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and DIALYSIS PATIENT CITIZENS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

Case No. 8:19-cv-2105-DOC-ADS

DECLARATION OF LAVARNE A. BURTON IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

Date: December 9, 2019
Time: 8:30 a.m.
Place: Courtroom 9D

I, LaVarne A. Burton, do hereby declare as follows:

1. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction in this case.

2. I am the President and Chief Executive Officer ("CEO") of the American Kidney Fund ("AKF") and have served in this role since 2005. As President and CEO, I have personal knowledge of AKF's operations and what is necessary for the organization to succeed in its mission of making life better for Americans with kidney disease.

3. Accordingly, I have personal knowledge of the facts set forth herein. If asked to do so, I could testify truthfully about these matters.

INTRODUCTION

4. For the past 14 years, I have spent most of my waking hours thinking about the lives and well-being of kidney disease patients. I have listened to their stories and heard how their conditions have devastated their lives, robbing them of financial security, time with their friends and loved ones, and, in the end, of their health and lives. The Declarations of Jane Doe and Stephen Albright are typical of the thousands of stories of which I am aware. My team at AKF and I have worked as hard as we can to make life better for these patients, to help them have the dignity and peace of mind that they deserve. It has been important and rewarding work of which I am proud. More importantly, it is work that helps tens of thousands of desperately ill and financially vulnerable Americans each year. AKF does not exist to assist the health and well-to-do; it is there to help those who cannot otherwise pay for the health care that they need to stay alive.

5. I do not exaggerate when I say that Assembly Bill 290 ("AB 290") poses an existential threat to AKF's efforts in California and possibly the entire United States. For more than twenty years, AKF has been able to provide financial assistance to help patients suffering from end-stage renal disease ("ESRD") pay for health insurance. AKF is able to provide this help only because of an advisory

opinion we obtained from the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS"). Advisory Opinion 97-1 provides a safe harbor that allows us to operate this vital program without any chance that we are violating federal law, which would pose great legal, financial, and reputation risks to AKF.

6. We are a charity. We do what we do because we care about those who suffer from kidney disease; not for profit, not for personal gain. We put 97 cents of every dollar we receive into our programs, and for that, we have been lauded by numerous charity publications and watchdogs. But it also means that we have zero tolerance for risk with respect to our operations, particularly our financial assistance operations. The very fact that we have engaged counsel to prosecute this litigation on our behalf is an indication of how seriously we take this, though.

7. Advisory Opinion 97-1 is thus critical to our mission and our most important financial assistance program, the Health Insurance Premium Program ("HIPP"). We operate HIPP to the highest ethical standard. It focuses solely on the financial neediness of ESRD patients who cannot afford the premiums of their health insurance—the program is otherwise blind to any other consideration. But Advisory Opinion 97-1 makes that high ethical standard a legal safe harbor. It ensures that there is no risk that our financial assistance program will be viewed by the federal government as providing impermissible remuneration under the Beneficiary Inducement Statute to ESRD patients based on donations we receive from providers. Without that assurance, we cannot operate HIPP.

8. Yet AB 290 requires us to breach the safeguards that Advisory Opinion 97-1 requires to maintain our safe harbor. California's Legislative Counsel has acknowledged as much. If AB 290 goes into effect on January 1, 2020, AKF must halt its financial assistance grants to low-income patients in California. Though AKF is loath to exit California, it must consider the circumstances of the tens of thousands of other HIPP grantees throughout the United States. Without the safe harbor

provided by Advisory Opinion 97-1, AKF will be putting at risk the critical assistance that it provides to those other patients, as well as its hard-won reputation. AKF cannot take that risk.

9. Ultimately, I am certain that AB 290 will make thousands of Californians who are already in a perilous situation worse off. I am also certain that any "benefits" the law generates will not be widely shared. The sole real beneficiaries of this bill will be insurance companies who have sought for years to force as many low-income dialysis patients as possible onto government insurance, regardless of the consequences for those patients and their families. I know this from my personal experience.

