



19-0025

Amdt. # 1

December 13, 2019

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INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Hon. Xavier Becerra
Attorney General
1300 I Street, 17th Floor
Sacramento, California 95814

Attention: Ms. Anabel Renteria
Initiative Coordinator

Dear Attorney General Becerra:

Pursuant to Elections Code Section 9005, we have reviewed the proposed statutory initiative (A.G. File No. 19-0025, Amendment #1) related to chronic dialysis clinics.

BACKGROUND

Dialysis Treatment

Kidney Failure. Healthy kidneys filter a person's blood to remove waste and extra fluid. Kidney disease refers to when a person's kidneys do not function properly. Over time, a person may develop kidney failure, also known as "end-stage renal disease." This means that the kidneys no longer function well enough for the person to survive without a kidney transplant or ongoing treatment referred to as "dialysis."

Dialysis Mimics Normal Kidney Functions. Dialysis artificially mimics what healthy kidneys do. Most people on dialysis undergo hemodialysis, a form of dialysis in which blood is removed from the body, filtered through a machine to remove waste and extra fluid, and then returned to the body. A hemodialysis treatment lasts about four hours and typically occurs three times per week.

Most Dialysis Patients Receive Treatment in Clinics. Individuals with kidney failure may receive dialysis treatment at hospitals or in their own homes, but most receive treatment at chronic dialysis clinics (CDCs). About 600 licensed dialysis clinics in California provide treatment to roughly 80,000 patients each month. Given patients' frequent need for dialysis and the length of individual treatments, clinics often offer services six days per week and often are open after typical business operating hours.

Patients Are Referred for Dialysis by Their Own Doctors. Physicians, typically nephrologists (specialists in kidney care), develop a plan of care for patients with kidney failure, including ongoing management of the disease. If the physician recommends dialysis, the plan of care will include a prescription for very specific aspects of the dialysis treatment, such as

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duration, frequency, and medications. Under Medicare rules for outpatient dialysis (see below for more information about the role of Medicare in treating patients with kidney failure), the physician (or specified representative) must visit the patient during dialysis at least once per month. Accordingly, CDCs provide treatment that is prescribed by a patient's physician who remains responsible for the overall care of that patient.

Various Entities Own and Operate CDCs, With Two Entities Owning/Operating the Vast Majority of Them. Two private for-profit companies—DaVita, Inc. and Fresenius Medical Care—are the “governing entity” of nearly three-quarters of licensed CDCs in California. (The measure refers to the governing entity as the entity that owns or operates the CDC.) The remaining CDCs are owned and operated by a variety of nonprofit and for-profit governing entities. Some of these other governing entities have many CDCs in California, while others may own or operate a single CDC. Currently, the vast majority of CDCs' earnings exceed costs, while a relatively small share of CDCs operate at a loss. Because most CDCs are owned and operated by a governing entity that owns and operates multiple clinics, a particular governing entity's higher-earning CDCs help subsidize its CDCs that operate at a loss.

Paying for Dialysis Treatment

Payment for Dialysis Treatment Comes From a Few Main Sources. We estimate that CDCs have total revenues of more than \$3 billion annually from their operations in California. These revenues consist of payments for dialysis treatment from a few main sources, or “payers”:

- ***Medicare.*** This federally funded program provides health coverage to most people age 65 and older and certain younger people who have disabilities. Federal law generally makes people with kidney failure eligible for Medicare coverage regardless of age or disability status. Medicare pays for dialysis treatment for the majority of people on dialysis in California.
- ***Medi-Cal.*** The federal-state Medicaid program, known as Medi-Cal in California, provides health coverage to low-income people. The state and the federal government share the costs of Medi-Cal. Some people qualify for both Medicare and Medi-Cal. For these people, Medicare covers most of the payment for dialysis treatment as the primary payer and Medi-Cal covers the rest. For people enrolled only in Medi-Cal, the Medi-Cal program is solely responsible to pay for dialysis treatment.
- ***Group and Individual Health Insurance.*** Many people in the state have group health insurance coverage through an employer or another organization (such as a union). Some people without group health insurance purchase health insurance individually. Group and individual health insurance coverage is often provided by a private insurer that receives a premium payment in exchange for covering the costs of an agreed-upon set of health care services. When an insured person develops kidney failure, that person can usually transition to Medicare coverage. However, federal law requires that a group insurer remain the primary payer for dialysis treatment for a “coordination period” that lasts 30 months.

