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1-21-2020

**AUTHORIZES STATE REGULATION OF KIDNEY DIALYSIS CLINICS.  
INITIATIVE STATUTE.**

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The Attorney General of California has prepared the following title and summary of the chief purpose and points of the proposed measure:

**AUTHORIZES STATE REGULATION OF KIDNEY DIALYSIS CLINICS.**

**INITIATIVE STATUTE.** Requires kidney dialysis clinics to report dialysis-related infection data to state and federal governments; requires Department of Public Health to conform state reporting, form, and schedule requirements to existing requirements under federal law. Requires written notice to State and patients at least 60 days before a clinic's permanent closure. Prohibits clinics from discriminating against patients based on the source of payment for care. Replicates existing federal law requiring clinics to have a medical director who is a licensed physician.

Fiscal Impact: **It is the opinion of the Legislative Analyst and Director of Finance that the measure would have no significant fiscal effect on state and local governments.**

(19-0030A1.)

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19-0030 Amdt. # 1

December 20, 2019

Anabel Renteria  
Initiative Coordinator  
Office of the Attorney General  
State of California  
PO Box 994255  
Sacramento, CA 94244-25550

RECEIVED

DEC 20 2019

INITIATIVE COORDINATOR  
ATTORNEY GENERAL'S OFFICE

Re: Initiative 19-0030 - Amendment Number One

Dear Initiative Coordinator:

Pursuant to subdivision (b) of Section 9002 of the Elections Code, enclosed please find Amendment #1 to Initiative No. 19-0030. The amendments are reasonably germane to the theme, purpose or subject of the initiative measure as originally proposed.

I am the proponent of the measure and request that the Attorney General prepare a circulating title and summary of the measure as provided by law, using the amended language.

Thank you for your time and attention processing my request.

Sincerely,



Thomas W. Hiltachk

Amendment #1  
INITIATIVE MEASURE SUBMITTED DIRECTLY TO VOTERS

SECTION 1. Statement of Findings and Declaration of Purpose.

- A. More than 70,000 California patients with kidney failure rely on kidney dialysis to stay alive. During dialysis, patients are connected to a machine that does the job of the kidneys, removing toxins and fluid from their bodies.
- B. Dialysis is a life-sustaining treatment. Patients receive dialysis three days a week, for three-to-four hours at a time.
- C. Preserving and improving dialysis quality care is essential for these vulnerable patients. A team of caregivers surrounds every California dialysis patient to provide high-quality care. This team typically includes a physician medical director, nurse, vascular surgeon, dietitian, patient care technician, nurse manager, nurse clinical coordinator, social workers, nephrologists and other specialists.
- D. According to the Centers for Medicare & Medicaid Services, dialysis clinics must adhere to 376 unique regulations and are surveyed regularly to ensure compliance.
- E. According to federal and state government regulators, California dialysis care exceeds the national average in both care quality and patient satisfaction. In fact, infection rates are far lower in California than the national average according to government regulators.
- F. According to the United States Renal Data System, in the last 10 years, mortality rates have decreased by 22% and hospitalization rates have decreased by 19% for dialysis patients in California.
- G. Protecting and maintaining access to dialysis is critical. Without treatment, patients with failing kidneys will die. Missing even one dialysis treatment increases patient risk of death by 30%.
- H. Today there are about 650 dialysis clinics in California. Over the next 10 years, the demand for dialysis in California is expected to increase by 5% annually. It is estimated that California will need an additional 350 clinics to meet that demand.
- I. Without access to regular care at community dialysis clinics, tens of thousands of patients would be forced into overcrowded emergency rooms and hospitals, where care is far more expensive – resulting in more ER overcrowding and increasing costs for taxpayers.
- J. Special interests in California have spent tens of millions of dollars pushing deceptive and flawed ballot measures and legislation that would jeopardize patient access to the dialysis care they need to survive, and measures that jeopardize care quality for dialysis patients.
- K. California laws covering dialysis care should protect dialysis quality of care, while also protecting and enhancing access to care that is vital for the 70,000 dialysis patients who need dialysis treatments to stay alive. Therefore, the people hereby enact the “Dialysis is Life Support Act” to further this purpose.

