PROPOSITION 29 Requires On-Site Licensed Medical Professional at Kidney Dialysis Clinics and Establishes Other State Requirements. Initiative Statute.

ANALYSIS OF MEASURE

BACKGROUND

Dialysis Treatment

Kidney Failure. Healthy kidneys remove waste and extra fluid from a person's blood. Kidney disease happens when a person's kidneys do not work properly. Over time, a person may develop kidney failure. 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 What a Normal Kidney Does. Dialysis copies 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, 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 (clinics), although some may receive dialysis at hospitals or in their own homes. About 650 licensed clinics 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 treatments six days per week and often are open outside of typical business operating hours.

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

Various Entities Own and Operate Dialysis Clinics. Two private for-profit companies—DaVita, Inc. and Fresenius Medical Care—own or operate nearly 75 percent of licensed clinics in California. A variety of nonprofit organizations and for-profit companies own or operate the other clinics. Most of these other owners and operators have multiple clinics in California, while a small number own or operate a single clinic. In recent years, the majority of clinics' revenues exceed costs, while a smaller

share of clinics operate at a loss. Some owners and operators with multiple clinics can use their higher-earning clinics to help support their clinics that operate at a loss. However, an owner or operator may be less likely to keep an individual clinic open over the longer term if that clinic is likely to keep operating at a loss.

Paying for Dialysis

Few Main Sources Pay for Dialysis. We estimate that clinics have total revenues of around \$3.5 billion each year (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 eligible low-income California residents. 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 main payer and Medi-Cal covers the rest. For people enrolled only in Medi-Cal, the Medi-Cal program alone pays 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 a group insurer to be the main payer for dialysis treatment for the first 30 months of treatment.

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 clinics to provide a dialysis treatment. Government regulations largely decide what these rates are. In contrast, group and individual health insurers negotiate with clinic owners and operators to set rates. On average, group and individual health insurers pay multiple times what government programs pay for a dialysis treatment.

How Chronic Dialysis Clinics Are Regulated

California Department of Public Health (CDPH) Licenses and Certifies Dialysis Clinics. CDPH licenses clinics to operate in California. CDPH also certifies clinics on behalf of the federal government. Certification allows clinics 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 Dialysis Clinic. Federal regulations require each clinic 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 set amount of time at the clinic. Federal guidelines, however, consider the position to reflect about one-quarter of a full-time position.

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

PROPOSAL

Proposition 29 includes several requirements affecting clinics, as discussed below. It gives duties to CDPH to implement and administer the proposition, including adopting regulations within one year after the law takes effect.

Requires Each Dialysis Clinic to Have a Physician, Nurse Practitioner, or Physician Assistant On-Site During All Treatment Hours. Proposition 29 requires each clinic to have, at its expense, at least one physician, nurse practitioner, or physician assistant on-site during all the hours patients receive treatments at that clinic. 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 clinic may ask CDPH to grant an exception from this requirement if there are not enough physicians, nurse practitioners, or physician assistants in the clinic's area. If CDPH approves the exception, the clinic can meet the requirement through telehealth. The exception lasts for one year.

Requires Dialysis Clinics to Report Infection-Related Information to CDPH. Proposition 29 requires clinics to report dialysis-related infection information to CDPH every three months. CDPH must specify which information clinics should report, and how and when to report the information. CDPH must post each clinic's infection information on the CDPH website, including the name of the clinic's owner or operator.

Requires Dialysis Clinics to Say Who Its Owners Are. Proposition 29 requires a clinic to give patients a list of all physicians who own at least 5 percent of the clinic. The clinic must give a patient this list when the patient is starting treatment, each year after that, or any time a patient (or potential patient) asks for it. The proposition also requires clinics to report to CDPH every three months persons who own at least 5 percent of the clinic. Both CDPH and clinics (or their owners or operators) must post this information on their websites.

Charges Penalties if Dialysis Clinics Do Not Report Required Information. If a clinic or its owner or operator does not report required information or reports inaccurate information, CDPH may issue a penalty of up to \$100,000 against the clinic. The clinic may request a hearing if it disagrees with the penalty. Any penalties collected would be used by CDPH to implement and enforce laws concerning clinics.

