- **Quality of care will improve, lowering costs for payers and improving outcomes for dialysis patients.**
- **Dialysis clinics will absorb the costs of meeting the onsite clinician requirement, without clinic closures.**
- **Medi-Cal, Medicare, and commercial payer costs will likely not increase.**

Key provisions of the Protect the Lives of Dialysis Patients Act

Clinics Prohibited from Discriminating Against Patients Based on Payer

Insurance-based discrimination is unfortunately common in healthcare and has been associated with patients being denied care or receiving suboptimal care.[i]

Current law does not protect patients seeking dialysis care from discrimination based on type of payor. The fact that private insurers reimburse dialysis clinics at much higher rates than Medicare and Medicaid[ii] raises concerns that clinics will turn away or otherwise discriminate against patients who are less profitable, especially as higher quality of care standards such as those this Act would require are implemented for clinics. Discrimination may include refusing to treat a patient, moving a patient to a less preferable time slot, or providing inferior care to certain patients based on their payor. For example, workers have described clinics giving preference to commercial patients over Medi-Cal and Medicare patients when choosing dialysis shifts.

More Transparency Around Ownership and Physician Joint Ventures

Increasingly, physicians have direct financial interests in clinics through joint ventures with dialysis clinics' governing entities.[iii] Nephrologists with a financial interest in a dialysis clinic may have an incentive to "cherry-pick" patients in better health for their own clinic while avoiding referring patients that are socioeconomically disadvantaged or otherwise high risk. Nephrologists who are joint venture partners may also have an incentive to start a patient earlier on dialysis rather than conservatively manage the disease, or may promote in-center hemodialysis over home dialysis or transplantation. These potential conflicts of interest may influence patients' ability to make informed decisions about their care.[iv]

Reliable and accurate information on joint venture partnerships in the dialysis industry is currently difficult to obtain, both from federal and state regulators. Academic researchers have tried unsuccessfully in the past to obtain comprehensive information through Freedom of Information Act requests,[v] and lack of information has hindered research into the costs and benefits of joint venture arrangements.[vi]

Requiring clinics to disclose to patients the names of physician owners of clinics will provide patients and prospective patients with information about whether the physician(s) directing their care have a significant financial interest in the chronic dialysis clinic, which may better enable these patients to make informed healthcare choices. Requiring clinics to report standardized, comprehensive information on ownership to the Department of Public Health ("DPH") and publicly on their websites will provide

valuable information to stakeholders beyond the clinics' and physicians' patients – including payors, regulators, and researchers.

Maintaining Physicians or Other Advanced Practitioners Onsite During Treatment Hours Will Improve Quality of Care

Under the Act, the onsite clinician has "authority and responsibility over patient safety and to direct the provision and quality of medical care." The sponsors expect that DPH may further define or provide regulatory guidance regarding the onsite clinicians' responsibilities. Generally, the sponsors expect that the onsite clinician will supervise other staff to ensure patients receive high-quality care, which may include working closely with patients' care teams, monitoring quality improvement activities and safety measures, and assisting with medical emergencies. This will benefit patients by providing physicians or other advanced practitioners with "greater opportunities to improve patient communication and build trust, monitor treatments, and detect new medical problems."[vii]

Dialysis Patients Experience High Levels of Complications, Hospitalizations and Emergency Visits

Better patient outcomes will lead to savings for payors and will increase capacity elsewhere in the healthcare system. Dialysis patients are at high risk for complications such as infections and cardiovascular disease which result in emergency department visits, hospitalizations, and death. In 2019, Medicare patients receiving dialysis in California visited the emergency room almost 90,000 times, and 45 percent of those visits resulted in hospitalization.[viii] By contrast, 29 percent of emergency department visits by Medicare patients in the general population resulted in admissions.[ix] Moreover, Medicare patients receiving dialysis in California had on average two hospital admissions per year and spent 12 days in the hospital.[x] This rate of hospitalization is much higher than the general Medicare population in California, which had on average 0.1 hospital stays per year and spent on average 2 days in the hospital per year.[xi]

