

Date of Hearing: April 27, 2021

ASSEMBLY COMMITTEE ON HEALTH  
Jim Wood, Chair  
AB 1050 Gray – As Amended April 19, 2021

**SUBJECT:** Medi-Cal: application for enrollment: prescription drugs.

**SUMMARY:** Prohibits the Department of Health Care Services (DHCS) director from taking any action that materially increases the administrative burden or cost of dispensing 340B drugs by federally qualified health centers (FQHCs) and rural health clinics (RHCs), including, but not limited to, changes that adversely impact the use of contract pharmacy arrangements. Requires the DHCS director, before taking an action that materially impacts the 340B drug program, to prepare a detailed report describing the proposed action, including a determination that the action does not violate this provision. Requires the application for enrollment for Medi-Cal to include a statement that permits DHCS, the county welfare department, and a Medi-Cal managed care (MCMC) organization or health care provider to which the person is assigned to communicate with the applicant regarding appointment reminders or outreach efforts through Free to End User (FTEU) text messaging, unless the person opts out. Specifically, **this bill:**

- 1) Prohibits the DHCS director, notwithstanding any other law, from taking any action that materially increases the administrative burden or cost of dispensing 340B drugs by FQHCs and RHCs, including, but not limited to, changes that adversely impact the use of contract pharmacy arrangements.
- 2) Requires the DHCS director, before taking an action that materially impacts the 340B drug program, to prepare a detailed report describing the proposed action, including a determination that the action does not violate 1) above.
- 3) Requires the DHCS director to publish the report on DHCS' internet website and distribute it to the respective Assembly and Senate Health Committees.
- 4) Requires the application for enrollment for Medi-Cal benefits to include the following statement, in a conspicuous location:

“I agree that if I am approved to receive Medi-Cal benefits, the State Department of Health Care Services, the county welfare department, and a managed care organization or health care provider to which I am assigned may communicate with me regarding appointment reminders or outreach efforts at no more than a sixth grade reading level through Free to End User (FTEU) text messaging unless I opt out.”

- 5) Makes legislative findings and declarations that:
  - a) California's FQHCs and RHCs are essential partners with the state in providing a health care safety net for underserved, uninsured, and underinsured populations in a cost-effective manner;
  - b) California's FQHCs and RHCs generate significant savings to the state and to local communities by providing primary and preventive care that responds to patients' needs before medical problems become serious or life threatening, and by reducing the reliance

- of patients, including the uninsured and underinsured, on costly emergency room care, inpatient treatment, and specialty care;
- c) California's FQHCs and RHCs are critical to the community providers that serve low-income patients, and are more necessary than ever now as many of these Americans are also the hardest hit by the COVID-19 pandemic;
  - d) Supporting and ensuring the stability of California's FQHCs and RHCs, and their continued ability to provide pharmaceutical services, is necessary if California is to ensure access to health care services for the low-income and minority patients served by these health centers and clinics;
  - e) A substantial number of covered entities enrolled in the 340B discount drug purchasing program (340B program) are financially constrained and have to rely on contract pharmacies to access the program;
  - f) Forcing these clinics and health centers to convert their services to onsite pharmacies would result in a significant waste of taxpayer and community resources that could otherwise be devoted to patient care.
- 6) States legislative intent that no changes in the coverage of pharmacy services be made by DHCS that would undermine its ability to provide pharmacy services to California's low-income and minority patients.

**EXISTING LAW:**

- 1) Establishes the Medi-Cal program administered by DHCS, under which qualified low-income individuals receive health care services. Requires the purchase of prescribed drugs to be a covered Medi-Cal benefit, subject to the Medi-Cal Contract Drug List (the Medi-Cal CDL is generally the prescription drugs in fee-for-service [FFS] that are available without prior authorization) and utilization controls.
- 2) Establishes Medi-Cal FFS reimbursement rates for prescription drugs for Medi-Cal pharmacy providers, consisting of a professional dispensing fee (which varies based on volume), and a drug ingredient cost equal to the lowest of the actual acquisition cost (AAC), the federal upper limit (FUL) or the maximum allowable ingredient cost (MAIC).
- 3) Establishes, under federal law, the 340B discount drug purchasing program (340B program), which generally requires pharmaceutical manufacturers participating in Medicaid to give discounts on pharmaceutical drugs to covered entities, as defined, serving the Medicaid population.
- 4) Prohibits, under state law, a covered entity from billing an amount not to exceed the entity's actual acquisition cost for a 340B drug, as charged by the manufacturer at a price consistent with federal 340B, plus one of two different professional dispensing fee amounts.
- 5) Requires a covered entity to identify a 340B drug on the claim submitted to the Medi-Cal program for reimbursement.
- 6) Requires DHCS to establish, implement, and maintain a supplemental payment pool for non-hospital 340B community clinics, subject to an appropriation by the Legislature.

