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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

Case No. 8:19-cv-02105-DOC-SDA

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR A PRELIMINARY INJUNCTION

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

1 **TO THE COURT AND DEFENDANTS AND THEIR ATTORNEYS:**
2 **PLEASE TAKE NOTICE** that, on December 9, 2019, at 8:30 a.m., or as
3 soon thereafter as the matter can be heard, in Courtroom 9D, located within the
4 Ronald Reagan Federal Building, United States Courthouse, 411 West Fourth Street,
5 Santa Ana, California, Plaintiffs Jane Doe, Stephen Albright, (collectively, the
6 "Patients"), American Kidney Fund, Inc. ("AKF"), and Dialysis Patient Citizens,
7 Inc. ("DPC") will, and hereby do, move pursuant to Federal Rule of Civil Procedure
8 under Federal Rule of Civil Procedure 65(a) and Local Rule 65-1 for a preliminary
9 injunction, enjoining Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard,
10 and Sonia Angell, each in his or her official capacity an agent of the State of
11 California, from enforcing or otherwise implementing California Assembly Bill 290
12 ("AB 290" or "Act"). *See* Act of Oct. 13, 2019, ch. 862, 2019 Cal. Stat. ___ (2019)
13 (to be codified at Cal. Health & Safety Code §§ 1210, 1367.016, 1385.09 and Cal.
14 Ins. Code §§ 10176.11, 10181.8).
15 Plaintiff's Motion for Preliminary Injunction is made on the grounds:
16 1. AB 290 conflicts with federal law and is thus void under the Supremacy
17 Clause; and
18 2. Enforcement of AB 290 would deprive Plaintiffs of their rights of free
19 speech, association, and petitioning under the First and Fourteenth Amendments.
20
21 Dated: November 8, 2019 **KING & SPALDING LLP**
22
23 By: */s/Joseph N. Akrotirianakis*
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MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

If allowed to go into effect, AB 290 will result in many California patients being unable to afford their health care, putting them at significant risk for health complications and even death. It will jeopardize a nation-wide program of financial support for thousands of very sick individuals. The drastic harm does not end there, however. AB 290 also violates federal law and the U.S. Constitution. Plaintiffs therefore request that this Court preliminarily enjoin the State from implementing AB 290 while this lawsuit is pending.

BACKGROUND

A. End-Stage Renal Disease and American Kidney Fund's Health Insurance Premium Program

End-stage renal disease ("ESRD"), or kidney failure, is a painful, chronic, and often fatal disease of the kidneys. Declaration of LaVarne A. Burton ("AKF Decl.") ¶ 14. To those who suffer from it, it causes a wide range of significant health problems, ranging from heart disease to cancer, and if it is left untreated, it is invariably fatal through a slow and agonizing process. *Id.*; Declaration of Jane Doe ¶ 5; Declaration of Stephen Albright ¶ 7. While dialysis, a process by which patients' blood is filtered, can mitigate ESRD's impacts for a time, ESRD patients ultimately need a kidney transplant. AKF Decl. ¶ 14.; Doe Decl. ¶ 4; Albright Decl. ¶ 8. Transplants involve significant surgical and recovery complications, in addition to delays due to a shortage of transplantable kidneys; many patients either cannot receive one promptly or are not medically suitable at all. AKF Decl. ¶ 14. The end result is that dialysis, though an imperfect solution, is the only option for many ESRD patients. *Id.* ¶ 14.

But dialysis is physically and financially challenging for ESRD patients. The filtering process requires multiple, hours-long sessions each week, either at home or, more often, at a clinic. Doe Decl. ¶¶ 6, 8; Albright Decl. ¶ 7. The time required for

1 these appointments can make employment difficult for many ESRD patients who
2 must also cope with the symptoms of ESRD and the draining side effects of dialysis.
3 AKF Decl. ¶ 21; Doe Decl. ¶ 10; Albright Decl. ¶ 5.
4 Plaintiffs Jane Doe and Stephen Albright personify these complications. Mr.
5 Albright, through immense personal effort and discipline, has managed to remain
6 employed despite his ESRD diagnosis. Albright Decl. ¶ 6. But he must undergo
7 dialysis every night overnight. *Id.* ¶ 7. And while he and his significant other both
8 work and are covered by her employer-provided health insurance, the premiums for
9 that insurance have pushed them to the financial edge. Albright Decl. ¶ 9. Jane Doe,
10 for her part, has lost everything that she has worked for due to ESRD. Doe Decl.
11 ¶ 11. Her illness has forced her to cease working and steadily depleted her savings
12 until she was forced out of her home. *Id.* Her finances are already desperately tight,
13 and her treatment must come first if she is to stay alive. *Id.* ¶¶ 12-13.
14 Both AKF and DPC are keenly aware of these costs. *See* AKF Decl. ¶¶ 21-
15 33; Declaration of Hrant Jamgochian ("DPC Decl.") ¶ 4. More than twenty years
16 ago, AKF undertook to alleviate the immense financial burdens faced by dialysis
17 patients through its Health Insurance Premium Program ("HIPP"). AKF Decl. ¶¶ 20,
18 36. HIPP provides financial assistance to 75,000 ESRD patients in the United States,
19 and 3,756 in California, for the health insurance that they have already selected and
20 obtained but are unable to pay for alone. *Id.* ¶¶ 18, 27. The program is strictly need
21 based, focusing on patients' incomes. *Id.* ¶ 41. AKF does not consider any other
22 factors, such as a patient's age, place of residency, or dialysis provider. *Id.* Founded
23 in 2004, and with 28,000 members, DPC serves as an advocate for ESRD patients
24 on dialysis. DPC Decl. ¶ 5.
25 **B. Advisory Opinion 97-1**
26 A key provision of the Health Insurance Portability and Accountability Act of
27 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, authorizes the U.S.
28 Department of Health & Human Services ("HHS") Office of Inspector General