10. If AB 290 goes into effect on January 1, 2020, AKF will have no choice but to leave California. The risks we face operating under that new regime are far beyond what we can or should have to tolerate. This forced departure means that not only will AKF's mission in California be irreparably injured, but that the 3,756 people receiving lifesaving premium-related assistance from AKF in California will also be irreparably injured.

THE AMERICAN KIDNEY FUND AND ITS MISSION

11. AKF fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease.

12. Since 1971, AKF has fulfilled its mission with programs of prevention, early detection, disease management, clinical research, innovation and advocacy that impact more lives than any other kidney nonprofit. For example, we offer Safety Net Grants for expenses that insurance does not cover, such as transportation to and from dialysis treatment, summer camp scholarship grants for children with kidney disease, and disaster relief grants for dialysis patients living in communities affected by natural disaster. In California, and as we did in late 2017, we are currently

providing disaster relief grants to ESRD patients who are affected by the wildfires. And through HIPP, we provide grants to low-income people living with ESRD that allow them to pay premiums on their existing health insurance, thus ensuring that they have access to the dialysis, transplants, and the other health care that keeps them alive.

13. AKF is one of the nation's top-rated nonprofits and invests 97 cents of every donated dollar in programs, not overhead. Because of its transparency and efficiency, AKF has held the highest 4-star (out of 4) rating from Charity Navigator for 18 straight years and the Platinum Seal of Transparency from GuideStar. Only a handful of the 9,000 charities evaluated by Charity Navigator have maintained a 4-star rating for this length of time.

THE CRITICAL ASSISTANCE PROVIDED BY HIPP

14. A silent killer, with no early signs or symptoms, kidney disease is one of the top-ten leading causes of death in the United States. People confronted with an ESRD diagnosis face life-altering challenges, including reduced ability to work and care for themselves and their families, the significant burden of needing regular dialysis treatment and other specialized health care, a decline in health and capacity (including an increase in other significant health problems such as heart disease and cancer), and the corresponding financial impact of living with and treating ESRD. Without treatment—either dialysis or a transplant—ESRD is fatal. However, transplants involve significant surgical and recovery complications, in addition to delays due to a shortage of transplantable kidneys, meaning that many patients either cannot receive one promptly or are not medically suitable at all. The end result is that dialysis is often the only viable option for many ESRD patients.

15. By providing financial assistance to qualifying low-income patients with kidney failure to help pay health insurance premiums, AKF allows these patients to receive comprehensive medical care, including dialysis, medications, the

work up for a kidney transplant, and specialized care from cardiologists, endocrinologists, vascular surgeons, and more.

16. HIPP assistance is limited to patients on dialysis or those who within the past year have received a kidney transplant. To qualify for HIPP assistance, a patient's monthly household income may not exceed reasonable monthly expenses by more than $600, and the patients AKF assists have an average annual household income of less than $25,000 (in California, the figure is less than $30,000). They must also show that they have existing insurance coverage, complete with billing statements.

17. Many HIPP applicants are referred to the program by their social workers at dialysis providers. Medicare rules require dialysis centers to provide dialysis patients with a social worker to navigate not only health care decisions but identify other resources the patient may need. Those social workers and other provider personnel assist applicants with gathering the necessary paperwork to file their grant applications. This dialogue continues over the lifetime of the grant to ensure that patients' needs are met.

18. In 2018, AKF provided direct financial assistance for health-insurance purposes to 75,000 low-income dialysis and transplant patients in all 50 states, the District of Columbia and every U.S. territory. That is, we help about one out of every six dialysis patients in the U.S. to afford their health insurance and therefore access the care they need to stay alive, including dialysis and transplant. Our programs help patients with all types of health insurance, including Medicare Part B, Medigap, Medicare Advantage, employer plans, and commercial plans.

19. In 2018, more than 1,000 low-income dialysis patients had kidney transplants and post-transplant care with AKF's financial support, a scope of assistance for kidney transplant that is unmatched in the nonprofit community. Each month, we help about 100 people get off dialysis by providing financial assistance that makes transplants possible.

