November 26, 2019

TO: Honorable Members of the Board of Supervisors
    Jeffrey V. Smith, M.D., J.D., County Executive

FROM: Rene G. Santiago, Deputy County Executive and
      Director, County of Santa Clara Health System
            Rene G. Santiago
            DocSigned by: A988A387F21F4003

      Paul E. Lorenz, Chief Executive Officer
            DocSigned by: 47E4FC3A58342B89
      Santa Clara Valley Medical Center

SUBJECT: Off Agenda Report Related to Impact of California Change in the 340B Drug Pricing Program

Under advisement from the Health and Hospital Committee (HHC) meeting of September 25, 2019 (per agenda item no. 7, ID # 98443), Supervisor Ellenberg requested that the Administration provide an off-agenda report on the Governor’s Executive Order changing the California 340B Drug Pricing Program and the estimated impact on the County of Santa Clara Health System and community clinics. The requested information is provided below.

The 340B Drug Pricing Program was passed by Congress in November 1992. The program requires drug manufacturers to provide drugs to certified 340B covered entities at discounted prices. Those covered entities then are either reimbursed at higher rates or provided dispensing fees that produce “savings” they can utilize to provide additional services to vulnerable patient populations. According to congressional report language, the savings are intended to enable covered entities, “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

The 340B Program requires pharmaceutical manufacturers to enter into pricing agreements with the Federal Health and Human Services Secretary to have drugs covered by the Medicare and Medicaid programs. In addition, 340B Drug Pricing is extended to “covered entities”, including disproportionate share hospitals (DSHs) and federally qualified health centers (FQHCs) among others, for outpatient and inpatient hospital service medications. To participate in the 340B program, covered entities must register, be enrolled and comply with all program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors must verify before allowing an organization to purchase discounted drugs. Covered entities must complete the recertification process every year. Two specific criteria are common to most of the 340B-eligible hospital types: the requirement for a "DSH adjustment percentage" above a certain level; and the requirement that the hospital: (a) be owned or operated by a state or local

---

1 Health Resources & Services Administration (HRSA) 340B Drug Pricing Program
   https://www.hrsa.gov/opa/index.html
government; (b) be a private nonprofit hospital "formally granted governmental powers" by a state or local government; or (c) be a private nonprofit hospital with a contract with a state or local government to provide care to low-income individuals who are not eligible for Medicare or Medicaid.

There is no government funding in the 340B Drug Pricing Program. The discounts are provided by the pharmaceutical industry to 340B covered entities. The savings produced by these discounts helps ensure covered entities that treat a disproportionate share of low-income patients are able to provide lifesaving medications and treatments. The 340B Program is a key component of the County’s and the nation’s health care safety nets.

The rising cost of pharmaceuticals had led to federal interest in imposing new requirements on the 340B Program and increase oversight. While the federal legislative efforts have stalled, there has been different but related attention to the 340B Program at the State level.

At the State level, two efforts are being implemented through Governor Newsom’s Executive Order (Executive Order N-01-19 signed Jan 7, 2019) that would significantly impact safety-net hospitals and community clinics in our County which currently utilize the 340B program to purchase discounted drugs.² ³

The executive order includes the following two (2) provisions:

1. **Department of Health Care Services (DHCS) directed to transition Medi-Cal pharmacy services from a Medi-Cal managed care benefit to a fee-for-service (FFS) benefit by January 1, 2021.**

   By January 1, 2021, this provision would transition Medi-Cal pharmacy services for Medi-Cal managed care to FFS), whereby the state would oversee all Medi-Cal patients’ pharmacy benefits. The state would negotiate pricing and purchasing of prescription drugs.

   In late August, in response to the Governor’s Executive Order (N-01-19), DHCS released a request for proposal (RFP) seeking a contractor to provide administrative services for managing the FFS pharmacy benefit. Request for Proposal (RFP) #19-96125 solicits proposals for the takeover, operation and eventual turnover of administration of the Medi-Cal FFS pharmacy services.⁴ DHCS awarded the contract to Magellan Medicaid Administration, Inc. last week.

2. **State Department of General Services directed to implement a bulk purchasing arrangement** for high-priority drugs. The program is intended to be accessible to public and private payers, and local governments are encouraged to participate.