Patients with ESRD are immunocompromised and at increased risk of infection. The invasive nature of dialysis heightens this risk. For example, patients commonly develop chills and fever after onset of dialysis and should be assessed for infection. It is recommended that patients undergo a physical examination to check for signs and symptoms of infection, and to identify the source of the infection. Patients would ideally be given antibiotics as soon as possible.[xii] Patients in this and similar scenarios could be more quickly assessed and appropriately treated when an advanced clinician is present onsite at all times during treatment hours.

California Dialysis Clinics Generally Operate 18 to 24 Treatment Shifts Per Week, and Medical Director Presence is Minimal

California dialysis clinics typically perform three treatment shifts a day for three to four hours per shift,

six days per week. Out of 650 licensed clinics, 146 perform a late shift.[xiii] Assuming a clinic without a late shift is open 6 days per week for 12 hours per day, and a clinic with a late shift is open 6 days per week for 16 hours per day, California clinics are open an average of approximately 77 hours per week.

Currently clinics are required by CMS to have a medical director who has completed a board-approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.[xiv] In addition, clinics must have a nurse manager who is an RN with at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.[xv] A typical clinic is staffed by patient care technicians who are supervised by a charge nurse.

We understand that medical directors typically spend time at clinics only when they briefly attend (or "round with") their own patients or attend meetings. Meeting attendance varies by clinic and medical director –for example, some medical directors may attend each weekly and monthly team meeting while others do not. The total time spent rounding with patients also varies – the medical director may be the nephrologist for most of the clinic's patients, or for just a few or none at all.

Evidence Links Physician-Patient Contact to Quality Outcomes

Studies have linked frequency of physician contact with better quality of care and lower mortality rates for dialysis patients.

1. More patient-doctor contact during hemodialysis treatments is associated with lower patient mortality and fewer hospitalizations.[xvi]
2. More frequent physician visits following hospital discharge are estimated to reduce rehospitalizations in patients undergoing hemodialysis.[xvii]
3. Japan, which has one of the best survival rates in the world for patients on dialysis, requires a patient to be seen by a doctor at every dialysis session.[xviii]
4. Patient-physician contact during every dialysis session is associated with achieving clinical targets.[xix]

Nurse Practitioners and Physician Assistants Onsite Will Also Improve Patient Outcomes

Advanced practitioners such as Nurse Practitioners ("NPs") and Physician Assistants ("PAs") play an important role in dialysis and nephrology care. These types of advanced practitioners often round with patients in dialysis clinics and may have responsibilities including patient assessment, helping to design care plans, and management of treatment and medication.[xx] Studies show that nurse practitioners, working in collaboration with a nephrologist or general practitioner, have positive impacts on outcomes of patients with chronic kidney disease.[xxi]

Nurse Practitioners and Physician Assistants in California are supervised by and work in collaboration with a physician who determines their scope of practice.[xxii] We anticipate the specific duties of a PA or NP fulfilling the requirements of the Act will depend upon the procedures of the clinic and the

relationship between the NP or PA and their medical director or other supervising position but that they will be able to fulfill all the requirements of the Act, including patient assessment, real-time response to patient needs, and having "authority and responsibility over patient safety and to direct the provision and quality of medical care." The Act is also drafted with adequate flexibility to take account of the ways California regulations over these practitioners' scope of practice may develop in future.

Dialysis Clinics Will Absorb the Costs of Maintaining Clinicians Onsite and Clinic Closures in Response to the Act Are Not Anticipated

Our analysis is that dialysis clinics are likely to be able to minimize or even eliminate any additional costs of the Act's requirement that a physician or other advanced practitioner be onsite while patients are being dialyzed, including in the following ways.

