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17 JANE DOE, STEPHEN ALBRIGHT,
18 AMERICAN KIDNEY FUND, INC.,
19 and DIALYSIS PATIENT CITIZENS, INC.

20
21 **UNITED STATES DISTRICT COURT**
22 **CENTRAL DISTRICT OF CALIFORNIA**
23 **SOUTHERN DIVISION**

24 JANE DOE; STEPHEN ALBRIGHT;
25 AMERICAN KIDNEY FUND, INC.;
26 and DIALYSIS PATIENT CITIZENS,
27 INC.,

28 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**

1 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

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

13 **JURISDICTION AND VENUE**

14 1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331
15 because this action arises under the Supremacy Clause and the First Amendment of
16 the Constitution, as well as the laws of the United States, specifically 42 U.S.C.
17 § 1320a-7a(a)(5), 42 U.S.C. § 1395y(b), and other provisions of Title 42 of the
18 United States Code.

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

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

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

3 4. Congress has granted Plaintiffs the right to declaratory and injunctive
4 relief in this case through the Civil Rights Act of 1871, as amended, *see* 42 U.S.C.
5 § 1983, and the Declaratory Judgment Act, *see* 28 U.S.C. §§ 2201–02.

6 INTRODUCTION

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

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

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

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

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

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

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

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

23 12. Undeterred, the opponents of HIPP tried again in the 2019 legislative
24 session, and again, by a slender margin, succeeded in obtaining passage of Assembly
25 Bill 290 (“AB 290” or “the Act”). This time, Governor Gavin Newsom signed the
26 legislation on October 13, and unless enjoined by this Court, AB 290 will begin
27 taking effect on January 1, 2020. Contrary to Governor Brown’s plea for narrow
28

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

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

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

28

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

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

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

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

15 **FACTS AND LAW COMMON TO ALL THE CLAIMS**

16 **II. End Stage Renal Disease and Congress’s Calibrated Efforts to Assist**
17 **Patients.**

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

28

1 25. To stay alive, ESRD patients must either obtain a kidney transplant or
2 undergo continuing kidney dialysis. Dialysis is a medical process that filters waste
3 and excess fluid from a patient’s blood. Although dialysis can keep a patient alive,
4 it is an arduous treatment that must be administered at least three times each week
5 in sessions that last hours and may even go overnight. Though dialysis can
6 sometimes be conducted at home, the majority of California dialysis patients have
7 their treatments conducted in centers, often rendering employment impossible. The
8 employment rate among dialysis patients is extremely low—under 20% according
9 to at least one study. See N. Kutner et al., *Dialysis facility characteristics and*
10 *variation in employment rates: A national study*, 3 *Clinical J. Am. Soc’y Nephrology*
11 111 (2008). Dialysis is also very costly, burdening patients with thousands to tens
12 of thousands of dollars in medical bills at the very time when their condition may
13 render them unable to work full or even part time.

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

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

1 Medicare coverage for ESRD patients requiring dialysis or transplantation,
2 regardless of age or disability. *See* Social Security Amendments of 1972, Pub. L.
3 No. 92-603, tit. II, § 299I, 86 Stat. 1329, 1463 (codified as amended at 42 U.S.C.
4 § 426-1(a)).

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

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

1 Act of 1981, Pub. L. 97-35, tit. XXI, § 2145, 95 Stat. 357, 880. Congress initially
2 set this “coordination period” between Medicare and private plans at 12 months,
3 later extending it to 18 and then 30 months, consistent with Congress’s cost-sharing
4 objectives. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, tit.
5 IV, § 4203, 104 Stat. 1388, 1388-107–108; Balanced Budget Act of 1997, Pub. L.
6 105-33, tit. IV, § 4631, 111 Stat. 251, 486.

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

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

24 42 C.F.R. § 411.161(b)(2)(iv).

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

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

11 32. Medi-Cal, which is California's Medicaid program, may be a strong
12 safety net, but only for those ESRD patients whose incomes and assets are low
13 enough to qualify. And while Medi-Cal is also an option for medically needy ESRD
14 patients whose income exceeds that for typical Medi-Cal coverage, the spenddown
15 requirements necessitate spending all but \$600 of monthly income on medical costs
16 before coverage under Medi-Cal is available. *See* Cal. Welf. & Inst. Code §§
17 14005.7, 14005.9 (requiring patients pay "share of cost" for services each month
18 based on countable income); *see also* California Medi-Cal Eligibility Procedures
19 Manual, Article 8(F)(15)¹ (setting Maintenance Need Income Level for one person
20 at \$600, with modest increases for larger families). Most Californians cannot live
21 on \$600 a month, particularly those with a chronic, serious illness.