SECTION 2. The Dialysis is Life Support Act

Sections 1226.7, 1226.8, 1226.9, and 1226.10 of article 3 of chapter 1 of division 2 of the Health and Safety Code are added to read:

§1226.7(a) A chronic dialysis clinic shall deliver the same quality and standard of dialysis treatment to each of its patients with no discrimination in such treatment standards on the basis that a payer is an individual patient, private entity, insurer, Medi-Cal, Medicaid, or Medicare. This section shall also apply to a chronic dialysis clinic's governing entity, which shall ensure that no discrimination prohibited by this section occurs at or among clinics owned or operated by the governing entity.

(b) Definitions

- (1) "Chronic dialysis clinic" has the same meaning as in Section 1204.
- (2) "Governing entity" means a person, firm, association, partnership, corporation, or other entity that owns or operates a chronic dialysis clinic for which a license has been issued, without respect to whether the person or entity itself directly holds that license.

§1226.8(a) A chronic dialysis clinic must have a medical director, who is a licensed physician, to be responsible for the delivery of patient care and outcomes in the facility as required by federal law. The medical director is accountable to the governing entity of the clinic for the quality of medical care provided to patients. A medical director's responsibilities include, but are not limited to, the following:

- (1) Quality assessment and performance improvement program.
- (2) Staff education, training, and performance.
- (3) Policies and procedures. The medical director must (A) Participate in the development, periodic review and approval of a policies and procedures manual for the facility; and (B) Participate in the implementation of the policies and procedures manual, including all policies and procedures relative to patient admissions, patient care, infection control, and safety; and (C) direct the interdisciplinary team in adhering to the discharge and transfer policies and procedures specified under federal law.

(b) For each chronic dialysis clinic, the clinic or its governing entity shall quarterly report to the department, on a form and schedule prescribed by the department, dialysis clinic health care associated infection ("dialysis clinic HAI") data, including the incidence of dialysis clinic HAIs at each chronic dialysis clinic in California. The department shall post on its Web site the dialysis clinic HAI data. The posted information shall include information identifying the governing entity of each chronic dialysis clinic. The department shall conform the reporting, form, and schedule required by this section to the HAI data reporting to the National Healthcare Safety Network in accordance with National Healthcare Safety Network requirements and procedures.

(c) In the event the department determines that a chronic dialysis clinic or governing entity failed to maintain the information or timely submit a report required under this section, or that the report submitted was inaccurate or incomplete, the department shall assess a penalty against the chronic dialysis clinic or governing entity not to exceed ten thousand dollars (\$10,000). The department shall determine the amount of the penalty based on the severity of the violation, the

materiality of the inaccuracy or omitted information, and the culpability of the chronic dialysis clinic or governing entity in causing the violation. Penalties collected pursuant to this paragraph shall be used by the department to implement and enforce laws governing chronic dialysis clinics. If a chronic dialysis clinic or governing entity disputes a determination by the department to assess a penalty pursuant to this section or the amount of the administrative penalty, the chronic dialysis clinic or governing entity may, within 10 working days, request a hearing pursuant to Section 131071. A chronic dialysis clinic or governing entity shall promptly pay all administrative penalties when all appeals have been exhausted and the department's position has been upheld.

(d) Definitions

For purposes of this section:

- (1) "Chronic dialysis clinic" has the same meaning as in Section 1204.
- (2) "Dialysis clinic HAI" means a bloodstream infection, local access site infection, or vascular access infection related to a dialysis event as defined by the National Health and Safety Network of the federal Centers for Disease Control and Prevention.
- (3) "Governing entity" has the same meaning as in Section 1226.7.
- (4) "Licensed physician" means a nephrologist or other physician licensed by the state pursuant to Chapter 5 of Division 2 of the Business and Professions Code.
- (5) "National Healthcare Safety Network" or "NHSN" means the secure, Internet-based system developed and managed by the federal Centers for Disease Control and Prevention (CDC) that collects, analyzes, and reports risk-adjusted Dialysis center HAI data related to the incidence of HAI and the process measures implemented to prevent these infections, or any successor data correction system that serves substantially the same purpose.

