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

INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Attention: Ms. Ashley Johansson
Initiative Coordinator

Dear Attorney General Becerra:

Pursuant to Elections Code Section 9005, we have reviewed the proposed statutory initiative regarding staffing and pricing requirements for kidney dialysis providers (A.G. File No. 17-0015 Amendment No. 1).

BACKGROUND

Chronic Dialysis Clinics

End Stage Renal Disease (ESRD) Is the Final Stage of Chronic Kidney Disease. Patients suffering from ESRD, the fifth and final stage of kidney disease, must receive kidney dialysis (or a kidney transplant) to survive. Kidney dialysis artificially mimics what healthy kidneys do—filtering out waste and toxins from the blood supply, either outside the body (hemodialysis) or inside the body (peritoneal dialysis). Peritoneal dialysis is typically conducted every day at the patient's home, whereas hemodialysis is typically administered at a clinic three times per week with each treatment lasting between three and four hours.

Many ESRD Patients Treated at Chronic Dialysis Clinics (CDCs). Although ESRD patients can receive hemodialysis treatments at hospitals or in their own homes, many receive treatments at CDCs. In California, about 650 CDCs serve more than 66,000 ESRD patients. While CDCs are sometimes owned and operated by private nonprofit or public entities, two private for-profit entities—DaVita Healthcare Partners and Fresenius Medical Care—and their CDCs treat the vast majority of ESRD patients in California.

Department of Public Health (DPH) Licenses and Inspects CDCs. DPH is responsible for licensing CDCs and conducting federal certification surveys for the Centers for Medicare and Medicaid Services (CMS). (While a license is issued to a CDC, the CDC itself may be owned or operated by a person, corporation, or other entity—referred to as a “governing entity” in this measure.) Through the federal certification process, DPH conducts inspections of each CDC about once every three years. DPH has not promulgated regulations for CDCs and currently follows federal certification standards for state licensing activities. It lacks the authority to

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impose penalties on CDCs that fail to comply with certification standards. DPH is also responsible for certifying hemodialysis technicians who work with nurses to carry out hemodialysis treatments, including inserting needles to draw and replace blood and monitoring patients' vital signs.

State Does Not Set Minimum Staffing Requirements. Currently, there are no federal or state minimum staffing requirements for CDCs, though federal regulations require an “adequate number” of qualified personnel (including direct care staff such as registered nurses) be present to maintain “appropriate” patient-to-staff ratios.

State Follows Federal Guidance on Patient Transitions. Through its inspections of CDCs, DPH monitors compliance with recent CMS requirements about patient transitions (time between patients) at dialysis stations. CMS based the new requirements on a recommendation from the federal Centers for Disease Control and Prevention that to avoid cross contamination, a patient must have completely vacated a dialysis treatment station before the station is cleaned, disinfected, and prepared for the next patient. There are currently no state or federal rules specifying a minimum amount of time for transitions.

CDCs Receive Compensation for Treatment From Various Payers. CDCs receive payments for their services from patients and third-party payers. Third-party payers pay CDCs (the second party) for services delivered to patients (the first party). Below, we describe the third-party payers that account for the greatest volume of patients treated and amount of revenues received by CDCs.

Government Programs

Federal, state, and local government programs provide health care benefits to certain eligible populations. The two largest government programs for outpatient dialysis services in terms of patient volume and spending are Medicare and Medi-Cal, as described below.

Medicare. This is the federally funded program that provides coverage to most individuals 65 and older and certain younger persons with disabilities. Individuals with ESRD who need regular dialysis are eligible for Medicare coverage at any age if they, their spouse, or (if a dependent child) either of their parents meet certain work requirements. Medicare coverage for individuals with ESRD typically starts three months after dialysis begins. During this three-month “waiting period,” an individual’s other health insurance coverage—such as an employer group health plan or Medicaid—pays for the individual’s dialysis. Once Medicare coverage starts, Medicare becomes the primary payer for dialysis except for individuals covered under an employer or union group health plan. (We discuss this exception in the commercial health insurers section below.) Medicare is the primary payer for the majority of patients receiving treatment at CDCs.

