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May 15, 2018

Initiative Statute: Authorizes State Regulation of Kidney Dialysis Clinics and Limits Charges for Patient Care.

L E G I S L A T I V E A N A L Y S T ' S O F F I C E

Presented to:

Assembly Health Committee

Hon. Jim Wood, Chair

and

Senate Health Committee

Hon. Ed Hernandez, Chair

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LAO Role in Initiative Process

☑ Fiscal Analysis Prior to Signature Collection

- State law requires our office, alongside the Department of Finance, to prepare an impartial fiscal analysis of each initiative.
- State law requires this analysis to provide an estimate of the measure's fiscal impact on state and local governments.
- A summary of the fiscal impact is included on petitions that are circulated for signatures.

☑ Analysis After Measure Receives Sufficient Signatures to Qualify for the Ballot

- State law requires our office to provide impartial analyses of all statewide ballot propositions for the statewide voter information guide.
- This analysis includes a description of the measure and its fiscal effects.
- We are currently in the process of preparing these materials for initiatives that have qualified—or have a reasonable likelihood of qualifying—for the November 2018 ballot.

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Background: Kidney Dialysis

☑ End Stage Renal Disease (ESRD) Is the Final Stage of Chronic Kidney Disease

- Patients suffering from ESRD must receive regular kidney dialysis (or a kidney transplant) to survive.
- Kidney dialysis artificially mimics what health kidneys do—filtering out waste and toxins from the blood supply.

☑ Many ESRD Patients Treated at Chronic Dialysis Clinics (CDCs)

- CDCs provide less than 24-hour care for the treatment of ESRD patients. They are licensed and inspected by the Department of Public Health (DPH).
- In California, about 580 licensed CDCs provide treatment to tens of thousands of patients in an average month. Total revenues to CDCs statewide are likely around $3 billion annually.
- The majority of CDCs in the state are owned and operated by one of two private for-profit parent companies—DaVita Healthcare Partners and Fresenius Medical Care.

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Background: Paying for Dialysis Treatment

Payment for Dialysis Treatment Comes From a Few Main Sources

- ***Medicare.*** This federally funded program provides health coverage to most individuals 65 and older and certain individuals with disabilities. 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 Medi-Cal are shared between the state and the federal government. Some individuals qualify for both Medicare and Medi-Cal. For these individuals, Medicare is the primary payer and covers 80 percent of dialysis treatment costs and Medi-Cal is the secondary payer and covers the remaining 20 percent. For individuals who are eligible for Medi-Cal only, the Medi-Cal program pays 100 percent of dialysis treatment costs.
- ***Private Health Insurance.*** Private health insurers provide coverage to members of employer groups, other organizations, or individuals who purchase such coverage. These insurers receive a premium payment in exchange for covering an agreed-upon set of health care services. Among private insurers, dialysis treatment is a widely covered benefit.

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Background: Paying for Dialysis Treatment *(Continued)*

☑ Private Insurers Contracting With Government Agencies and Programs

- Most state and local government agencies provide health coverage as a benefit to their employees and retirees. In some cases, these agencies contract with a private insurer to provide health benefits. For example, the majority of individuals with health benefits through the California Public Employees' Retirement System (CalPERS) are enrolled with a contracted private health insurer.
- For some ESRD patients enrolled in Medi-Cal or Medicare, coverage is actually provided by a contracted private insurer. These private insurers receive a per-person per-month payment in exchange for the responsibility of managing the health care of enrolled patients paying for the dialysis treatment and other covered health services as needed.

☑ Rates Paid by Private Insurance Are Higher Than Rates Paid by Government Programs

- ***Government Programs.*** For most ESRD patients, Medicare and Medi-Cal pay fixed rates that are established by regulation. On average, Medicare rates only slightly exceed the average cost for CDCs to provide a dialysis treatment. It is difficult to directly compare Medi-Cal rates for dialysis treatment with Medicare rates, but Medi-Cal rates appear to be lower than Medicare rates.
- ***Private Insurance.*** Private insurers negotiate rates with CDCs and their parent companies. Rates paid by a private insurer vary depending on the relative bargaining power of the insurer and the dialysis providers. On average, private insurers pay multiple times what government programs pay for outpatient dialysis services.

