State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

DATE:

ALL PLAN LETTER XX-XXX

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: MEDICAID DRUG REBATE PROGRAM

PURPOSE:
The purpose of this All Plan Letter (APL) is to clarify for Medi-Cal managed care health plans (MCPs) the Medicaid Drug Rebate Program (MDRP) requirements and the MCPs' associated responsibilities. The requirements of the MDRP, outlined herein, apply to all MCPs contracted with the Department of Health Care Services (DHCS) to provide covered outpatient drugs under the Medi-Cal program.

BACKGROUND:
In 1991, the federal government initiated the MDRP to help offset federal and state Medicaid costs for outpatient prescription drugs. Title XIX, Section 1927 of the Social Security Act[1] (SSA) requires drug manufacturers participating in the Medicaid program to enter into a National Drug Rebate Agreement (NDRA)[2] with the Centers for Medicare & Medicaid Services (CMS) to pay rebates for drugs provided to Medicaid members. Rebate revenues are shared between states and the federal government.

Medi-Cal Fee-For-Service (FFS) pharmacy claims have been included in the MDRP since the program's inception. Although Physician Administered Drug (PAD) claims were always rebate eligible under the MDRP, the vast majority of PADs were not included until the passage of the Deficit Reduction Act (DRA) of 2005.[3] The DRA amended Title 42, Code of Federal Regulations (CFR), Section 447.520[4] to require states to collect the National Drug Code (NDC) on PAD claims in order for states to invoice manufacturers for rebates.

States became eligible to collect drug rebates for covered outpatient drugs dispensed to Medi-Cal members by Medi-Cal managed care organizations, including MCPs, with the

[1] 42 USCA 1396r-8.
[2] CMS-2397-FN updated NDRA on March 23, 2018
[3] Public Law 109-171 [Feb. 8, 2006].
[4] The Electronic Code of Federal Regulations is accessible at: https://www.ecfr.gov/cgi-bin/ECFR?SID=109e4ec90691b51122679c6299de4728&mc=true&page=browse

passage of the Patient Protection and Affordable Care Act (ACA)[5] on March 23, 2010.[6] The ACA made covered outpatient drugs subject to the same rebate agreement with the manufacturers participating in MDRP, for both, pharmacy-dispensed outpatient drugs and PADs. The ACA also requires MCPs to report the utilization of covered outpatient drugs[7] for both pharmacy-dispensed outpatient drug claims and PAD claims to DHCS.[8]

Pursuant to Section 1927(b)(2) of the SSA,[9] each State agency shall report to each manufacturer not later than 60 days after the end of each rebate period, which coincides with a calendar quarter. A drug manufacturer may assert a rebate claim dispute based on, but not limited to, erroneous units, use of generic substitutions, quantity outliers, 340B drug pricing program utilization, duplicate billings, terminated NDC, improper NDC/Healthcare Common Procedure Coding System (HCPCS) code combinations, etc.

The 340B drug pricing program is a federal drug discount program where drug manufacturers provide outpatient drugs at a reduced rate to eligible entities.[10] Federal law[11] prohibits duplicate discounts for a single drug. Accordingly drug manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug.

Pursuant to CMS guidance, states must have a mechanism in place to exclude utilization data for covered outpatient drugs subject to discounts under the 340B drug pricing program.[12] State Medicaid programs have the flexibility to determine how to identify 340B claims.[13] DHCS requires MCPs to use service-line claim-level identifiers to automatically exclude 340B drugs from being placed on a manufacturer's Medicaid drug rebate invoice. An MCP's failure to accurately identify the claim on an encounter submission may lead to a request for duplicate discount.

MCPs whose networks contain, or have contained, covered entities, as described by the 340B drug pricing program, must ensure that rebate claims are properly identified as such prior to submission to DHCS as part of the MCP's encounter data report to avoid requesting duplicate discounts.

---

[5] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010).
[6] Section 1903(m) of the SSA as amended by the ACA.
[7] As defined in 42 USCA 1396r-8(k)(2).
[8] CMS outlined these requirements in 42 CFR Section 438.3(s).
[9] 42 USCA 1396r-8(b)(2).
[10] 42 U.S.C. 256b
[11] ibid
[12] 42 CFR 438.3(s)(3).
[13] Federal Register / Vol. 81, No. 88 / Friday, May 6, 2016.

On March 5, 2010, Health Resources & Services Administration (HRSA) released the final rulemaking Notice regarding 340B Contract Pharmacy Services.[14] Unless a covered entity, its contracted pharmacies, and the state Medicaid agency have established an arrangement to prevent duplicate discounts, the Notice prohibits the covered entity and its contracted pharmacies from using drugs purchased under the 340B program to be dispensed to Medicaid members. In addition, the Notice stipulates that the covered entity must report any arrangement to prevent duplicate discounts to HRSA. If the covered entity does not utilize contract pharmacies, no such arrangement with the state Medicaid agency is required. DHCS incorporated this requirement into the California Medicaid State Plan for the Medi-Cal program (FFS and managed care) via State Plan Amendment 17-002.