Medi-Cal. In California, the federal-state Medicaid program, known as Medi-Cal, provides health care services to low-income Californians. The costs of the Medicaid program are generally shared between states and the federal government, and the percentage of Medi-Cal costs paid by the federal government varies depending on the enrollee and/or service. For Medi-Cal beneficiaries with ESRD who are also eligible for Medicare—dual eligibles—Medicare is the primary payer for dialysis (after the three-month waiting period) and Medi-Cal is the secondary payer. Medicare covers 80 percent of the costs of outpatient dialysis services for dual

eligibles, and Medi-Cal covers the remaining 20 percent. Medi-Cal also covers any Medicare premiums, deductibles, or other costs that otherwise would be paid by the dual eligible. For Medi-Cal beneficiaries with ESRD who are not eligible for Medicare—non-dual eligibles—Medi-Cal is the sole payer for dialysis.

Medi-Cal Delivery Systems. Medi-Cal provides health care services through two main delivery systems: fee-for-service (FFS) and managed care. In the FFS system, a health care provider receives an individual payment for each medical service delivered to a beneficiary. Most dual eligibles receive dialysis through the Medi-Cal FFS system. In the managed care system, Medi-Cal generally contracts with managed care plans to provide health care for beneficiaries enrolled in these plans. Managed care enrollees may obtain services from providers—including CDCs—that accept payments from the plans. The plans are paid a predetermined amount per enrollee, per month (known as a capitation payment) regardless of the number of services each enrollee actually receives. Some Medi-Cal managed care plans are administered by government entities such as counties, whereas other plans are operated by commercial health insurers that contract with Medi-Cal. Most non-dual eligibles receive dialysis through the Medi-Cal managed care system.

Major Risk Medical Insurance Program (MRMIP). The MRMIP provides health insurance coverage to individuals who, prior to the Patient Protection and Affordable Care Act (ACA), could not obtain coverage or were charged unaffordable premiums in the individual health insurance market because of their preexisting conditions. Given the ACA's prohibition on health plans denying coverage to individuals based on preexisting conditions, most MRMIP enrollees can now obtain other coverage. A few individuals with ESRD, however, remain enrolled in MRMIP because, for example, they are ineligible for other coverage based on their immigration status.

Commercial Health Insurers

Commercial health insurers provide coverage to members of employer groups, organizations, or individuals who purchase health insurance. These insurers receive a premium in exchange for covering an agreed-upon set of health care services.

Commercial Health Insurers and Medicare. During Medicare's three-month waiting period, an individual's other health insurance coverage pays for dialysis. After the waiting period, if an individual is covered under an employer or union group health plan, the plan must continue to pay for dialysis as the primary payer (with Medicare as the secondary payer) for another 30 months. These additional 30 months are referred to as a "coordination period." After this coordination period, Medicare becomes the primary payer and the employer or union group health plan becomes the secondary payer.

Health Benefits for State and Local Government Employees and Retirees. The state, California's two public university systems, and many local governments in California provide health benefits for their employees and related family members and for some of their retired workers. Typically, state and local governments contract with commercial health insurers to cover health care services. Together, state and local governments pay tens of billions of dollars for employee and retiree health benefits each year.

Rates Paid by Commercial Health Insurers Significantly Exceed Rates Paid by Government Programs

Government Program Rates Are Primarily Set Through Medicare. Outpatient dialysis rates for government programs are primarily set by CMS in Medicare. Dialysis providers cannot directly negotiate higher rates from CMS. Because Medi-Cal FFS rates for outpatient dialysis provided to dual eligibles are based on Medicare rates, these rates are also not subject to negotiation. CDCs and governing entities can, however, negotiate higher rates from Medi-Cal managed care plans serving non-dual eligibles. In many cases, Medi-Cal managed care plans base their rates on Medi-Cal FFS rates (and thus on Medicare rates), but in some cases will pay providers higher rates depending on a provider's availability in a given service area in order to maintain access to services needed for their beneficiaries.

Commercial Rates Are Negotiated Between Insurers and Providers. Outpatient dialysis rates for commercial health insurers are set through negotiations between the commercial health insurers and CDCs' governing entities. Depending on the governing entity's market power, the entity can potentially negotiate rates that are much higher than the Medicare rates.

Relative to Patients Covered, Commercial Health Insurers Represent a Disproportionate Share of CDC Revenue. For example, based on financial information from one major governing entity in the state, commercial health insurers account for about one-tenth of this particular governing entity's patients and treatments, but generate about one-third of the governing entity's total annual revenues. (CDCs receive a significant portion of their revenues during the 30-month coordination period when an employer or union health plan is the primary payer for dialysis services and Medicare is the secondary payer.) Government programs, on the other hand, account for about nine-tenths of the governing entity's patients and treatments, but generate only two-thirds of its total annual revenues. We estimate that commercial health insurers, on average, pay multiple times what government programs pay for outpatient dialysis services.