1 ("OIG") to seek civil monetary penalties against any entity offering remuneration to
2 a Federal health care program beneficiary with knowledge that such remuneration is
3 likely to influence that individual's choice of a health care provider. *See* HIPAA
4 §231(h), codified at 42 U.S.C. § 1320a-7a(a)(5) (the "Beneficiary Inducement
5 Statute"). Such "remuneration" includes "transfers of items or services for free or
6 for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6).

7 Congress also enacted an advisory opinion process to provide guidance on the
8 statute, empowering OIG to opine on "whether any activity or proposed activity
9 constitutes grounds for the imposition of a sanction under . . . [the Beneficiary
10 Inducement Statute] . . . ." *See* HIPAA § 205, codified at 42 U.S.C. § 1320a-
11 7d(b)(2)(E). A favorable advisory opinion acts as a safe harbor against a federal
12 enforcement action. *See* 42 U.S.C. § 1320a-7d(b)(4)(A).

13 Following HIPAA's enactment, AKF and certain dialysis provider donors
14 proactively sought an advisory opinion addressing HIPP. *See* Advisory Opinion 97-
15 1; AKF Decl. ¶ 36. They did so to make sure that the HIPP program did not run
16 afoul of HIPAA's prohibition on offering remuneration. *Id.* The OIG concluded
17 that HIPP did not "constitute grounds for the imposition of civil monetary penalties
18 under Section 231(h) of HIPAA." Advisory Op. at 1. The OIG first found that the
19 dialysis providers' donations to AKF do not constitute impermissible
20 "remuneration" because "the interposition of AKF, a <u>bona</u> <u>fide</u>, independent,
21 charitable organization, and its administration of HIPP provides sufficient insulation
22 so that the premium payments should not be attributed to the [provider] Companies."
23 Advisory Op. at 6 (emphasis in original). The OIG noted that, once in possession of
24 coverage, beneficiaries will likely have already selected a provider before applying
25 for assistance, concluding, "[s]imply put, AKF's payment of premiums will expand,
26 rather than limit, beneficiaries' freedom of choice." *Id.* at 7. Finally, the OIG noted
27 that AKF provides "[a]ssistance . . . to all eligible patients on an equal basis." *Id.* at
28 3.

Advisory Opinion 97-1 provides a safe harbor only so long as "the arrangement in practice comports with the information provided," *id.* at 8; *see also* 42 C.F.R. § 1008.43. Should HIPP change in any material way, AKF will lose its safe harbor and face potential exposure under the Beneficiary Inducement Statute.[1] For over 20 years, AKF has operated HIPP in strict compliance with Advisory Opinion 97-1. AKF Decl. ¶¶ 34-42. As a charitable organization, AKF cannot take the business, legal, and reputational risk of losing this critical safe harbor. *Id.* ¶ 42.

C. The Medicare Secondary Payer Act

In 1972, Congress extended special Medicare coverage to 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)). Time and again, Congress has reaffirmed its commitment to ESRD patients, including through the Medicare Secondary Payer Act ("MSPA"), 42 U.S.C. § 1395y(b) by:

1) Lengthening the amount of time that Medicare will be secondary payer behind a private plan, Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1330, 1463–64 (1972); Omnibus Budget Reconciliation Act ("OBRA") 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, codified as amended at 42 U.S.C. § 1395y(b)(1)(C); and

2) Prohibiting insurers from differentiating based on or "taking into account" a patient's ESRD diagnosis, OBRA 1989, Pub. L. No. 101-239, tit. VI, § 6202(b), 103 Stat. 2106, 2231; OBRA 1989, § 6202(b), codified at 42 U.S.C. § 1395y(b)(3).