HIPP SERVES THE MOST VULNERABLE

20. For over 20 years, AKF has worked effectively to remove significant barriers to maintaining appropriate health coverage for the low-income, chronically ill population we serve.

21. More than 80% of dialysis patients are unemployed and some of the remainder work only part-time. This reflects that the dialysis treatment regimen and the debilitating effects of the disease make it extremely difficult to remain employed. At the same time, our nation's ESRD patients have average annual out-of-pocket medical expenses of close to $7,000, which can often make supplemental coverage in the form of a Medigap, employer, COBRA, or exchange plan a necessity. AKF addresses this problem by providing HIPP assistance for both primary and secondary coverage to ensure patients have comprehensive coverage.

22. Maintaining insurance coverage is critical for ESRD patients. A loss of insurance coverage can cause a patient to miss treatments or lose access to critical medication, with devastating health consequences. It can also disrupt their access to a transplant, as that procedure is almost always predicated on access to both Medicare and supplemental non-governmental insurance.

23. Finally, it is important to note that kidney failure disproportionately impacts racial and ethnic minority populations. About 14% of Hispanics have chronic kidney disease, and for every three non-Hispanics who develop ESRD, four Hispanics develop ESRD. African Americans are three times more likely than whites to develop ESRD. These minority groups, which have been underserved historically, are thus also disproportionally affected by barriers to maintaining health coverage. Accordingly, the majority of our HIPP grant recipients are members of racial and ethnic minorities: 61% nationwide, and 74% in California (including 41% Hispanics).

HIPP ALLOWS ITS GRANTEES TO AFFORD THE COVERAGE BEST FOR THEM

24. The key purpose of HIPP is to allow low-income ESRD patients to maintain the health care coverage that best meets their health needs when they otherwise could not afford to do so. Over 60% (52% in California) of our HIPP grants fund premiums for Medicare-related program coverage, such as Medicare Part B and Medigap. HIPP also helps a smaller number of recipients pay premiums for other coverage, often as a supplement to Medicare: employment group health plans ("EGHPs"), COBRA plans, and qualified health plans ("QHPs") individual marketplace plans offered pursuant to the Patient Protection and Affordable Care Act (the "ACA") and commercial plans offered outside of the marketplace exchanges.

25. As noted above, patients apply for HIPP when they cannot afford the premiums for the health insurance they already have in place, such as employer-based plans or QHPs. Patients with new policies (for example, Medicare Part B and Medigap) have selected the health plan that best meets their financial and medical needs, following consultation with their social worker or other advisor provided through his or her renal care provider, as required by the Medicare Conditions of Coverage, or other advisers chosen by the patient.

HIPP IS VITAL FOR CALIFORNIA ESRD PATIENTS

26. Nearly 95,000 Californians are living with ESRD. Of that group, 69,000 of them depend on dialysis to stay alive and over 25,000 have functioning transplants.

27. In 2018, 3,756 Californians received grants from AKF to pay their health insurance premiums while on dialysis and post-transplant. The payments from that assistance went to the following kinds of insurance: 33.2% Employer Group Health Plans and COBRA, 26.4% for Medicare Part B, 20.2% for Medigap, 8% for Exchange plans, 7.1% other commercial plans and 5.1% Medicare Advantage premiums. Sixty-eight percent (68%) of the patients AKF assists in

California are African American, Latino or Asian, and another 7% are American Indian or Alaskan Native, Native Hawaiian or Other Pacific Islander, or Multiracial.

28. It is important to understand that for these Californians, Medicare is not a complete solution. Medicare covers only the ESRD patient, not dependents. ESRD patients are younger than the typical Medicare beneficiary, and are often supporting families. Medicare also leaves recipients with substantial cost-sharing obligations—including a 20% coinsurance requirement that can be financially crushing for individuals with chronic conditions like ESRD. In fact, Medicare has no limit on out-of-pocket expenditures.

