

DATE: July 27, 2021

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SUBJECT: Annual Report Required by Welfare & Institutions Code Section 14105.34

This memorandum serves as the annual report from the Department of Health Care Services (DHCS) for specified Medi-Cal pharmacy costs or Medi-Cal drug costs for State Fiscal Year 2019-2020. This annual report is mandated by Welfare & Institutions (W&I) Code Section 14105.34, which states:

- (a) The department shall provide for an annual written report of Medi-Cal pharmacy costs or Medi-Cal drug costs, as defined in subdivision (e) of Section 14105.31.
- (b) The annual report shall be consistent with the relevant sections of the Quarterly Report of Expenditures for the Medi-Cal Assistance Program, known as the CMS-64 Report, provided to the federal Centers for Medicare and Medicaid Services. The report shall include the following expenditure and receipt information:
 - (1) The total annual rebate amounts received by the department pursuant to agreements with the federal Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services.
 - (2) The total annual rebate amounts received pursuant to state contracts with drug manufacturers.
 - (3) Total drug cost amounts upon which rebate payments were made.

Overview

The federal Medicaid rebate is a mandatory payment made by drug manufacturers pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for all drug manufacturers wanting to have their Federal Drug Administration (FDA) approved drug covered by Medicaid programs. In California, this rebate applies to utilization occurring in all Medi-Cal delivery systems. The amount of rebate due for each unit of a drug is based on statutory formulas as follows:

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- <u>Innovator Drugs</u> the greater of 23.1 percent of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.
- <u>Blood Clotting Factors</u> the greater of 17.1 percent of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.
- <u>Drugs Approved by FDA Exclusively for Pediatric Indications</u> the larger of 17.1 percent of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on federal release date and current quarter AMP.
- <u>Line Extensions</u> For a drug that is a new formulation (line extension) of a brand name drug that is provided in an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:
 - The AMP for the line extension drug, the highest additional rebate for any strength of the original brand name drug, and the total number of units of each dosage form and strength of the line extension drug (section 1206 of the Health Care and Education Reconciliation Act of 2010, which replaced section 1927(c)(2)(C) as added by section 2501(d) of the Patient Protection and Affordable Care Act of 2010).
- <u>Cap on Total Rebate Amount for Innovator Drugs</u> The limit on the total rebate amount for each innovator drug is at 100 percent of the AMP.
- Non-innovator Drugs (Generics) 13 percent of the AMP per unit.

State supplemental rebates are additional rebates (over and above the federal Medicaid rebate) negotiated between states and manufacturers and are collected only on Medi-Cal fee-for-service and County Organized Health System plan utilization. W&I Code, Section 14105 provides the primary statutory authority to contract with drug manufacturers for state supplemental rebates. There is no requirement that drug manufacturers contract with a state for supplemental rebates; the program is voluntary. California shares all supplemental rebates collected with the federal government.

The annual report for this and ongoing years is posted on the DHCS <u>Pharmacy Benefits</u> <u>webpage</u>.

Attachment

California Department of Health Care Services Annual Medi-Cal Drug Cost and Rebate Report Required by Welfare & Institutions Code Section 14105.34 State Fiscal Year (SFY) 2019-20

Line 7 – Prescribed Drugs*			
	Title XIX	Title XXI	Total
Expenditures	\$ 2,821,883,525	\$ 196,953,541	\$ 3,018,837,066
Rebates**			
	TF	FF	GF
FF Federal Rebates	(\$2,490,327,450)	(\$1,705,079,397)	(\$785,248,053)
MCO Federal Rebates	(\$2,197,001,221)	(\$1,538,185,275)	(\$658,815,946)
State Supplemental Rebates	(\$155,768,512)	(\$118,801,546)	(\$36,966,966)
Total	(\$4,843,097,183)	(\$3,362,066,218)	(\$1,481,030,965)

Source: Data as of October 28, 2020, as reported quarterly to the federal Centers for Medicare and Medicaid Services on Line 7 of the CMS-64 Quarterly Expense Report

*Amounts shown under "Prescribed Drugs" represent only Fee-For-Service (FFS) spending prior to rebates and does not include any drug costs for managed care other than what is carved out of the managed care capitation rate. Managed care plans are capitated; therefore, actual expenditures on a per drug basis are not available.

**The federal rebate amounts reflect rebates collected for FFS, County Organized Health System (COHS) plan and Managed Care Organization (MCO) plan are combined utilization for MCO. State rebate amounts reflect rebates collected for both FFS and COHS plan utilization. Per State statute, with limited exception, state supplemental rebates are not collected on MCO plan drug utilization.