[1] *See*, *e.g.*, Rescinded Advisory Opinion 06-04 (rescinding favorable opinion related to non-AKF charitable premium and cost-sharing assistance because "Requestor failed to comply with certain factual certifications it made to OIG . . . [that] were material to OIG's conclusions."), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

D. The Provisions of AB 290

For years, the commercial health insurance industry and its labor union allies have lobbied the California legislature to impose restrictions on HIPP. In 2018, the legislature did so, but then-Governor Jerry Brown vetoed the bill and suggested that "all stakeholders . . . find a more narrowly tailored solution that ensures patient access to coverage."[2] Undeterred, opponents of HIPP succeeded in passing Assembly Bill 290 ("AB 290"), signed by Governor Gavin Newsom on October 13. Unless enjoined by this Court, AB 290 will take effect on January 1, 2020.

In no sense is AB 290 a "narrowly tailored solution" ensuring "patient access to coverage." The Legislature intended AB 290 to focus on AKF, its HIPP program, and its donors: The Act mentions AKF by name, *see* AB 290 § 1(j), and AKF and "large dialysis organizations" are the explicit targets of the legislation, *see id.* §§ 1(g), 1(h), 1(i). AB 290's central purpose is to destroy AKF's premium assistance program in California. *See id.* § 1(h) (legislative findings targeting AKF and its donors); *see also* AB-290 Ca. Assembly Floor Analysis, at 2 (Sept. 9, 2019) (statement of Assemblyman Jim Wood singling out AKF and its donors).

AB 290 regulates three groups of entities: (1) insurance companies and health benefit plans, AB 290 §§ 3(h)(3), 5(h)(2); (2) dialysis providers, *id.* §§ 3(h)(2)(A), 3(h)(4), 5(h)(1)(A), 5(h)(4); and (3) "[f]inancially interested entities," meaning AKF, *id.* §§ 3(h)(2)(B), 5(h)(1)(B). In particular, two interrelated mechanisms are uniquely harmful to AKF's and DPC's mission of assisting vulnerable ESRD patients with high health care costs.

First, AB 290 compels AKF to "[d]isclose[] 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); *see also id.* § 5(c)(2). AB 290 changes how

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[2] *See* https://leginfo.legislature.ca.gov/faces/billStatusClient.xhtml?bill_id=201720180SB1156.

1 AKF operates by obligating it to turn over the names of the patients it assists to
2 private insurers—information that it otherwise would not reveal. AKF Decl. ¶ 45.
3 *Second*, AB 290 sharply reduces providers' reimbursement rates for HIPP
4 patients. Starting on January 1, 2022, if AKF makes a premium assistance payment
5 to a health care service plan on behalf of a patient, the reimbursement for any
6 "contracted financially interested provider" will be cut to the higher of either the
7 Medicare rate or a rate determined by a "rate determination" process, if sought by
8 the provider or heath care plan. *Id.* §§ 3(e)(1), 5(e)(1). Out-of-network providers
9 will see a similar reimbursement decrease. *See id.* §§ 3(e)(2), 5(e)(2). Providers are
10 also prohibited from billing the beneficiary for the balance; instead, they may
11 attempt to collect only a cost-sharing percentage related to the insurance payment
12 actually received. *Id.* §§ 3(e)(1), 3(e)(2), 5(e)(1), 5(e)(2).
13 In sum, the above provisions work in tandem: the first forces AKF to hand
14 over patient names to insurers so that they can implement the second provision,
15 penalizing providers that donate to AKF by cutting their reimbursement. These
16 provisions will irreparably damage AKF's charitable efforts in California (and
17 possibly nationwide) and upset the delicate balance Congress intended when it
18 passed the MSPA, 42 U.S.C. § 1395y(b).
19 *Third*, AB 290 requires that AKF inform a patient of "all available health
20 coverage options," including Medicare and Medicaid. AB 290 §§ 3(b)(3), 5(b)(3);
21 *see also id.* §§ 3(b)(1), 5(b)(1). The State is attempting to conscript AKF into
22 delivering the State's chosen message to patients. But, under the terms of Advisory
23 Opinion 97-1, AKF currently plays no role in patients' insurance selection
24 decision—patients come to AKF only after they have insurance in place. AKF Decl.
25 ¶¶ 41, 50.
26 The compelled speech required by the third provision is exacerbated by a
27 fourth provision. AKF must "agree not to steer, direct, or advise the patient into or
28 away from a specific coverage program." AB 290 §§ 3(b)(4), 5(b)(4). Thus, AB

290 forces AKF into a bind: AKF must assume the role of insurance navigator, yet AKF cannot "advise" patients on the insurance options it is forced to discuss.

Finally, and perhaps most outrageously, AB 290 forces AKF "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) (emphasis added). But HIPP assistance is limited to patients on dialysis (a "procedure") or those who within the past year have received a kidney transplant. AKF Decl. ¶ 16. This provision would frustrate AKF's ability to fulfill its nearly 50-year-old mission of serving ESRD patients, transforming it into an all-purpose medical charity in violation of its articles of incorporation.

E. AB 290 Threatens Irreparable Harm

The Act creates a severe disincentive for AKF's donors: if a provider donates to AKF, it is punished by a much lower rate of reimbursement for its services within the State of California.