Nephrology Practices and Medical Directors Could Play a More Active Role in Clinics

First, nephrologists who are financially interested in chronic dialysis clinics through joint ventures and medical directorships may spend more time onsite at the clinic as a way to reduce costs. Governing entities can reduce the costs of having an onsite physician by contractually requiring the medical director to be onsite during the 25% of a standard workweek that they are expected to spend on their clinic-related duties. Alternatively, clinics could require the medical director to work full-time at the clinic.

Nephrology practices often already employ NPs or PAs – between 2004 and 2013, 75% of nephrology practices added an advanced practitioner.[xxiii] Practices that own clinics and employ NPs and PAs may structure these clinicians' work in a way that meets the requirements of the Act.

Clinics May Earn More Through Better Quality Ratings

Second, clinics with physicians onsite are likely to be able to improve payments through improving quality. CMS' ESRD Quality Improvement Program (QIP) links facility payment to performance on quality improvement measures. CMS calculates a Total Performance Score based on scores for individual quality measures. Clinic payments are reduced by up to 2% for the year if the Total Performance Score does not meet or exceed performance standards.[xxiv] Performance measures include indicators for hospitalization, dialysis adequacy, bloodstream infections, ultrafiltration rate, and other measures.[xxv] For the 2021 payment year, 234 of 598 California dialysis clinics received payment reductions between 0.5% and 2% because they did not meet minimum quality targets.[xxvi]

Clinics Spread Costs Between High and Low Earning Facilities

Third, as noted in the LAO's initial analysis of the 2020 "Protect the Lives of Dialysis Patients Act", the large dialysis companies---as "governing entities"—can absorb negative operating margins at individual clinics.

Dialysis clinics are unlikely to close in response to the Act, as the LAO recognized in its 2020 analysis,

because the more clinics that a governing entity operates the greater its market power. For example, it is our understanding from conversations with payers that DaVita engages in all-or-nothing contracting in which plans are required to contract with all or a group of the company's clinics, even if there are lower-priced alternatives in the market.

A State Approval Process Before Dialysis Clinics Close or Substantially Reduce Services Is Appropriate

The Act will require that CDCs obtain written consent from DPH before closing or substantially reducing or eliminating services. In making its decision about whether to approve a closure or reduction in services, the Department may consider any factors it deems relevant, including 1) the impact on access to dialysis treatment for the clinic's patients, 2) efforts by the current owner to transfer ownership of the clinic in order to maintain adequate access to care for patients, and 3) the financial status of the clinic and its governing entity.

The closure notice and approval requirement will ensure that there is a process to protect patient welfare by giving DPH authority to intervene if a dialysis company decides to reduce or eliminate services without considering the impact on patients' welfare. While the proponent is not aware of other California statutes that require state approval before closing a medical facility or other business, there are other laws that ensure the state can act to protect vulnerable patients' continuity of care, such as the long-term health care facility receivership process.[xxvii] The Act's closure approval process is also consistent with approaches taken by other states that require approval by a state agency before certain health care facilities can close or cut services. For example, many types of medical facilities in New York must obtain the Department of Health's approval before closing.[xxviii] Similarly, hospitals and other health facilities in a number of other states, including Connecticut, Illinois, Rhode Island, and New Jersey, require approval by their state departments of health or other state agencies before closing pursuant to their Certificate of Need (CON) programs.[xxix]

The proponent drafted the initiative to ensure that CDPH has the flexibility not only to determine what factors it will consider when making determinations about proposed closures and reductions in service, but what processes it will follow when making such determinations. For example, the Department may choose to establish an appeal process that would permit it to review its original determination and consider additional information submitted by the clinic or governing entity.

The Act is Not Likely to Increase Costs to State and Local Governments

In the private market, reimbursements are determined by market power, not patient care costs. Dialysis clinics which operate in a concentrated, uncompetitive market,[xxx] already maximize revenue with commercial insurers, who pay on average almost four times the cost of a treatment.[xxxi] Thus, we believe that CalPERS and other commercial insurance rates paid by state and local governments will not increase in response to the ballot initiative.

