No. 24-3654
***consolidated with* No. 24-3655, No. 24-3700**

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

FRESENIUS MEDICAL CARE ORANGE COUNTY, LLC, *et al.* ,
Plaintiffs-Appellants,

and

JANE DOE, *et al.* ,
Plaintiffs

v.

ROB BONTA, in his official capacity as Attorney General of California, *et al.*,
Defendants-Appellees.

[CAPTIONS CONTINUED ON INSIDE COVER]

On Appeal from the United States District Court for the Central District of California, Nos. 8:19-cv-02105-DOC-ADS, 8:19-cv-02130-DOC-ADS, Hon. David O. Carter, District Judge

BRIEF OF *AMICI CURIAE* CALIFORNIA MEDICAL ASSOCIATION IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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v.

ROB BONTA, *et al.*,

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a), *amici curiae* is a non-profit organization committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

Dated: September 30, 2024

/s/ Jamie Ostroff
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United States Renal Data System. 2023 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023 4,5,6,7,8

Amici California Medical Association ("CMA") submits this brief urging the Court to reverse the portions of the District Court's ruling granting summary judgment in favor of Defendant-Appellees Rob Bonta, et al., and affirm those portions of the District Court's ruling denying summary judgment in favor of Plaintiff-Appellant Fresenius Medical Care Orange County, LLC, *et al.* (the "Dialysis Providers") because (1) AB290 will decrease end stage renal disease (ESRD) patients' access to life-saving dialysis and (2) will deprive ESRD patients of commercial insurance coverage for dialysis treatments.

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

CMA is a not-for-profit professional association for physicians with over 50,000 members throughout California. For more than 160 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings and treat all manner of ailments and diseases, including patients with ESRD who will be directly affected by AB290. CMA regularly carries out this mission through advocacy on behalf of organized medicine in the courts and before legislatures and regulators.

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* affirm that no party's counsel authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

INTRODUCTION

Chronic kidney disease, which can ultimately progress to ESRD, is the ninth leading cause of death in America. An estimated 14 percent of adults have chronic kidney disease, and the vast majority do not know they have it. Data show that minority groups are disproportionately affected. ESRD patients account for significant percentages of overall healthcare spending and utilization. Physicians who diagnose and treat patients with chronic kidney disease, including ESRD patients, know firsthand the devastating impact of the disease not only on the healthcare ecosystem but also on the lives of patients and their families. The physician community also understand the importance to the public health and healthcare delivery system of ensuring that ESRD patients – who often come from underserved communities – have meaningful access to life-saving dialysis treatment, by far the most viable option for the survival of those with ESRD.

From CMA's perspective, this case brought by Fresenius Medical Care Orange County, LLC, *et al.* (the "Dialysis Providers") challenging AB290 is primarily about preserving access to urgently needed care for California's ESRD patients. On its face, AB290 purportedly seeks to address conflicts in reimbursement for and delivery of dialysis. However, CMA believes that AB290 will ultimately decrease the availability of dialysis for California's ESRD population and thereby push these patients into more expensive settings, such as hospitals and their emergency departments. CMA further

believes that AB290, the genesis of which is based less on sound evidence-based medicine than on political motivations, may operate to place the financial interests of health insurers over the medical needs of patients. AB290 therefore cannot pass constitutional scrutiny.

Accordingly, CMA opposed AB290 in the California Legislature and hereby supports the Dialysis Providers' appeal to prevent the remaining aspects of the statute from taking effect.

ARGUMENT

I. Background on the Vulnerable ESRD Patient Population

ESRD is the final, permanent stage of chronic kidney disease, where kidney function has declined to the point that the kidneys can no longer function on their own. To survive, a patient with ESRD faces two options: dialysis treatment or kidney transplantation. Dialysis treatment can be very impactful on patient lives, typically involving 4-hour sessions, three times a week, and constant monitoring and lifestyle and diet modifications. As kidney failure progresses, ESRD patients may experience a wide array of symptoms. These include fatigue, drowsiness, decrease in urination or inability to urinate, dry skin, itchy skin, headache, weight loss, nausea, bone pain, skin and nail changes, and easy bruising.