With fewer donations for HIPP, AKF will be able to assist fewer patients across the United States. In turn, those patients will be forced from their insurance plans. *See*, *e.g.*, Doe Decl. ¶ 16; Albright Decl. ¶ 11. Although some will be eligible for Medicare, the majority of patients AKF assists cannot afford even Medicare's modest premium or the 20% Medicare does not cover. This out-of-pocket cost of treating ESRD can be as much as $7,000 for dialysis patients. AKF Decl. ¶ 21. Patients who can afford Medicare will nonetheless generally face a 3-month waiting period. For indigent patients who are ineligible for Medicare and who cannot avail themselves of Medi-Cal (California's Medicaid program with its own stringent requirements), emergency room treatments are often the only option. AKF Decl. ¶ 32. This disruption to insurance coverage will imperil the lives of countless ESRD patients by subjecting them to inferior treatment options (or none at all, which would result in death), additional financial burdens, and further stress and uncertainty. *See*, *e.g.*, Doe Decl. ¶¶ 16-17; Albright Decl. ¶¶ 11-14.

These consequences will be especially severe in California because AB 290 will force AKF to halt HIPP within that State. AKF Decl. ¶¶ 47, 52. The safe harbor of Advisory Opinion 97-1 is contingent on AKF strictly adhering to the terms of the program OIG approved. AB 290, however, would require material changes to HIPP, and, as California's Legislative Counsel Bureau concluded, "remove the legal protection afforded by Opinion 97-1." Ca. Legislative Counsel Bur., Assembly Bill No. 290: Dialysis Providers: Charitable Donations - #1916414, at 6 (June 28, 2019). For this reason, unless this Court enjoins AB 290, AKF must withdraw from California entirely on or before January 1, 2020. AKF Decl. ¶ 47. A cascade of irreparable harms will quickly follow.

ARGUMENT

A preliminary injunction is necessary and appropriate to prevent the dire consequences that will follow the State's implementation of AB 290 in contravention of the U.S. Constitution. Such relief is appropriate when the movant has shown that "(1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) 'the balance of equities tips in [its] favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "Under [the Ninth Circuit's] 'sliding scale' approach, 'the elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another.'" *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017) (citation omitted). As a result, "[a] preliminary injunction may also be appropriate if a movant raises 'serious questions going to the merits' and the 'balance of hardships . . . tips sharply towards' it, as long as the second and third *Winter* factors are satisfied." *Disney Enters., Inc.*, 869 F.3d at 856 (citation omitted).

For the following reasons, all four of the *Winter* factors strongly support entry of a preliminary injunction in this case.

A. Plaintiffs Will Likely Succeed on the Merits.

Plaintiffs will likely succeed on the merits of this case because AB 290 is unlawful in two crucial respects. *First*, AB 290 is preempted by federal health care law because it removes AKF's safe harbor for operating the HIPP program, and it presents obstacles to Congress' objectives in the Medicare Secondary Payer Act. *Second*, AB 290 infringes Plaintiffs' First Amendment rights to free speech, petition, and association.

1. *AB 290 Is Preempted by Federal Law.*

Plaintiffs are likely to succeed on their claim that AB 290 is preempted by federal law. AB 290 conflicts with both the safe harbor in Advisory Opinion 97-1, as well as Congress's carefully calibrated structure for reimbursement of ESRD treatments. "Conflict preemption exists where 'compliance with both state and federal law is impossible,' or where 'the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.''" *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101 (1989)). "In either situation, federal law must prevail." *Id.*

Several preemption principles are relevant here. Impossibility preemption exists when it is "not lawful under federal law for [affected parties] to do what . . . state law require[s] of them." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). "The question for 'impossibility,'" then, "is whether the private party c[an] independently do under federal law what state law requires of it." *Id.* at 620. It is not enough to "imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* (emphasis in original). Indeed, Congress could always rewrite federal law to follow state law, *id.* at 620-21, but unless and until it does, state law must yield to federal law.

Obstacle preemption occurs when state law "present[s] an obstacle to the

variety and mix of [regulatory approaches]" selected by Congress. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000). Among the "special features" of federal law that may require obstacle preemption, *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990), is a specialized federal enforcement regime that would be thwarted by state legislation, *see Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 144 (1990).

a. AB 290 Requires AKF to Operate Outside the Federally Approved Safe Harbor of Advisory Opinion 97-1 and Must Be Preempted.

On its face, AB 290 demands that AKF act in a manner that is inconsistent with Advisory Opinion 97-1. Advisory Opinion 97-1 serves as a critical safe harbor for AKF, which, as a charitable organization, cannot take the business, legal, and reputational risk of losing that safe harbor. AKF Decl. ¶ 42. As approved by the OIG, HIPP is carefully structured to avoid conflict with the Beneficiary Inducement Statute. First, AKF accepts voluntary donations from providers, but in approving assistance does not consider whether the patient-applicant is using a provider that donated to HIPP. Second, beneficiaries receiving premium assistance are unaware of whether their specific providers donated to HIPP. And finally, HIPP treats all eligible patients equally on a first-come, first-served basis, so long as funding is available.