We do not expect Medicare reimbursement rates to change in the near future in response to the initiative. Adjustments to the wage index for the ESRD PPS per treatment amount must be budget neutral,[xxxii] therefore an increase in California reimbursement rates would require a decrease elsewhere.

Furthermore, the ESRD PPS wage index is based on the hospital wage index,[xxxiii] which will not change in response to the initiative. Prices paid by Medicare Advantage plans are linked closely to traditional Medicare rates and we don't expect the initiative to change this dynamic.[xxxiv] [xxxv]

Finally, we do not expect Medi-Cal reimbursement rates to increase. Our understanding is that dialysis fee-for-service rates have not meaningfully increased since at least the year 2001, despite numerous regulatory changes (such as substantial increases to the minimum wage). The dialysis clinics have not negotiated higher rates despite their substantial market power, and nothing in the Act would provide increased negotiating power to the dialysis clinics.

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[i] Han X., Call K.T., Pintor J.K., Alarcon-Espinoza G., Simon A.B., Reports of insurance-based discrimination in health care and its association with access to care. Am J Public Health. 2015;105 Suppl 3(Suppl 3):S517-S525. doi:10.2105/AJPH.2015.302668 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455519/

[ii] Childers C, et al., A Comparison of Payments to a For-profit Dialysis Firm From Government and Commercial Insurers. JAMA Internal Medicine. August 2019. Volume 176 Number 8.

[iii] https://www.davita.com/physicians/partnerships/joint-ventures-acquisitions (DaVita more than doubled the number of joint venture clinics from 2008 to 2018).

[iv] Glickman A., Lin E., Berns J.S., Conflicts of interest in dialysis: A barrier to policy reforms. Semin Dial. 2020;33(1):83-89. doi:10.1111/sdi.12848

[v] J.S. Berns et al., "Dialysis-Facility Joint-Venture Ownership — Hidden Conflicts of Interest" The New England Journal of Medicine 379;14, October 4, 2018.

[vi] Glickman, et al.

[vii] L. C. Plantinga, et al., "Frequency of patient–physician contact in chronic kidney disease care and achievement of clinical performance targets" International Journal for Quality in Health Care 2005; Volume 17, Number 2: pp. 115–121.

[viii] Dialysis Facility Report data and documentation is publicly available here: https://data.cms.gov/dialysis-facility-reports. Patients included in the hospitalization summary include patients who received dialysis in the facility and satisfied the Medicare payment criterion as Medicare patients.

[ix] OSHPD 2019 Hospital Emergency Department - Characteristics by Facility (Pivot Profile). Where expected payer source is Medicare, ED Admit as a percent of Total ED.

[x] 2019 Dialysis Facility Reports Hospitalization Summary for California. Dialysis Facility Report data and documentation is publicly available here: https://data.cms.gov/dialysis-facility-reports. Patients included in the hospitalization summary include patients who received dialysis in the facility and satisfied the Medicare payment criterion as Medicare patients.

[xi] Data from the Kaiser Family Foundation available here: https://www.kff.org/medicare/state-indicator/medicare-service-use-hospital-inpatient-services/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[xii] Nguyen D.B., Arduino M.J., Patel P.R., Hemodialysis-Associated Infections. Chronic Kidney Disease, Dialysis, and Transplantation. 2019;389-410.e8. doi:10.1016/B978-0-323-52978-5.00025-2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7152337/pdf/main.pdf page 399.

[xiii] DPH current healthcare facilities; late shift information from CMS certified facility listing.

[xiv] 42 C.F.R. § 494.140(a).

[xv] 42 C.F.R. § 494.140(b).

[xvi] Kawaguchi, Takehiko, et al., "Associations of frequency and duration of patient-doctor contact in hemodialysis facilities with mortality." Journal of the American Society of Nephrology : JASN vol. 24,9 (2013): 1493-502. doi:10.1681/ASN.2012080831 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3752943/.