The California state government, the state's two public university systems, and many local governments in California provide group health insurance coverage for their current workers, eligible retired workers, and their families.

Group and Individual Health Insurers Typically Pay Higher Rates for Dialysis Than Government Programs. The rates that Medicare and Medi-Cal pay for dialysis treatment are relatively close to the average cost for CDCs to provide a dialysis treatment and are largely determined by regulation. In contrast, group and individual health insurers establish their rates by negotiating with CDCs. The rates paid by these insurers depend on the relative bargaining power of insurers and the CDCs. On average, group and individual health insurers pay multiple times what government programs pay for dialysis treatment.

How CDCs Are Regulated

California Department of Public Health (CDPH) Licenses and Certifies Dialysis Clinics. CDPH is the state entity responsible for licensing CDCs to operate in California and certifying CDCs on behalf of the federal government. Federal certification is required to receive payment from Medicare and Medi-Cal. Currently, California does not have its own state regulations governing CDCs, but instead relies on federal regulations as the basis for its licensing program.

Federal Regulations Require a Medical Director at Each CDC . . . Among other staffing requirements, federal regulations require that each CDC have a medical director who is a board-certified physician. The medical director is responsible for quality assurance, staff education and training, and development and implementation of clinic policies and procedures. Federal regulations do not require medical directors to spend a specific amount of time at the CDC.

. . . And Require CDCs to Report Infection-Related Information to a National Network. As a condition of participating in Medicare, CDCs must report specified infection-related information to the National Healthcare Safety Network at the federal Centers for Disease Control.

PROPOSAL

The measure includes four key provisions and requires CDPH to oversee implementation and administration of these provisions. The measure requires CDPH to adopt regulations to administer the provisions of this measure within one year after the law takes effect. If CDPH cannot meet that deadline, it can issue emergency regulations as it completes the regular process.

Requires Each CDC to Have a Physician Onsite During All Treatment Hours. The measure requires each CDC to maintain, at its expense, at least one physician onsite during all the hours patients receive treatments at that CDC. The physician is responsible for patient safety and the provision and quality of medical care. A CDC may apply to CDPH for an exception if there is a demonstrable shortage of physicians in the CDC's area. If CDPH approves the exception, the CDC can fulfill the requirement with a nurse practitioner or physician's assistant, rather than a physician. The exception lasts for one year.

Prohibits CDCs From Discriminating Against Patients Based on Who Pays for Their Treatment. Under the measure, CDCs and their governing entities must offer the same quality of care to all patients, and cannot refuse to offer or provide care to patients based on who pays for patients' treatments. The payer could be the patient, a private entity, the patient's health insurer, Medi-Cal, Medicaid, or Medicare.

Requires CDCs to Report Infection-Related Information to CDPH and Federal Government . . . The measure requires each CDC—or its governing entity—to report data about healthcare-associated infections (HAIs) to CDPH every three months. CDPH must specify what and how the information should be reported, set the reporting schedule, and post each CDC's HAI information on the CDPH website, including the name of a CDC's governing entity. The chief executive officer, or other principal officer of each CDC or governing entity, must certify under penalty of perjury that the reviewed information submitted is accurate and complete. The measure would state in California law the fact that CDCs must comply with federal HAI reporting requirements as well.

. . . And Imposes Penalties if They Fail to Do So. If a CDC or its governing entity fails to report HAI information or if the information is inaccurate, CDPH may issue a penalty of up to \$100,000 against the CDC depending on the severity of the violation. The CDC may request a hearing if it disputes the penalty or penalty amount. Any penalty fees collected would be used by CDPH to implement and enforce laws concerning CDCs.

