



October 14, 2021

Hon. Rob Bonta
Attorney General
1300 I Street, 17th Floor
Sacramento, California 95814

Attention: Ms. Anabel Renteria
Initiative Coordinator

Dear Attorney General Bonta:

Pursuant to Elections Code Section 9005, we have reviewed the proposed statutory initiative (A.G. File No. 21-0013) 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 the kidneys no longer work well enough for the person to live without a kidney transplant or ongoing treatment called “dialysis.”

Dialysis Mimics Normal Kidney Functions. Dialysis artificially mimics what healthy kidneys do. Most people on dialysis undergo hemodialysis. This form of dialysis removes blood from the body, filters it through a machine to remove waste and extra fluid, and then returns it to the body. A single treatment lasts about four hours and happens about three times per week.

Most Dialysis Patients Receive Treatment in Clinics. Most people with kidney failure receive dialysis at chronic dialysis clinics (CDCs), although some may receive dialysis at hospitals or in their own homes. About 650 licensed CDCs in California provide dialysis to roughly 80,000 patients each month. Given how often patients need dialysis and how long treatments last, clinics often offer services six days per week and often are open outside of typical business operating hours.

Patients’ Own Physician Oversee Treatment. When a patient has kidney failure, the patient’s physician develops a plan of care, which could include a referral for dialysis. The patient’s physician designs the dialysis treatment plan, including specific aspects such as frequency, duration, and associated medicines. CDCs carry out the treatment. The patient’s physician continues to oversee the patient’s care. Under federal rules, the physician must visit the patient during dialysis treatment at the CDC at least once per month.

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—


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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. Most of these other governing entities have multiple CDCs in California, while a small number own or operate a single CDC. In recent years, the majority of CDCs’ earnings exceed costs, while a smaller share of CDCs operate at a loss. A governing entity that owns or operates multiple CDCs can use its higher-earning CDCs to help support its CDCs that operate at a loss.

Paying for Dialysis

Payment for Dialysis Comes From a Few Main Sources. We estimate that CDCs have total revenues of more than \$3.5 billion annually from their operations in California. These revenues consist of payments for dialysis from a few main sources, or “payers”:

- **Medicare.** This federally funded program provides health coverage to most people ages 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 federal governments 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 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.
- **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). Other people purchase health insurance individually. When an insured person develops kidney failure, that person can usually transition to Medicare coverage. 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 a dialysis treatment are fairly close to the average cost for CDCs to provide a dialysis treatment. These rates are largely determined by regulation. In contrast, group and individual health insurers negotiate with CDCs and their governing entities to set rates. The rate agreed upon depends in large part on how many people the insurer covers and how many people the governing entity’s CDCs treat. On average, group and individual health insurers pay multiple times what government programs pay for a dialysis treatment.

How CDCs Are Regulated

California Department of Public Health (CDPH) Licenses and Certifies Dialysis Clinics. CDPH is responsible for licensing CDCs to operate in California. CDPH also certifies CDCs on

behalf of the federal government, which allows CDCs to receive payment from Medicare and Medi-Cal. Currently, California relies primarily on federal regulations as the basis for its licensing program.

Federal Regulations Require a Medical Director at Each CDC. Federal regulations require each CDC to 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; however, federal guidance indicates that the medical director's responsibilities reflect about one-quarter of a full-time position.

CDCs Must Report Infection-Related Information to a National Network. To receive payments from Medicare, CDCs must report specified dialysis-related infection information to the National Healthcare Safety Network at the federal Centers for Disease Control. For example, CDCs must report when a patient develops a bloodstream infection and the suspected cause of the infection.

PROPOSAL

The measure includes several provisions affecting CDCs, as discussed below. It gives duties to CDPH to implement and administer the measure, including adopting regulations 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, Nurse Practitioner, or Physician Assistant Onsite During All Treatment Hours. The measure requires each CDC to maintain, at its expense, at least one physician, nurse practitioner, or physician assistant onsite during all the hours patients receive treatments at that CDC. This individual must have at least six months of experience providing care to kidney patients and is responsible for patient safety and the provision and quality of medical care. A CDC may request CDPH to grant an exception from this requirement if there is a valid shortage of physicians, nurse practitioners, or physician assistants in the CDC's area. If CDPH approves the exception, the CDC can meet the requirement through telehealth. The exception lasts for one year.

