



April 2, 2018

Jennifer Kent
Director
California Department of Health Care Services
1501 Capitol Avenue
Sacramento, CA 95814

Subject: Draft All Plan Letter 18-XXX - Medicaid Drug Rebate Program

Via e-mail: Jennifer.Kent@dhcs.ca.gov

Dear Director Kent:

The California Hospital Association (CHA), the California Children's Hospital Association, the California Association of Public Hospitals and Health Systems, Private Essential Access Community Hospitals, Inc., California Health+ Advocates and the District Hospital Leadership Forum appreciate the opportunity to comment on the Draft All Plan Letter (APL) 18-XXX on the Medicaid Drug Rebate Program (MDRP), published by the Department of Health Care Services (DHCS) on March 19, 2018. Notably, the APL provides clarification to all Medi-Cal managed care health plans (MCPs) about the reporting requirements needed to avoid duplicate discounts in the 340B Drug Discount Program. We appreciate that DHCS has identified a process to eliminate the risk of duplicate discounts, and we offer the following comments to ensure the 340B program's benefits continue to serve California's most vulnerable patients and communities.

Benefits of the 340B Program

Savings from the 340B drug discount program help safety-net hospitals and clinics preserve vital health care programs and services. The discounts providers receive from the pharmaceutical industry through the 340B program support providers' efforts to improve care for all patients, including offering specialized programs for some of our most vulnerable Medi-Cal populations who rely on safety-net providers. These services include:

- Extended hours of operation for community clinics and health centers
- HIV clinics that include a full range of health and mental health services for patients
- Hepatitis C clinics, which are safety-net centers of excellence that provide lifesaving, curative treatments for Medi-Cal patients
- Post-operative services, including "meds to beds" programs that allow patients to be discharged from major operations, such as cardiac surgeries or organ transplants, with critical medications needed for proper recovery and ensure that patients receive necessary follow-up with pharmacists
- Specialized treatments at infusion clinics, such as those provided to patients with congestive heart failure, hemophilia, multiple sclerosis and cancer

- Case workers for individuals experiencing homelessness and additional support staff to address complicated care needs
- Increased access to specialty care through expanded transportation services to patients without reliable transportation
- Expanded pharmacy access for Medi-Cal and uninsured patients so that pharmacies are available throughout local communities

340B Drug Discount Program versus Medicaid Drug Rebate Program

With bipartisan support, Congress created the 340B Drug Discount Program in 1992 to enable safety-net hospitals, community-based clinics and other providers that serve low-income, vulnerable patients to purchase outpatient medications at a discount from drug manufacturers. One year prior, the MDRP was initiated to help offset federal and state Medicaid costs for outpatient prescription drugs. Unlike the 340B program, the MDRP requires that states share the manufacturer rebates with the federal government. According to a recent report by the Legislative Analyst's Office¹, the state general fund was entitled to only \$1.3 billion of the \$4.1 billion in Medicaid drug rebates in 2017-18. In contrast, covered entities are able to retain 100 percent of the savings available through the 340B program, allowing them to expand health care services and programs that benefit the entire community and supporting the state's goal of ensuring Medi-Cal beneficiaries have access to high quality services.

The Affordable Care Act (ACA) amended the MDRP by requiring manufacturers to provide rebates for drugs dispensed to individuals enrolled in MCPs², but specifically excluded 340B MCP drugs from the rebate requirements³. Thus, **340B MCP drugs are not eligible for rebates**. This means that the duplicate discount provision in the 340B statute does not apply to 340B MCP drugs, because that provision only applies to 340B drugs that are subject to rebates. In sum, states have no authority to collect rebates on 340B MCP claims.

However, the 340B statute protects manufacturers from being subject to both a Medicaid rebate and a 340B program discount on 340B drugs that *are* subject to payment of a Medicaid rebate. The relevant provision states that a provider shall not purchase a drug through the 340B program that is "subject to the payment of a rebate to the state."⁴ This language applies to 340B fee-for-service (FFS) claims, as the statute does not exempt these claims from the states' rebate eligibility. Thus, covered entities have an obligation to follow the U.S. Department of Health and Human Services Secretary's guidance for preventing duplicate discounts for FFS claims.

With this in mind, we recommend amending the APL to clarify the federal differentiation between FFS and MCP drugs as follows:

The 340B drug pricing program is a federal drug discount program whereby drug manufacturers provide outpatient drugs at a reduced rate to eligible **covered** entities. **Federal law protects manufacturers from being required to provide both the 340B discount to a 340B covered entity and a Medicaid drug rebate to the state (a "duplicate discount").** ~~Covered entities, as defined by the 340B drug pricing program, are prohibited from seeking reimbursement on drug sales that are also eligible for a Medicaid drug rebate.~~ MCPs whose networks contain, or have contained,

¹ Legislative Analyst Office – *The Governor's Medi-Cal Proposal for the 340B Drug Pricing Program* (March 2018)

² 42 U.S.C. at §1396r-8(b)(1)(A).

³ Id. at §1396r-8(j)(1).

⁴ Id. at §256b(a)(5)(A)(i).

covered entities ~~participating in 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.