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Proposal

☑ **Requires Clinics to Pay Rebates When Total Revenues Exceed a Specified Cap**

- The measure requires CDCs to pay rebates to certain payers equal to the amount by which revenues exceed 115 percent of specified "direct patient care services costs" and "health care quality improvement costs."
- CDCs would additionally be required to pay a penalty to DPH of 5 percent of the amount of any rebates, up to $100,000, plus interest on the rebates calculated from date of the initial payment for treatment.
- Revenues, costs, and rebate amounts would be calculated at the level of a CDC's "governing entity," which refers the entity that owns or operates the clinic, such as a parent company.
- The measure provides that rebates would be provided only to nongovernment payers.

☑ **Legal Process to Raise Revenue Cap in Certain Circumstances**

- The measure envisions the possibility that a CDC/governing entity might challenge the measure in court on the grounds that the rebate requirement is an unconstitutional taking of private property without due process or just compensation.
- If such a legal challenge is successful, the measure requires that the rebate provision still apply, but only after the court replaces the measure's revenue cap with the lowest possible alternative (a ratio of specified costs higher than 115 percent) that would not be unconstitutional. The measure places the burden of identifying the alternative cap on the CDC/governing entity.

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Proposal *(Continued)*

☑ **Annual Reporting Requirements**

- The measure requires governing entities to submit annual reports to DPH related to the rebate requirement. These reports would 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 exceed the cap, and the amount of rebates paid.

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Potential Impact on CDCs and Governing Entities

☑ CDC Revenues Likely Exceed Cap

- Current CDC revenues likely exceed the cap that would be put in place by this measure. We estimate that rebates roughly in the hundreds of millions of dollars would likely be required if the cap were put in place today and CDCs continued operating as they do currently without changing their behavior.

☑ Precise Amount of Rebates and Impact on Clinic Viability Depend on Many Factors

- The amount of rebates is significant for the ongoing economic viability of CDCs and governing entities. Rebates would reduce or could potentially exceed the operating income of CDCs/governing entities.
- While rebates would be likely under the measure, the precise amount of these rebates, and their impact on the ongoing economic viability of CDCs and their governing entities, depend on (1) how the measure is interpreted and implemented and (2) what changes CDCs and their governing entities make to limit the amount of required rebates.

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Uncertainty as to How Some Provisions Would Be Interpreted and Implemented

☑ Which Costs Would Be Included When Calculating Revenue Cap?

- There is some uncertainty about which costs would be included when calculating CDCs' revenue caps and rebates. Including more costs when determining the revenue cap makes the cap higher, results in relatively lower rebates, and has a smaller impact on CDC/governing entities' bottom line. Including fewer costs makes the cap lower, results in greater rebates, and a greater likelihood of negatively affecting CDC viability.

- For example, when defining direct patient care services costs, the measure requires that CDCs count salaries, wages, and benefits of "non-managerial" staff, including staff that "furnish direct care to dialysis patients." CDCs are required to maintain a medical director and a nurse manager as conditions of receiving federal Medicare reimbursement. These positions may be involved in some degree with providing direct patient care, but overall perform managerial functions. The proponents and opponents of the measure disagree about whether the costs of these mandatory staff positions would be included when determining the revenue cap.

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Uncertainty as to How Some Provisions Would Be Interpreted and Implemented *(Continued)*

☑ **Would Private Insurers That Contract With Government Agencies and Programs Be Eligible for Rebates?**

- As noted previously, the measure requires that rebates be paid only to nongovernment payers. The measure also defines payer as the entity that is financially responsible for paying for the dialysis treatment to a particular patient.
- It is unclear whether private insurers that contract with government agencies or programs, such as private health insurers that contract with the CalPERS or Medi-Cal, would be eligible for rebates under the measure. These insurers pay for treatment on behalf of a government agency or program, but are financially responsible to pay for dialysis treatment *for any particular patient* for whom they have received a premium or per-person per-month payment.

☑ **How Would Legal Process to Increase Revenue Cap Work in Practice?**

- Other state policies that regulate the prices that private entities may charge for goods and services have administrative processes in place for the regulated entity to justify its rates. This measure defines its revenue cap by formula, with adjustments to the formula possible only through a court challenge.
- We are not aware of other regulatory systems that use a court-based process as outlined in this measure. As a result, it is uncertain how the process would work in practice. For example, it is unclear what level of rebates a court would consider to result in an unconstitutional takings for any particular CDC or governing entity.