29. Medigap policies sold by private insurance companies may be available to help cover the annual deductible and coinsurance obligations under Medicare. HIPP grants also pay premiums for those plans. However, the federal government does not require carriers to offer Medigap to ESRD patients under 65, and its availability, therefore, varies from state to state. California unfortunately remains one of 20 states that does not mandate insurers to provide Medigap to ESRD patients under age 65, leaving patients without access to this important supplemental insurance.

30. Medi-Cal, California's implementation of Medicaid, provides health care coverage for a number of individuals living with ESRD, but it may not be the ideal choice for those who are eligible. Though Medi-Cal requirements are complex, in many cases, patients are subject to so-called "spenddown requirements," which require that they spend all but $600 of their monthly income on medical costs before Medi-Cal is available. It goes without saying that most Californians cannot live on $600 per month.

31. For undocumented immigrants in California, the situation is even more dire. Undocumented immigrants under age 19 are eligible for full scope Medi-Cal and, beginning on January 1, 2020, undocumented young adults aged 19-25 will also be eligible for full scope Medi-Cal. By contrast, while undocumented adults over

age 25 who need dialysis can receive that specific treatment under Medi-Cal, they are not eligible for the full scope of Medi-Cal benefits that would cover their other substantial health care needs.

32. For anyone who is not eligible for Medicare or Medi-Cal, commercial plans are the only option for comprehensive coverage. But those plans are expensive, and ESRD patients already face significant financial hurdles, meaning that many will be forced to seek treatment in emergency rooms.

33. Overall, then, in California, AKF provides essential support to 3,756 patients facing day-to-day decisions about how they can best manage their ESRD while having enough money to pay their bills and support their families as best they can.

THE IMPORTANCE OF ADVISORY OPINION 97-1 FOR HIPP

34. As a charity, AKF's reputation is everything. We ask donors to trust that we will use their funds transparently and effectively. Without our reputation, we cannot effectively pursue our mission. For us, succeeding at combatting kidney disease and meeting the highest ethical standards are interlocked. Without the latter, we cannot achieve the former. This is an issue without flexibility for us.

35. It follows, then, that AKF has always been intensely focused on compliance with the laws that govern our work. One such law is the so-called Beneficiary Inducement Statute. That law prohibits giving financial or other benefits to patients to influence their decisions regarding which health care provider they will select for treatment. Given that we take donations from dialysis providers, among more than 60,000 other distinct donors, this law was of particular concern for HIPP.

36. In 1997, together with six dialysis providers, we requested an advisory opinion from the HHS OIG, seeking approval of, and guidance regarding, continued operation of HIPP while allowing providers to donate to the program in light of the then-recently enacted Beneficiary Inducement Statute. At that time, AKF described for the OIG in detail how AKF had been operating its premium assistance program.

We explained that the program was entirely need-based and that we would not treat patients differently depending on who their provider was.

37. The resultant opinion, Advisory Opinion 97-1, was the first of its kind and remains in effect and is published on the OIG's website at: https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/.

38. In that opinion, the OIG reviewed the information provided and concluded that continuation of AKF's operating procedures in an expanded HIPP program—one which would allow dialysis providers to donate to the program—would enhance patient choice with regard to dialysis providers and ensure that provider contributions would not be used to influence patients.

39. The OIG ultimately concluded that "the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."

40. Advisory Opinion 97-1 identified the key aspects of AKF's operation of HIPP that prevented the program from constituting impermissible renumeration:

a. AKF is an independent 501(c)(3) organization.

b. Providers are not required to contribute to HIPP in order for their patients to receive assistance.

c. AKF has complete discretion to determine applicant eligibility, based on AKF-established criteria of financial need.

d. Patients are not informed whether their provider contributes to HIPP.

e. Patients' applications and HIPP grants are treated equally, without regard to considerations such as their dialysis provider.

f. Assistance from AKF does not restrict patients' choice of provider.

g. Grants follow patients, regardless of insurers or providers chosen, and as a result, these grants increase patient choice instead of restricting it.

