December 14, 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) and the draft 340B Provider Bulletin, published by the Department of Health Care Services (DHCS) on November 15, 2018.

The 340B covered entity community appreciates and fully acknowledges that we are one component of a much larger Medi-Cal program — a program that, to best deliver the continuum of health care services Medi-Cal beneficiaries need and deserve, requires both the 340B program and the MDRP to be robust. Fully leveraging each of these programs relies upon strong partnerships and agreements between covered entities, health plans and the state. The draft APL aims to facilitate this cohesion by clarifying for all Medi-Cal managed care plans (MCPs) the reporting requirements needed to avoid duplicate discounts in the 340B program. We appreciate that DHCS has identified a process to eliminate the risk of duplicate discounts, and believe that covered entities working with health plans can achieve the state's requirements.

We believe the comments detailed below are aligned with the state's proposal. However, we suggest a few important modifications. First, MCPs should be required to participate in the flow of appropriate data, but should also have some flexibility in how they oversee the compliance obligations so long as they are meeting the state's objectives. In addition, further preventing duplicate discounts can absolutely be accomplished, but — in many cases — requires more time than point of service data submission allows. If the state submits its rebate request to the manufacturers in a quarterly fashion, covered entities and health plans should have sufficient time to ensure the data they submit to the state is accurate. Lastly, building reliable processes that can ensure data integrity require time; we request reasonable timeframes for MCPs and covered entities to work together to achieve the state's goals.

Benefits of the 340B Program

With bipartisan support, Congress created the 340B 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. The program has been deeply beneficial to California, as the savings from the 340B program help safety-net hospitals and clinics preserve vital health care programs and services for Medi-Cal beneficiaries. The discounts providers receive from the pharmaceutical industry through the 340B program help increase access to care by enabling providers to redirect these savings toward specialized programs for some of our most vulnerable Medi-Cal populations who rely on safety-net providers. For small and rural hospitals and community health centers (CHCs), savings from the 340B program can be the difference between continued operation and closure. Some of the services supported by 340B savings 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 Program Versus MDRP

Just as the covered entity community relies on 340B savings, we are fully aware that DHCS relies on rebates from the MDRP to support the Medi-Cal program. Ultimately, each program was developed to support safety-net providers and low-income communities. Through these comments and continued partnership, we intend to best leverage both programs for California and our respective patients.

It is important to note, as we develop the parameters for operation, that the Affordable Care Act amended the MDRP to require that manufacturers provide rebates for drugs dispensed to individuals enrolled in MCPs[1]; however, this amendment specifically excluded 340B MCP drugs from the rebate requirements[2]. We believe the exclusion of 340B was meant to ensure that the 340B program and the MDRP could operate simultaneously without conflicting. 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.

[1] 42 U.S.C. at §1396r-8(b)(1)(A).
[2] Id. at §1396r-8(j)(1).

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 Medicaid rebates. 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."[3] This language applies to 340B fee-for-service (FFS) claims, as the statute does not specifically exempt these claims from state 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 on FFS claims.

The 340B program extends the reach of precious health care dollars to best serve Californians. Hospitals and community clinics are committed to being good stewards of the 340B program, and support reporting modifications that strengthen program integrity, while also ensuring the long-term sustainability of the program. To that end, we offer the following comments to ensure that safety-net providers can implement the appropriate 340B changes and continue to serve California's most vulnerable patients and communities.

I. Draft APL 18-XXX Comments

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 "08" or "20" for pharmacy claims) to all drugs purchased through the 340B program. In turn, MCPs should 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 that DHCS update the APL to convey this expectation more clearly.** Absent such clarification, providers that 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 law allows 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 comply 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 (OIG) report[4], 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.

[3] Id. at §256b(a)(5)(A)(i).
[4] Office of Inspector General - *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* (June 2016)

The APL appears to require three-way agreements. However, we do not believe HRSA requires these agreements for 340B in Medicaid managed care, and **we request further conversation about their necessity.** We would like to explore opportunities to achieve the department's goals and ensure compliance, without this requirement.

As noted above, the HRSA requirements were published prior to the ACA's expansion of the MDRP to include MCP drugs. Therefore, as confirmed by the OIG, the HRSA requirement — and, therefore, the approved State Plan Amendment (SPA) 17-002 — are only applicable when 340B-purchased drugs are dispensed to Medi-Cal FFS beneficiaries.