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Industry Response Is Also Uncertain

☑ Potential Clinic Responses

The effect of the rebate provisions on CDC operations—and ultimately on state and local government finances—would depend on how CDCs change operations to limit the amount of rebates they must pay. Some possible responses the CDCs could take individually or in combination include:

- ***Modify Cost Structures.*** If the amount of rebates required is relatively small, CDCs may in some cases attempt to reduce costs that are not considered direct patient care services costs or health care quality improvement costs (costs that are not counted toward determining the revenue cap). Alternatively, CDCs may increase direct patient care services costs or health care quality improvement costs. Both of these responses would increase the revenue cap and reduce rebates.

- ***Modify Revenue Structures.*** In some cases, CDCs may charge lower rates in order to bring total revenues closer to the cap, in order to avoid penalties and interest associated with paying rebates.

- ***Seek Adjustments to Revenue Cap.*** If the amount of rebates required is relatively large and 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 outlines, successful challenges could result in higher revenue caps for some CDCs or parent companies in some years.

- ***Scale Back Operations.*** Finally, reduced revenues under the rebate provisions would decrease incentives for some CDCs and their parent companies to participate in the market. In some cases, CDCs and their parent companies may decide to open fewer new clinics or close clinics if the amount of required rebates is large and reduced revenues do not provide sufficient return to remain in the market.

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Industry Response Is Also Uncertain *(Continued)*

☑ **Clinic Responses Depend in Part on How Measure Is Interpreted and Implemented**

- If the measure is implemented with a broader, more inclusive, interpretation of what costs count toward determining the revenue cap, rebates would be smaller have less of an impact on CDC/governing entity returns. In this case, CDCs and their governing entities would be more likely to make adjustments to cost and revenue structures to reduce the amount of rebates.
- If the measure is implemented with a narrower, more restrictive, interpretation of what costs count toward determining the revenue cap, rebates would be larger and have a larger impact on CDC/governing entity returns. In this case, CDCs and their governing entities would be more likely to seek adjustments to the revenue cap or scale back operations.

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Fiscal Effects on State and Local Governments

☑ **Range of Possible Fiscal Effects; Net Fiscal Effect Unclear**

There is range of possible fiscal effects of the measure, resulting from uncertainty as to how it is interpreted and implemented and how CDCs respond to the measure's implementation. Overall, based on the information reviewed to date, and in light of this significant uncertainty, the net fiscal effect on state and local governments is unclear.

☑ **Under Broad Interpretation, Potential for State and Local Government Savings From Rebates and Reduced Prices for Dialysis Treatment**

- If the measure is implemented with a broad interpretation of what costs count toward the revenue cap, clinics might modify their cost and revenue structures in such a way as to receive a sufficient return to continue operations. Those that cannot make such modifications might receive upward adjustment to their revenue cap through the legal process outlined in the measure. Under these conditions, private insurers that provide health coverage for state and local government employees might receive rebates (if they are found to be eligible) and might also benefit from reduced dialysis treatment rates.
- These insurers may pass some portion of this benefit on to state and local government agencies in the form of reduced premiums. The amount of these potential savings is uncertain, but could be as much as low millions of dollars annually.

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Fiscal Effects on State and Local Governments *(Continued)*

☑ **Under Narrow Interpretation, Potential for State and Local Government Costs From Reduced Access to Outpatient Dialysis**

- If the measure is implemented with a narrow interpretation of what costs count toward the revenue cap, it could negatively affect the economic viability of CDCs and their governing entities. In the short term, this could result in fewer new clinics opening or some clinics closing, potentially leading to some ESRD patients receiving dialysis treatment in more expensive non-clinic settings, such as hospitals. This would increase state costs in Medi-Cal and increase costs for state and local governments that provide health benefits for their employees. The amount of these potential costs is uncertain, but could be significant.
- In the longer run, broader adjustments in the dialysis industry and potentially changes to how the measures' provisions are implemented (such as through regulatory, legislative, or judicial action) would likely tend to reduce these higher costs over time.

☑ **State Administrative Costs**

- We estimate that DPH would have increased costs in the low millions of dollars annually associated with administering the provisions of the measure. These costs would be funded with increases to CDC licensing fees.