§1226.9. (a) Prior to permanently closing a chronic dialysis clinic, the clinic or its governing entity must provide written notice to the department at least sixty (60) days before such closure.

(b) The governing body shall provide written notice to patients at least sixty (60) days before such permanent closure and the chronic dialysis clinic's interdisciplinary team shall assist patients to obtain dialysis treatment in other facilities.

(c) Definitions:

- (1) "Chronic dialysis clinic" has the same meaning as in Section 1204.
- (2) "Governing entity" has the same meaning as in section 1226.7.

1226.10(a) If a chronic dialysis clinic or governing entity disputes a determination by the department pursuant to Section 1226.8, the chronic dialysis clinic or governing entity may, within 10 working days, request a hearing pursuant to Section 131071. A chronic dialysis clinic or governing entity shall pay all administrative penalties when all appeals have been exhausted if the department's position has been upheld.

(b) Definitions

(1) "Chronic dialysis clinic" has the same meaning as in Section 1204.

(2) "Governing entity" has the same meaning as in Section 1226.7.

SECTION 3. No Cost to Taxpayers

Section 1266.3 is added to the Health and Safety Code, to read:

§1266.3. It is the intent of the People that California taxpayers not be financially responsible for implementation and enforcement of the Dialysis is Life Support Act. In order to effectuate that intent, when calculating, assessing, and collecting fees imposed on chronic dialysis clinics pursuant to Section 1266, the department shall take into account all costs associated with implementing and enforcing Sections 1226. 7 through 1226.10.

SECTION 4. Nothing in this act is intended to affect health facilities licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code.

SECTION 5. (a) The State Department of Public Health is authorized to and, within one year following the Act's effective date, shall adopt regulations implementing Sections 1226.8 and 1226.9 of the Health and Safety Code to further the purposes of this Act.

SECTION 6. General Provisions

(a) The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid application.

(b) If any other measure relating to the regulation of chronic dialysis clinics or the treatment and care of dialysis patients is approved by the voters at the same election that this act is approved by the voters, the provisions of the other measure shall be deemed to be in conflict with this act. This act is intended to be comprehensive regarding the subject of the regulation of chronic dialysis clinics and the treatment and care of dialysis patients. In the event that this act receives a greater number of votes than the other measure, the provisions of this act shall prevail in their entirety and the provisions of the other measure shall be null and void.

(c) The act may be amended by the Legislature to further the purposes of the act, but only upon a statute passed in each house of the Legislature by rollcall vote entered into the journal, four-

fifths of the membership concurring, provided that the statute is consistent with and furthers the purposes of the act.



19 - 0030

January 3, 2020

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

RECEIVED

JAN 03 2020

INITIATIVE COORDINATOR  
ATTORNEY GENERAL'S OFFICE

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.

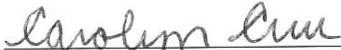
### **No Other Fiscal Effects**

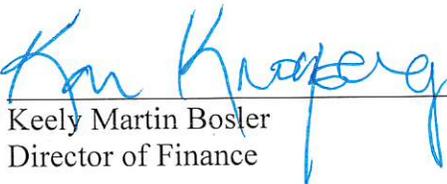
Apart from the relatively minor impact on state costs that is covered by fees, we find that the measure would have no other significant effects on state and local governments.

### **Summary of Fiscal Effects**

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

Sincerely,

*for*   
\_\_\_\_\_  
Gabriel Petek  
Legislative Analyst

*for*   
\_\_\_\_\_  
Keely Martin Bosler  
Director of Finance