The National Institutes of Health funds the United States Renal Data System (the "USRDS"), a national data registry that collects, analyzes, and distributes information

on the United States' ESRD population, including treatments and outcomes. The USRDS issues an annual data report highlighting and analyzing statistics and trends. According to the 2023 USRDS Annual Report, in 2021 there were 135,972 newly reported cases of ESRD in the nation, bringing the total number of cases of ESRD to 808,536 as of December 31, 2021. This represents an approximate 9% increase in new cases of ESRD and a 10% rise in national ESRD prevalence compared to the figures reported in 2018, when AB290 was drafted.[2] The number of ESRD cases has risen by about 20,000 annually; after a year-by-year rise in the number of incident ESRD cases from 1980 through 2019, the count dropped between 2019 and 2020 but rose again from 2020 to 2021.[3]

Other than kidney transplantation, dialysis remains the best treatment for the survival of ESRD patients. Over half a million people were on dialysis in 2021.[4] Put another way, 37 percent of all ESRD patients in 2021 were receiving dialysis treatment, and the virtually all (85 percent) used in-center dialysis such as those provided by the Dialysis Providers.[5]

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[2] *See* UNITED STATES RENAL DATA SYSTEM. 2023 USRDS ANNUAL DATA REPORT: EPIDEMIOLOGY OF KIDNEY DISEASE IN THE UNITED STATES. NATIONAL INSTITUTES OF HEALTH, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, Bethesda, MD, 2023, https://www.usrds.org/2018/view/Default.aspx (USRDS Report").

[3] *Id*.

[4] *Id*.

[5] *Id*.

There are racial and ethnic disparities in the prevalence of ESRD. The standardized incidence rate among Blacks is higher than among Whites. Scholars have identified numerous sources of disparities in ESRD unique to the Black community, including unequal access to higher education, inequitable income level, and low awareness of the effects of social determinants of health.[6] In fact, education and income levels have been shown to contribute to excess ESRD rates in Blacks.[7]

The ratio of ESRD prevalence between Blacks and Whites had been 3.8 in 2000, and the downward trend from 2000 through 2016 is being found with other ethnic racial groups: from 2.9 to 1.2 in American Indians/Alaska Natives and from 1.3 to 1.1 in Asians.[8] The trend reflects a decrease in incidence rate among minorities while the rate for Whites has remained constant.[9] Researchers believe these changes may represent a reduction in health inequalities in the population with chronic kidney disease.[10] That is, progress is being made to reach historically underserved, often poorer minority communities. Premium assistance programs like that offered by the American Kidney Fund ("AKF") may play a role in this improvement in access to care for ESRD patients.

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[6] See Kimberly Harding et al., *Current State and Future Trends to Optimize the Care of African Americans with End-Stage Renal Disease*, 46 AM. J. NEPHROLOGY 156, 157 (Aug. 5, 2017), https://www.karger.com/Article/PDF/479479 ("Harding").

[7] *Id*.

[8] USRDS Report, *supra* note 2.

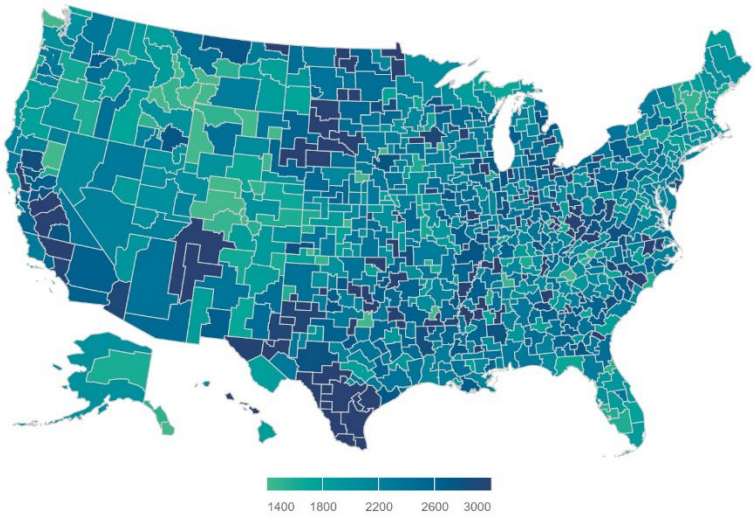
[9] *Id*.