[xvii] Erickson, Kevin F, et al., "Physician visits and 30-day hospital readmissions in patients receiving hemodialysis." Journal of the American Society of Nephrology : JASN vol. 25,9 (2014): 2079-87. doi:10.1681/ASN.2013080879 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147977/ .

[xviii] Global Dialysis Perspective: Japan, Norio Hanafusa and Masafumi Fukagawa, Kidney360 May 2020, 1 (5) 416-419; DOI: https://doi.org/10.34067/KID.0000162020.

[xix] Plantinga L.C., et al., *supra.*

[xx] https://www.kidney.org/sites/default/files/NNI0818pgs2628-29_ADVPRCTNEWS.pdf (page 28).

[xxi] McCrory G., Patton D., Moore Z., O'Connor T., Nugent L., The impact of advanced nurse practitioners on patient outcomes in chronic kidney disease: a systematic review. Journal of Renal Care (2018).

[xxii] https://www.rn.ca.gov/pdfs/regulations/npr-b-23.pdf (page 1); CA Business and Professions Code § 3502.

[xxiii] Zuber K., Davis J., Erickson K. Nephrology Advanced Practitioners in the United States, 2010-2018 CJASN Sep 2019, 14 (9) 1381-1382; DOI: 10.2215/CJN.0160021https://cjasn.asnjournals.org/content/14/9/1381

[xxiv] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP

[xxv] https://www.cms.gov/files/document/esrd-qip-summary-payment-years-2021-2024.pdf

[xxvi] ESRD QIP - Total Performance Scores - Payment Year 2021. Our analysis eliminated hospital-based clinics and those providing only home-based dialysis

[xxvii] *See* Health and Safety Code §§ 1325-1335.

[xxviii] N.Y. Comp. Codes R. & Regs. tit. 10, § 401.3; N.Y. Comp. Codes R. & Regs. tit. 18, § 485.5. *See also* https://www.health.ny.gov/professionals/nursing_home_administrator/docs/dal_nh_17-06_revised_nh_closure_guidelines_att.pdf (summarizing requirements for DOH approval of nursing home closures); https://www.health.ny.gov/facilities/cons/more_information/ (approval from the Department of Public Health required before "[a]dding or deleting services" at hospitals, treatment centers, hospitals and other clinics).

[xxix] *See* https://portal.ct.gov/DSS/Health-And-Home-Care/Reimbursement-and-Certificate-of-Need/Certificate-of-Need (under Connecticut's CON process, approval is required before "[t]ermination of a health service including facility closure or a substantial decrease in total bed capacity"); https://www2.illinois.gov/sites/hfsrb/CONProgram/Pages/default.aspx (entities subject to Illinois's CON program, including dialysis centers, must seek an "exemption" from the state review board in order to close or discontinue a category of service); 23 R.I. Gen. Laws Ann. § 23-17.14-18 (hospitals that have been open for one year and that serve uninsured or underinsured patients may be "eliminated or significantly reduced" without first obtaining approval of the Director of the Rhode Island Department of Health); N.J. Admin. Code § 8:33-3.2 (closure of a general hospital in New Jersey must be approved by stated under CON process).

[xxx] Blue Sky report, provided herewith.

[xxxi] Childers C, et al., *supra*.

[xxxii] https://www.cms.gov/newsroom/fact-sheets/end-stage-renal-disease-esrd-prospective-payment-system-pps-calendar-year-cy-2021-proposed-rule-cms

[xxxiii] http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_dialysis_final_sec.pdf?sfvrsn=0 page 2

[xxxiv] Trish E., Ginsburg P., Gascue L., Joyce G., Physician Reimbursement in Medicare Advantage Compared With Traditional Medicare and Commercial Health Insurance. JAMA Intern Med. 2017;177(9):1287-1295. doi:10.1001/jamainternmed.2017.2679

[xxxv] Berenson R. et al., Why Medicare Advantage Plans Pay Hospitals Traditional Medicare Prices. Health Affairs. August 2015. https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1427