



January 3, 2020

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. 19-0030, 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). They are referred to the CDCs by their own physicians. About 600 licensed dialysis clinics in California provide treatment to roughly 80,000 patients each month.

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": (1) Medicare, the federally funded program that pays for dialysis treatment for the majority of people on dialysis in California; (2) Medi-Cal, California's federal-state Medicaid program that

provides health coverage to low-income people; and (3) group and individual health insurance, coverage that is provided through an employer or purchased individually.

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.

. . . 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

Beyond asserting in state law the federal requirement that each CDC must have a medical director, the measure includes three key provisions and requires CDPH to oversee implementation and administration of these provisions. The measure requires CDPH to adopt regulations to carry out the measure within one year after the law takes effect.

Prohibits CDCs From Discriminating Against Patients Based on Who Pays for Their Treatment. Under the measure, CDCs and their governing entities must deliver the same quality and standard of dialysis treatment to all patients, regardless of who pays for patients' treatments. (The measure refers to the governing entity as the entity that owns or operates the CDC.) 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 . . . The measure requires each CDC or its governing entity to report data about healthcare-associated infections (HAIs) to CDPH every three months and for CDPH to post this information on its website, including the name of each CDC's governing entity. The measure requires CDPH to apply the same reporting, form, and schedule requirements on CDCs as is required by the National Healthcare Safety Network, meaning reporting requirements would be the same at the state and federal levels.

. . . And Imposes Penalties if They Fail to Do So. If a CDC or its governing entity fails to report HAI information or the information is inaccurate, CDPH may issue a penalty of up to \$10,000 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 CDPH Before Closing Permanently. If a CDC plans to close permanently, the measure requires the CDC or its governing entity to notify CDPH in writing at least 60 days in advance. It also requires the governing entity to notify patients in writing at least 60 days before a permanent closure and assist them in finding dialysis services elsewhere.

FISCAL EFFECTS

Increased Administrative Costs for CDPH Covered by Fees on CDCs

This measure imposes new regulatory responsibilities on CDPH. We estimate the annual cost to fulfill these new responsibilities likely would not exceed \$1 million annually. The measure requires CDPH to adjust the annual licensing fee paid by CDCs to cover these costs.

No Other Fiscal Effects

Apart from the relatively minor impact on state costs that is covered by fees, we find that the measure would have no other significant effects on state and local governments.

Summary of Fiscal Effects

We estimate that the measure would have no significant fiscal effect on state and local governments.

Sincerely,

Gabriel Petek
Legislative Analyst

Keely Martin Bosler
Director of Finance