[10] *Id*.

There also are regional variations in ESRD prevalence. California and the Southwest have the highest rates, as shown in the following map from the 2021 USRDS Annual Report.[11]

Standardized Prevalence of ESRD, by Health Service Area, 2020-2021

Figure 1.7 Prevalence of ESRD by Health Service Area, 2020-2021



Data Source: 2023 United States Renal Data System Annual Data Report

The Central Valley of California, a data region by itself, has one of the highest prevalence rates of ESRD in the country with a range of 940-10,300 per million people (similar to the region covering West Virginia, southern and western Texas, northeastern Arizona, and northwestern New Mexico).[12]

Not only are ESRD patients more likely to come from underserved, minority communities, but the monitoring and treatment programs they must endure can have significant negative impacts on their lives. In general, ESRD patients already suffer with deteriorating health status, including cognitive impairment and frequent

[11] *Id.*
[12] *See Id.*

depression.[13] They also must struggle with complex dietary restrictions, polypharmacy and complex care coordination, and, with respect to dialysis treatment, a chronic dependence on nurses, social workers, nutritionists, technicians, vascular surgeons, and nephrologists for at least three hours, three times a week

II. Physician's Central Role in Caring for Patients with ESRD

Physicians take a central role in the diagnosis and care of patients with ESRD, who as shown above, are a vulnerable population. Often, physicians have been caring for these patients before they deteriorated to ESRD, addressing chronic kidney disease and other health ailments that lead to ESRD. Physicians – i.e., family medicine and other primary care doctors – also sometimes care for ESRD patients' family members, giving them special insight into the social and home environment from which ESRD patients come.

Physicians lead the healthcare team that diagnoses ESRD with blood tests, urine tests, kidney ultrasounds, kidney biopsies, and CT scans. Physicians perform the surgical and other procedures to address ESRD health consequences as well as other related medical issues. Finally, physicians remain closely involved when ESRD patients undergo dialysis treatment, including continued monitoring of the patients' health conditions, their compliance with treatment protocols, and any trends or deteriorations of kidney functions.

[13] Harding, *supra* note 6, at 157.

Physicians also provide palliative care and end-of-life care for ESRD patients when appropriate. In 2021, Medicare alone spent over $15 billion on ESRD patient care, according to Medicare statistics.[14]

In sum, physicians have a deep professional relationship with ESRD patients and thereby have gained unique insight into the impacts on their lives and health of changes in treatment as well as changes in policy relating to the availability and accessibility of professional care, including dialysis treatment.

III. Organized Medicine's Opposition to AB290

California physicians practice throughout a large state with a great degree of diversity in practice settings, clinical protocols and standards, availability of resources, patient populations, and health care delivery systems. Despite this heterogeneity, the interests and voices of California physicians have been singularly embodied in the California Medical Association for over a century and a half. Today, CMA is a not-for-profit professional association for physicians with more than 50,000 members throughout California. Since 1856, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of the public health and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings and treat all manner of ailments and diseases, including patients with ESRD.

[14] USRDS Report, *supra* note 2.

Accessibility to affordable, high quality health care has been a top priority for CMA in the past several years. Each year, nearly five hundred elected CMA delegates comprising the House of Delegates — collectively representing the various interests and perspectives of California physicians – convene for an annual meeting to discuss, debate, and ultimately establish CMA priorities and positions on current issues. The theme of the 2018 House of Delegates session was accessibility and affordability of health care. The 2018 House of Delegates focused on four topics arising from this theme:

- Addressing utilization through improved care delivery;
- Addressing increasing pharmaceutical costs;
- Reducing administrative burdens on physician practices; and
- Enhancing competitiveness of the healthcare market.

It is against this backdrop of CMA's attention on affordability and accessibility that efforts to reform dialysis treatment and reimbursement arose.