41. Since Advisory Opinion 97-1 was handed down, AKF has consistently operated HIPP in tight accordance with the opinion:

a. All contributions to HIPP are always voluntary.

b. Donor funding is provided to AKF without any restrictions or conditions whatsoever—funds go into one funding pool, and from that pool AKF administers the program, providing grants to eligible low-income dialysis patients on a first-come first-served basis to pay for their insurance premiums.

c. Our Board of Trustees is independent and includes a subcommittee with responsibility for oversight of HIPP. Our Trustees are volunteers who are not compensated and have a wide range of backgrounds and expertise. Membership on the HIPP subcommittee excludes anyone investing in dialysis centers or associated with a dialysis center, including employees, officers, shareholders, or owners of such centers.

d. Using voluntary donor funding, we provide help to patients solely on the basis of their financial need. We do not consider a patient's health status in awarding financial assistance.

e. We carefully review each applicant's financial status and require that they meet specific income-to-expense criteria in order to qualify for assistance.

f. As part of the application process, the patient must complete and sign a detailed statement of income, assets, and expenses.

g. We provide financial assistance without regard to the type of insurance a patient has, where they live, who their dialysis provider is, or whether their dialysis provider is a contributor to our program. In fact, most of

our beneficiaries are enrolled in government health insurance programs.

h. Patients choose their health insurance coverage with no input from AKF. While we support providing patients with the information they need to make an informed choice about their health insurance, AKF is not involved in helping patients find new insurance and does not advocate that patients keep or switch insurance.

i. Patients may change their health insurance coverage—and their provider—at any time, and AKF will continue to help them until their grant period expires. Their grant period is at least equal to their full health insurance premium year so long as the patient continues to meet qualifying criteria. (Patients who so change are of course eligible, like all other AKF grant recipients, to apply for a new grant at the end of the grant period.)

j. Many dialysis providers with patients being assisted by our program do not contribute to AKF. In fact, more than half of the referring providers do not make voluntary contributions to the pool at all.

k. Our staff responsible for processing and approving grants are barred from accessing information about which providers have contributed to HIPP.

l. Donors' contributions to AKF are not contributions made on behalf of individual patients. By participating in HIPP, providers agree that there is no "earmarking" of contributions to specific patients within the HIPP pool.

m. There is no guarantee that the patients referred by donors to the HIPP program will receive assistance.

n. The decision to provide assistance is at all times subject to the sole and absolute discretion of AKF—there is no "right" to a grant of financial

assistance, regardless of the amount or frequency of donations by the referring provider.

42. These conditions are sacrosanct to AKF. We do not vary from them because to do so would expose AKF and HIPP to legal and reputation risk that we cannot and will not tolerate.

AB 290 DIRECTLY THREATENS AKF AND HIPP

43. On October 13, 2019, Governor Gavin Newsom signed AB 290 into law. AB 290 passed through the Senate and Assembly by only the slimmest of margins. It represents the expenditure of a stunning amount resources by the insurance industry and labor unions to disrupt and drive HIPP from California. AKF fought AB 290 with everything we had; we explained exactly what would happen if it was enacted and how we would have to cease operating HIPP in California. Indeed, I personally testified before the California Senate Health Committee on these issues. But we are not a large insurance company or a powerful labor union; we are a charity. We don't exist to move the levers of power; we exist to help the ill and their families.

44. It is telling that then Governor Jerry Brown vetoed an earlier version of AB 290 and asked that all stakeholders come together to find a more narrowly tailored solution that would not hurt patients or their access to coverage. Yet AB 290 is neither narrowly tailored nor pro-patient; in fact, it will place thousands of low-income kidney failure patients in California into crisis, facing loss of their health insurance coverage and access to lifesaving care.

45. To begin, AB 290 requires us to disclose the names of HIPP recipients to insurers. Indeed, AB 290 is so strangely drafted that we are unsure whether we have to disclose the names of California grantees to all possible insurers, or to individual patients' insurers. Either way, it is not our policy to share this kind of information with insurers.