In addition, the ACA amendment to the MDRP that allows states to collect manufacturer rebates on MCP claims does not expressly allow MCPs to collect drug rebates. Therefore, we would recommend the following change to the APL:

~~States became eligible to collect rebates for covered outpatient drugs dispensed by~~ 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 23, 2010, passage of the Patient Protection and Affordable Care Act (ACA).

Claim-Level Identification of 340B Drugs

The APL includes the following reporting requirement for drugs purchased through the 340B program: 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.

Our understanding is that this requirement refers to the need for covered entities to apply a modifier (UD for physician administered claims and 20 for pharmacy claims) to all drugs purchased through the 340B program. In turn, the MCPs can identify those claims on the encounter data files to ensure the state does not claim a rebate. Assuming our interpretation is correct, we concur that this is a reliable way to avoid duplicate discounts and we recommend DHCS update the APL to convey this expectation more clearly. Absent such clarification, providers who are less familiar with the DHCS Companion Guide for X12 Standard File Format and Post Adjudication Payer sheets may not understand the expectation.

340B Contract Pharmacy Arrangements

Existing federal laws allow a covered entity, regardless of the availability of an in-house pharmacy, to contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients, provided the arrangement is in accordance with all other statutory 340B requirements. In addition, Health Resources and Services Administration (HRSA) guidance allows contract pharmacies to dispense 340B-purchased drugs to Medicaid patients only if "the covered entity, the contract pharmacy, and the state Medicaid agency have established an arrangement to prevent duplicate discounts." As confirmed in a 2016 Office of Inspector General report⁵, the HRSA requirement for an approved three-way agreement only applies to FFS drugs because it was developed before the ACA expanded the MDRP to include MCP drugs.

The APL appears to impose this requirement on 340B drugs dispensed to MCP patients, and implies that this requirement exists within the HRSA guidance and California Medicaid State Plan. Based on the OIG report, we disagree that there is a federal requirement that covered entities have approved three-way agreements in place prior to using contract pharmacies to dispense 340B purchased drugs to MCP patients.

⁵ Office of Inspector General - *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* (June 2016)

In addition, SPA 17-0002, Prescribed Drugs, has the following requirement under section 7.c:

A contract pharmacy, under contract with a 340B covered entity described in Section 1927(a)(5)(B) of the Social Security Act may only use 340B drugs to dispense Medicaid prescriptions if the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts as outlined in the HRSA Final Notice regarding Contract Pharmacy Services published at 75 Fed. Reg. 10272 (Mar. 5, 2010) and the details of that arrangement have been shared with HRSA.

As noted above, the HRSA requirements were published prior to the ACA expansion of the MDRP to include MCP drugs. Therefore, as confirmed by the OIG, the HRSA requirement — and arguably the approved SPA 17-0002 — are only applicable to FFS drugs. That said, we share DHCS' desire to prevent duplicate discounts on 340B drugs dispensed through contract pharmacies to MCP patients and offer the following suggestions:

- As noted above, the APL already requires that 340B entities and MCPs identify 340B claims using the appropriate indicators. We recommend that the same requirement apply to 340B drugs dispensed to MCP patients through contract pharmacies. This would eliminate the need for a three-way agreement between the covered entity, state and contract pharmacy.
- MCPs could contractually require 340B covered entities to comply with their policies and procedures to prevent duplicate discounts. We recommend that MCPs and 340B entities work together to identify any other processes and procedures that may be necessary to track claims appropriately.
- Partnership HealthPlan of California has proven that these methods for preventing duplicate discounts are effective, and has been using a model to flag 340B contract pharmacy claims since 2014. We recommend sharing the Partnership model broadly with other MCPs and covered entities that may be interested in adopting a similar system for preventing duplicate discounts.

In addition, we propose striking the language below, as the APL already requires 340B indicators that would prevent duplicate discounts:

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.⁶ Unless a covered entity,⁷ 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~~

⁶ Federal Register Vol. 75, No. 43

⁷ Covered entity definition is codified in 42 U.S.C. 256b(a)(4) and is available at <http://uscode.house.gov/>

~~separate and apart from any other pharmacy or provider network related policies and procedures.~~

Implementation Timeline

The 340B Drug Discount Program is a lifeline for vulnerable patients and local communities. California hospitals and clinics are committed to ensuring that the program's integrity is maintained and patients continue to have access to life-saving care. To that end, it is critical that DHCS allow ample time for MCPs to update policies and procedures and ensure that all information systems have the infrastructure in place to accurately capture 340B drugs before the encounter data is submitted to the state. We encourage DHCS to include an implementation timeline in the APL that allows for collaborative dialogue between all stakeholders.

We appreciate the opportunity to provide input on the draft APL, and look forward to continued collaboration on this important topic. If you have any questions, or would like to schedule a time to meet about this critical matter, please contact Amber Ott at (916) 552-7669.

Sincerely,

California Hospital Association
California Association of Public Hospitals and Health Systems
California Children's Hospital Association
California Health+ Advocates
District Hospital Leadership Forum
Private Essential Access Community Hospitals, Inc.

cc: Ms. Mari Cantwell, Chief Deputy Director, Health Care Programs
Ms. René Mollow, Deputy Director, Health Care Benefits & Eligibility
Mr. Nathan Nau, Chief, Managed Care Quality and Monitoring Division