AB 290 is a direct assault on this structure. It requires AKF to inform insurers of those patients for whom it provides premium assistance, so that the insurers can reduce reimbursement rates to providers for those patients. *See* AB 290 §§ 3(c)(2), 3(e), 5(c)(2), 5(e). When HIPP participants receive their Explanations of Benefits reflecting lower payments, they will know their provider is a HIPP donor and may feel bound to stay only with providers who donate to HIPP. AB 290 also requires HIPP to treat patients in California differently from patients in other states who are not subject to AB 290. It even requires HIPP to treat certain "grandfathered" ESRD

patients in California differently from those patients who are not grandfathered, and both differently from patients who were formerly grandfathered.[3]

These AB 290-enforced notifications, coupled with the compulsory patient differentiation, are also improper under the terms of Advisory Opinion 97-1: first, AB 290 requires AKF to notify insurers of patients participating in HIPP; second, patients receive access to the identities of providers that donated to AKF; and third, AB 290 creates different classes of patients. Advisory Op. at 3. Thus, AB 290 requires AKF to deviate from the facts upon which the OIG issued Advisory Opinion 97-1 and puts AKF at serious—and intolerable—risk of claims under the Beneficiary Inducement Statute, which prohibits remuneration (here, free premium assistance) that may to influence an individual's choice of health care provider. *See* 42 U.S.C. § 1320a-7a(a)(5); *see also* AKF Decl. ¶¶ 34-42. The California Legislative Counsel Bureau agreed: "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." Ca. Legislative Counsel Bur., Assembly Bill No. 290: Dialysis Providers: Charitable Donations - #1916414, at 6 (June 28, 2019). The Bureau concluded: "*the changes in the premium assistance program required by AB 290 would remove the legal protection afforded by Opinion 97-1*." *Id.* (emphasis added).[4]

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[3] *See* AB 290 §§ 3(d)(1), 5(d)(1) (grandfathering against name disclosure and rate reductions for beneficiaries receiving premium assistance prior to October 1, 2019); §§ (3)(d)(2)–(3), 5(d)(2)–(3) (removing grandfathered status if those beneficiaries change their insurance plan on or after March 1, 2020); §§ 3(c)(2), 3(e), 5(c)(2), 5(e) (requiring name disclosure and reduction of patient rates for all others).

[4] Nonetheless, the Legislative Counsel Bureau illogically concluded that AKF "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

These facts establish impossibility preemption under Supreme Court precedent. For instance, in *PLIVA,* the Supreme Court found impossibility preemption when state tort law demanded a stricter warning label than federal law, which required that generic manufacturers adopt an exact, invariable warning label for their drugs. *PLIVA*, 564 U.S. at 618-19. The Court explained: "It was not lawful under federal law for the Manufacturers to do what the state law required of them. . . . Thus, it was impossible . . . to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 618.

So too here. The OIG, charged with interpreting the Beneficiary Inducement Statute, has indicated in Advisory Opinion 97-1 that the safe harbor is available only if AKF complies strictly with its terms. AB 290 requires that AKF operate HIPP without those safeguards. The result is that it "[i]s not lawful under federal law for [AKF] to do what the state law required of [it]." *PLIVA*, 564 U.S. at 618.

The very text of AB 290 concedes the preemption issue. By "inducing" AKF to seek a new advisory opinion by delaying the effective date of the statute, California recognizes that AKF cannot simultaneously comply with AB 290 and Advisory Opinion 97-1. *See* AB 290 § 7. As the Supreme Court explained in *PLIVA*, however, "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." 564 U.S. at 620. The Court then made short shrift of a proposal that new, non-conflicting labeling requirements could be obtained from HHS:

> We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers

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available to [it]," *id.* at 8.

> could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. Following [the plaintiffs'] argument to its logical conclusion, it is also *possible* that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments.

Id. at 620-21 (emphasis original). That AKF might convince the OIG to issue a new advisory opinion is therefore irrelevant to the preemption analysis. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA*, 564 U.S. at 623–24. Rather than allaying the preemption problem, Section 7 strongly confirms it.

California also ignores the deep practical difficulties that would accompany an effort by AKF to obtain a new advisory opinion. It is impossible for AKF to request a new advisory opinion because it cannot certify in good faith under 42 C.F.R. § 1008.43 that it will enact AB 290's scheme. AKF Decl. ¶ 49. It must, after all, treat all patients equally under the HIPP program, and to assure compliance would need to adopt AB 290's requirements throughout the country. AKF also believes that compliance with AB 290 would expose it to claims under the Beneficiary Inducement Statute, and AKF cannot and will not risk a program that last year helped 75,000 desperately ill patients across the country. *Id.* ¶ 18. Instead, if AB 290 is not enjoined, AKF will have no choice but to cease its grant assistance operations within California to safeguard the interests of its operations and patients elsewhere. *Id.* ¶¶ 47, 52.

