California Department of Health Care Services
Proposed Trailer Bill Legislation

Pharmacy Proposals

FACT SHEET

Issue Title: Pharmacy Proposals.

Background: Medi-Cal covers all drugs approved by the federal Food and Drug Administration (FDA), subject to medical necessity. On January 7, 2019, Governor Gavin Newsom issued Executive Order N-01-19 (EO-N-01-19) to consider options to maximize the state's bargaining power when negotiating drug purchases, to reduce state's drug spending and more broadly promote access to affordable health care.

A key component of EO N-01-19 requires the Department of Health Care Services (DHCS) to transition all Medi-Cal pharmacy services from managed care (MC) to fee for service (FFS) by January 1, 2021. Transitioning pharmacy services from MC to FFS will, among other things:

- Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system.
- Improve access to pharmacy services with a pharmacy network that includes approximately 97 percent of the state's pharmacies.
- Apply statewide utilization management protocols to all outpatient drugs.
- Strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers.

Additionally, EO N-01-19 requires DHCS to consider options to create significant negotiating leverage for the state to decrease prescription drug costs and improve access to medical necessary drugs.

California Best Price: Existing law defines "Best Price" as, **"**the negotiated price, or the manufacturer's lowest price available to any class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, that contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits, shall be based upon the manufacturer's commonly used retail package sizes for the drug sold by wholesalers to retail pharmacies." Federal law has a similar definition of Best Price (Social Security Act Section 1927(c)(i)(C)). These federal and state statutory authorities guarantee California's Medi-Cal program the lowest drug price that any manufacture offers to any entity in the US.

Rebates for Select Non-Medi-Cal Drug Purchases: Currently the Medi-Cal program, under the federal Medicaid Drug Rebate Program, collects both federal and state supplemental drug rebates. DHCS maintains the Medi-Cal Contract Drug List, which generally includes drugs for which there is a current state supplemental drug rebate agreement in place. To the extent there is no supplemental rebate agreement in place, the covered drug would be available subject to prior authorization establishing medical necessity.

CMS policy guidance provides states an opportunity to seek Medicaid State Plan authorization to secure prescription drug benefits, rebates, or discounts for non-Medicaid populations by linking such benefits to a Medicaid prior authorization program, and demonstrating that their inclusion furthers the goals and objectives of the Medicaid program, increases the efficiency and economy of the Medicaid program, and sufficiently benefits the Medicaid population as a whole.

Monthly Six Prescription Limit: The *monthly six prescription limit* was established in the FFS delivery system in 1994 with the intent to address inappropriate overuse of prescribed drugs.

Currently, the six prescription limit is the number of prescriptions that can be dispensed to a beneficiary during a month without obtaining a Treatment Authorization Request (TAR) to exceed the limit. If a drug is dispensed four times in a month, it counts as four of the six prescriptions. If a beneficiary needed that same drug, or any other drug, dispensed more than two additional times in that same month, it would require a TAR. The prescription limit does not apply to:

- Nursing facility patients
- Family planning drugs (for example, oral contraceptives)
- Claims that must be submitted on paper (claims with required attachments)
- Claims for newborns, where the baby uses the mother's identification number
- Drugs for the treatment of Acquired Immune Deficiency Syndrome (AIDS) or AIDS-related conditions
- Cancer drugs
- Drugs paid per authorized TAR for the period of time approved in the TAR
- Medical supplies do not count toward the prescription limit

Experience has shown that despite the prescription limit's original intent, the majority of cases of it being implemented have resulted in a tremendous administrative burden for providers and DHCS, rather than the hoped for significant reduction in inappropriate overuse of prescribed drugs. The Governor's Executive Order (EO) N-01-19 is expected to exacerbate this administrative burden and will result in a dramatic increase in the number of FFS pharmacy claims (and associated TARs) that must be processed each month. DHCS currently processes approximately one million pharmacy claims per month. Upon completion of the transition of managed care pharmacy services to FFS, it is estimated that DHCS will process over nine million pharmacy claims per month. Removal of this limit is a necessary component of making Medi-Cal Rx successful and achievable.

Medi-Cal FFS Drug Prescription Copayments: The *one dollar ($1) copayment for prescriptions and refills* has been in place since the beginning of the Medi-Cal program. However, W&I Code Section 14134(a) states that: 1) the copayment may be collected and retained, or waived by the provider; and 2) DHCS cannot reduce the reimbursement otherwise due to providers. In practice, this copayment is rarely collected due to these provisions.