46. Conversely, patients will be made aware that their dialysis providers contribute to AKF when the insurers implement reduced reimbursement rates following the receipt of patient names. That means that a key firewall of Advisory Opinion 97-1—whereby patients are not informed of whether their particular provider donated to AKF—will be removed by AB 290.

47. Thus, when AB 290 takes effect on January 1, 2010, AKF will begin to accrue obligations under that Act that will directly undermine the safe harbor of Advisory Opinion 97-1. For instance, AB 290 and AKF's own HIPP policy obligate us to provide premium assistance for a full plan year, which will trigger AB 290's unconstitutional reporting obligations. Unless AB 290 is enjoined prior to its effective date, AKF will have to cease operating HIPP in California.

48. California was well aware of this when it enacted AB 290. Not only did we inform legislators of this possibility, but California's own Legislative Counsel concluded that AB 290 would require AKF to exit the safe harbor created by Advisory Opinion 97-1. Indeed, the strongest evidence of California's awareness of this risk is found in AB 290 itself, as the law has a provision that delays some of its implementation if AKF seeks a revised advisory opinion from OIG.

49. Yet this is wholly inadequate. To obtain a new OIG opinion that accounts for AB 290, we would have to certify in good faith that we will actually pursue such a program if given authorization. This is something that we cannot do, particularly given that the advisory opinion process can take years and leave HIPP in limbo. More fundamentally, it would be irresponsible of AKF to put at risk our existing nationwide arrangement simply to accommodate an unconstitutional and ill-conceived law such as AB 290. After all, there is no guarantee that the OIG would reach a favorable conclusion.

50. Nor does AB 290 stop with requiring AKF to operate outside the boundaries of Advisory Opinion 97-1. It also forces us to change our behavior with respect to the patients we support. As I explained above, patients apply to HIPP with

their preferred insurance already in place. We do not steer patients toward one form of insurance or another; we simply seek to help the needy pay for the insurance they already have. Yet AB 290 would obligate AKF to inform patients of "all available coverage options," including Medicare and Medicaid, before those patients may receive grant assistance. Conversely, AB 290 also obliges us to "agree not to steer, direct, or advise the patient into any or away from a specific coverage program."

51. We do not know how we will manage these conflicting dictates. Though we do not seek to promote any particular form of insurance, if we are required to discuss available coverage with patients, we would not want to refrain from providing advice to the patients who come to us. Instead, we would somehow have to inform patients with insurance that they have a range of other options, but simultaneously avoid "steering, directing, or advising" patients in any way. We would never impose on ourselves such obligations to speak and refrain from speaking. Our goal is to help patients, not confuse them, as these new obligations will do. Nor can we risk California punishing us with fines and other adverse consequences for being unable to comply with its vague directives.

CONCLUSION

52. AB 290 has placed AKF in the most tenuous situation it has faced in its existence. If AB 290 is not halted, we will be forced to halt our operations in California. Not because we want to leave California—having to do so is a grave injury to all we stand for—but because we want to preserve our mission everywhere else and to continue to provide vital support to the approximately 90% of HIPP grantees who do not live in California. That mission is about kidney patients nationwide and making the lives they lead better. AB 290 does just the opposite. By actively seeking to force AKF from California's borders, it ensures that thousands of patients will lose the critical financial assistance that helps them lead healthier and more dignified lives. And for what? To appease special interests who

seek to gain ground against dialysis providers. Patients should never be the collateral damage for cheap politics.

53. In the end, this case is about those patients and their families. Though AB 290 was written to punish AKF, we exist only to serve patients, like Jane Doe and Stephen Albright. We have no pecuniary motives or great political ambitions. Our goal—our only goal—is to make life a bit better for people who have had the terrible misfortune to become gravely ill. A law that crushes that goal just to put a few more cents in insurance companies' pockets should not stand for reasons even apart from its unconstitutionality.

I declare under the penalty of perjury and the laws of the United States that the foregoing is true and correct this 7th day of November, 2019, at Washington, District of Columbia.

LAVARNE A. BURTON