Driving HIPP from California would not, however, alleviate the preemption concerns. In *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), the Supreme Court rejected an argument that a generic drug manufacturer could comply

1 with federal law by simply halting sale of the drug within a state requiring stronger
2 warning labels, writing "if the option of ceasing to act defeated a claim of
3 impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* at 488.
4 The same logic is compelling here.

5 **b. AB 290 Presents a Significant Obstacle to Congress's**
6 **Objectives for Medicare Coverage of Individuals with**
7 **ESRD.**

8 Congress passed, and then several times amended, the MSPA, 42 U.S.C.
9 § 1395y(b), to ensure that private health plans share in the cost of treating ESRD.
10 AB 290 precludes this system from functioning as intended, allowing insurers to
11 skirt their fair share of the burden, and therefore presents a clear obstacle to
12 Congress's "accomplishment and execution of . . . important means-related federal
13 objectives." *Geier*, 529 U.S. at 881.

14 The MSPA and its implementing regulations require that group insurers treat
15 ESRD patients the same as non-ESRD patients, and plans cannot pay providers less
16 for the same service for individuals with ESRD than without. 42 U.S.C.
17 § 1395y(b)(1)(C)(i); 42 C.F.R. § 411.161(b)(2)(iv). AB 290 impermissibly does just
18 that. For example, a healthcare provider (for instance, a cardiologist) who
19 contributes to AKF becomes a "financially interested provider" under AB 290
20 §§ 3(h)(2)(A), 5(h)(1)(A). That contributor would therefore receive differing
21 reimbursement pursuant to AB 290 §§ 3(e) and 5(e) for services provided: one
22 amount for HIPP recipients (who necessarily have ESRD) and another amount for
23 everyone else. Such a scheme cuts directly against Congress's mandate that ESRD
24 patients receive equal treatment as all other patients.

25 **2. *AB 290 Tramples Plaintiffs' First Amendment Rights.***

26 AB 290 tramples free expression in almost too many ways to count. It singles
27 out disfavored speakers, prohibits communications by those disfavored speakers
28 based on content, and coerces those speakers to tout a state-approved message. It

burdens the right of association in numerous ways and punishes the acts of giving and receiving charitable donations. It coerces AKF to file a petition with OIG for a result it opposes. Its violation of the First Amendment is not a close call.

The Act specifically targets AKF for extensive speech restrictions because it is a "financially interested entity" that makes "third-party premium payments."[5] These oppressive speech restrictions include:

- AKF "shall inform an applicant . . . of *all available health coverage options*, including, but not limited to, Medicare, Medicaid, individual market plans, and employer plans, if applicable." (§§ 3(b)(3), 5(b)(3) (emphasis added).)
- In so informing HIPP applicants, however, AKF must "agree" (although the Act is unclear how it must agree or with whom) "not to steer, direct, or advise the patient into or away from a specific coverage program option or health care service plan contract." (§§ 3(b)(4), 5(b)(4).)
- AKF must annually provide "a statement to the health care service plan that it meets" these and other requirements. (§§ 3(c)(1), 5(c)(1).)
- And, before making the initial payment on behalf of any beneficiary, AKF must disclose "to the health care service plan . . . 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." (§§ 3(c)(2), 5(c)(2).)[6]

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[5] The Act deems AKF "financially interested" because AKF "receives the majority of its funding from one or more financially interested providers." (§§ 3(h)(2)(B), 5(h)(1)(B).) "Financially interested providers" here include the Provider Plaintiffs, who are "large dialysis clinic organization[s]," (§§ 3(h)(2)(C), 5(h)(1)(C)), as well as any "provider of health care services that receives a direct or indirect financial benefit from a third-party premium payment," (§§ 3(h)(2)(A), 5(h)(1)(A).)

[6] Use of passive voice in this provision creates an ambiguity: Must AKF disclose only those payments *AKF* is making, or is it also obligated to report premium payments made by *any other* third party? If the latter, this provision is also overbroad and unworkable.

Failure by AKF to make the report required by sections 3(c) and 5(c) will expose it to substantial liabilities to the health care service plan. *Id.* §§ 3(i), 5(i).[7]

Any provider that contributes to AKF, and then treats a patient receiving assistance from HIPP, will suffer a dramatic reduction in reimbursement. The predictable (and no doubt intended) consequence of these provisions is to deter any "financially interested" provider, a term which encompasses AKF's primary donors, from donating to AKF. Each of these restrictions is subject to heightened judicial scrutiny, and none can pass any version of that test. *See* Part A.2.d below.

a. AB 290 Violates the First Amendment by Restricting AKF's Speech.