Requires CDCs to Report Infection-Related Information to CDPH. The measure requires each CDC—or its governing entity—to report dialysis-related infection information to CDPH every three months. CDPH must specify which information CDCs should report, and how and when to report the information. CDPH must post each CDC's infection information on the CDPH website, including the name of a CDC's governing entity.

Requires CDCs to Disclose Owners. The measure requires a CDC to provide patients with a list of all physicians who have an ownership interest in the clinic of at least 5 percent. This list must be provided when the patient is starting treatment, annually thereafter, or upon request by a patient or potential patient. The measure also requires a CDC or its governing entity to report to CDPH every three months with a list of persons who have an ownership interest of at least 5 percent in the clinic. Both CDPH and the CDC or its governing entity must post this information on their websites.

Charges Penalties if CDCs Fail to Report Required Information. If a CDC or its governing entity does not report information as required by the measure or if the reported information is inaccurate, CDPH may issue a penalty against the CDC. The amount of the penalty depends on how severe the violation is, but cannot be more than \$100,000. The CDC may request a hearing if it

disputes the penalty. Any penalties 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. The measure allows CDPH to determine whether or not to consent. It allows CDPH to base its decision on such information as the CDC's financial resources and the CDC's plan for ensuring patients have uninterrupted dialysis care. A CDC may dispute CDPH's decision by requesting a hearing.

Prohibits CDCs From Refusing Care to a Patient Based on Who Is Paying for the Patient's Treatment. Under the measure, CDCs and their governing entities are required to offer the same quality of care to all patients and they 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.

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, the measure's requirement that each CDC have a physician, nurse practitioner, or physician assistant onsite during all treatment hours would increase each CDC's costs by several hundred thousand dollars annually on average. Other requirements of the measure would not significantly increase CDC costs.

Clinics Could Respond to Higher Costs in Different Ways. The cost to have a physician, nurse practitioner, or physician assistant onsite would affect individual CDCs differently depending on their finances. Most CDCs operate under a governing entity that owns/operates multiple CDCs such that the governing entity could spread costs across multiple locations. Governing entities might respond in one or more of the following ways:

- ***Negotiate Increased Rates With Payers.*** First, governing entities might try to negotiate higher rates from the entities that pay for the dialysis treatment to cover some of the costs imposed by the measure. Specifically, governing entities may be able to negotiate higher rates with private commercial insurance companies and to a lesser extent with Medi-Cal managed care plans.
- ***Continue Current Operations, but With Lower Profits.*** For some governing entities, the higher costs due to the measure could reduce their profits, but they could continue to operate at current levels without closing clinics.
- ***Close Some Clinics.*** Given the higher costs due to the measure, some governing entities, particularly those with fewer clinics, 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:

- Governing entities negotiating higher payment rates.

- Patients requiring treatment in more costly settings like hospitals (due to fewer CDCs should some close in response to the measure).

Overall, we assume that CDCs and their governing entities generally would: (1) be able to negotiate with some payers to receive higher payment rates to cover some of the new costs imposed by the measure, and (2) continue to operate (with reduced income) with relatively limited individual CDC closures. This scenario would lead to increased costs for state and local governments likely in the low tens of millions of dollars annually. This represents a minor increase in the state's total spending on Medi-Cal and state and local governments' total spending on employee and retiree health coverage. This cost represents less than 1 percent of state General Fund spending. In the less likely event that a more significant number of CDCs closed, 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

The measure imposes new regulatory responsibilities on CDPH. The annual cost of 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 Major Fiscal Effects

We estimate that this measure could have the following major fiscal effects on state and local governments:

- Increased state and local government costs likely in the low tens of millions of dollars annually.

Sincerely,

Gabriel Petek
Legislative Analyst

Keely Martin Bosler
Director of Finance