As previously discussed, 340B covered entities strive to be good stewards of the program. We share DHCS' desire to prevent duplicate discounts on 340B drugs dispensed through contract pharmacies to MCP patients and offer the following suggestions:

- A covered entity, contract pharmacy and MCP must have an arrangement in place to prevent duplicate discounts prior to dispensing 340B drugs through a contract pharmacy.
- DHCS should work with covered entities, contract pharmacies and MCPs to develop template language for the arrangements. The arrangements will outline what is required of the covered entity, contract pharmacy and MCP to prevent duplicate discounts.
- While each MCP may have one or more model arrangement(s) in place with various covered entities to identify 340B drugs purchased through contract pharmacies, the arrangement(s) should include the requisite DHCS-approved template language. As a result, DHCS would not need to approve each individual arrangement. However, MCPs could be required to share all 340B arrangements with DHCS.
- The model arrangements must ensure that all encounter data MCPs submit to DHCS include the nationally approved claim modifier for 340B-purchased drugs. Covered entities should be allowed sufficient time to ensure the claim modifier is appended to the claim; meaning point of sale adjudication is not a requirement. If MCPs incur a cost to facilitate the capture and transfer of the 340B modifier, MCPs may not charge the covered entity more than those operational costs.
- A covered entity may choose not to dispense 340B-purchased drugs to Medi-Cal managed care beneficiaries through contract pharmacies (carve-out). In this case, DHCS would be entitled to claim the Medicaid rebates from the manufacturer and there would be no risk for duplicate discounts. For a covered entity to carve-out Medi-Cal managed care from contract pharmacies, MCPs must provide the bank identification number, processor control number and group numbers for all of their Medi-Cal managed care patients. Without this information, contract pharmacies and covered entities are unable to identify all of the Medi-Cal managed care claims and exclude them from the 340B program.

Payment Implications

As previously noted, the draft APL appears to imply the approved SPA 17-002 applies to both FFS and Medi-Cal beneficiaries. DHCS has clarified that the draft APL does not speak to managed care reimbursement of 340B drugs, but instead seeks to prevent duplicate discounts by appropriately identifying 340B drugs that are used in managed care arrangements. However, since the draft APL implies the approved SPA 17-002 applies to both FFS and managed care in the context of state-approved three-way arrangements with contract pharmacies, it is difficult not to presume that application extends to the restrictive billing and reimbursement components of Section 7. **We urge DHCS to clarify the draft**

APL and explicitly confirm that billing and reimbursement for 340B drugs dispensed to Medi-Cal managed care beneficiaries is outside the draft APL's purview, and that covered entities using contract pharmacies are not required to use only 340B-purchased drugs when dispensing drugs to Medi-Cal beneficiaries.

Implementation Timeline

The 340B program is a lifeline for safety-net providers that serve vulnerable patients, including nearly 14 million Medi-Cal beneficiaries. California hospitals and health centers are committed to maintaining program integrity and ensuring that 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. DHCS must also allow time to 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 recommend that the effective date be a minimum of six months from the final APL's publication date.**

II. Draft 340B Provider Bulletin Comments

SPA 17-002 Applicability to FFS

As previously stated, we disagree that SPA 17-002 applies to managed care delivery systems. We also disagree that Welfare and Institutions (W&I) code 14105.46 applies to managed care beneficiaries — in fact, DHCS confirmed that position in a 2009 communication.[5]

Based on DHCS' position, as outlined in that communication, covered entities have never billed nor been paid the actual acquisition cost of a 340B-purchased drug by MCPs outside of county-organized health system counties. Further, in 2016 the Centers for Medicare & Medicaid Services confirmed[6] that the actual acquisition cost billing and payment requirements of the Covered Outpatient Drug final rule only apply to the FFS population.

We urge DHCS to amend the draft provider bulletin to specify that billing and reimbursement of 340B drugs dispensed to Medi-Cal managed care beneficiaries is outside of the bulletin's scope.

Medicare Crossover Claims

The draft provider bulletin clarifies that — because drug manufacturers are liable for payment of rebates for claims when Medi-Cal pays any portion of the claim — 340B-purchased drugs must include the "08" or "UD" modifiers even when Medi-Cal is the secondary payer. Often, when Medi-Cal is the secondary insurance provider, it never makes a payment on the claim because the primary payer pays more than the Medi-Cal allowable amount. For example, if Medicare is the primary payer and there is a $100 co-pay billed to Medi-Cal as secondary, the Medi-Cal program will not pay the hospital $100 if Medicare already paid the hospital more than Medi-Cal would have allowed as the primary payer. In this scenario, Medi-Cal does not pay any portion of the claim, even though the beneficiary has Medi-Cal as secondary coverage. **We request that DHCS clarify whether the "UD" or "08" modifiers need to be appended in this scenario.**

[5] https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_10802.asp
[6] https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

We appreciate the opportunity to provide input on the draft APL and provider bulletin, and look forward to continued collaboration on this important topic. If you have any questions or would like to schedule time to meet about this critical matter, please contact Amber Ott, CHA group vice president, data and analytics, 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
Ms. Sarah Brooks, Deputy Director, Health Care Delivery System
Mr. Nathan Nau, Chief, Managed Care Quality and Monitoring Division