Sections 3(b)(3), 5(b)(3). By policy and practice, AKF does not discuss coverage options with patients. It simply pays for coverage submitted by the patients. The Act forces a change in these practices by compelling AKF to inform patients of "*all available health coverage options,*" including government options. AB 290 §§ 3(b)(3), 5(b)(3).[8] These provisions also offend the First Amendment by imposing a State-favored speech requirement on a disfavored speaker. They "compel[] speech" in violation of the First Amendment. The difference between "compelled speech and compelled silence . . . in the context of protected speech . . . is without constitutional significance." *Riley v. National Fed. of the Blind*, 487 U.S.

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[7] The penalties include payment to the health care service plan of 120 percent of the difference between (i) the actual payment to the provider for provided services and (ii) the amount to which the provider would have been entitled under the rate control provisions imposed on services provided to participants in HIPP. The penalty to AKF could be tens of thousands of dollars for a single beneficiary in a year.

[8] AKF cannot possibly know "all" such options that might be available, and it would incur considerable expense to gather such information. The provision is both vague and overbroad. "Vague laws may not only trap the innocent by not providing fair warning or foster arbitrary and discriminatory application but also operate to inhibit protected expression by inducing citizens to steer far wider of the unlawful zone . . . than if the boundaries of the forbidden areas were clearly marked." *Buckley v. Valeo*, 424 U.S. 1, 41 n. 48 (1976) (citation and internal quotation marks omitted).

781, 796 (1988) (rejecting effort by North Carolina to require certain disclosures by professional fundraisers). Both offend the First Amendment.

As in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*"), the Act requires AKF to deliver "a government-drafted script about the availability" of public and private coverage, and "plainly 'alters the content' of [AKF's] speech." In *NIFLA*, the Court reversed the refusal to grant a preliminary injunction against a statute that required a pro-life organization to inform patients about state-sponsored abortion services. The Court deemed the required statements "content-based regulation of speech," *id*. at 2371, which "[a]s a general matter . . . 'are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.'" *Id*. (citation omitted). As in *NIFLA*, Plaintiffs are "likely to succeed on the merits of [their] claim that [AB 290] violates the First Amendment." *Id.* at 2378.

Sections 3(b)(4), 5(b)(4). Having compelled AKF to communicate with the aid recipients, even when it would not otherwise, the Act then prohibits AKF from "steer[ing], direct[ing], or advis[ing]" any patient with regard to any "specific coverage program option or health care service plan contract." These provisions fail for two reasons. *First*, they are void because they do not give "ordinary people [] 'fair notice' of the conduct [they] proscribe[]." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018). Indeed, lacking definition of "steer, direct, or advise," AKF is left to guess at the meaning of those terms. Because sections 3(b)(5) and 5(b)(5) already specifically prevent AKF from conditioning premium assistance on "specific coverage type[s]," sections 3(b)(4) and 5(b)(4) must be intended to restrict AKF's freedom to inform patients, for example, of Medicare costs and deductibles, or to state its view that particular types may better fit a patient than other plan types, or to "advise" patients about the availability of better, more appropriate, or less expensive coverage. For unsophisticated or uninformed patients, this information could be immensely valuable.

Because these provisions restrict AKF's speech, they offend the First Amendment. In *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), the Supreme Court struck down a Vermont statute that prohibited sale of certain prescription data to pharmaceutical marketers, called "detailers," but did not restrict sale of the data to other persons. Even assuming Vermont had a "significant interest" in medical privacy and in untainted prescription decisions, *id.* at 557, the Court noted that the statute "has the effect of preventing detailers—and only detailers—from communicating with physicians in an effective and informative manner." *Id.* at 564. Like AB 290, the statute was "designed to impose a specific, content-based burden on protected expression," and required "heightened judicial scrutiny." *Id.* at 565. *See also id.* at 567 ("[b]oth on its face and in its practical operation, Vermont's law imposes a burden based on the content of speech and the identity of the speaker"). Like Vermont, California has infringed the First Amendment by targeting a specific group of disfavored speakers and imposing restrictions on their communications about medical and public health information.

Sections 3(c)(1), 5(c)(1). These provisions compel AKF to provide an annual statement certifying compliance with the whole of Sections 3(b) and 5(b) to the health insurer. Insurers may use these certifications to detect violations, and then seek a 120% bounty from AKF if they detect any violations. Again, these provisions are content-based speech regulations targeting disfavored speakers and are subject to heightened scrutiny. This "compelled speech" is also offensive to the First Amendment. *See Riley*, 487 U.S. at 795. "Mandating speech that a speaker would not otherwise make necessarily alters the content of the speech. We therefore consider the Act as a content-based regulation of speech." *Id.* at 795. *See also NIFLA*, 138 S. Ct. at 2371 ("plainly 'alters the content'" of [] speech). Indeed, "the government, even with the purest of motives, may not substitute its judgment as to how best to speak for that of speakers and listeners." *Riley*, 487 U.S. at 791.