POLICY:

REQUIREMENTS:
To ensure compliance with applicable federal law, accurately invoice mandated Medicaid rebates, and to minimize rebate disputes, MCPs are required to do the following:

1) **340B Encounters:** Complete and accurate claim-level identification of 340B drugs are essential to preventing duplicate discounts. In order to avoid duplicate discounts and ensure MCPs fulfill their obligation to submit complete, accurate, reasonable, and timely encounter data to DHCS, MCPs must have a mechanism in place to identify 340B claims when transmitted as encounters to DHCS.

    a. Encounters utilizing 340B-purchased covered outpatient drugs must be identified with the appropriate indicators as outlined in the most recent DHCS Companion Guide for X12 Standard File Format and Post Adjudication Payer sheet 2.2 or 4.2 for the National Council for Prescription Drug Programs standard file format.

    b. Pursuant to the California Medicaid State Plan, unless a covered entity, its contracted pharmacies, the MCO and DHCS have established an arrangement to prevent duplicate discounts, contract pharmacies are prohibited from using drugs purchased under the 340B program for Medicaid members.[15]
        i. The terms of the required arrangement must be formalized in the MCP's policies and procedures and approved by DHCS, prior to the

[14] Final Notice regarding Contract Pharmacy Services is published at 75 Fed. Reg. 10272 (Mar. 5, 2010)
[15] Supplement 2 of Section 4.19-B of the California State Plan

MCP allowing or initiating a 340B contract pharmacy arrangement within its provider network.

ii. The MCP's 340B contract pharmacy policies and procedures must be submitted to DHCS separate and apart from any other pharmacy or provider network related policies and procedures.

2) **Accurate NDC:** Require providers to use the drug's NDC found on the package, bottle, or container of the drug. MCPs must provide clear policy and guidance to its provider network to ensure the actual NDC administered/dispensed to the patient is submitted on the claim.

3) **Accurate Quantity:** Ensure the quantity billed on the pharmacy claim is consistent with the associated NDC. MCPs must provide clear policy and guidance to their provider network to ensure quantity accuracy. For example, if an inhaler contains 6.7 grams, then the quantity on the claim should reflect the same, i.e. 6.7 grams (1 inhaler) or 13.4 grams (2 inhalers).

4) **Rebate Resolution Liaison:** Identify a rebate liaison to work with the DHCS Drug Rebate Branch (DRB) to facilitate resolution of Medicaid drug rebate disputes. If the MCP's rebate liaison leaves the MCP or changes positions, the MCP must notify its DHCS Managed Care Operations Division (MCOD) contract manager and provide a replacement contact.

5) **Rebate Dispute Response:** Acknowledge the receipt of email notifications of Medicaid drug rebate disputes within five (5) business days. MCPs must make reasonable efforts to resolve rebate disputes in a timely manner, which will be based upon the complexity of the issue and the number of claims disputed by the drug manufacturer.

6) **Encounter Correction Submissions:** Require their providers to submit corrected encounter data whenever it is determined that the original data submitted was in error. The corrected encounter data must comply with current APLs, policies and regulations dealing with encounter data submission requirements; including, but not limited to the following:

- Consistent with APL 14-019, MCPs are required to submit complete, accurate, reasonable, and timely encounter data on at least a monthly basis. DHCS allows MCPs to submit on a more frequent basis if preferable.

- All managed care encounter data must be submitted through the DHCS Secured File Transfer Protocol (SFTP) site. DHCS has established SFTP accounts for each MCP and their identified personnel who are granted secure

access on the MCP's behalf. Each MCP has a set of two SFTP folders for Test and Production submissions that include a "Submit" folder and a "Response" folder. MCPs can submit encounter data files by saving them in the "Submit" folder where DHCS' system will automatically pick up the files for processing. Once a file has been successfully processed, DHCS' system will automatically remove the files from the "Submit" folder and DHCS will post a response file(s) to the "Response" folder as confirmation.

- MCPs must not change the SFTP folder structures in any way as this will disrupt file processing. Subsequent review and approval by DHCS is only required if changes are made to reporting of encounter data.

Repeated failure to submit complete, accurate, reasonable, and timely encounter data may result in a corrective action pursuant to Title 42, CFR, Section 438.606 and APL 17-005.[16] All data, information, and documentation submitted and certified pursuant to Title 42, CFR, Sections 438.604 and 438.606 and APL 17-005 are subject to audit.

MCPs must communicate the above requirements to all providers, delegated entities and subcontractors as appropriate. MCPs are responsible for ensuring that their delegates comply with all applicable state and federal laws and regulations, contract requirements, and other DHCS guidance, including APLs and Dual Plan Letters.

For questions regarding this APL, please contact your MCOD contract manager.

Sincerely,

Nathan Nau, Chief
Managed Care Quality and Monitoring Division

[16] APL 17-005 can be accessed at the following link:
http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2017/APL17-005.pdf