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and DIALYSIS PATIENT CITIZENS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE; STEPHEN ALBRIGHT; AMERICAN KIDNEY FUND, INC.; and DIALYSIS PATIENT CITIZENS, INC.,

Plaintiffs,

v.

XAVIER BECERRA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Comm'r; SHELLY ROUILLARD in her Official Capacity as Director of the California Department of Managed Health Care; and SUSAN FANELLI, in her Official Capacity as Acting Director of the California Department of Public Health

Defendants.

Case No. 8:19-cv-2105

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs *Jane Doe, Stephen Albright*, the *American Kidney Fund, Inc.*, a 501(c)(3) charitable organization, and *Dialysis Patient Citizens, Inc.*, a 501(c)(4) charitable organization, bring this Complaint against Defendants *Xavier Becerra*, in his official capacity as Attorney General of California, *Ricardo Lara*, in his official capacity as California Insurance Commissioner, *Shelley Rouillard*, in her official capacity as Director of the California Department of Managed Health Care, and *Susan Fanelli*, in her official capacity as Acting Director of the California Department of Public Health, for Declaratory and Injunctive Relief against AB 290. *See* Act of Oct. 13, 2019, ch. 862, 2019 Cal. Stat. ___ (2019) [hereinafter AB 290] (to be codified at Cal. Health & Safety Code §§ 1210, 1367.016, 1385.09 and Cal. Ins. Code §§ 10176.11, 10181.8).

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the Supremacy Clause and the First Amendment of the Constitution, as well as the laws of the United States, specifically 42 U.S.C. § 1320a-7a(a)(5), 42 U.S.C. § 1395y(b), and other provisions of Title 42 of the United States Code.

2. Venue is proper in the Central District of California because a substantial part of the events or omissions giving rise to the claims in this case has occurred in this district, Plaintiffs will be impacted by AB 290 in this district, and Plaintiffs Jane Doe and Stephen Albright reside in Orange County, which is within the Southern Division of this district. *See* 28 U.S.C. § 1391(b).

3. Plaintiffs have standing and ripe claims for relief because AB 290 purports to apply directly to Plaintiff American Kidney Fund and its financial assistance program for dialysis patients (a program that benefits Plaintiff Dialysis Patient Citizens' members and the individual Plaintiffs), but is preempted by federal law and deprives Plaintiff American Kidney Fund, its donors, and its beneficiaries

(which includes Plaintiff Dialysis Patient Citizens' members) of their rights to association, free expression, and petition under the Constitution of the United States.

4. Congress has granted Plaintiffs the right to declaratory and injunctive relief in this case through the Civil Rights Act of 1871, as amended, *see* 42 U.S.C. § 1983, and the Declaratory Judgment Act, *see* 28 U.S.C. §§ 2201–02.

INTRODUCTION

5. This case is about some of the most vulnerable and ill patients in California; the charitable organization that seeks to help them; and an unconstitutional and ill-conceived law that will destroy that organization's efforts in California, leaving the patients it serves sicker and poorer.

6. Plaintiffs Jane Doe and Stephen Albright ("Patient Plaintiffs") are Orange County residents who suffer from end-stage renal disease ("ESRD"), a chronic, painful, and potentially fatal illness. Without a kidney transplant—a procedure that is often fraught with risks and delays—only the blood filtering procedure known as dialysis stands between ESRD patients like the Patient Plaintiffs and prolonged sickness and death. Yet while dialysis keeps ESRD patients alive, it burdens them physically and financially. Dialysis is a draining, difficult procedure that must be done several times a week, making it extraordinarily difficult for patients to maintain employment. And dialysis is expensive, requiring specialized equipment and trained personnel to administer it. Like many ESRD patients in California, the Patient Plaintiffs are not wealthy. They and many other ESRD patients face constant anxiety about affording the premiums for their health insurance. Without health insurance, these patients do not know how they would afford their dialysis treatments. Without health insurance, they face the possibility of poverty or worse.

7. For years, the two non-profit plaintiffs in this case have sought to assist and defend the interests of ESRD patients like the Patient Plaintiffs. The American Kidney Fund, Inc. ("AKF") is recognized as one of the nation's leading and most

admired charitable organizations, having received a four-star rating from Charity Navigator for 17 straight years. In pursuit of its mission to fight kidney disease and help people live healthier lives, AKF raises money from many sources and funds a broad range of programs to help some of the 37 million Americans suffering from kidney disease and the many millions more who are at risk. Dialysis Patient Citizens, Inc. ("DPC"), is a non-profit educational and social welfare organization whose purpose is to improve the quality of life of patients with kidney disease, including those with ESRD, through advocacy and education. DPC's membership of 28,000 comprises kidney disease patients and their family members.

8. AKF has long had a special interest in individuals like the Patient Plaintiffs: lower income ESRD patients who face financial constraints on their ability to pay for dialysis. To assist such patients, AKF created its Health Insurance Premium Program ("HIPP") more than two decades ago. Through HIPP, AKF helps financially-challenged dialysis and transplant patients with ESRD make the premium payments necessary to retain their health insurance policies through charitable grants. As the circumstances of the Patient Plaintiffs and other ESRD patients show, retaining health insurance coverage is vital for ESRD patients to help defray the extraordinary costs of life-sustaining dialysis and, when available, kidney transplants, as well as the numerous other health care treatments and hospitalizations that arise because of the many comorbidities that accompany ESRD.

9. HIPP thus helps financially vulnerable and chronically ill ESRD patients access the health care they need without falling into destitution to pay for that care. HIPP provides this assistance based solely on a patient's lack of personal funds to pay the premiums on their health insurance. In 2018, the last full year for which data are available, AKF assisted more than 75,000 ESRD patients nationwide in maintaining their insurance, including more than 3,700 ESRD patients who reside in California. Indeed, 23% of DPC members with ESRD self-identify as having received charitable grants from AKF to pay their health insurance premiums.

10. Unfortunately, the commercial health insurance industry has long-opposed HIPP. That industry would prefer that all ESRD patients have their health care, including dialysis treatments, funded by the federal government through the Medicare program, or by State governments through state Medicaid programs, rather than through commercial insurance. The fact is that the majority of ESRD patients are on Medicare or Medicaid and most of AKF's grants pay for Medicare and Medicare supplemental insurance. But as AKF, DPC, and ESRD patients know all too well, Medicare and Medicaid often fall short in providing the full spectrum of support and protection that ESRD patients need. Medicare Part B, for example, pays only 80% of medical care costs with no limit on out-of-pocket expenses. For ESRD patients, these expenses can come to thousands of dollars each year.

11. Notwithstanding the dire circumstances in which ESRD patients find themselves, the commercial health insurance industry and its labor union allies—seeking to pressure dialysis providers into unionizing their workforces—have lobbied the California legislature to impose severe restrictions on HIPP. These restrictions are not designed to improve the program, protect patients, or save money. Instead, the restrictions on HIPP are designed to kill it. The legislature first passed such legislation in 2018, but then-Governor Jerry Brown vetoed the bill, explaining that "it would permit health plans and insurers to refuse premium assistance payments and to choose which patients they will cover," and urged "all stakeholders . . . to find a more narrowly tailored solution that *ensures patient access to coverage*."