- 7) Requires DHCS, beginning January 1, 2021, and any subsequent fiscal year to the extent funds are appropriated by the Legislature for this purpose, to make available FFS-based supplemental payments from a fixed-amount payment pool to qualifying non-hospital 340B community clinics and the terms of federal approval.

**FISCAL EFFECT:** Unknown. This bill has not been analyzed by a fiscal committee.

**COMMENTS:**

- 1) **PURPOSE OF THIS BILL.** According to the author, FQHCs are true safety net providers serving the most vulnerable communities in California. They offer medical services in communities that face a lack of health insurance coverage, access to care, shortages of medical professionals, and elevated rates of poverty. Any cost saving measures adopted by the state must not jeopardize vital revenue sources made available by Congress expressly to help FQHCs stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The author concludes this bill allows the state to continue to explore drug pricing opportunities, while safeguarding the revenues that FQHCs currently rely on and are legally obligated to invest in the communities they serve.
- 2) **BACKGROUND - LEGISLATIVE ANALYST'S OFFICE REPORT (LAO) ON 340B.** In its 2018-19 Analysis of then Governor Brown's 340B Medi-Cal Proposal, the LAO provided an overview of the 340B Program. The federal 340B Drug Pricing Program, established in 1992, requires drug manufacturers to provide discounts on the outpatient prescription drugs they sell to certain eligible health care providers, referred to as "covered entities." There are various criteria that health care providers may meet in order to be designated as covered entities that are eligible for the 340B Program. Major health care providers that are generally eligible to participate in the program include certain hospitals that serve large numbers of low-income patients (including both the uninsured and Medicaid enrollees), certain rural hospitals and community health clinics, such as FQHCs. Under 340B, discounted prescription drugs are available to covered entities' patients regardless of payer. Under federal law, covered entities may dispense or arrange for the dispensing of 340B prescription drugs to their own patients, regardless of who ultimately pays for the prescription drugs. As such, the 340B discounts apply regardless of whether the covered entity is ultimately reimbursed for the dispensed prescription drugs by Medicaid, Medicare, commercial health insurance, or the patient. The 340B program provides significant discounts for covered entities. The 340B Program generally requires covered entities to receive prescription drug discounts that reduce the prices paid by a covered entity to at least the lower of (a) the best price offered to most public and private entities or (b) the average manufacturer sales prices minus a percentage of between 13% and 23.1% (depending on the type of the prescription drug).

Nationwide, the LAO indicated that the 340B program was estimated to have saved covered entities around \$6 billion in 2015. In 2015 (the most recent year for which the information was available to the LAO for their report), covered entities are estimated to have saved around \$6 billion on prescription drugs through the 340B Program. Net of the 340B discounts, covered entities are estimated to have spent over \$12 billion on 340B prescription drugs in 2015. Covered entities retain a portion of 340B savings. 340B savings result from the lower relative cost of 340B prescription drugs compared to non-340B drugs. Ultimately,

the LAO states that savings resulting from the 340B Program are likely shared by multiple participants in the health care system rather than entirely retained by covered entities themselves. Covered entities retain 340B savings by charging external payers of 340B prescription drugs—such as health insurers—prices that are higher than the 340B prices at which they acquired the drugs. The 340B Program does not place restrictions on how covered entities may use any retained savings. To the extent covered entities charge external payers lower prices for prescription drugs than they would have if the drugs had been purchased without the 340B discounts, then these external payers benefit from the 340B discounts as well.

- 3) **LAO DESCRIPTION OF 340B IN MEDI-CAL FFS vs. MCMC.** The LAO states that state law requires Medi-Cal to reimburse covered entities for 340B prescription drugs dispensed to Medi-Cal enrollees through the FFS delivery system at covered entities' actual acquisition costs plus a professional dispensing fee. Because actual acquisition costs for 340B drugs should at least roughly equal the 340B prices paid, covered entities should not be retaining savings under the 340B Program for prescription drugs dispensed to Medi-Cal enrollees through FFS. Instead, covered entities' 340B savings are passed onto the state (and shared with the federal government) in the form of lower reimbursement rates for the 340B prescription drugs dispensed to Medi-Cal enrollees within the FFS system.