Requires Dialysis Clinics to Notify and Obtain Consent From CDPH Before Closing or Substantially Reducing Services. If a clinic plans to close or substantially reduce its services, Proposition 29 requires the clinic or its owner or operator to notify CDPH in writing and obtain



CDPH's written consent. The proposition allows CDPH to determine whether or not to consent. It allows CDPH to base its decision on such information as the clinic's financial resources and the clinic's plan for making sure patients have uninterrupted dialysis care. A clinic may dispute CDPH's decision by requesting a hearing.

Prohibits Dialysis Clinics From Refusing Care to a Patient Based on Who Is Paying for the Patient's Treatment. Under Proposition 29, clinics are required to offer the same quality of care to all patients. Clinics 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, or Medicare.

FISCAL EFFECTS

Increased Costs for Dialysis Clinics Affect State and Local Costs

Proposition 29 Increases Costs for Dialysis Clinics. Overall, the proposition would increase costs for clinics. In particular, the proposition's requirement that each clinic have a physician, nurse practitioner, or physician assistant on-site during all treatment hours would increase each clinic's costs by several hundred thousand dollars annually on average. Other requirements of the proposition would not significantly increase clinic costs.

Clinics Could Respond to Higher Costs in Different Ways. The cost to have a physician, nurse practitioner, or physician assistant on-site would affect individual clinics differently depending on their finances. For example, the additional cost could cause some clinics to operate at a loss, or at a greater loss than previously. As noted earlier, an owner or operator might be able to support these clinics with its higher-earning clinics. However, the owner or operator might not be willing or able to do this over the longer term. Owners and operators might respond to Proposition 29 in one or more of the following ways:

- *Negotiate Increased Rates With Payers.* Owners and operators might try to negotiate higher rates from payers to cover some of the costs. Specifically, owners and operators 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 owners and operators, the higher costs would reduce their profits, but they still could operate at current levels without closing clinics.
- *Close Some Clinics.* Given the higher costs a clinic would face, some owners and operators may decide to seek consent from CDPH to close some of their clinics that are operating at a loss.

Proposition 29 Could Increase Health Care Costs for State and Local Governments. Under the proposition, state Medi-Cal costs, and state and local employee and retiree health insurance costs, could increase due to:

• Owners and operators negotiating higher payment rates.



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• Some patients requiring treatment in costlier settings like hospitals if some clinics closed in response to the proposition.

Overall, we assume that clinic owners and operators 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 proposition, particularly if many clinics were to close otherwise; (2) continue to operate some clinics with reduced income; and (3) close some clinics, with the consent of CDPH. This scenario would lead to **increased costs for state and local governments likely in the tens of millions of dollars annually.** (State and local governments currently spend more than \$65 billion on Medi-Cal and employee and retiree health coverage.) This amount is less than one-half of 1 percent of the state's total General Fund spending. (The General Fund is the state's main operating account, which pays for education, prisons, health care, and other public services.)

In the less likely event that a relatively large number of clinics would close due to this proposition, having obtained consent from CDPH, state and local governments could have additional costs in the short run. These additional costs are highly uncertain.

Increased Administrative Costs for CDPH Covered by Dialysis Clinic Fees

Proposition 29 imposes new regulatory responsibilities on CDPH. The annual cost of these new responsibilities likely would not exceed the low millions of dollars annually. The proposition requires CDPH to adjust the annual licensing fee paid by clinics to cover these costs.

YES/NO STATEMENT

A **YES** vote on this measure means: Chronic dialysis clinics would be required to have a physician, nurse practitioner, or physician assistant on-site during all patient treatment hours.

A **NO** vote on this measure means: Chronic dialysis clinics would not be required to have a physician, nurse practitioner, or physician assistant on-site during all patient treatment hours.

SUMMARY OF LEGISLATIVE ANALYST'S ESTIMATE OF NET STATE AND LOCAL GOVERNMENT FISCAL IMPACT

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

BALLOT LABEL

Fiscal Impact: Increased state and local government costs likely in the tens of millions of dollars annually.

