12-30-2019

AUTHORIZES STATE REGULATION OF KIDNEY DIALYSIS CLINICS. ESTABLISHES MINIMUM STAFFING AND OTHER REQUIREMENTS. INITIATIVE STATUTE.

December 30, 2019
Initiative 19-0025 (Amdt. #1)

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.

ESTABLISHES MINIMUM STAFFING AND OTHER REQUIREMENTS. INITIATIVE STATUTE. Requires at least one licensed physician on site during treatment at outpatient kidney dialysis clinics; authorizes Department of Public Health to exempt clinics from this requirement due to shortages of qualified licensed physicians if at least one nurse practitioner or physician assistant is on site. Requires clinics to report dialysis-related infection data to state and federal governments. Requires state approval for clinics to close or reduce services. Prohibits clinics from discriminating against patients based on the source of payment for care. Summary of estimate by Legislative Analyst and Director of Finance of fiscal impact on state and local governments: **Increased state and local health care costs, likely in the low tens of millions of dollars annually, resulting from increased dialysis treatment costs.** (19-0025A1.)

19-0025 Amdt. # 1

November 26, 2019

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DEC 02 2019

INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Anabel Renteria
Initiative Coordinator
Office of the Attorney General
1300 I Street
Sacramento, CA 95814

Re: **Initiative No.: 19-0025 - Amendment**

Dear Ms. Renteria:

Pursuant to subdivision (b) of Section 9002 of the Elections Code, enclosed please find an amendment to the above-referenced initiative, also known as the "Protect the Lives of Dialysis Patients Act." The amendments are reasonably germane to the theme, purpose or subject of the initiative measure as originally submitted.

I am one of the proponents of the measure and request the Attorney General prepare a circulating title and summary of the measure using the amended language.

Sincerely,

Sarah Steck

Elliott Perry

Enclosures

304498.DOCX

This initiative measure is submitted to the People in accordance with the provisions of Article II, Section 8, of the California Constitution.

This initiative measure adds sections to the Health and Safety Code; therefore, new provisions proposed to be added are printed in *italic* type to indicate that they are new.

SEC. 1. Name

This Act shall be known as the "Protect the Lives of Dialysis Patients Act."

SEC. 2. Findings and Purposes

This Act, adopted by the People of the State of California, makes the following Findings and has the following Purposes:

A. The People make the following findings:

(1) Kidney dialysis is a life-saving process in which blood is removed from a person's body, cleaned of toxins, and then returned to the patient. It must be done at least three times a week for several hours a session, and the patient must continue treatment for the rest of their life or until they can obtain a kidney transplant.

(2) In California, at least 70,000 people undergo dialysis treatment.

(3) Just two multinational, for-profit corporations operate or manage nearly three-quarters of dialysis clinics in California and treat more than 75 percent of dialysis patients in the state. These two multinational corporations annually earn billions of dollars from their dialysis operations, including more than $350 million a year in California alone.

(4) The dialysis procedure and side effects from the treatments present several dangers to patients, and many dialysis clinics in California have been cited for failure to maintain proper standards of care. Failure to maintain proper standards can lead to patient harm, hospitalizations, and even death.

(5) Dialysis clinics are currently not required to maintain a doctor on site to oversee quality, ensure the patient plan of care is appropriately followed, and monitor safety protocols. Patients should have access to a physician on site whenever dialysis treatment is being provided.

(6) Dialysis treatments involve direct access to the bloodstream, which puts patients at heightened risk of getting dangerous infections. Proper reporting and transparency of infection rates encourages clinics to improve quality and helps patients make the best choice for their care.

(7) When health care facilities like hospitals and nursing homes close, California regulators are able to take steps to protect patients from harm. Likewise, strong protections should be provided to vulnerable patients when dialysis clinics close.

(8) Dialysis corporations have lobbied against efforts to enact protections for kidney dialysis patients in California, spending over $100 million in 2018 and 2019 to influence California voters and the Legislature.

B. Purposes:

(1) It is the purpose of this Act to ensure that outpatient kidney dialysis clinics provide quality and affordable patient care to people suffering from end stage renal disease.

(2) This Act is intended to be budget neutral for the State to implement and administer.

SEC. 3. Section 1226.7 is added to the Health and Safety Code, to read:

1226.7. (a) Chronic dialysis clinics shall provide the same quality of care to their patients without discrimination on the basis of who is responsible for paying for a patient's treatment. Further, chronic dialysis clinics shall not refuse to offer or to provide care on the basis of who is responsible for paying for a patient's treatment. Such prohibited discrimination includes, but is not limited to, discrimination 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.

SEC. 4. Section 1226.8 is added to the Health and Safety Code, to read:

1226.8. (a) Every chronic dialysis clinic must maintain, at the chronic dialysis clinic's expense, at least one licensed physician present on site during all times that in-center dialysis patients are being treated. This physician shall have authority and responsibility over patient safety and to direct the provision and quality of medical care.

(1) A chronic dialysis clinic may apply to the department for an exception to the requirement in subdivision (a) on the grounds that a bona fide shortage of qualified physicians prevents it from satisfying the requirement. Upon such a showing, the department may grant an exception that permits the clinic to satisfy the requirement in subdivision (a) by having at minimum one of the following on site during all times that in-center dialysis patients are being treated: a licensed physician, a nurse practitioner, or a physician assistant.