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

26 _____
27 ¹ [https://www.dhcs.ca.gov/services/medi-cal/eligibility/Documents/Article8-RR-
28 UnitDeterminations.pdf](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](http://file.lacounty.gov/SDSInter/dpss/237810_Copyof2016Medi-CalIncomeLevelChart4(2).pdf).

1 young adults age 19-25 will also be eligible for full-scope Medi-Cal. *See* Cal. Welf.
2 & Inst. Code § 14007.8(a)(1); Act of July 9, 2019, ch. 67, § 8, 2019 Cal. Stat. ____
3 (2019) (SB 104) (amending Cal. Welf. & Inst. Code § 14007.8(b)).² Unfortunately,
4 the same is not true for undocumented adults; for those individuals, Medi-Cal covers
5 emergency dialysis but not the full scope of health coverage that such individuals,
6 with their co-morbidities and complicated health needs, will necessarily require
7 when facing ESRD. *See* Cal. Welf. & Inst. Code § 14007.5(d).

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

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

21 //

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23 _____
24 ² Other undocumented individuals may also be eligible for full Medi-Cal benefits if
25 they permanently reside in California under color of law (“PRUCOL”). Cal. Welf.
26 & Inst. Code § 14007.5(b). One PRUCOL category is individuals residing under the
27 Deferred Action for Childhood Arrivals program. *See* Ca. Dep’t of Health Care
28 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](https://www.dhcs.ca.gov/formsandpubs/publications/Pages/Deferred-Action-for-Childhood-Arrivals-FAQ.aspx).

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

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

7 37. Since its founding in 1971, AKF has become the nation’s leading
8 501(c)(3) charity focused on kidney disease patients and their families. AKF
9 describes its mission as a “360-degree approach,” in which it combats kidney disease
10 on all fronts: awareness, advocacy, prevention, public education, professional
11 engagement, clinical research, and financial assistance. Publication after
12 publication—including *Consumer Reports* and *Consumers Digest*—as well as
13 charity watchdogs—such as *Charity Navigator* and *Guidestar*—have lauded AKF
14 as among the best run and most effective charities in America. This praise stems
15 from AKF’s financial transparency (AKF makes its tax forms and audited financial
16 statements available online) and its efficiency (a remarkable 97 cents of every dollar
17 donated to AKF goes to patients and programs). The foundation of AKF’s support
18 is the general public. Over 61,000 distinct donors who care about kidney disease
19 contribute annually to support AKF’s full range of programs, from prevention, to
20 disease education, to clinical research, to financial support for kidney patients.
21 AKF’s corporate supporters range from dialysis providers, to pharmaceutical
22 companies, to financial services companies, to household names like Google.

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

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

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

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

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

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

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

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

22 44. The financial needs of HIPP beneficiaries are stark. For example,
23 within Orange County, HIPP recipients report a median yearly income of around
24 \$31,000, while the most recent census estimate indicates that the median household
25 income for the county is just above \$81,000 per year. *See* U.S. Census Bureau,
26 *Quick Facts—Orange County, California*, available at
27 <https://www.census.gov/quickfacts/fact/table/orangecounty%20california/INC1102>
28 17# (last accessed Oct. 17, 2019).

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

7 **III. Advisory Opinion 97-1**

8 46. From the beginning of HIPP, AKF has always sought to ensure that the
9 program complies with federal law. Of particular concern to AKF at the start of
10 HIPP was § 231(h) of the Health Insurance Portability and Accountability Act of
11 1996 ("HIPAA"), Pub. L. No. 104-191, tit. II, § 231(h), 110 Stat. 1936. That law
12 provides for civil monetary penalties against any entity which—

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

19 42 U.S.C. § 1320a-7a(a)(5). "Remuneration" is defined to include "transfers of
20 items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6).