PROPOSAL

Places New Operational Requirements on CDCs

Sets Minimum Direct Care Staffing Requirements. This measure requires CDCs to have at least one registered nurse for every eight patients and at least one certified hemodialysis technician for every three patients. The measure also requires CDCs to ensure the patient caseloads of a full-time equivalent social worker or dietician does not exceed 75. Staffing requirements would take effect March 31, 2019.

Establishes Minimum Transition Times. This measure would require that the transition time between patients at a dialysis treatment station be at least 45 minutes, unless DPH can demonstrate with clinical evidence why a shorter amount of time would be sufficient. Requirements about minimum transition times would take effect March 31, 2019.

Requires Annual Inspections by DPH. This measure requires DPH to conduct inspections of each CDC at least annually, and as often as necessary, to ensure compliance with hygiene and sanitation protocols, compliance with the staffing and transition time requirements of this measure, and adequacy of the quality of patient care.

Requires Quarterly Reporting. This measure requires CDCs to provide information about actual staffing ratios and transition times to DPH at least four times per year, including: (1) the daily total number of hours and actual hours worked by nurses and hemodialysis technicians, (2) the daily total number of patients and actual hours they received direct care, (3) the daily average transition time for each dialysis station, and (4) the weekly number of full-time equivalent social workers and registered dietitians and their patient caseload numbers. The report must also include information about any instances in which the CDC was out of compliance with this measure and the reasons for noncompliance.

Requires Timely Investigation of Complaints. This measure requires DPH to investigate complaints about violations of this measure's provisions within 60 days and specifies that the complaints can come from a patient, a patient's family member, or an association of patients; an employee or association of employees; a vendor; or a contractor. If the investigation reveals that a CDC was in violation of the provisions, the measure requires DPH to assess an appropriate penalty (as specified below).

Establishes Penalty Structure. This measure requires DPH to promulgate regulations about the criteria to be used to assess administrative penalties against CDCs that have violated provisions of this measure. It stipulates the criteria should include, at a minimum, consideration of patient risks, actual harm to patients, the severity of the violation, the CDC's history of compliance with regulations, whether it had any control over the violation, whether it willfully committed the violation, and whether it acted quickly to remedy a known violation. The measure allows DPH to assess administrative penalties (which a CDC may contest by requesting a hearing) as follows:

- Up to \$100,000 for major violations,
- Up to \$20,000 for intermediate violations, and
- Up to \$2,000 for minor violations.

Beginning January 1, 2019, and up until DPH has promulgated its penalty regulations described above, DPH can assess penalties of up to \$100,000 for violations that put patients in immediate jeopardy of serious injury or death.

Limits, in Effect, Prices Clinics May Charge Commercial Health Insurers

Requires Rebates to Commercial Health Insurers When Total Revenues Exceed Specified Cap. Beginning in 2019, the measure requires each governing entity to annually calculate the amount by which total dialysis treatment revenues in all of its clinics exceed a cap equal to 115 percent of certain specified costs for direct patient care plus certain specified costs related to treatment quality (such as health information technology or clinic staff training). The measure then requires the governing entity or its CDCs to annually distribute rebates that equal the amount by which total treatment revenues exceed the cap. The measure specifies that Medicare and other federal, state, or local government payers would not receive rebates, such that rebates would be primarily paid to commercial health insurers. There is some uncertainty as to whether commercial plans that contract with state and local governments to provide health benefits (such as plans that cover employees and retirees or Medi-Cal beneficiaries in the managed care

delivery system) would be eligible for rebates under the initiative. This is because the commercial plans are providing services on behalf of a government entity, but they are themselves private entities and are financially responsible for paying for the services. Whether these commercial plans would be eligible for rebates will depend on how the measure is implemented. Rebates would be allocated to each commercial health insurer proportional to the amount initially paid for dialysis treatment. By requiring rebates to in the event that total revenues exceed the cap, the measure would effectively limit the average rate CDCs and their governing entities may charge commercial health insurers.

In the event that a governing entity or its CDCs are required to provide a rebate, the measure further requires the governing entity to pay interest on the rebate to the payer (calculated from the date that the initial payment for treatment was made) and a penalty to DPH in the amount of 5 percent of the amount of the rebates (up to a maximum of \$100,000), the proceeds of which would go to fund DPH's costs to administer the functions required in the measure.