12. Undeterred, the opponents of HIPP tried again in the 2019 legislative session, and again, by a slender margin, succeeded in obtaining passage of Assembly Bill 290 ("AB 290" or "the Act"). This time, Governor Gavin Newsom signed the legislation on October 13, and unless enjoined by this Court, AB 290 will begin taking effect on January 1, 2020. Contrary to Governor Brown's plea for narrow

tailoring and guaranteed patient access to coverage, the Act is a broad-ranging legislative tour de force that unabashedly undermines patient access to coverage.

13. Under the guise of addressing increasing health care costs, AB 290 singles out HIPP with punitive requirements that are literally forcing AKF to abandon its assistance to the thousands of California residents who currently benefit from the program. The Act unconstitutionally conflicts with federal law by forcing AKF to depart from the federally sanctioned safe harbor under which AKF has operated HIPP for over twenty years. Indeed, the very text of AB 290 recognizes that conflict by requiring AKF to request a change in a federal agency's construction of federal law to make AB 290 effective. Moreover, AB 290 improperly requires AKF to disclose the identity of virtually every patient who receives AKF's charitable grants—including many of the over 4,500 DPC members in California—to the very insurance companies that oppose HIPP. It also unconstitutionally requires AKF to deliver to each and every patient receiving assistance a state-scripted message that strongly encourages the patient to enroll in Medicare or Medi-Cal (California's implementation of Medicaid). If AB 290 is not enjoined, AKF will be forced to cease supporting HIPP in California as of January 1, 2020, the effective date of the Act.

14. The State of California has advanced no compelling, or even substantial, interest in imposing these unconstitutional requirements on AKF. Any suggestion that AB 290 will reduce health care costs is unsupported and illusory, because AB 290 does not contain *any* provisions ensuring that premiums will actually be reduced. Instead, it is likely that any savings will redound solely to the benefit of the health insurance industry that supported passage of the Act. The statute contains no material protections for patients, and indeed appears calculated to push them into Government programs with less desirable attributes and at great cost to taxpayers.

15. As Plaintiffs will show, AB 290 is preempted by federal law and unconstitutionally abridges their rights to association, free speech, and petition. For these reasons, it cannot stand.

THE PARTIES

16. Plaintiff Jane Doe is a resident of Orange County. She is an ESRD patient who is currently undergoing dialysis and receiving HIPP assistance from AKF. Because of her concerns regarding her personal privacy, including her rights under federal law to have details about her medical condition and financial status remain confidential, she is proceeding in this case pseudonymously. Upon entry of an appropriate protective order by the Court, information regarding her identity can be disclosed the Defendants' attorneys. As detailed below, Jane Doe is personally and significantly injured by AB 290.

17. Plaintiff Stephen Albright is a current resident of Orange County, which falls within the Southern Division of this judicial district. He is an ESRD patient who is currently undergoing dialysis and receiving HIPP assistance from AKF. As detailed below, Mr. Albright is personally and significantly injured by AB 290.

18. Plaintiff American Kidney Fund, Inc. ("AKF") is a District of Columbia corporation headquartered in Rockville, Maryland. Founded in 1971, AKF's mission is to fight kidney disease and help people live healthier lives. The Internal Revenue Service recognizes AKF as a 501(c)(3) nonprofit charity.

19. Plaintiff Dialysis Patient Citizens, Inc. ("DPC") is a Delaware corporation headquartered in the District of Columbia. Founded in 2004, DPC works to improve the quality of life of individuals suffering with ESRD through membership and advocacy. DPC has more than 28,000 members, consisting solely of kidney disease patients and their families, including 4,587 members in California. The Internal Revenue service recognizes DPC as a 501(c)(4) non-profit educational and social welfare organization.

20. Defendant Xavier Becerra is the Attorney General of the State of California. In this capacity, Attorney General Becerra enforces California's civil and criminal laws, including AB 290. *See* AB 290 §§ 3(k), 5(k).

21. Defendant Ricardo Lara is the California Insurance Commissioner. In this capacity, Commissioner Lara administers California's Insurance Code, including the provisions at issue in this case. *See* Cal. Ins. Code § 12921(a).

22. Defendant Shelley Rouillard is the Director of the California Department of Managed Health Care. Director Rouillard administers portions of the California Health and Safety Code, including the provisions at issue in this case. *See* Cal. Health & Safety Code § 1341(a), (c).

23. Defendant Susan Fanelli is the Acting Director of the California Department of Public Health. In this capacity, Acting Director Fanelli administers portions of the California Health and Safety Code, including the provisions at issue in this case. *See* Cal. Health & Safety Code §§ 1200-1245.

FACTS AND LAW COMMON TO ALL THE CLAIMS

II. End Stage Renal Disease and Congress's Calibrated Efforts to Assist Patients.

24. End stage renal disease ("ESRD") is a chronic, painful, and potentially fatal condition. It is the final, irreversible stage of chronic kidney disease, when a patient's kidneys can no longer sustain life. Even with proper treatment, patients with kidney failure must cope with debilitating exhaustion, extreme fluid buildup, irregular heart rhythms, and other serious health issues. Without proper treatment, they will die. In fact, kidney disease is one of the ten leading causes of death in the United States. *See* Ctrs. for Disease Control, *Mortality in the United States, 2017* (Nov. 2018), *available at* https://www.cdc.gov/nchs/products/databriefs/db328.htm. In addition, ESRD patients routinely face a host of difficult comorbidities, including diabetes, anemia, heart disease, cancer, and hypertension.

25. To stay alive, ESRD patients must either obtain a kidney transplant or undergo continuing kidney dialysis. Dialysis is a medical process that filters waste and excess fluid from a patient's blood. Although dialysis can keep a patient alive, it is an arduous treatment that must be administered at least three times each week in sessions that last hours and may even go overnight. Though dialysis can sometimes be conducted at home, the majority of California dialysis patients have their treatments conducted in centers, often rendering employment impossible. The employment rate among dialysis patients is extremely low—under 20% according to at least one study. *See* N. Kutner et al., *Dialysis facility characteristics and variation in employment rates: A national study*, 3 Clinical J. Am. Soc'y Nephrology 111 (2008). Dialysis is also very costly, burdening patients with thousands to tens of thousands of dollars in medical bills at the very time when their condition may render them unable to work full or even part time.

26. Without support, many ESRD patients can find themselves physically and financially devastated. In fact, 23% to 38% of ESRD patients are said to "crash" into dialysis, meaning they are unaware of their kidney disease until their initial diagnosis of kidney failure, leaving them unprepared to manage their immediate need for ongoing dialysis. *See* A.O. Molnar et al., *Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis*, 5 Sys. Rev. 117 (2016). ESRD also disproportionately affects certain financially vulnerable minority groups; it is much more prevalent among black, Hispanic, Asian, and Native American populations than Caucasian populations. *See* United States Renal Data System, *2018 Annual Data Report*, available at https://www.usrds.org/adr.aspx. Because of these challenges, the vast majority of ESRD patients are unable to afford treatment without medical insurance or government assistance.

27. Fortunately, the ESRD patient population has been a special focus of concern for the United States Congress. Since 1972, Congress has provided special

Medicare coverage for ESRD patients requiring dialysis or transplantation, regardless of age or disability. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 299I, 86 Stat. 1329, 1463 (codified as amended at 42 U.S.C. § 426-1(a)).

