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IN THE UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

FRESENIUS MEDICAL CARE ORANGE COUNTY, LLC, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as California Attorney General, *et al.*,

Defendants.

Case No. 8:19-cv-02130 DOC (ADSx)

THE CALIFORNIA MEDICAL ASSOCIATION'S *AMICUS CURIAE* BRIEF; *AMICUS CURIAE* BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Date: Dec. 16, 2019
Time: 8:30 a.m.
Judge: Hon. David O. Carter
Court: 9D

AMICUS CURIAE BRIEF OF THE CALIFORNIA MEDICAL ASSOCIATION

INTRODUCTION

Chronic kidney disease, which can ultimately progress to end-stage renal disease ("ESRD"), is the ninth leading cause of death in America. An estimated 15 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 knows the importance for the public health and the healthcare delivery system as a whole 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 the perspective of *amicus curiae* the California Medical Association ("CMA"), this case brought by Fresenius Medical Care Orange County, LLC, *et al.* (the "Dialysis Providers") to challenge Assembly Bill no. 290 ("AB 290") is primarily about preserving access to urgently needed care for ESRD patients in California. On its face, AB 290 purportedly seeks to address conflicts of interests in reimbursement for and delivery of dialysis. However, CMA believes that AB 290 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 AB 290, whose genesis is based less on sound evidence-based medicine than on political motivations, may operate to better serve the interests of health insurers than the medical needs of patients. AB 290 therefore cannot pass constitutional scrutiny.

Accordingly, CMA opposed AB 290 in the California Legislature and hereby

supports the Dialysis Providers' motion for preliminary injunction to stop the statute from taking effect on January 1, 2020.

DISCUSSION

A. 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. A patient with ESRD must receive dialysis treatment or kidney transplantation in order to survive. 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. ESRD patients may experience a wide variety of symptoms as kidney failure progresses. 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 ESRD population in the United States, including treatments and outcomes. The USRDS issues an annual data report highlighting and analyzing statistics and trends. According to the 2018 USRDS Annual Data Report, in 2016 there were 124,675 newly reported cases of ESRD in the nation, bringing the total number of cases of ESRD to 726,331 as of December 31, 2016. *See* End-stage Renal Disease (ESRD) in the United States, 2018 USRDS ANNUAL DATA REPORT, vol. 2, ch. 1 at 294 ("USRDS Report").[1] 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 2000, the count plateaued between 2007 and 2011 but rose again from 2012 to 2016. *Id.*

Other than kidney transplantation, dialysis remains the best treatment for the survival of ESRD patients. Nearly three quarters of a million people were on dialysis in

[1] Available online at https://www.usrds.org/2018/view/Default.aspx.

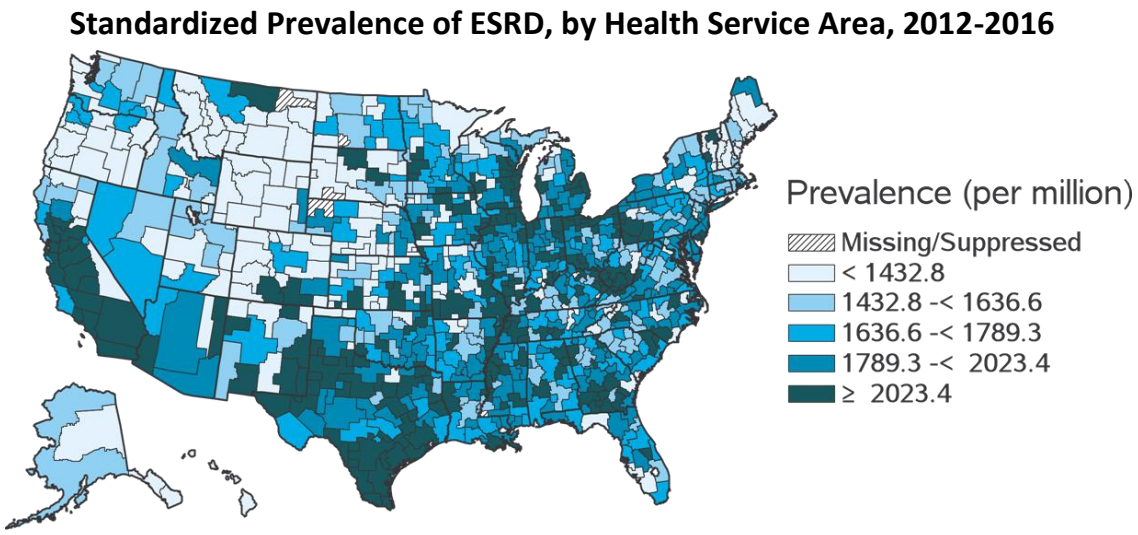
2016. *Id.* at 291. Put another way, 63 percent of all ESRD patients in 2016 were receiving dialysis treatment, and virtually all (98 percent) used in-center dialysis such as those provided by the Dialysis Providers. *Id.*