Outlines Legal Process for Revenue Cap to Be Raised in Certain Circumstances. The measure envisions the possibility that a CDC or governing entity might bring a legal challenge against the measure's rebate provisions on the basis that, for a particular fiscal year, requiring the payment of rebates amounts to an unconstitutional taking of private property without due process or just compensation. In the event that such a challenge is successful, the measure requires that the rebate provisions would still apply, but only after the court replaces the measure's revenue cap with the lowest possible alternative revenue cap (a ratio of specified direct patient care and quality costs higher than 115 percent) that would not be unconstitutional. The measure places the burden on the challenging CDC or governing entity to propose the alternative revenue cap.

Requires Annual Reporting. This measure requires governing entities to prepare annual reports relative to the rebate provisions and to submit them to DPH for each fiscal year starting on or after January 1, 2019. These reports are to list the number of treatments provided, the amount of direct care and quality improvement costs, the amount of the governing entity's revenue cap, the amount by which revenues exceeded the cap, and the amounts of rebates provided to various payers. The DPH may assess penalties of up to \$100,000 if a governing entity fails to maintain required reporting information, fails to submit reports in a timely manner, inaccurately reports information about treatment costs, or fails to justify why rebates were not issued in a timely manner. Any resulting penalty funds must be used by DPH for the implementation and enforcement of laws concerning CDCs.

FISCAL EFFECTS

State Agency Administrative Costs

The measure imposes new administrative, regulatory, oversight, and workload responsibilities on DPH. Although the total cost to comply with these new duties is likely around \$10 million annually, the measure requires DPH to adjust the annual license fee paid by CDCs, which is currently set at \$3,407 per facility, to cover these costs. Some implementation and enforcement costs would be offset by penalties assessed on CDCs or their governing entities for failing to comply with reporting requirements, but the amount of this offset is unknown.

Fiscal Impact Depends on CDC's Response to Measure's Requirements

Staffing Ratios and Transition Time Requirements Would Increase CDC Costs. While we do not have comprehensive data on current staffing levels or transition times at CDCs in California, it appears that many CDCs are not currently meeting staffing ratio and transition time requirements in the measure. For these entities, coming into compliance with the measure's requirements would involve hiring additional staff, expanding hours of operation, and acquiring additional treatment stations, which would increase these CDCs' operating costs.

Various Potential Responses to Rebate Provisions. Based on our research into the operations of major dialysis governing entities, many CDCs and governing entities have revenues that exceed the measure's 115 percent revenue cap and, as such, we expect the rebate provisions in the measure would apply under existing revenue and cost structures. However, the effect of the measure on CDC operations—and ultimately on state and local government finances—would depend on how, if at all, CDCs change operations in response to the measure to avoid having to pay rebates. Some potential behavioral responses to the rebate provisions are:

- *Modify Revenue and Cost Structures.* In order to avoid paying rebates (and the accompanying 5 percent penalty on the amount of rebates) CDCs and governing entities would likely modify their revenue and cost structures. For example, CDCs and governing entities could charge lower rates to commercial health insurers in order to bring total revenue below the cap. CDCs and governing entities could also modify their cost structures to increase the portion of their costs that count toward setting the revenue cap. For example, CDCs and governing entities could increase spending on direct services and specified quality improvement items while reducing overhead and management costs that are not counted toward determining the revenue cap. This would increase the revenue cap and the effective rates that could be charged to commercial health insurers without triggering rebates for those CDCs and governing entities.
- *Seek Adjustments to the Revenue Cap.* In instances where CDCs believe they cannot achieve a reasonable return on their operations, they may choose to challenge the application of the rebate provisions in court. If such challenges proceed as the measure envisions, successful challenges could result in higher revenue caps for some CDCs in some years.
- *Cease Operations.* Finally, reduced revenues under the rebate provisions would decrease incentives for CDCs and their governing entities to participate in the market. CDCs and governing entities in some cases may decide to cease operations if reduced revenues under the rebate provisions do not provide sufficient inducement to remain in the market.