28. Beginning with that initial legislation, Congress has continued to take steps to ensure that ESRD patients receive appropriate care. For example, several years after enactment of the initial legislation, Congress extended the Medicare coverage periods following transplant and increased coverage of certain costs. *See* End-Stage Renal Disease Amendments of 1978, Pub. L. 95-292, 92 Stat. 307. Generally speaking, upon application and with a confirmed ESRD diagnosis, patients are entitled to Medicare Part A coverage and eligible for Medicare Part B coverage (even if under age 65) if they have worked a sufficient amount of qualifying time under the Social Security program, already receive Social Security Income benefits, or are a child or spouse of someone meeting either Social Security requirement. 42 U.S.C. § 426-1(a). Those without sufficient work history cannot enroll. Medicare coverage is generally available the first of the month an ESRD patient receives a kidney transplant or the first day of the fourth month after dialysis is started, with retroactive coverage available for one year if a beneficiary does not enroll when first eligible. *Id.* § 426-1(b)(1). If under age 65, Medicare coverage terminates 36 months following a kidney transplant or one year after dialysis is no longer needed. *Id.* § 426-1(b)(2). Congress does not require that ESRD patients enroll in Medicare.

29. Although Congress thought it crucial to provide Medicare coverage to ESRD patients, it also wanted private payers to help share the costs. In 1981, Congress made Medicare the secondary payer for ESRD patients during a specified, limited coordination period, meaning that if a beneficiary is covered by a commercial insurance policy for ESRD services, that private plan must make initial payment before Medicare will step in to pay. *See* Omnibus Budget Reconciliation

Act of 1981, Pub. L. 97-35, tit. XXI, § 2145, 95 Stat. 357, 880. Congress initially set this "coordination period" between Medicare and private plans at 12 months, later extending it to 18 and then 30 months, consistent with Congress's cost-sharing objectives. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, tit. IV, § 4203, 104 Stat. 1388, 1388-107–108; Balanced Budget Act of 1997, Pub. L. 105-33, tit. IV, § 4631, 111 Stat. 251, 486.

30. As a result, if an ESRD patient is entitled to Part A or eligible for Part B Medicare benefits on the basis of the ESRD diagnosis and sufficient work history, and is otherwise covered by a group health plan, the group health plan must serve as first payer for a 30-month coordination period. 42 U.S.C. § 1395y(b)(1)(C). During that 30-month period, the group health plan may not "take into account" that an individual might be eligible for ESRD Medicare benefits, including, *e.g.*, by imposing higher premiums, longer coverage wait times, or lesser coverage. *Id.*; *see also* 42 C.F.R. § 411.108. Even once the 30-month period has passed, the plan may not "differentiate" between covered services on the basis of the ESRD diagnosis. *Id.* The implementing regulations are stringent: group health plans may not differentiate benefits on the basis of ESRD, including by

> [p]aying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD, such as paying 80 percent of the Medicare rate for renal dialysis on behalf of a plan enrollee who has ESRD and the usual, reasonable, and customary charge for renal dialysis on behalf of an enrollee who does not have ESRD.

42 C.F.R. § 411.161(b)(2)(iv).

31. As important as Medicare coverage is for the community of patients suffering from ESRD, that coverage alone is not sufficient. Individuals without sufficient qualifying work time under Social Security may not enroll in Medicare at all. Further, for those who do enroll, Medicare pays only 80% of the costs of medical

care and does not cap out-of-pocket expenses. That means, in AKF's experience, that an ESRD patient who is covered by Medicare and requires frequent medical care can end up facing out-of-pocket expenses that average $9,000 per year. As a result, most ESRD patients who are covered by Medicare must turn to private supplemental insurance, such as Medigap, to afford their deductibles and co-insurance. And, if those patients are lower income, they may not be able to afford supplemental insurance, though it may provide the only protection between them and destitution. These problems are uniquely compounded in California, where insurers are not required to offer Medigap policies to ESRD patients under age 65. *See* Ca. Health & Safety Code § 1358.11(a)(2).

32. Medi-Cal, which is California's Medicaid program, may be a strong safety net, but only for those ESRD patients whose incomes and assets are low enough to qualify. And while Medi-Cal is also an option for medically needy ESRD patients whose income exceeds that for typical Medi-Cal coverage, the spenddown requirements necessitate spending all but $600 of monthly income on medical costs before coverage under Medi-Cal is available. *See* Cal. Welf. & Inst. Code §§ 14005.7, 14005.9 (requiring patients pay "share of cost" for services each month based on countable income); *see also* California Medi-Cal Eligibility Procedures Manual, Article 8(F)(15)[1] (setting Maintenance Need Income Level for one person at $600, with modest increases for larger families). Most Californians cannot live on $600 a month, particularly those with a chronic, serious illness.

33. For low-income undocumented ESRD patients, the situation is even more dire, as many do not have insurance coverage and therefore do not receive appropriate treatment until their symptoms are severe. Undocumented immigrants under age 19 are eligible for full-scope Medi-Cal and, beginning on January 1, 2020,

[1] https://www.dhcs.ca.gov/services/medi-cal/eligibility/Documents/Article8-RR-UnitDeterminations.pdf, page 94. *See also* http://file.lacounty.gov/SDSInter/dpss/237810_Copyof2016Medi-CalIncomeLevelChart4(2).pdf.

young adults age 19-25 will also be eligible for full-scope Medi-Cal. *See* Cal. Welf. & Inst. Code § 14007.8(a)(1); Act of July 9, 2019, ch. 67, § 8, 2019 Cal. Stat. ___ (2019) (SB 104) (amending Cal. Welf. & Inst. Code § 14007.8(b)).[2] Unfortunately, the same is not true for undocumented adults; for those individuals, Medi-Cal covers emergency dialysis but not the full scope of health coverage that such individuals, with their co-morbidities and complicated health needs, will necessarily require when facing ESRD. *See* Cal. Welf. & Inst. Code § 14007.5(d).

34. For patients who cannot access Medicare or Medi-Cal, commercial insurance is the only alternative to emergency room care. Emergency room care is not a solution for patients with ESRD, however, due to the need for constant management of their chronic disease process. This means that patients receiving dialysis through emergency room care deteriorate quickly, facing severe illness and death. Moreover, emergency room care for dialysis patients also places a severe hardship on already financially overburdened community hospitals.

35. In short, then, private insurance is an indispensable component for the treatment of patients with ESRD and serves as an important complement to government programs. As Plaintiffs will explain below, HIPP provides access to both Medicare and private insurance for many patients suffering from ESRD who otherwise are unable to afford public or private coverage. AB 290 cuts directly at this only source of relief for many of these patients.

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[2] Other undocumented individuals may also be eligible for full Medi-Cal benefits if they permanently reside in California under color of law ("PRUCOL"). Cal. Welf. & Inst. Code § 14007.5(b). One PRUCOL category is individuals residing under the Deferred Action for Childhood Arrivals program. *See* Ca. Dep't of Health Care Servs., Deferred Action for Childhood Arrivals (DACA) Rescission Frequently Asked Questions, available at https://www.dhcs.ca.gov/formsandpubs/publications/Pages/Deferred-Action-for-Childhood-Arrivals-FAQ.aspx.

II. The American Kidney Fund and Its Health Insurance Premium Program

36. Even as Congress has provided special Medicare coverage to ESRD patients, many of them and their families face significant hardships. The Amercan Kidney Fund ("AKF") and Dialysis Patient Citizens ("DPC") have made these patients the central part of their missions.