21 47. AKF asked the Office of the Inspector General ("OIG") of the
22 Department of Health and Human Services for an advisory opinion on its proposed
23 HIPP because it was rightly concerned that such a program could trigger this
24 sanction. Because many ESRD patients are eligible for Medicare benefits, *id.* § 426-
25 1(a), and AKF's premium payments could arguably be viewed as remuneration,
26 AKF sought to confirm that HIPP was not inconsistent with that provision.

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

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

8 49. Advisory Opinion 97-1 provides the safe harbor under federal law for
9 HIPP. After describing HIPP in detail, the Advisory Opinion found that dialysis
10 providers’ donations to AKF did not constitute “remuneration” to an individual
11 eligible for federal health care benefits because “the interposition of AKF, a bona
12 fide, independent, charitable organization, and its administration of HIPP provides
13 sufficient insulation so that the premium payments should not be attributed to the
14 [provider] Companies.” Advisory Op. at 6 (emphasis in original); *see id.* (observing
15 that “AKF will have absolute discretion regarding the use of provider contributions
16 made to AKF”). As OIG noted, HIPP “[a]ssistance is available to all eligible patients
17 on an equal basis,” *id.* at 4, AKF will not advise dialysis companies which patients
18 are enrolled in HIPP and the companies will not track payments made by AKF at
19 their facilities, *id.* at 6-7. Moreover, the Advisory Opinion observed that “HIPP will
20 not be advertised to the public by the [provider] Companies,” thus “reduc[ing] the
21 probability that a beneficiary would select a Company based on its participation in
22 HIPP.” *Id.* The Advisory Opinion noted that, once in possession of coverage,
23 beneficiaries will be able to select any provider of choice, concluding, “[s]imply put,
24 AKF’s payment of premiums will expand, rather than limit, beneficiaries’ freedom
25 of choice.” *Id.* Finally, the OIG required that AKF provide “[a]ssistance . . . to all
26 eligible patients on an equal basis.” *Id.* at 3.

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

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

7 **IV. California Assembly Bill 290**

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

16 52. Unlike most legislation, which is generally applicable, the Act is laser
17 focused on a discrete set of entities: AKF and large dialysis providers that operate in
18 California. This is not speculation. AKF is mentioned by name in the text of the
19 Act, *see* AB 290 § 1(j) and, alongside “large dialysis organizations,” is referred to at
20 length in its findings of fact as the “nonprofit” at which the Act is directed, *see id.*
21 §§ 1(g), 1(h), 1(i).

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

25 Large dialysis companies contribute more than 80 percent of the
26 revenue to a nonprofit [an unmistakable reference to AKF] that pays
27 health insurance premiums for patients on dialysis for kidney failure.

28 In turn, this nonprofit [again, AKF] generates hundreds of millions of

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

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

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

19 **A. The Act’s Provisions**

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

- 22 • Insurance companies and health benefit plans that issue health
23 insurance policies or “health care service plan contracts” –
24 “[I]ndividual or group health care service plan contract[s] that
25 provide[] medical, hospital, and surgical benefits,” excluding
26 Medicare-related contracts with the federal government. AB 290
27 § 3(h)(3).
28 • Dialysis providers through two provisions:

- 1 ○ “Financially interested providers” – These are
2 “providers”—“a professional person, organization, health
3 facility, or other person or institution that delivers or
4 furnishes health care services”—“that receive[] a direct or
5 indirect financial benefit from a third-party premium
6 payment.” *Id.* §§ 3(h)(4), 3(h)(2)(A).
- 7 ○ Clinics owned by large dialysis providers – “A chronic
8 dialysis clinic that is operated, owned, or controlled by a
9 parent entity or related entity that meets the definition of a
10 large dialysis clinic organization (LDO) under the federal
11 Centers for Medicare and Medicaid Services
12 Comprehensive ESRD Care Model as of January 1, 2019.
13 A chronic dialysis clinic that does not meet the definition
14 of an LDO or has no more than 10 percent of California’s
15 market share of licensed chronic dialysis clinics shall not
16 be considered financially interested for purposes of this
17 section.” *Id.* §§ 3(h)(2)(C).
- 18 ● “Financially interested entities” – “An entity that receives the
19 majority of its funding from one or more financially interested
20 providers of health care services, parent companies of providers
21 of health care services, subsidiaries of health care service
22 providers, or related entities.” *Id.* § 3(h)(2)(B). This provision
23 targets AKF, falsely implying that AKF is anything other than a
24 highly reputable, nonprofit charity.