There are racial and ethnic disparities in the prevalence of ESRD. The standardized incidence rate among Blacks is higher than among Whites. In 2016, the age-sex-standardized incidence rate ratio (Blacks/Whites) was 2.9. *Id.* at 301. 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. *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)[2] ("Harding"). In fact, education and income levels have been shown to contribute to excess ESRD rates in Blacks. *Id.*

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. USRDS Report at 301. The trend reflects a decrease in incidence rate among minorities while the rate for Whites has remained constant. *Id.* Researchers believe these changes may represent a reduction in health inequalities in the population with chronic kidney disease. *Id.* That is, modest 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 some role in this improvement in access to care for ESRD patients.

There also are regional variations in ESRD prevalence. California and the Southwest have the highest rates, as shown in the following map from the 2018 USRDS Annual Report.

[2] Available online at https://www.karger.com/Article/PDF/479479.



USRDS Report at 312. Southern California, a data region by itself, has the second highest prevalence rate of ESRD in the country at 2,466 per million people (behind the region covering New Jersey, Puerto Rico, and the U.S. Virgin Islands). *See id.* at 311.

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 depression. Harding at 157. They also must struggle with complex dietary restrictions, polypharmacy and complex care coordination, and for dialysis treatment, the chronic dependence on nurses, social workers, nutritionists, technicians, vascular surgeons, and nephrologists for at least three hours, three times a week.

B. 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. Such involvement includes continuing to monitor the patients' health conditions, their compliance with treatment protocols, and any trends or deteriorations of kidney functions.

Physicians also provide palliative care and end-of-life care for ESRD patients when appropriate. According to Medicare statistics, about half of all ESRD patients see 10 or more physicians (from 5 or more specialties) during the last 90 days of life. USRDS Report at 595.

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.

C. Organized Medicine's Opposition to AB 290

California physicians practice across 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 approximately 44,000 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.

Accessibility to affordable, high quality health care has been a top priority for CMA in the past few 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 AB 290, 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 AKD have provided critical assistance 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.

Similar to AB 290, Senate Bill no. 1156 ("SB 1156") 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 Brown vetoed SB 1156, 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." *See* Gov. Brown Veto Message re SB 1156 (Sept. 30, 2018).[3] A better approach, according to the Governor, would be "to find a more narrowly tailored solution that ensures patients' access to coverage." *Id.* (emphasis added). Proposition 8 also met a similar fate when voters rejected the measure at a rate of 59.9 percent.

As with the prior efforts, CMA opposed AB 290 throughout its journey in the California Legislature. The opposition was based primarily on CMA's belief that AB 290 would have a significant, negative impact on ESRD patients' accessibility to high quality, life-saving dialysis. By its terms, AB 290 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 AB 290 and the absence of charitable premium assistance, patients would have fewer coverage options.

CMA believes AB 290 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 recent 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

[3] Available online at https://www.ca.gov/archive/gov39/wp-content/uploads/2018/09/SB-1156-veto.pdf.

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 the Dialysis Providers' memorandum of points and authorities in support of its motion, a preliminary injunction should be issued.

DATED: November 19, 2019

Respectfully,

CALIFORNIA MEDICAL ASSOCIATION
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ATHENE LAW, LLP

By: /s/ Long X. Do

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Attorneys for California Medical Association