37. Since its founding in 1971, AKF has become the nation's leading 501(c)(3) charity focused on kidney disease patients and their families. AKF describes its mission as a "360-degree approach," in which it combats kidney disease on all fronts: awareness, advocacy, prevention, public education, professional engagement, clinical research, and financial assistance. Publication after publication—including *Consumer Reports* and *Consumers Digest*—as well as charity watchdogs—such as *Charity Navigator* and *Guidestar*—have lauded AKF as among the best run and most effective charities in America. This praise stems from AKF's financial transparency (AKF makes its tax forms and audited financial statements available online) and its efficiency (a remarkable 97 cents of every dollar donated to AKF goes to patients and programs). The foundation of AKF's support is the general public. Over 61,000 distinct donors who care about kidney disease contribute annually to support AKF's full range of programs, from prevention, to disease education, to clinical research, to financial support for kidney patients. AKF's corporate supporters range from dialysis providers, to pharmaceutical companies, to financial services companies, to household names like Google.

38. In 2004, DPC joined the fight against kidney disease and the suffering it inflicts on patients and families. DPC's central mission is to give voice to the issues that face dialysis patients and their families. DPC effectuates its mission through public education and advocacy efforts, ranging from grassroots advocacy campaigns, to training Patient Ambassadors to educate legislators about the issues surrounding dialysis, to providing briefings to politicians and regulators on the key

concerns that face the ESRD community. Thanks to its efforts, DPC's membership, which consists solely of ESRD patients and their family members, numbers 28,000, with members coming from all walks of life. DPC is also very active in California, with over 4,500 members residing in the state. Moreover, DPC works closely with AKF to ensure that its members have the support they need to live longer, healthier lives. In particular, DPC and AKF have worked together to inform ESRD patients of the financial assistance that AKF can provide to lower income patients.

39. It is this financial assistance to the desperately ill that this lawsuit seeks to protect. Among AKF's flagship charitable efforts is HIPP. Based solely on the financial needs of ESRD patients, HIPP provides confidential charitable grant assistance to individuals with ESRD who require dialysis, but who cannot afford the premiums to keep their health insurance coverage.

40. To meet the diverse needs of ESRD patients, many of whom are working-age with families, HIPP supports coverage under both government and private plans. In some states, ESRD patients under age 65 who are on Medicare may enroll in supplemental Medigap plans, which often pay the deductibles and co-insurance associated with Medicare Part B. California, however, does not require insurers to offer Medigap plans to ESRD patients under 65, *see* Ca. Health & Safety Code § 1358.11(a)(2), and accordingly, California insurers generally fail to offer such coverage. Lacking access to Medigap, ESRD patients under 65 in California turn to AKF to support commercial secondary coverage to supplement their Medicare coverage, or they elect to stay on employer, COBRA, or on- or off-exchange plans as their primary coverage, with Medicare as their secondary coverage.

41. AKF's ability to support HIPP grant recipients in a wide range of insurance circumstances is critical. Although many of the patients whom AKF assists are enrolled in Medicare-related insurance, a good portion of ESRD patients simply do not qualify for Medicare. Moreover, the majority of the HIPP patients

enrolled in Medicare cannot afford the Medicare Part B premium, the 20% unlimited Medicare coinsurance costs, or the costs of a Medigap policy to cover the 20% Medicare expenses. Indeed, the importance of AKF's support reaches beyond just the recipient patients. In many situations in which AKF pays the insurance premiums for a needy ESRD patient, the spouses and children of those patients are also covered, with AKF generally paying the equivalent of the patient cost to the plan and the family paying the remainder. If AB 290 becomes effective, and forces AKF to withdraw HIPP from California, the spouses and children covered by those policies may also lose their coverage, while also facing further economic hardships.

42. Eligibility for HIPP is first-come-first-served and is based only on whether an applicant is on dialysis and lacks financial means to afford appropriate health insurance coverage for ESRD. Moreover, to receive assistance under the program, an applicant must prove that he or she already has insurance coverage and produce a bill for that coverage.

43. HIPP patients thus come to the program only *after* they have qualified for and obtained health insurance of their choosing. AKF does not tell its applicants or grantees to acquire any particular form of health insurance or to seek treatment from any particular provider, regardless of whether the insurer or provider has contributed to AKF. Rather, it simply seeks to help chronically ill, predominantly minority, and financially vulnerable individuals make payments to keep their health insurance and get the care they desperately need.

44. The financial needs of HIPP beneficiaries are stark. For example, within Orange County, HIPP recipients report a median yearly income of around $31,000, while the most recent census estimate indicates that the median household income for the county is just above $81,000 per year. *See* U.S. Census Bureau, *Quick Facts—Orange County, California*, available at https://www.census.gov/quickfacts/fact/table/orangecounty%20california/INC110217# (last accessed Oct. 17, 2019).

45. AKF takes seriously the confidentiality of information that its applicants and grantees share with the organization. A HIPP grantee's need for charitable assistance is a private matter, and AKF treats it as such. Accordingly, AKF does not identify grantees publicly unless it receives explicit authorization to do so. Such disclosures would intrude on a grantee's right to keep such intimate matters private.

III. Advisory Opinion 97-1

46. From the beginning of HIPP, AKF has always sought to ensure that the program complies with federal law. Of particular concern to AKF at the start of HIPP was § 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, tit. II, § 231(h), 110 Stat. 1936. That law provides for civil monetary penalties against any entity which—

> offers or transfers remuneration to any individual eligible for benefits under [federal health care programs (including Medicare or Medicaid)] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, [by a federal health care program].

42 U.S.C. § 1320a-7a(a)(5). "Remuneration" is defined to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6).

47. AKF asked the Office of the Inspector General ("OIG") of the Department of Health and Human Services for an advisory opinion on its proposed HIPP because it was rightly concerned that such a program could trigger this sanction. Because many ESRD patients are eligible for Medicare benefits, *id.* § 426-1(a), and AKF's premium payments could arguably be viewed as remuneration, AKF sought to confirm that HIPP was not inconsistent with that provision.

48. In response, AKF and several dialysis providers sought and obtained a formal advisory opinion from the OIG that AKF's premium assistance program did

not violate HIPAA's anti-inducement provision. *See* 42 C.F.R. pt. 1008 (regulations governing the issuance of advisory opinions); 42 U.S.C. § 1320a-7d(a)(1)(A) (providing that individuals who have concerns that a proposed arrangement may violate the anti-inducement provision may obtain an advisory opinion that acts as a safe harbor for that arrangement). In fact, that opinion—Advisory Opinion 97-1—was the very first issued by OIG under the provisions permitting such safe harbor guidance. *See generally* Advisory Op. 97-1 (hereinafter, the "Advisory Opinion").