Fiscal Impact of Various Behavioral Responses

Potential Savings to State and Local Governments Providing Employee Health Coverage. Commercial health insurers that provide health benefits for state and local government employees—if they are considered eligible under the measure—would likely pay lower rates for dialysis treatment, either through receiving rebates or by negotiating lower prices (since CDCs

and governing entities would have an incentive to negotiate rates low enough to avoid having to pay a penalty of 5 percent of the rebated amount). The extent to which commercial health insurers pay lower rates would depend on how CDCs and governing entities respond to the provisions of the measure. For example, reductions in commercial health insurer rates would be partially offset to the extent that CDCs and governing entities increase spending on direct services and quality improvements in order to comply with the measure's requirements. How much these lower rates might reduce health insurance premiums paid by state and local governments for their employees is uncertain. For example, commercial health plans that contract with the California Public Employees' Retirement System (CalPERS)—which provides health coverage to state employees, some local government employees, retirees, and their families—paid about \$70 million for dialysis services in 2016 (for enrollees for which the CalPERS plan was the primary payer). We assume that there could be a significant reduction in these costs under the initiative. Some portion of these savings could be retained by the health plans, with the remainder of the savings passed on as reductions in employer health insurance premiums paid by state and local governments. Given these assumptions—as well as the number of commercial health insurers who provide health benefits for local government and school district employees that do not participate in CalPERS—we estimate that state and local governments could potentially save up to tens of millions of dollars under this initiative.

Net State Government Costs for Medi-Cal. As discussed above, the initiative's staffing ratio and transition time requirements would increase operating costs for CDCs. Increased costs at CDCs could increase state costs in the Medi-Cal program, both in the short term and long term. In the short term, it is unclear to what extent, if at all, potential increases in CDC operating costs would ultimately be reflected in Medicare and Medi-Cal FFS rates. As noted previously, CDCs and governing entities do not directly negotiate rates with Medicare, and Medi-Cal FFS rates (for dual eligibles) are based on Medicare rates. Most non-dual eligibles with ESRD, however, receive dialysis through Medi-Cal managed care. CDCs with increased operating costs could charge higher rates to Medi-Cal managed care plans, and plans' higher costs could ultimately be reflected in higher capitation payments from the state. Non-dual eligibles with ESRD, however, are a small population within Medi-Cal managed care. Commercial Medi-Cal managed care plans' higher costs could also be offset somewhat—either through receiving rebates or negotiating lower prices with providers—if such plans are considered eligible for rebates under this measure. To the extent such commercial plans do receive rebates or negotiate lower prices, there could be modest offsetting savings to the Medi-Cal program. Over the long term, increased costs for CDCs could put upward pressure on Medicare rates. To the extent that Medicare rates are adjusted upward to reflect increased costs, the state would eventually have increased costs for dual eligibles with ESRD in the Medi-Cal FFS delivery system. We estimate that total net state costs could be in the low tens of millions of dollars annually in the long run.

Highly Uncertain Fiscal Effects From Potential Changes in Quality and Availability of Treatment. Depending on how CDCs respond to the measure, the quality and availability of dialysis treatment in California could change, with potential fiscal effects on state and local governments. For example, it is possible that the staffing and transition time requirements imposed by the measure could improve the overall quality of dialysis treatment in the state and result in an improvement in health outcomes for dialysis patients, such as reduced

hospitalizations. To the extent that the requirements of the measure reduce dialysis patients' need for health care services beyond dialysis treatment, state and local government costs related to health care (including costs to provide health care to employees and retirees or costs to fund Medi-Cal and other state programs that provide health coverage for certain California residents) could be reduced. On the other hand, if CDCs collectively reduce operations in the state as a result of the measure's requirements, the availability of outpatient dialysis services might be reduced. In that case, patients might seek dialysis treatment in more expensive inpatient settings or could require additional treatment related to not having timely access to dialysis treatment. This could potentially result in higher state and local government costs related to health care. Whether these effects would ultimately materialize or what their potential magnitude would be are highly uncertain.

Summary of Fiscal Effects

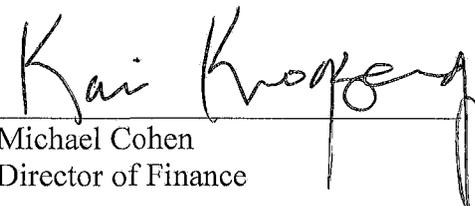
We estimate that the measure would have the following major fiscal impacts:

- State administrative costs of around \$10 million annually to be covered by increases in license fees on chronic dialysis clinics.
- State and local government savings associated with reduced government employee and retiree health benefits spending on dialysis treatment, potentially up to tens of millions of dollars annually.
- Net state government costs for Medi-Cal, potentially in the low tens of millions of dollars annually in the long run.

Sincerely,



for Mac Taylor
Legislative Analyst



for Michael Cohen
Director of Finance