Prior to AB290, there had been two major efforts to enact changes to insurance premium assistance programs in the provision of dialysis treatments. For decades, charitable premium assistance programs like that offered by AKF have provided critical support to patients suffering from ESRD. Through these programs, ESRD patients, many of whom are unable to work due to their condition and the demands of their dialysis regime, receive direct assistance to help pay their commercial insurance

premiums, allowing them to retain coverage they had before their diagnosis. In recent years, several attempts have been made by special interests to place extensive requirements on these premium assistance programs and to limit reimbursement to dialysis providers who provide financial support to these charitable funds.

Like AB290, Senate Bill 1156 ("SB1156") in the 2018 California Legislature would have, among other things, required disclosure of information about patients who were aided by premium assistance programs and would have placed restrictions on private health insurance reimbursement for dialysis when a financially interested entity makes a third-party premium assistance contribution. Proposition 8, put before the California voters in November 2018, would have required dialysis providers to issue refunds to patients or their health insurers for revenue above 115 percent of the costs of direct patient care and healthcare improvements. CMA actively opposed both efforts out of concerns for their impact on ESRD patients' accessibility to health care. Governor Jerry Brown vetoed SB1156, noting that it "goes too far as it would permit health plans and insurers to refuse premium assistance payments and to choose which patients they will cover."[15] A better approach, according to Governor Brown, would be "to find a more narrowly tailored solution that ensures patients' access to coverage."[16]

[15] *See* Gov. Brown Veto Message re SB 1156 (Sept. 30, 2018), https://www.ca.gov/archive/gov39/wpcontent/uploads/2018/09/SB-1156-veto.pdf.

[16] *Id.* (emphasis added).

Proposition 8 met a similar fate when voters rejected the measure at a rate of 59.9 percent.

As with the prior efforts, CMA opposed AB290 throughout its journey in the California Legislature. The opposition was based primarily on CMA's belief that AB290 would have a significant, negative impact on ESRD patients' accessibility to high quality, life-saving dialysis. By its terms, AB290 will deprive ESRD patients of commercial insurance coverage for dialysis treatments. Shifting these patients from private insurance coverage to government-based health care has been estimated to cost California millions of dollars annually in increased Medi-Cal case volume. These are patients currently choosing to maintain their existing commercial coverage and access to their existing specialists with the help of charitable premium assistance. With the passage of AB290 and the absence of charitable premium assistance, patients would have fewer coverage options.

CMA believes AB290 will also decrease access to dialysis clinics for patients in rural and urban medically underserved areas, where there are fewer commercially insured patients. The loss of just a few commercial patients in a medically underserved area will constrict access to appointments in dialysis clinics. Even more concerning, due to efforts against dialysis providers, investment in new California clinics has slowed by as much as one-third, depending on the provider. Dialysis patients will have to turn to hospital emergency departments for treatment. These fragile patients will have no

other option but to be treated in these high traffic impacted settings with additional health complications and at a much higher cost to the health care system.

CONCLUSION

For the foregoing reasons, as well as the reasons stated in Dialysis Providers' brief in support of its appeal, the Court should reverse the portions of the District Court's ruling granting summary judgment in favor of Defendant-Appellees and affirm those portions of the District Court's ruling denying summary judgment in favor of Plaintiff-Appellant Dialysis Providers.

Dated: September 30, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the length limits set forth in Fed. R. App. P. 29(a)(5) (permitting amicus briefs that are "no more than the one-half the maximum length authorized by these rules for a party's principal brief"), 9th Cir. R. 27-1(1)(d) (permitting motions and responses to motions of up to 20 pages), and 9th Cir. R. 32-3 (deeming compliant a "brief or other document in which the word count divided by 280 does not exceed the designated page limit") because, excluding the parts of the document exempted by Fed. R. App. 32(f), the word count feature in Microsoft Word reports that this document contains 3,026 words.

2. The foregoing proposed brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

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CERTIFICATE OF CONFERENCE

I hereby certify that, pursuant to 9th Cir. R. 29-3, on September 23, 2024, counsel for Plaintiff-Appellant consented by telephone to the filing of this brief of *Amici Curiae*. On September 26, 2024, I contacted counsel for Defendant-Appellees by electronic mail seeking consent to file this brief of *Amici Curiae*, for which counsel provided on September 29, 2024.

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of September, 2024, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Ninth Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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