49. Advisory Opinion 97-1 provides the safe harbor under federal law for HIPP. After describing HIPP in detail, the Advisory Opinion found that dialysis providers' donations to AKF did not constitute "remuneration" to an individual eligible for federal health care benefits because "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 [provider] Companies." Advisory Op. at 6 (emphasis in original); *see id*. (observing that "AKF will have absolute discretion regarding the use of provider contributions made to AKF"). As OIG noted, HIPP "[a]ssistance is available to all eligible patients on an equal basis," *id.* at 4, AKF will not advise dialysis companies which patients are enrolled in HIPP and the companies will not track payments made by AKF at their facilities, *id.* at 6-7. Moreover, the Advisory Opinion observed that "HIPP will not be advertised to the public by the [provider] Companies," thus "reduc[ing] the probability that a beneficiary would select a Company based on its participation in HIPP." *Id*. The Advisory Opinion noted that, once in possession of coverage, beneficiaries will be able to select any provider of choice, concluding, "[s]imply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice." *Id.* Finally, the OIG required that AKF provide "[a]ssistance . . . to all eligible patients on an equal basis." *Id.* at 3.

50. AKF has followed the Advisory Opinion rigorously since its issuance. Without the Advisory Opinion, AKF could not provide the charitable assistance that

helps one in six dialysis patients nationwide. Because the Advisory Opinion is "limited to the facts presented," *id*. at 1, it provides a safe harbor only so long as "the arrangement in practice comports with the information provided," *id*. at 8. A change to any aspect of HIPP would thus pose a mortal threat to the program and the insurance premium assistance that it offers thousands of patients nationwide, including 3,700 in California alone. Without question, AB 290 is such a threat.

IV. California Assembly Bill 290

51. On October 13, 2019, with Governor Gavin Newsom's signature, California Assembly Bill 290 became law. The Act represents the culmination of a years-long effort, spearheaded by private health insurers, to punish the dialysis industry. Governor Jerry Brown had vetoed an earlier iteration of the Act, encouraging proponents to work with "all stakeholders . . . to find a more narrowly tailored solution that ensures patients' access to coverage." AB 290 is anything but "narrowly tailored" and jeopardizes rather than "ensures patients' access to coverage."

52. Unlike most legislation, which is generally applicable, the Act is laser focused on a discrete set of entities: AKF and large dialysis providers that operate in California. This is not speculation. AKF is mentioned by name in the text of the Act, *see* AB 290 § 1(j) and, alongside "large dialysis organizations," is referred to at length in its findings of fact as the "nonprofit" at which the Act is directed, *see id*. §§ 1(g), 1(h), 1(i).

53. Just as the Act makes its targets clear, it is also plain about its central purpose: to destroy AKF's premium assistance program in California. The Act's findings leave no doubt on this score:

> Large dialysis companies contribute more than 80 percent of the revenue to a nonprofit [an unmistakable reference to AKF] that pays health insurance premiums for patients on dialysis for kidney failure. In turn, this nonprofit [again, AKF] generates hundreds of millions of

> dollars for large dialysis organizations by artificially increasing the number of their patients who have commercial insurance coverage.

Id. § 1(h). The Act is supposed to correct this purported "market failure," *id.* § 1(i), and thus bring about lower private health insurance costs within California, *id.* § 1(e). In truth, AB 290 has no provisions ensuring that whatever small gains it produces, if any, will trickle down to patients, rather than remaining in the insurers' coffers.

54. Nonetheless, as Assemblyman Jim Wood, the author of the Act, has explained: "This bill provides certain parameters on a practice where companies that provide certain types of care, donate money to a nonprofit that, in turn, pays for a patient's private coverage even though they qualify for coverage under Medicare or Medi-Cal, in order to receive a higher reimbursement rate." AB-290 Ca. Assembly Floor Analysis, at 2 (Sept. 9, 2019). Those "parameters" are inconsistent with and preempted by federal law as reflected in the Advisory Opinion, and have the explicit objective of discouraging donations to AKF, in violation of its constitutional right of association. Such a motive is inexcusable on its own terms. But the Act inflicts further constitutional injuries on AKF, DPC, and the patients they serve.

A. The Act's Provisions

55. At its core, the Act regulates the relationships among three groups of entities:

- Insurance companies and health benefit plans that issue health insurance policies or "health care service plan contracts" – "[I]ndividual or group health care service plan contract[s] that provide[] medical, hospital, and surgical benefits," excluding Medicare-related contracts with the federal government. AB 290 § 3(h)(3).
- Dialysis providers through two provisions:

- "Financially interested providers" – These are "providers"—"a professional person, organization, health facility, or other person or institution that delivers or furnishes health care services"—"that receive[] a direct or indirect financial benefit from a third-party premium payment." *Id.* §§ 3(h)(4), 3(h)(2)(A).
- Clinics owned by large dialysis providers – "A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019. A chronic dialysis clinic that does not meet the definition of an LDO or has no more than 10 percent of California's market share of licensed chronic dialysis clinics shall not be considered financially interested for purposes of this section." *Id.* §§ 3(h)(2)(C).

- "Financially interested entities" – "An entity that receives the majority of its funding from one or more financially interested providers of health care services, parent companies of providers of health care services, subsidiaries of health care service providers, or related entities." *Id.* § 3(h)(2)(B). This provision targets AKF, falsely implying that AKF is anything other than a highly reputable, nonprofit charity.

56. Although the Act is littered with constitutionally suspect provisions, there are two interrelated mechanisms that are uniquely harmful to AKF and DPC's mission of assisting financially vulnerable ESRD patients with their health care costs. The first is the Act's tight linking of AKF with large dialysis providers by

sharply reducing the rates at which such providers may be reimbursed for HIPP patients:

> Commencing January 1, 2022, if a financially interested entity makes a third-party premium payment to a health care service plan on behalf of an enrollee, reimbursement to a provider who is also a financially interested entity for covered services provided shall be determined by the following: . . .
>
> For a contracted financially interested provider that makes a third-party premium payment or has a financial relationship with the entity making the third-party premium payment, the amount of reimbursement for covered services that shall be paid to the financially interested provider on behalf of the enrollee shall be the higher of the Medicare reimbursement or the rate determined pursuant to the process described in this subdivision, if a rate determination pursuant to that process is sought by either the provider or the health care service plan. Financially interested providers shall neither bill the enrollee nor seek reimbursement from the enrollee for services provided, except for cost sharing pursuant to the terms and conditions of the enrollee's health care service plan contract. If an enrollee's contract imposes a coinsurance payment for a claim that is subject to this paragraph, the coinsurance payment shall be based on the amount paid by the health care service plan pursuant to this paragraph.

Id. §§ 3(e)(1), 5(e)(1).

57. As the above indicates, "contracted financially interested providers," defined as those which donate to AKF and hold long-term, in-network agreements with insurers to furnish dialysis services to HIPP patients, will have their contracted reimbursement rates drastically slashed to a rate no higher than the rates would be under Medicare. Out-of-network providers ("noncontracting financially interested

providers") will also see a payment decrease. *See id.* §§ 3(e)(2), 5(e)(2) (calling for payment rates at the lower of those allowable under the beneficiary's plan for out-of-network care or at a rate established by a "dispute resolution process" focused on the Medicare and Medi-Cal rates). Like in-network providers, they may not bill the beneficiary for the balance and are limited to collecting only the typical cost-sharing percentage related to the insurer payment actually received. *Id.*

58. To implement this rate cutting, the Act conscripts AKF and its confidential information into the Government's service:

> A financially interested entity shall not make a third-party premium payment unless the entity complies with . . . the following requirements: Discloses to the health care service plan, prior to making the initial payment, the name of the enrollee for each health care service plan contract on whose behalf a third-party premium payment described in this section will be made.