The LAO states that paying for 340B prescription drugs in MCMC differs from FFS in a number of respects. Under a simplified model of the use of 340B prescription drugs in MCMC, a covered entity would, as under the FFS example above, purchase a prescription drug at its 340B price (\$10) directly from a drug manufacturer. The covered entity would then dispense the 340B drug to a patient with Medi-Cal coverage from an in-house pharmacy. Then, instead of submitting a claim for reimbursement to the state through FFS, the covered entity would bill the MCMC plan MCMC plan in which the patient is enrolled. The MCMC plan would then pay the covered entity (\$12.50) using funds it receives from the state in the form of ongoing per-member per-month payments (\$15). Provided the 340B drug is properly identified as a 340B drug and this information is conveyed to DHCS in a timely manner, Medi-Cal would not retroactively seek a Medicaid rebate on the drug from its manufacturer.

Unlike in Medi-Cal FFS, covered entities may receive reimbursement from MCMC plans for 340B prescription drugs that is higher than their actual (discounted) cost of acquiring the prescription drugs. This is because state and federal rules allow covered entities to bill MCMC plans for the 340B prescription drugs dispensed to their members at whatever reimbursement rates are agreed to between the particular covered entity and MCMC plan. MCMC plans, in turn, are funded by the state through per-member per-month payments that account for the prescription drug costs of the MCMC plans' members. Because a) MCMC plans' costs in paying for 340B prescription drugs can be higher than covered entities' costs in purchasing them and b) state payments to MCMC plans generally reflect MCMC plans' costs, the state may ultimately reimburse covered entities for 340B prescription drugs at higher than their 340B costs. The LOA points out that it is their understanding this is commonly the case in practice. This allows covered entities to retain savings through the use of the 340B Program in MCMC and increases Medi-Cal costs beyond what they would otherwise be. Under MCMC, information identifying that a 340B drug was dispensed is not always communicated to DHCS, potentially resulting in duplicate discounts.

- 4) **LAO DESCRIPTION OF “CONTRACT PHARMACIES” AND 340B.** The use of “contract pharmacies” in the 340B Program introduces additional complexity into how the 340B Program operates in relation to the Medicaid prescription drug rebate program. Contract pharmacies (used here used solely in the context of the 340B Program) are pharmacies that are owned and operated separately from a covered entity but who have a contract with a covered entity to dispense 340B prescription drugs on the covered entity’s behalf. Contract pharmacy arrangements occur in both Medi-Cal FFS and MCMC. (The LAO’s discussion of contract pharmacies below focuses on managed care because it is generally under managed care that covered entities and contract pharmacies can share in a portion of the 340B savings.) The use of contract pharmacies has increased significantly following federal guidance, released in 2010, that authorized their expanded use.

The LAO provides an example of how 340B contract pharmacy arrangement might work in MCMC. While covered entities’ arrangements with contract pharmacies vary, an example of how the use of a contract pharmacy in MCMC can work is as follows. The contract pharmacy purchases a prescription drug from a manufacturer at a negotiated sales price (\$13), which generally would be higher than the 340B price at which that drug would have been sold to a covered entity. A MCMC enrollee visits a covered entity for a medical appointment and obtains a prescription. The enrollee then visits the contract pharmacy, which dispenses the prescribed drug. Without identifying at the time of the transaction that the Medi-Cal enrollee was a patient of a contracted covered entity, the contract pharmacy would bill the enrollee’s MCMC plan at the customary non-340B prescription drug reimbursement rate (\$14) agreed to between the pharmacy and the MCMC plan. Later, the contract pharmacy and covered entity would review the pharmacy’s records to determine whether any prescription drugs were dispensed to patients of the covered entity. After it is determined that the Medi-Cal enrollee who obtained the prescription was a patient of the covered entity, the covered entity and the contract pharmacy would go through a reconciliation process with the manufacturer that effectively lowers the purchase price of the dispensed drug to its 340B price (\$10). According to DHCS, information indicating that the dispensed drug was reclassified as a 340B prescription drug is often not provided to DHCS in a timely manner to allow for the exclusion of the drug from the Medicaid drug rebate claims list sent to the drug’s manufacturer, raising the possibility of a duplicate discount.

- 5) **BACKGROUND ON MEDI-CAL PRESCRIPTION DRUG COVERAGE.** Outpatient prescription drug coverage is an optional benefit under federal law that all state Medicaid programs provide. California’s Medi-Cal program provides outpatient prescription drug coverage through MCMC plans for the approximately 10.6 million people enrolled in a MCMC plan. MCMC plans (with exceptions) typically contract with a pharmacy benefit manager (PBM) for administration of the pharmacy benefit.