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

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

3 Commencing January 1, 2022, if a financially interested entity makes a
4 third-party premium payment to a health care service plan on behalf of
5 an enrollee, reimbursement to a provider who is also a financially
6 interested entity for covered services provided shall be determined by
7 the following: . . .

8 For a contracted financially interested provider that makes a third-party
9 premium payment or has a financial relationship with the entity making
10 the third-party premium payment, the amount of reimbursement for
11 covered services that shall be paid to the financially interested provider
12 on behalf of the enrollee shall be the higher of the Medicare
13 reimbursement or the rate determined pursuant to the process described
14 in this subdivision, if a rate determination pursuant to that process is
15 sought by either the provider or the health care service plan. Financially
16 interested providers shall neither bill the enrollee nor seek
17 reimbursement from the enrollee for services provided, except for cost
18 sharing pursuant to the terms and conditions of the enrollee's health
19 care service plan contract. If an enrollee's contract imposes a
20 coinsurance payment for a claim that is subject to this paragraph, the
21 coinsurance payment shall be based on the amount paid by the health
22 care service plan pursuant to this paragraph.

23 *Id.* §§ 3(e)(1), 5(e)(1).

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

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

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

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

15 *Id.* §§ 3(c)(2), 5(c)(2).

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

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

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

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

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

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

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

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

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

1 66. These harms will come to pass very soon. AB 290 will become
2 effective on January 1, 2020, and from that date on, AKF will begin to accrue
3 significant obligations. AKF's own HIPP policy, as well as AB 290 §§ 3(b)(1) and
4 5(b)(1), as operative July 1, 2020, require that AKF provide premium assistance for
5 a full plan year. Thus, unless the Act is enjoined, AKF will be forced to cease
6 assisting low-income dialysis and transplant patients in California by January 1,
7 2020. AKF cannot stop its assistance mid-year on July 1, 2020, without violating
8 both its own policies and AB 290.

9 **B. The Harmful Consequences of the Act**

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

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

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

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

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

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

20 72. These consequences will apply with particular force for California
21 patients because the Act will force AKF to halt HIPP within that State. AKF’s
22 nationwide HIPP operations are conducted under the aegis of Advisory Opinion 97-
23 1; without that safe harbor, AKF and its donors are exposed to the patient inducement
24 statute, and the civil penalties and reputational costs that its violation would bring.
25 The Advisory Opinion itself, as well as the implementing regulations for the
26 advisory opinion process, make clear that the Advisory Opinion’s safe-harbor status
27 is contingent on AKF continuing to follow rigorously the terms of the program
28 presented to and approved by the OIG. *See* Advisory Op. at 8 (“This advisory

1 opinion is limited in scope to the specific arrangement described in this letter and
2 has no applicability to other arrangements, even those which appear similar in nature
3 or scope.”); 42 C.F.R. § 1008.15(a) (“The facts must relate to an existing
4 arrangement, or one which the requestor in good faith plans to undertake.”); *id.* §
5 1008.43(b) (advisory opinions are “based on the facts provided to the OIG”).

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

14 74. But the Act goes still further. It requires AKF to treat applicants to
15 HIPP differently, in contravention of the Advisory Opinion’s requirement that AKF
16 provide HIPP assistance to all patients on an equal basis. For instance, AB 290
17 requires AKF to treat California HIPP recipients differently than recipients from any
18 other state by forcing AKF to disclose California HIPP recipients’ names to insurers.
19 Even within California, AB 290’s grandfathering clauses require AKF to
20 differentiate amongst its HIPP beneficiaries on a range of dimensions. *See* AB 290
21 §§ 3(d)(1), 5(d)(1) (grandfathering against name disclosure and rate reductions for
22 those beneficiaries receiving premium assistance prior to October 1, 2019); *id.*
23 §§ 3(d)(2), 5(d)(2) (removing grandfathered status if those beneficiaries change their
24 insurance plan on or after March 1, 2020); *id.* §§ 3(c)(2), 3(e), 5(c)(2), 5(e) (requiring
25 name disclosure and reduction of patient rates for all others). The Act requires that
26 HIPP patients be treated differently based on the size of their dialysis provider,
27 because clinics operated by “large dialysis clinic organizations” fall within the Act’s
28 ambit. *Id.* §§ 3(h)(2)(C), 5(h)(2)(C). And, perhaps most troubling, because AB 290

