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 associated responsibilities. The requirements of the MDRP 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 (SSA)[1] requires drug manufacturers participating in the Medicaid program to enter into a contract 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.[2] The implementation of the DRA required the amendment to Title 42, Code of Federal Regulations (CFR), Section 447.520[3] to require states to collect the National Drug Code (NDC) on PAD claims in order for states to invoice manufacturers for rebates.

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

[1] Title XIX, Section 1927 of the SSA is codified in Title 42 United States Code (U.S.C.) section 1396r-8, available at: http://uscode.house.gov/browse/prelim@title42&edition=prelim
[2] Public Law 109-171 [Feb. 8, 2006] is available at: https://www.gpo.gov/fdsys/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf
[3] 42 CFR 447.520 at: https://www.ecfr.gov/cgi-bin/ECFR?SID=109e4ec90691b51122679c6299de4728&mc=true&page=browse

23, 2010, passage of the Patient Protection and Affordable Care Act (ACA).[4] The ACA made drug rebates eligible for both pharmacy-dispensed outpatient drugs and PADs. The ACA also requires MCPs to report to DHCS on the utilization of covered outpatient drugs[5] for both pharmacy-dispensed outpatient drug claims and PAD claims.[6]

Pursuant to Section 1927(b)(2) of the SSA,[7] each state agency must report to each manufacturer not later than 60 days after the end of each rebate period. The reporting periods coincide with a calendar quarter. A drug manufacturer may assert a rebate claim dispute based on, but not limited to, any of the following occurances: erroneous units, use of generic substitutions, quantity outliers, 340B drug pricing program utilization, duplicate billings, terminated NDCs, or improper NDC/Healthcare Common Procedure Coding System (HCPCS) code combinations.

The 340B drug pricing program is a federal drug discount program whereby drug manufacturers provide outpatient drugs at a reduced rate to eligible entities.[8] Covered entities, as defined by the 340B drug pricing program,[9] are prohibited from seeking reimbursement on drug sales that are also eligible for a Medicaid drug rebate. 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. This proper identification requirement is in place to avoid requests for duplicate discounts.

Pursuant to CMS guidance, MCPs must have in place a mechanism to exclude utilization data for covered outpatient drugs subject to discounts under the 340B drug pricing program.[10] CMS clarified that state Medicaid programs have the flexibility to determine how to identify 340B claims.[11] DHCS requires MCPs to use 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 a duplicate discount.

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[4] Patient Protection and Affordable Care Act; Public Law 111-148, SEC. 2501(c), is available at: https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf
[5] As defined in 42 U.S.C. 1396r-8(k)(2), available at: http://uscode.house.gov/browse/prelim@title42&edition=prelim
[6] CMS outlined these requirements in 42 CFR Section 438.3(s).
[7] Section 1927 of the SSA is codified in 42 U.S.C. 1396r-8(b)(2), available at: http://uscode.house.gov/browse/prelim@title42&edition=prelim
[8] Codified in 42 U.S.C. 256b, available at: http://uscode.house.gov/browse/prelim@title42&edition=prelim
[9] 42 U.S.C. 256b(a)(4), available at: http://uscode.house.gov/browse/prelim@title42&edition=prelim
[10] 42 CFR 438.3(s)(3), available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=730879294dca12e0dff483da728427a7&mc=true&node=se42.4.438_13&rgn=div8
[11] Federal Register / Vol. 81, No. 88 / Friday, May 6, 2016, available at: https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf

POLICY:

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

1) **340B Claims:** DHCS utilizes encounter data files for the purpose of collecting Medicaid drug rebates; therefore, MCPs are required to identify 340B claims. 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. Claim-level identification of 340B drugs is essential in preventing duplicate discounts, as required by federal law.

   340B Contract Pharmacies
   On March 5, 2010, the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, released the final rulemaking notice regarding 340B Contract Pharmacy Services.[12] Unless a covered entity,[13] 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 allowing drugs purchased under the 340B program to be dispensed to Medicaid members. In addition, the notice stipulates that the covered entity must report to HSRA on any arrangement to prevent duplicate discounts. If the covered entity does not utilize contract pharmacies, no such arrangement with the state Medicaid agency is required.

   Consistent with the above HRSA notice and the California Medicaid State Plan, the terms of the required arrangement must be formalized in the MCP's policies and procedures approved by DHCS prior to the MCP allowing or initiating a contract pharmacy arrangement within its provider network. The MCP's contract pharmacy policies and procedures must be submitted separate and apart from any other pharmacy or provider network related policies and procedures.

2) **Accurate NDC:** MCPs must require providers to use the drug's NDC found on its package, bottle, or container. MCPs must also ensure that a hospital's charge

[12] Federal Register /Vol. 75, No. 43, available at: https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf#page=1
[13] Covered entity definiton is codified in 42 U.S.C. 256b(a)(4) and is available at: http://uscode.house.gov/

description master database is accurate and corresponds to the NDCs in the provider's inventory.

3) **Accurate Quantity:** MCPs must ensure that the quantity billed on a pharmacy claim is consistent with the associated NDC. 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). The quantity on a PAD claim should be consistent with the HCPCS units. For example, if each HCPCS unit is 10 international units (IUs), then a 100 IU claim should be billed as a "quantity of 10."

4) **Rebate Resolution Liaison:** MCPs must identify a rebate liaison to work with the DHCS Drug Rebate Branch 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:** MCPs must respond to 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:** MCPs must submit corrected encounter data whenever DHCS or the MCP determines that the original data submitted was in error. The corrected encounter data must comply with current APLs dealing with encounter data submission requirements.

Encounter Data Submission Requirements
Consistent with APL 14-019[14] or any superseding letter, 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 its 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

[14] APLs are available at: http://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx

automatically remove the files from the "Submit" folder and DHCS will post response file(s) to the "Response" folder as confirmation. MCPs must not change the SFTP folder structures in any way, as this would disrupt file processing.

Repeated failure to submit complete, accurate, reasonable, and timely encounter data as required in Title 42, CFR, Section 438.606[15], and APL 17-005[16] or any superseding letter, may result in corrective action. All data, information, and documentation submitted and certified pursuant to Title 42, CFR, Sections 438.604[17] and 438.606, and APL 17-005 are subject to audit.

RECOMMENDATIONS:
In addition to the above policy requirements, MCPs can decrease the number of disputes by adhering to the following recommendations. MCPs should consider establishing claim edits to ensure the proper identification and quantities of drugs are accurately reported on encounter data. The following are steps MCPs should take to prevent common rebate claim disputes:

1) **PAD Procedure Codes:** MCPs should implement controls to ensure that the HCPCS procedure code is compatible with the NDC used on the claim. HCPCS billing units should comply with CMS' Table of Drugs, which establishes standardized billing units for specific HCPCS codes.

2) **Terminated NDC:** MCPs should ensure that formularies are updated to reject provider claims that include a terminated NDC. Providers should be required to correct the claim with the appropriate NDC.

MCPs must communicate the above requirements to all delegated entities and subcontractors. 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.

[15] 42 CFR 438.606 available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=36b6ba901937dddf9b31ca6a412b5b93&mc=true&node=pt42.4.438&rgn=div5#se42.4.438_1606
[16] APLs are available at: http://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx
[17] 42 CFR 438.604 available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=36b6ba901937dddf9b31ca6a412b5b93&mc=true&node=pt42.4.438&rgn=div5#se42.4.438_1604

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

Sincerely,

Nathan Nau, Chief
Managed Care Quality and Monitoring Division