section 14105.436 of the Welfare and Institutions Code is amended to read as follows:

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.

~~—(c) In no event shall a beneficiary be denied continued use of a drug that is part of a prescribed therapy and that is the subject of an administrative mechanism pursuant to subdivision (b) until the prescribed therapy is no longer prescribed.~~

(c) “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 Title 42 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(5)(A) and 1396r-8(a)(5)(C), 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) 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.

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

(f) Effective January 1, 2010, all pharmaceutical manufacturers who have not entered into a supplemental rebate agreement pursuant to subdivisions (d) and (e), 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).

(g) For a drug product added to the Medi-Cal List of contract drugs pursuant to Section 14105.43 and 14133.2 on or after January 1, 2010 a pharmaceutical manufacturer shall provide to the department a state rebate pursuant to subdivision (d). 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 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. 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). 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.

(h) Notwithstanding any other provision of law, drug products of manufacturers who do not execute an agreement to pay additional rebates pursuant to this section, shall be available only through an approved treatment authorization request.

(i) For drug products added on or before December 31, 2009, a beneficiary may obtain a drug product that requires a treatment authorization request pursuant to subdivision (h) if the beneficiary qualifies for continuing care status. To be eligible for continuing care status, a beneficiary must be taking the drug product and the department has record of a reimbursed claim for the drug product with a date of service that is within 100 days prior to the date the drug product was placed on treatment authorization request status. A beneficiary may remain eligible for continuing care status, provided that a claim is submitted for the drug product 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 drug product .

(j) Changes made to the Medi-Cal list of contract drugs under this 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.