Id. §§ 3(c)(2), 5(c)(2).

59. This provision radically and unconstitutionally changes how AKF has operated for decades by obligating it to turn over the names of the patients it assists to private insurers. Under the terms of Advisory Opinion 97-1, AKF does not disclose the names of patients who receive premium assistance to its donors, including dialysis providers, or to insurers. *See* Advisory Op. at 5. Of course, it is possible that insurers, who have long had a financial interest in removing the ESRD patients that AKF helps from their plans, on occasion may have discovered this information for some patients from other sources other than patients or AKF (such as payment statements). But that information never comes from AKF, which takes both its patients' privacy and obligations under Advisory Opinion 97-1 very seriously.

60. AB 290 thus compels AKF to make a statement that it otherwise would not make, containing confidential information that it otherwise would not disclose

to non-governmental adversaries hostile to HIPP. That is a canonical example of compelled speech. Indeed, the Act is so poorly drafted that it is unclear whether AKF must give the insurer the name of an individual patient who is applying for coverage from the particular insurer, or whether AKF must give the names of *all* HIPP beneficiaries to *all* insurers who have such patients on their rolls. Nor are there any guardrails around how the insurers may use this confidential information once it is provided. AKF, DPC, and patients participating in HIPP have no guarantee that the forcibly disclosed patient information will not be used to penalize those very same patients or for other improper purposes.

61. Ultimately, then, these two of the Act's provisions work in tandem: the first effectively penalizes donating providers for donating to AKF, and the second pressgangs AKF into giving over patient names to insurers so that this penalty can be implemented. Together, these provisions—if allowed to go into effect—will irreparably damage AKF's charitable efforts in California and likely nationwide and trample over the careful statutory arrangement that Congress has constructed for ESRD patients. (It also bears noting that these provisions also damage the rights of AKF's donors to speak and associate, as well as HIPP patients' rights to associate.)

62. The third provision that undermines HIPP is the requirement that AKF inform the patient of "all available coverage options," including Medicare and Medicaid, before granting the patient access into HIPP. AB 290 §§ 3(b)(3), 5(b)(3); *see also id.* §§ 3(b)(1), 5(b)(1) (imposing similar requirements). In essence, the State is attempting to conscript AKF into delivering the State's message for the purpose of persuading patients not to take advantage of HIPP, thereby forcing AKF to undermine its own program. This is particularly perverse because, in accordance with Advisory Opinion 97-1, AKF currently plays no role in patients' insurance selection decision; patients come to AKF only *after* they have insurance in place.

63. This compelled speech provision is exacerbated by a fourth offending provision, which obligates AKF to "agree not to steer, direct, or advise the patient

into any or away from a specific coverage program." *Id.* §§ 3(b)(4), 5(b)(4). What is meant by "steer, direct, or advise" in this context is anyone's guess, meaning that the provision is unconstitutionally vague. And, conversely, this provision completely prohibits AKF from "advising" patients about the consequences of their health insurance choices with respect to the impact on dialysis. While AKF does have a robust interest in being able to provide accurate general information when patients come to it, AKF is not an insurance navigator. But AB 290 forces AKF into that role, and then prohibits it from crossing a vague and wavy line. If AKF deviates from California's script, by, for example, answering patient questions about the pros and cons of particular plans, it faces a real risk of violating the Act.

64. Together, the third and fourth provisions of AB 290 mean that when patients seek HIPP assistance with an insurance policy that they have selected, AKF must respond with a menu of alternative insurance options, while also ensuring that it does not "steer, direct, or advise" regarding any of them. How AKF will be able to comply with these conflicting demands is unclear. What is clear is that both AKF and patients will be left confused about what to do.

65. Finally, if there was any question that AB 290 is drafted to undermine AKF and HIPP, it is eliminated by the Act's requirement that AKF "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." *Id.* §§ 3(b)(2), 5(b)(2). HIPP assistance, consistent with AKF's mission, is limited to patients receiving dialysis or patients who are in the plan year after receiving a transplant. Dialysis and transplant are the only treatments for kidney failure. This provision, by its very terms, would eliminate AKF's ability to limit HIPP to dialysis patients. It would transform a keystone program intended to support patients with kidney failure, the focus of the American *Kidney* Fund for decades, into non-descript medical charity. It would deplete AKF's funding for desperately ill patients by forcing AKF to fund insurance for individuals who do not suffer from ESRD. That is unfair and constitutionally unacceptable.

66. These harms will come to pass very soon. AB 290 will become effective on January 1, 2020, and from that date on, AKF will begin to accrue significant obligations. AKF's own HIPP policy, as well as AB 290 §§ 3(b)(1) and 5(b)(1), as operative July 1, 2020, require that AKF provide premium assistance for a full plan year. Thus, unless the Act is enjoined, AKF will be forced to cease assisting low-income dialysis and transplant patients in California by January 1, 2020. AKF cannot stop its assistance mid-year on July 1, 2020, without violating both its own policies and AB 290.

B. The Harmful Consequences of the Act

67. As intended and as can be fully expected, the Act will have numerous harmful consequences to HIPP. It will also have a devastating effect on HIPP beneficiaries and their families.

68. To begin, the Act creates a severe disincentive for some of AKF's most important donors to continue donating. If a dialysis provider gives to AKF and provides services to a patient who is on HIPP, that provider is punished with a much lower rate of reimbursement. The end result is that donating providers—which have sound corporate social responsibility reasons to support AKF—will be forced by the raw economics of AB 290 to curtail their donations to AKF. In this manner, the Act directly injures AKF's associational interest in its relationship with these important donors, which are also key partners in the treatment of kidney disease. This injury, acute as it is, is just part of a cascade of injuries to patients and entities.

69. With fewer donations and less money for HIPP, AKF will be able to assist fewer patients across the United States in paying their insurance premiums, and those patients, already financially strained, will be forced off their current insurance plans. Although many of those patients will be eligible for Medicare, some simply will not qualify for that program. Even those who do qualify for Medicare will face real risks. As noted above, the vast majority of the patients AKF assists cannot, without HIPP assistance, even afford the modest Medicare premium,

much less the 20% Medicare co-insurance costs or the cost of a Medigap policy (assuming they can obtain one). These patients come to AKF precisely because they are confronted with possible destitution due to their illness; AB 290 will revive that nightmare for them.

70. Nor are these immediate financial consequences the sole concern for Medicare patients. Even assuming they can pay the high costs of Medicare, such patients generally face a waiting period of 3 months—a critically long period when one requires dialysis at least three times a week to stave off grave illness and death—and fill that gap with dialysis through emergency rooms, complete with long waits, subpar specialized kidney care, and potentially crippling expenses. Their spouses and children who were previously covered by private insurance may lose that coverage. Their opportunities for treatment may diminish. And through all of this, they will face uncertainty and anxiety.

71. For those who are ineligible for Medicare due to work history or immigration status, the situation is still more grim. If Medi-Cal is unavailable to them, many may have to seek treatment in emergency rooms. For them, AB 290 carries immediate and concrete risks of disability and death. Though California may prefer to talk in arid terms of "market failures," these are matters of life and death for ESRD patients.