(2) The duration of an exception granted by the department pursuant to paragraph (1) shall be one calendar year from the date the clinic is notified of the department's determination.

(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 and type of dialysis clinic HAIs at each chronic dialysis clinic in California and such other information as the department shall deem appropriate to provide transparency on dialysis clinic HAI infection rates and promote patient safety. The chief executive officer or other principal officer of the clinic or

governing entity shall certify under penalty of perjury that he or she is satisfied, after review, that the dialysis clinic HAI report submitted to the department is accurate and complete. The department shall post on its Web site the dialysis clinic HAI data from this report, at the same level of detail as provided in the report. The posted information shall include information identifying the governing entity of each chronic dialysis clinic.

(1) In addition to reporting to the department pursuant to the requirements of this subdivision, chronic dialysis clinics shall report dialysis clinic HAI data to the National Healthcare Safety Network in accordance with National Healthcare Safety Network requirements and procedures.

(2) 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 subdivision, 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 one hundred thousand dollars ($100,000). 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 strength of the explanation, if any, for the violation. Penalties collected pursuant to this paragraph shall be used by the department to implement and enforce laws governing chronic dialysis clinics.

(c) 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 Healthcare Safety Network of the federal Centers for Disease Control and Prevention, or any appropriate additional or alternative definition that the department defines by regulation.

(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" means the secure, Internet-based system developed and managed by the federal Centers for Disease Control and Prevention that collects, analyzes, and reports risk-adjusted dialysis clinic HAI data related to the incidence of HAI and the process measures implemented to prevent these infections, or any successor data collection system that serves substantially the same purpose.

(6) "Nurse practitioner" means a registered nurse licensed pursuant to Chapter 6 of Division 2 of the Business and Professions Code and certified as a nurse practitioner by the Board of Registered Nursing.

(7) "Physician assistant" means a physician assistant licensed pursuant to Chapter 7.7 of Division 2 of the Business and Professions Code.

SECTION 5. Section 1226.9 is added to the Health and Safety Code, to read:

1226.9. (a) Prior to closing a chronic dialysis clinic, or substantially reducing or eliminating the level of services provided by a chronic dialysis clinic, the clinic or its governing entity must provide written notice to, and obtain the written consent of, the department.

(b) The department shall have discretion to consent to, give conditional consent to, or not consent to, any proposed closure or substantial reduction or elimination of services. In making its determination, the department may take into account information submitted by the clinic, its governing entity, and any other interested party, and shall consider any factors that the department considers relevant, including, but not limited to, the following:

(1) The effect on the availability and accessibility of health care services to the affected community, including but not limited to the clinic's detailed plan for ensuring patients will have uninterrupted access to care.

(2) Evidence of good faith efforts by the clinic or governing entity to sell, lease, or otherwise transfer ownership or operations of the clinic to another entity that would provide chronic dialysis care.

(3) The financial resources of the clinic and its governing entity.

(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.

SEC. 6. Section 1226.10 is added to the Health and Safety Code, to read:

1226.10. (a) If a chronic dialysis clinic or governing entity disputes a determination by the department pursuant to Sections 1226.8 or 1226.9, 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.

SEC. 7. 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 Protect the Lives of Dialysis Patients 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.

SEC. 8. 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.

SEC. 9. (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.

(b) If the Department is unable to adopt the required final regulations within one year following the Act's effective date, the adoption of emergency implementing regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare, in which case the Department shall adopt initial emergency implementing regulations no later than one year following the Act's effective date, or as soon thereafter as is practicable. If such emergency regulations are adopted, the Department shall adopt the required final regulations by the time the emergency regulations expire.

SEC. 10. Pursuant to subdivision (c) of Section 10 of Article II of the California Constitution, this Act may be amended either by a subsequent measure submitted to a vote of the People at a statewide election; or by a statute validly passed by the Legislature and signed by the Governor, but only to further the purposes of the Act.

SEC. 11 (a) In the event that this initiative measure and another initiative measure or measures relating to dialysis (including but not limited to the regulation of chronic dialysis clinics or the treatment and care of dialysis patients) shall appear on the same statewide election ballot, the other initiative measure or measures shall be deemed to be in conflict with this measure. In the event that this initiative measure receives the highest number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the provisions of the other initiative measure or measures shall be null and void.

(b) If this initiative is approved by the voters but superseded in whole or in part by any other conflicting ballot measure approved by the voters at the same election, and such conflicting measure is later held invalid, this measure shall be self-executing and given full force and effect.

SEC. 12. The provisions of this Act are severable. If any provision of this Act or its application is held invalid, that invalidity shall not affect the remaining portions of this Act or any application that can be given effect without the invalid provision or application. The People of the State of California hereby declare that they would have adopted this Act and each and every portion, section, subdivision, paragraph, clause, sentence, phrase, word, and application not declared invalid or unconstitutional without regard to whether any portion of this Act or application thereof would be subsequently declared invalid.

LAO

19-0025

Amdt. # 1

December 13, 2019

RECEIVED

DEC 13 2019

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