Justification for the Changes:

California Best Price: As part of the Governor's Executive Order N-01-19, Medi-Cal Rx will be implemented on January 1, 2021, and will result in a dramatic increase in the number of beneficiaries receiving drugs via Medi-Cal's FFS delivery system (from the current approximately 2 million, to over 13 million individuals). This large increase will provide the state more leverage when negotiating with pharmaceutical manufacturers for state supplemental drug rebates. By amending state law to include drug pricing from foreign entities, DHCS may be able to negotiate even lower drug pricing than what it's currently receiving for the Medi-Cal program.

The infrastructure of the global pharmaceutical marketplace has resulted in pricing asymmetry, which occurs when US consumers or healthcare purchasers lack meaningful, verifiable information related to the true cost of drugs marketed by manufacturers to countries outside of the US (transparency). This asymmetry is foundational to high drug pricing and drug price inflation. The ability to easily understand and compare the cost of the same drugs available to purchasers/consumers outside of the US is integral to achieving lower drug costs in the Medi-Cal program.

Specifically, this portion of the proposal would:

- Expand the definition of "best price" to include a manufacturer's lowest price negotiated or available to foreign entities (W&I Code Section 14105.31(b)).
- Require the effective of date of the expanded definition be no sooner than January 1, 2021, and to implement only to the extent any necessary federal approvals are obtained and federal financial participation is available (proposed W&I Code Section 14105.31(i) and (j)).

Rebates for Select Non-Medi-Cal Drug Purchases: DHCS will explore options to leverage the state's purchasing volume to establish and administer a drug rebate program to collect rebate payments from drug manufacturers for drugs utilized by selected populations who are ineligible for full-scope Medi-Cal benefits.

Specifically, this proposal would:

- Require DHCS to seek necessary federal approvals to establish and administer a drug rebate program for selected populations consistent with the applicable requirements and procedures of the federal Medicaid Drug Rebate Program, upon approval of the Department of Finance (DOF).
- Require DHCS, in consultation with DOF, to determine the non-Medi-Cal populations to be included in the drug rebate program.
- Require DHCS to seek federal approvals from CMS and implement only to the extent that any necessary federal approvals are obtained and federal financial participation is available and not otherwise jeopardized.
- Authorize DHCS to implement, interpret, or make specific the drug rebate program, in whole or in part, by means of provider bulletins or other similar instructions, without taking regulatory action.

- Allow DHCS to enter into contractual arrangements or amend existing contracts, which are exempt from public contracting requirements and Department of General Services review and approval.
- Require the contracts to be confidential and exempt from disclosure under the California Public Records Act.

Eliminate Both the Medi-Cal FFS Monthly Six Prescription Limit and Medi-Cal FFS Drug Prescription Copays: DHCS proposes to eliminate the current six prescription limitation as well as the one dollar ($1) copayment for prescriptions and refills pharmacy policies in order to be consistent with efforts to reduce administrative burdens for beneficiaries and providers and ensure continuity of care. The proposal will also align with current practice guidelines and the desire to ensure medically appropriate services are provided in the right amount, at the right time as DHCS has other means that it can rely upon to maintain program integrity and to manage prescribing practices. This change will also allow DHCS to more effectively manage TARs that deal with more complex medications.

Specifically, this portion of the proposal would:

- Require the section governing the monthly six prescription limitation become inoperative on January 1, 2021, and subsequently repealed on July 1, 2021, unless a later enacted statute, enacted before that date, deletes or extends that date (proposed W&I Code Section 14133.22(f)).
- Remove the prescription copayment requirement for any prescription or refill and associated exclusions (W&I Code Section 14134(a),(a)(2), and (a)(7)).
- Authorize DHCS to implement, interpret, or make specific the removal of prescription copayments by means of policy letter, provider bulletin, or other similar instruction without taking regulatory action (proposed W&I Code Section 14134(d)).
- Require the effect date of removing prescription copayments to be no sooner than January 1, 2021, and implemented only to the extent any necessary federal approvals are obtained and federal financial participation is available (proposed W&I Code Section 14134(e) and (f)).

Summary of Arguments in Support:

- Creates parity of review and contracting requirements across all drug categories covered by Medi-Cal.
- Promotes lower drug prices and cost savings for the Medi-Cal program.
- Establishes a stronger negotiating framework with drug manufacturers to negotiate drug-pricing agreements commensurate with the state's purchasing power for residents who are ineligible for Medi-Cal.