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

5 75. In light of the above, it is clear that if AB 290 is allowed to go into
6 effect, AKF would be unable to comply with the terms of Advisory Opinion 97-1,
7 and AKF would be at risk of facing ruinous civil penalties and the loss of its hard-
8 earned reputation. Indeed, California’s Legislative Counsel Bureau opined that
9 “because th[e] disclosure requirements [contemplated by AB 290] were not part of
10 the arrangement considered by OIG when it issued Opinion 97-1, that opinion would
11 not ensure that the version of the patient assistance program operated by AKF in
12 compliance with AB 290 would be immune from OIG sanctions” and concluded that
13 “the changes in the premium assistance program required by AB 290 would remove
14 the legal protection afforded by 97-1.” Ca. Legislative Counsel Bur., *Assembly Bill*
15 *No. 290: Dialysis Providers: Charitable Donations - #1916414*, at 6 (June 28,
16 2019).³ Under these circumstances, AKF cannot risk the entirety of its other HIPP
17 operation across the United States. AKF will simply be unable to operate HIPP in
18 California to the detriment of patients there.

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

25
26 ³ Notwithstanding this conclusion, the Legislative Counsel Bureau still somehow
27 concluded that “the American Kidney Fund would remain in compliance with the
28 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.

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

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

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

21 **C. The Impact of the Act on Real Patients**

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

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

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

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

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

20 **CLAIMS FOR RELIEF**

21 **COUNT I**

22 **Federal Preemption Under the Supremacy Clause of the**
23 **United States Constitution**
24 **(Against All Defendants)**

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

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

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

4 85. AB 290 conflicts with federal law, and thus violates the Supremacy
5 Clause, in numerous ways. First, federal law, as construed and applied to HIPP in
6 Advisory Opinion 97-1, requires that HIPP treat all eligible patients the same. AB
7 290 requires AKF to treat different categories of patients differently within
8 California, by requiring different treatment of grandfathered patients (those
9 receiving assistance from AKF as of October 1, 2019) differently from non-
10 grandfathered patients (who first obtain their policies after October 1, 2019), and
11 from previously grandfathered patients who change policies on or after March 1,
12 2020. Moreover, AB 290 creates a unique set of requirements for patients in
13 California that are not applicable to patients outside California.

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

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

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

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

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

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

9 **COUNT II**

10 **Federal Preemption Under the Supremacy Clause of the**
11 **United States Constitution**
12 **(Against All Defendants)**

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

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

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

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

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

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

1 **COUNT III**

2 **Abridgement of the Rights of Association, Speech, and Petition**
3 **in Violation of the First and Fourteenth Amendments to the**
4 **United States Constitution**
5 **(Against All Defendants)**

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

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

12 99. AB 290 abridges AKF’s freedom of speech by coercing AKF to deliver
13 the State’s message in three ways. First, Sections 3(b)(1) and (3), as well as Sections
14 5(b)(1) and (3), coerce AKF into notifying each potential recipient of patient
15 assistance of “alternative coverage options, including but not limited to Medicare,
16 Medicaid, and individual market plans,” and of “all available health coverage
17 options, including but not limited to, Medicare, Medicaid, individual market plans,
18 and employer plans, if applicable.” Consistent with the overall purpose of the
19 statute, these coerced messages are intended to discourage patients from
20 participating in HIPP. In effect, the statute attempts to use AKF as the messenger to
21 undermine its own program.

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

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

1 102. The statute also directly restricts AKF’s ability to speak. Sections
2 3(b)(4) and 5(b)(4) require AKF to “agree not to steer, direct, or advise the patient
3 into any or away from a specific coverage program.” This provision abridges AKF’s
4 speech in at least two ways. To begin, it is vague and overbroad, which will deter
5 AKF from speaking to grant recipients at all beyond the required statements in
6 Sections 3(b)(1) and (3) and 5(b)(1) and (3) due to the risk of violating the provision.
7 Moreover, the provision suppresses protected speech by prohibiting AKF from
8 “advising” patients about the existence of particular coverages, or from assisting the
9 patients in their selection of appropriate coverages.

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

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

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

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

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

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

5 **PRAYER FOR RELIEF**

6 Plaintiffs request that this Court grant the following relief:

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

16
17 DATED: November 1, 2019

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