Medi-Cal beneficiaries who are not enrolled in a MCMC plan receive their prescription drug coverage through FFS. In addition, certain drugs are “carved out” of the MCMC plan benefit (typically because of cost) and reimbursed through FFS. The carve out varies by MCMC model type and includes antipsychotics, certain cancer and HIV treatment and prevention drugs.

MCMC plans and their contracting PBMs determine pharmacy reimbursement for their enrollees for whom they provide drug coverage. In FFS, Medi-Cal pays pharmacies for two components: a) an amount to cover the estimated cost of the drug, known as the ingredient cost; and, b) an amount to cover the pharmacist’s overhead and services to fill the prescription, known as the dispensing fee. As a result of a change in federal law and regulation, the

dispensing fee and ingredient cost reimbursement was changed in Medi-Cal (described further below). The state had several options to determine the actual acquisition cost under federal guidance.

On January 7, 2019, Governor Gavin Newsom issued Executive Order N-01-19 with the stated purpose of achieving cost-savings for drug purchases made by the state. A key component of the Executive Order requires DHCS to transition all Medi-Cal outpatient pharmacy services from MCMC plans to FFS by January 1, 2021. DHCS arguments for Medi-Cal Rx were:

- a) Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system;
- b) Improve access to pharmacy services with a pharmacy network that includes the vast majority of the state's pharmacies and is generally more expansive than individual Medi-Cal managed care plan pharmacy networks;
- c) Apply statewide utilization management protocols to all outpatient drugs, as appropriate; and,
- d) Strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers as the largest Medicaid program in the state with approximately 13 million beneficiaries.

Originally proposed for implementation on January 2021, DHCS announced on February 17, 2021 that it was delaying the planned "go live" date of April 1, 2021 for Medi-Cal Rx because of the need to review new conflict avoidance protocols submitted by Magellan Health, the project's contracted vendor. In January 2021, Centene Corporation announced that it planned to acquire Magellan. Centene operates – through subsidiaries – managed care plans and pharmacies that participate in Medi-Cal. DHCS stated this transaction was unexpected and required additional time for exploration of acceptable conflict avoidance protocols to ensure that there will be acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal beneficiaries, and to protect other proprietary information. DHCS stated that Medi-Cal Rx remains of utmost importance to the State of California, and it anticipated providing further information in May. Prior to the delay, the Governor's Budget assumed savings from Medi-CalRx of \$612 million total funds (\$238 General Fund) in 2021-22 and on-going savings of \$1.1 billion total funds (TF) (\$407 million GF), with the bulk of the proposed savings coming from higher state supplemental rebates. The 340B fiscal components of the estimate includes savings on 340B drugs of \$147 million TF (\$74 million) in 2021-22 and \$147 million TF on-going (\$74 million GF), and additional costs resulting from the supplemental payment program of \$105 million TF (\$53 million GF) in 2021-22 and on-going.

When Medi-CalRx is implemented, the state will no longer provide outpatient prescription drug coverage through MCMC plans, and the current FFS requirements applicable to prescription drugs generally and to 340B will apply. This shift affects the extra revenue 340B covered entities obtained when the drugs were being reimbursed through MCMC plans.

- 6) **SUPPLEMENTAL PAYMENT POOL.** Non-hospital 340B clinics that currently receive reimbursement from MCMC plans for pharmacy services will begin billing Medi-Cal FFS at their acquisition cost, which will result in savings to the state. To mitigate the revenue impact to these 340B clinics, the Governor proposed and Legislature established via the health budget trailer bill (AB 80, Ting Chapter, 12, Statutes of 2020) a supplemental payment pool

for non-hospital 340B clinics. The supplemental payment pool for non-hospital 340B clinics was a part of the Governor's 2020-21 Budget. The enacted state budget included \$52.5 million (\$26.3 million General Fund) in 2020-21 to provide supplemental payments to specified non-hospital clinics who participated in the federal 340B pharmacy program. These payments were intended to grow to \$105 million (\$52.5 million General Fund) in 2021-22 and annually thereafter. These payments are intended to support their overall safety net services that might otherwise be limited or eliminated due to the change in billing to a FFS delivery system. Per the requirements of the trailer bill, DHCS convened a stakeholder workgroup to develop the methodology for the distribution of supplemental pool payments to qualifying non-hospital 340B community clinics. The workgroup topics include the eligibility criteria for receipt of supplemental payments, the aggregate amount of pool funding available in a respective fiscal year, and the criteria for apportioning the pool funding among qualifying non-hospital 340B community clinics including the timing, frequency, and amount of the resultant supplemental payments. Because Medi-Cal Rx has not taken effect, no 340B supplemental payments have been made.