Requires CDCs to Notify and Obtain Consent From CDPH Before Closing or Substantially Reducing Services. If a CDC plans to close or significantly reduce its services, the measure requires the CDC or its governing entity to notify CDPH in writing and obtain CDPH's written consent before it closes or substantially reduces services. While the measure provides CDPH the discretion about whether or not to give its consent, CDPH may base its determination on information provided by the CDC or its governing entity, or any other interested party, and the measure lists factors that CDPH might consider in making its determination. For example, CDPH might consider the CDC's financial resources; how a closure or service reduction would affect the community (including how the CDC would ensure patients have uninterrupted dialysis care); and evidence the CDC or its governing entity attempted to sell, lease, or transfer the CDC to another company that would provide dialysis services. A CDC may dispute CDPH's decision by requesting a hearing.

FISCAL EFFECTS

Increased Costs for Dialysis Clinics Affect State and Local Costs

How the Measure Increases Costs for CDCs. Overall, the measure's provisions would increase costs for CDCs. In particular, we estimate that the measure's requirement that each CDC have a physician onsite during all treatment hours would increase each CDC's costs by several hundred thousand dollars annually on average. For the data reporting requirement, we assume that CDPH would not require significantly different reporting than is already required by the federal government and that CDC costs associated with this requirement would therefore be

minor. We assume that other requirements of the measure would not significantly increase CDC costs.

Clinics Could Respond to Higher Costs in Different Ways. The costs associated with having a physician onsite would affect individual CDCs differently depending on their financial circumstances. Because most CDCs operate under a governing entity that owns/operates multiple CDCs—which could spread costs across multiple locations—we evaluated potential responses to the measure’s requirements in terms of the actions *governing entities* could take in response to the measure’s *overall* impact across all of their CDCs. Governing entities may respond in one or more of the following ways:

- ***Negotiate Increased Rates With Payers.*** First, governing entities might try to negotiate higher reimbursement rates from the entities that pay for the dialysis treatment to offset some of the costs imposed by the measure. Specifically, governing entities may be able to negotiate higher rates with Medi-Cal managed care plans and private commercial insurance companies.
- ***Continue to Operate as Currently, but With Lower Profits.*** For some governing entities, the higher costs due the measure could reduce their profits, but they could continue to operate at current levels without closing clinics. (For the minority of governing entities that operate on a not-for-profit basis, this would mean reduced net income.)
- ***Scale Back Operations.*** Given the higher costs due to the measure, some governing entities may decide to close some clinics.

Measure Could Increase Health Care Costs for State and Local Governments by Low Tens of Millions of Dollars Annually. Under the measure, state Medi-Cal costs, and state and local employee and retiree health insurance costs could increase due to: (1) governing entities negotiating higher reimbursement rates, and (2) individuals requiring treatment in more costly settings (due to fewer CDCs). Overall, we believe the most likely scenario is that CDCs and their governing entities would generally: (1) be able to negotiate with some payers to receive increased reimbursement to partially offset new costs imposed by the measure, and (2) continue to operate (with reduced bottom lines), with relatively limited individual CDC closures. We estimate that this scenario would lead to increased costs for state and local governments in the low tens of millions of dollars annually. This represents a small increase relative to the state’s total spending on Medi-Cal and to state and local governments’ total spending on employee and retiree health coverage. In the less likely event that CDC closures are more significant, state and local governments could have additional costs in the short run. These additional costs could be significant, but are highly uncertain.

Increased Administrative Costs for CDPH Covered by CDC Fees

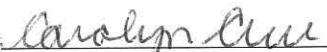
This measure imposes new regulatory responsibilities on CDPH. We estimate the annual cost to fulfill these new responsibilities likely would not exceed the low millions of dollars annually. The measure requires CDPH to adjust the annual licensing fee paid by CDCs to cover these costs.

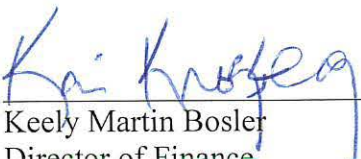
Summary of Fiscal Effects

We estimate that the measure would have the following major fiscal impact:

- Increased state and local health care costs, likely in the low tens of millions of dollars annually, resulting from increased dialysis treatment costs.

Sincerely,


for Gabriel Petek
Legislative Analyst


for Keely Martin Bosler
Director of Finance