---

² Governor of California’s Executive Order N-01-19


⁴ Department of Health Care Services, Medi-Cal RX Request for Proposal #19-96125
https://www.dhcs.ca.gov/provgovpart/rfa_rfp/Pages/CSBmcrxHome.aspx
Through these changes, the State believes it will contain costs, make prescription drugs more affordable, and create negotiating leverage to generate annual savings to the State. The State reports that the shift, directed by the Executive Order, could result in hundreds of millions of dollars in savings for the State annually. However, this estimate is debated, and some believe that savings incurred by the state government may essentially take money away from safety net providers and that savings would flow to the state, as the purchaser of the drugs. 5,6

**Statewide impact on safety-net hospitals and community clinics**

Movement of the pharmacy benefit out of managed care and into fee-for-service would significantly reduce prescription drug revenues for safety net providers participating in the 340B program. In addition, group purchasing is not permissible for disproportionate share hospitals while participating in the 340B program.

If enacted, the Governor’s pharmacy proposal would result in an estimated $240 million annual loss for public health care systems statewide that participate in the 340B Drug Discount Program. The California Primary Care Association estimates that the cost to community health clinics statewide is approximately $150 million and will leave a gap in budget for essential services. 5 In turn, eliminating savings from the drug discount program will impact essential drugs and services safety net hospitals are able to provide their vulnerable populations.

**Local impact on County of Santa Clara Health System**

It is estimated that the projected financial impact as a result of transitioning Medi-Cal pharmacy services from Medi-Cal managed care to FFS, based on CY2018 Data, would be a loss of over $30 million in revenue to Santa Clara Valley Medical Center (SCVMC) annually.

For County of Santa Clara Health System, the executive order would decrease the 340B benefit and reduce supplemental payment rates and the overall managed care rate. These changes would widen the gap in covering costs and prevent investment in services otherwise unavailable to our patients.

**Local impact on community health clinics**

Community Health Partnership (CHP), in a September 25, 2019 memo, expressed to the County Executive’s Office that there would be a significant revenue loss for some of the community health clinics as a result of the governor’s Executive Order. In a September 10, 2019 letter sent from CHP to state legislators, and a Congressional letter from our California representatives to Governor Newsom on behalf of Community Health Centers Statewide, concerns were expressed that a transition from pharmacy benefit services to fee for service would deprive community health centers of savings and a vital revenue stream used to support coordinated systems of care and critical safety net systems for the poor - precisely those the Governor purports to be helping.

CHP reports an annual impact of $8.8 million across the 3 clinics in Santa Clara County impacted at this time. This estimation reflects Medi-Cal only patients and does not include potential impact related to Medicare patients.

---

5 Politico: “Senate health chair: Newsom drug plan could hurt clinics, safety-net hospitals”

6 Legislative Analyst’s Office (LAO) Report: Analysis of the Carve Out of Medi-Cal Pharmacy Services from Managed Care
In addition, according to CHP, the Menges Group, who conducted a preliminary assessment on the 340B program, reported that thousands of clinic staff positions, statewide, would be eliminated along with primary care and prevention services and programs; programs and services that provide free or discounted prescription drugs, expanded access to healthcare, workforce development, quality improvement, patient navigation and case management, and other services that address Social Determinants of Health that would, otherwise, have no source of funding.7

**Current status**

Under current state law, DHCS has authority to effectuate the transition of Medi-Cal pharmacy services coverage from managed care to a FFS benefit.

In response to concerns that impacted organizations have had little input into the process thus far, the Newsom Administration recently announced it is soliciting applications for a “Medi-Cal RX Advisory Workgroup” that will meet from January 2020 through April 2021. To date, an impact analysis has not been conducted nor have the revenue losses that will be experienced by safety net providers been addressed by DHCS.

The Legislative Analyst’s Office (LAO) has analyzed the proposal and has shared their recommendations, including that the legislature withhold implementation funding until the state provides key information that adequately answers major outstanding questions such as (1) how the transition will be implemented and (2) how the administration believes it will affect Medi-Cal spending and stakeholders.6

The report concurs that the pharmacy transition would having major and disparate impacts on key Medi-Cal stakeholders, including enrollees, pharmacies, health care providers, and Medi-Cal managed care plans, information yet to be released by the state. The same conclusion was reached by the Menges Group, who conducted an assessment on the proposal. In their assessment, they reported that the pharmacy carve-out model inherently diminishes the integrated health system of coverage being delivered to California most vulnerable residents. The report also notes that the cost reduction is debatable but that there is overwhelming evidence that the pharmacy carve-out will diminish Medi-Cal’s ability to achieve 3 critical components – effective drug mix management, optimal integration and coordination across pharmacy and medical services, and robust access and adherence support mechanisms - all essential to this population.7

The LAO has outlined the opportunity and role for the Legislature to determine whether and how Medi-Cal pharmacy services are delivered going forward, given that the Governor’s action also involves costs and policy trade-offs.

---