72. These consequences will apply with particular force for California patients because the Act will force AKF to halt HIPP within that State. AKF's nationwide HIPP operations are conducted under the aegis of Advisory Opinion 97-1; without that safe harbor, AKF and its donors are exposed to the patient inducement statute, and the civil penalties and reputational costs that its violation would bring. The Advisory Opinion itself, as well as the implementing regulations for the advisory opinion process, make clear that the Advisory Opinion's safe-harbor status is contingent on AKF continuing to follow rigorously the terms of the program presented to and approved by the OIG. *See* Advisory Op. at 8 ("This advisory

opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."); 42 C.F.R. § 1008.15(a) ("The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake."); *id.* § 1008.43(b) (advisory opinions are "based on the facts provided to the OIG").

73. California's Act would require material changes in HIPP and undermine the protections set forth in Advisory Opinion 97-1. Because AB 290 mandates that providers treating HIPP beneficiaries receive lower reimbursement, providers would know upon receipt of the lower reimbursement which of their patients are supported by HIPP, and discerning patients would be aware upon receiving their Explanations of Benefits that their particular provider was a donor to AKF. That alone breaches the terms for Advisory Opinion 97-1's safe harbor provision.

74. But the Act goes still further. It requires AKF to treat applicants to HIPP differently, in contravention of the Advisory Opinion's requirement that AKF provide HIPP assistance to all patients on an equal basis. For instance, AB 290 requires AKF to treat California HIPP recipients differently than recipients from any other state by forcing AKF to disclose California HIPP recipients' names to insurers. Even within California, AB 290's grandfathering clauses require AKF to differentiate amongst its HIPP beneficiaries on a range of dimensions. *See* AB 290 §§ 3(d)(1), 5(d)(1) (grandfathering against name disclosure and rate reductions for those beneficiaries receiving premium assistance prior to October 1, 2019); *id.* §§ 3(d)(2), 5(d)(2) (removing grandfathered status if those beneficiaries change their insurance plan on or after March 1, 2020); *id.* §§ 3(c)(2), 3(e), 5(c)(2), 5(e) (requiring name disclosure and reduction of patient rates for all others). The Act requires that HIPP patients be treated differently based on the size of their dialysis provider, because clinics operated by "large dialysis clinic organizations" fall within the Act's ambit. *Id.* §§ 3(h)(2)(C), 5(h)(2)(C). And, perhaps most troubling, because AB 290

specifically targets HIPP, it means that those patients who seek the help of the program—low income and predominantly minority—are treated differently from ESRD patients who do not need such assistance. AB 290 has placed AKF, and the patients it supports, in an unfair, untenable, and unconstitutional situation.

75. In light of the above, it is clear that if AB 290 is allowed to go into effect, AKF would be unable to comply with the terms of Advisory Opinion 97-1, and AKF would be at risk of facing ruinous civil penalties and the loss of its hard-earned reputation. Indeed, California's Legislative Counsel Bureau opined that "because th[e] disclosure requirements [contemplated by AB 290] were not part of the arrangement considered by OIG when it issued Opinion 97-1, that opinion would not ensure that the version of the patient assistance program operated by AKF in compliance with AB 290 would be immune from OIG sanctions" and concluded that "the changes in the premium assistance program required by AB 290 would remove the legal protection afforded by 97-1." Ca. Legislative Counsel Bur., *Assembly Bill No. 290: Dialysis Providers: Charitable Donations - #1916414*, at 6 (June 28, 2019).[3] Under these circumstances, AKF cannot risk the entirety of its other HIPP operation across the United States. AKF will simply be unable to operate HIPP in California to the detriment of patients there.

76. Yet the Act's pernicious consequences do not end with the impact on HIPP patients. The Act also severely disrupts the ESRD system that Congress envisioned, whereby private plans share with Medicare the financial burden of treating ESRD patients. Specifically, Congress mandates a 30-month period during which time private payers continue to make payments first even where a patient is also enrolled in Medicare. 42 U.S.C. § 1395y(b)(1)(C). The Act effectively makes

[3] Notwithstanding this conclusion, the Legislative Counsel Bureau still somehow concluded that "the American Kidney Fund would remain in compliance with the arrangement approved in Advisory Opinion 97-1," *id.* at 9, even as it also acknowledged that "this would be a factual determination made by the OIG and could involve a consideration of facts not available to [it]," *id.* at 8.

the continuation period zero months from providers' perspectives, effectively forcing low-income patients off their private insurance if they lose AKF's assistance. Moreover, Congress forbids private plans from differentiating between ESRD and non-ESRD enrollees, including, under the implementing regulations, in payments to providers. *Id.*; 42 C.F.R. § 411.161(b)(2)(iv). The Act does just this, allowing plans to pay reduced rates for dialysis services on the basis of ESRD diagnoses (made known through HIPP).

77. These foreseeable and avoidable harms contrast sharply with the state's negligible interest in its intrusive new policy. In the best case, the effect, if any, on California's private health insurance marketplace will be vanishingly small, and the reduction, if any, in monthly premiums for individuals would be miniscule. Perhaps more important, the statute lacks any mechanism for passing savings for the dramatically lower dialysis reimbursements on to enrollees: there is no guarantee that these small savings will go to patients rather than into the pockets of insurance companies.

78. Finally, even assuming California's leaders have pursued appropriate ends, the means provided in the Act are wholly inappropriate. The state has a host of options for regulating health-insurance cost, most of which do not require any imposition on the privacy, dignity, or health of low income, predominantly minority, and highly vulnerable ESRD patients.

C. The Impact of the Act on Real Patients

79. Though AB 290 will inflict real harm on AKF and its mission, the true victims of the Act are the ESRD patients who will lose access to a critical source of financial support. At core, this case is and should be about the human consequences of California's unconstitutional Act.

80. Mr. Albright is emblematic of these harms. He is in his mid-50s and has been on dialysis for almost two years. His regimen is arduous: he does dialysis every night at home for hours at a time. His health care is expensive, and entirely

unaffordable without health insurance. Mr. Albright receives his health insurance through Medicare and his significant other's employer, but he cannot afford to pay for the premiums. Without AKF's financial assistance, Mr. Albright could not afford his insurance, and without that insurance, he will not be able to pay for his dialysis treatment or any other health care that keeps him healthy enough to stay employed. For Mr. Albright, the stakes of AB 290 could not be higher.

81. Jane Doe has also suffered immense hardship as a result of her life-altering ESRD diagnosis. She is in her mid-50s and has been on dialysis for over a year and a half. It took her doctors well over a month to diagnose her kidney issues, and by that time, she was already in kidney failure. She now receives dialysis three times a week at a clinic. As a result of the time-consuming dialysis and the physical difficulties that come with ESRD, Jane Doe had to stop her full-time job. It is only through AKF's assistance that Jane Doe is able to afford the premiums of her expensive COBRA insurance and Medicare. Without that coverage, Jane Doe would not be able to pay the substantial costs associated with treating kidney failure including dialysis and other health care specialties.

82. But the Patient Plaintiffs are not alone in this. There are thousands of Californians who face the same risks, the same anxieties that keep them up at night. This case is about them, and striking down the Act that puts them in jeopardy.

CLAIMS FOR RELIEF

COUNT I

Federal Preemption Under the Supremacy Clause of the United States Constitution

(Against All Defendants)

83. Plaintiffs reallege and incorporate by reference paragraphs 5 - 82 as if set forth in full.

84. The Supremacy Clause of the United States Constitution provides that "This Constitution, and the Laws of the United States which shall be made in

Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2.