- 7) **SUPPORT.** This bill is sponsored by the Community Health Center Alliance for Patient Access (Alliance) and the Central California Partnership for Health and supported by FQHCs which argue that unless steps are taken to ensure protection of FQHCs, the state's plan to "carve out" Medicaid prescription drugs will hurt safety net providers that participate in what's known as the 340B program. This program allows providers to purchase prescription drugs at a discounted price, which in turn allows them to provide more clinically integrated services as well as to provide important medical intervention programs that combat homelessness, substance abuse and opioid addiction. Without protections for FQHCs, the result will be more clinically fragmented and haphazard care to minority and low-income Californians, and fewer services to these populations hardest hit by the the pandemic that has claimed the lives of over 60,000 Californians. The Alliance argues that, unless the Legislature ensures that Medi-Cal Rx will not be implemented in a manner that forces them to replace less costly contract pharmacy arrangements with significantly more costly on-site pharmacies, and that fails to reimburse their costs for on-site pharmacy services, FQHC's administrative costs and burdens will be dramatically increased, as well patient non-compliance and the attendant avoidable outpatient, specialty and inpatient visits. This will inevitably cause significant disruption in care to lower-income and minority Californians without any real financial benefit to California. The Alliance writes that, while DHCS' current budget assumptions estimate General Fund savings of \$174 million over FY 2020-21 and FY 2021-22, these assumptions do not take into account costs associated with the disruption of clinical care, increased patient non-compliance with respect to fulfillment of prescriptions, and discontinuation of programs currently funded by drug manufacturers through the 340B program, instead of through taxpayer dollars. California's health centers cannot absorb these losses without a dramatic and negative impact on their ability to provide health care to California's minority and low-income communities.

Supporters also argue the savings on medications purchased through the 340B program are by law and mission utilized by FQHCs to support operations and invest in meaningful programs and services that increase access to care. Unless modified by this bill, the program in California will move those savings out of disadvantaged communities and into the state's coffers. The state's Medi-Cal Rx transition plan aims to lower drug prices by leveraging the state's buying power, but without any significant impact on manufacturers or for-profit pharmacies. Instead, it requires FQHCs to forfeit one of the limited resources available to

support their efforts in the communities they serve —participation in 340B. The Alliance concludes that, while it wholeheartedly support efforts to lower exorbitant drug prices, it should not at the expense of historically underserved communities that depend on services made possible by the 340B program.

## 8) POLICY ISSUES.

- a) **Timing unclear.** Medi-Cal Rx was scheduled for implementation on January 1, 2021, was postponed till April 1, 2021 and a subsequent implementation date has not been announced until DHCS is satisfied with the conflict of interest policy submitted on the issue. However, because this bill does not have an urgency clause, it is unclear if would achieve its goal of not adversely affecting FQHCs participating in the 340B program if it takes effect after Medi-CalRx has been implemented.
- b) **How should the state address the loss of revenue resulting from the transition to Medi-CalRx to clinics that are 340B covered entities?** The supplemental payment fund established as part of the budget was intended to partially backfill the loss of 340B revenue from one segment of the 340B covered entities (clinics) but not other 340B entities (such as hospitals clinics). After implementation, multiple entities expressed interest in receiving funds from the supplement payment fund, including entities that had not submitted data that was used as the basis to establish the dollar size of the fund. The approach taken by this bill is to prohibit DHCS from taking any action that materially increases the administrative burden or cost of dispensing 340B drugs by FQHCs and RHCs, including, but not limited to, changes that adversely impact the use of contract pharmacy arrangements. If enacted prior to implementation of Medi-Cal Rx, this language would appear to effectively prevent implementation of Medi-CalRx. Another approach being pursued through the budget process to address the loss of the 340B revenue to FQHCs and RHCs is to increase the amount of the supplemental fund by \$50 million GF.

## REGISTERED SUPPORT / OPPOSITION:

### Support

Community Health Center Alliance for Patient Access (sponsor)  
 Central California Partnership for Health (sponsor)  
 Avenal Community Health Center  
 Camarena Health  
 Clinicas De Salud Del Pueblo, Inc.  
 Community Health Centers of The Central Coast  
 Desert AIDS Project D/b/a DAP Health  
 Eisner Health  
 Family Health Centers of San Diego  
 Gardner Family Health Network, Inc.  
 Golden Valley Health Centers  
 LA Maestra Family Clinic Inc.  
 Lifelong Medical Care  
 Mendocino Community Health Centers  
 North County Health Services

North East Medical Services  
Omni Family Health  
Ravenswood Family Health Network  
San Ysidro Health  
Shasta Community Health Center  
Shingletown Medical Center  
Vista Community Clinic  
Wellspace Health

**Opposition**

None on file.

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