85. AB 290 conflicts with federal law, and thus violates the Supremacy Clause, in numerous ways. First, federal law, as construed and applied to HIPP in Advisory Opinion 97-1, requires that HIPP treat all eligible patients the same. AB 290 requires AKF to treat different categories of patients differently within California, by requiring different treatment of grandfathered patients (those receiving assistance from AKF as of October 1, 2019) differently from non-grandfathered patients (who first obtain their policies after October 1, 2019), and from previously grandfathered patients who change policies on or after March 1, 2020. Moreover, AB 290 creates a unique set of requirements for patients in California that are not applicable to patients outside California.

86. Second, and also contrary to the mandate of federal law, AB 290 requires AKF to disclose the name of each patient receiving charitable assistance to each plan or insurer providing coverage, which, through the modified reimbursement rates in the Act, will result in the disclosure to particular providers of the names of all patients receiving charitable assistance.

87. Third, by effectively causing disclosure to the patient that particular providers are participating in the patient assistance program, AB 290 requires AKF to violate federal law as set forth in Advisory Opinion 97-1.

88. For these reasons, AKF cannot comply with AB 290 without running afoul of Advisory Opinion 97-1.

89. Moreover, AB 290 attempts to force AKF to seek a revision of Advisory Opinion 97-1 by making AB 290 effective on July 1, 2020, unless AKF files such a request for revision of Advisory Opinion 97-1. In other words, only by seeking a new or revised Advisory Opinion can AKF avoid, if only temporarily, the drastic effects of AB 290. Under settled precedent, the State may not require AKF

to seek a change in federal law to allow an otherwise preempted state law to become effective.

90. Each of these provisions, together and separately, render impossible or unnecessarily burdensome AKF's efforts to comply with federal law 42 U.S.C. § 1320a-7a(a)(5), as interpreted by the Inspector General in Advisory Opinion 97-1. Accordingly, Plaintiffs are entitled to, and hereby seek, a declaration that AB 290 is preempted by federal law, and an injunction against enforcement of the statute. Plaintiffs will suffer irreparable harm without this requested relief.

COUNT II

Federal Preemption Under the Supremacy Clause of the United States Constitution

(Against All Defendants)

91. Plaintiffs reallege and incorporate by reference paragraphs 5 - 82 as if set forth in full.

92. AB 290 violates the Supremacy Clause, U.S. Const., art. VI, cl. 2, by conflicting with the Medicare Secondary Payer Act, 42 U.S.C. § 1395y(b).

93. AB 290 seriously interferes with the Medicare Secondary Payer Act's objective of creating a public-private partnership to cover and pay for the costs associated with treatment for ESRD patients.

94. Furthermore, AB 290 permits insurers to treat insureds differently on the basis of their ESRD diagnosis, in contravention of the Medicare Secondary Payer Act.

95. Both of these provisions present an obstacle to the objective Congress sought to accomplish when enacting and amending the Medicare Secondary Payer Act.

96. Accordingly, Plaintiffs are entitled to, and hereby seek, a declaration that AB 290 is preempted by federal law, and an injunction against enforcement of the statute. Plaintiffs will suffer irreparable harm without this requested relief.

COUNT III

Abridgement of the Rights of Association, Speech, and Petition in Violation of the First and Fourteenth Amendments to the United States Constitution

(Against All Defendants)

97. Plaintiffs reallege and incorporate by reference paragraphs 5 - 82 as if set forth in full.

98. The First Amendment to the United States Constitution, applicable to the States through the Fourteenth Amendment, proscribes any law "abridging the freedom of speech . . . or the right of the people peaceably to assemble, and to petition the government for redress of grievances." U.S. Constitution, amend. I.

99. AB 290 abridges AKF's freedom of speech by coercing AKF to deliver the State's message in three ways. First, Sections 3(b)(1) and (3), as well as Sections 5(b)(1) and (3), coerce AKF into notifying each potential recipient of patient assistance of "alternative coverage options, including but not limited to Medicare, Medicaid, and individual market plans," and of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable." Consistent with the overall purpose of the statute, these coerced messages are intended to discourage patients from participating in HIPP. In effect, the statute attempts to use AKF as the messenger to undermine its own program.

100. Second, sections 3(c)(1) and 5(c)(1) require an annual "statement" that AKF meets all the requirements of sections 3(b) and 5(b). The statute requires AKF to provide the statement to each health care service plan and each insurer to which AKF makes any premium payment.

101. Third, Sections (3)(c)(2) and 5(c)(2) require AKF to disclose, to each health care service plan and each insurer to which it makes any premium payment, the names of the specific patients receiving the assistance.

102. The statute also directly restricts AKF's ability to speak. Sections 3(b)(4) and 5(b)(4) require AKF to "agree not to steer, direct, or advise the patient into any or away from a specific coverage program." This provision abridges AKF's speech in at least two ways. To begin, it is vague and overbroad, which will deter AKF from speaking to grant recipients at all beyond the required statements in Sections 3(b)(1) and (3) and 5(b)(1) and (3) due to the risk of violating the provision. Moreover, the provision suppresses protected speech by prohibiting AKF from "advising" patients about the existence of particular coverages, or from assisting the patients in their selection of appropriate coverages.

103. By imposing these and other burdens on AKF, the statute interferes with AKF's ability to associate freely with patients.

104. In addition, the statute imposes onerous rate regulation on providers who donate to HIPP. By punishing providers for donating to HIPP, the statute will have the actual and intended effect of deterring providers from donating to HIPP. Thus, the statute interferes with AKF's ability to associate freely with its major donors.

105. AB 290 also abridges AKF's freedom to petition. Under Section 7, unless AKF petitions the Inspector General for a review of Advisory Opinion 97-1 on or before July 1, 2020, Sections 3 and 5 of the statute "shall become operative on July 1, 2020." Thus, only by complying with a coercive mandate to petition the Inspector General, a mandate that abridges AKF's First Amendment right to petition by compelling AKF to file a petition it actually opposes, can AKF avoid the imminent infringements of its other First Amendment rights of speech and association.

106. No compelling, or even rational, government interest supports this full scale assault on AKF's First Amendment rights.

107. Accordingly, each of these provisions, together and separately, abridges AKF's First Amendment rights, and they are not severable from the

remaining provisions of the Act. AKF is entitled to, and hereby seeks, a declaration that AB 290 infringes its First Amendment rights to free speech, association, and petition, and an injunction against enforcement of the statute. AKF will suffer irreparable harm without this requested relief.

PRAYER FOR RELIEF

Plaintiffs request that this Court grant the following relief:

1. Declare the California law unconstitutional and void due to its infringement on the speech, association, and privacy rights protected by the United States Constitution;
2. Enjoin Attorney General Becerra, Commissioner Lara, Director Rouillard, and Acting Director Fanelli from any and all enforcement of California Assembly Bill 290, as passed and codified;
3. Award Plaintiffs costs, disbursements, and reasonable attorney's fees associated with this litigation pursuant to applicable authority; and
4. Provide such other relief as the Court deems appropriate.

DATED: November 1, 2019

KING & SPALDING LLP

By: /s/ *Joseph N. Akrotirianakis*
Joseph N. Akrotirianakis
Bobby R. Burchfield (*pro hac vice* pending)

Counsel for Plaintiffs
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