Sections 3(c)(2), 5(c)(2). These provisions compel AKF to disclose patient

names, and by implication (because they are receiving assistance) their health and financial status. For the reasons set forth above, this compelled speech offends the First Amendment.

b. AB 290 Abridges the First Amendment Right of Association.

By imposing mandatory and prohibitory restraints on the relationships among patients, dialysis providers, and AKF, AB 290 abridges their individual and collective rights of association. AB 290 burdens Plaintiffs' ability to associate in pursuit of that goal in several ways. *First and foremost*, it strikes directly at the heart of AKF's 50-year mission by requiring AKF to "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." AB 290 §§ 3(b)(2), 5(b)(2). Yet HIPP assistance is intentionally limited to patients on dialysis (a "procedure") or those who within the past year have received a kidney transplant. AKF Decl. ¶ 16. Through this provision, AKF will be inhibited from associating with the ESRD patients it desires to serve, since its resources will be depleted by the requirement to serve a broader audience, and with the donors who desire to support the fight against kidney disease.

Second, the Act punishes providers for donating to AKF by dramatically reducing reimbursement for treatments provided to any HIPP recipient. The reports AKF must submit to the insurers allow the insurers to reduce reimbursement for services provided by AKF's donors to HIPP beneficiaries.

A provider is penalized the same for any amount of contribution to AKF, large, small, or even minute. A $10 donation to AKF by a provider draws the same penalty as a $10 million donation; in both instances the provider's reimbursement for treating any and all HIPP participants is dramatically reduced, a draconian penalty with no function other than to deter donations. Like political contributions, charitable giving is associational activity protected by the First Amendment. *See Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002) ("contributions, in both

political and charitable contexts . . . are speech entitled to protection under the First Amendment."). Accordingly, restrictions on contributions must be "'closely drawn' to match a 'sufficiently important interest.'" *Nixon v. Shrink Missouri PAC*, 528 U.S. 377, 387-88 (2000).

In *Randall v. Sorrell*, 548 U.S. 230, 247 (2006) (Breyer, J., announcing judgment of the Court), the Court struck down Vermont's political contribution limits as offensive to the First Amendment because they were "sufficiently low as to generate suspicion that they are not closely drawn." *Id.* at 249. The Court found "nowhere in the record any special justification that might warrant a contribution limit so low or so restrictive as to bring about the serious associational and expressive problems that we have described." *Id.* at 261. AB 290 unabashedly punishes any provider who makes any donation to AKF in any amount, at any time, for any reason. This is not a "closely drawn" statute.

The Act also burdens AKF's right to associate with patients by imposing mandatory and prohibitory speech restrictions on how AKF communicates with them, and by requiring AKF to disclose their identities, along with their medical and financial status, to the insurance companies. Thus, the burden on ESRD patients of associating with AKF is disclosure of intensely personal information; this burden on their right of association is an affront to the First Amendment.

Finally, the Act burdens the right of patients to associate with the dialysis providers of their choice. It does so by allowing more generous reimbursement for providers who do not donate to AKF than for providers that do.

c. AB 290 Infringes the First Amendment Right of Petition.

As a condition for delaying its effective date beyond July 1, 2020, the Act requires AKF to petition for revision of the Advisory Opinion. AB 290 § 7. As shown (p. 12, above), the purpose of the putative petition would be to change the Advisory Opinion in a way that will allow the Act to avoid preemption and become effective. Because the State is not covered by the Advisory Opinion, and cannot

seek the revision on its own, the Act seeks to force one of the entities to whom the Advisory Opinion was issued to do so.

To forestall the effective date of the Act and avoid its numerous injuries, AKF would be required to submit a new advisory opinion request to the OIG, state an intention to comply with AB 290, and ask OIG to revise the Advisory Opinion in ways that would allow compliance with the Act. This provision attempts to force AKF to submit a petition advocating a result it vigorously opposes. By doing so, it violates the petition clause. *See Wayte v. United States*, 470 U.S. 598, 610 n.11 (1985) ("Although the right to petition and the right to free speech are separate guarantees, they are related and generally subject to the same constitutional analysis.").

d. The State's Purported Interests Cannot Justify These Restraints.

Under any version of heightened First Amendment scrutiny, AB 290 fails. The Act states its "intent" as "protect[ing] the sustainability of risk pools," "shield[ing] patients from potential harm caused by being steered into coverage options" not in their best interests, and "correct[ing] a market failure that has allowed large dialysis organizations . . . to inflate commercial reimbursement rates and unjustly drive up the cost of care." (§ 1(i)). The State must show that these concerns are "real, not merely conjectural," *Turner Broadcasting System v. FCC*, 512 U.S. 622, 664 (1994), and bears the burden of showing that the remedy it has adopted does not "'burden substantially more speech than is necessary,'" *id.* at 665 (citation omitted). Here, the Act fails these tests.

If the goal is to avoid "steer[ing]" patients into inappropriate coverage, the restrictions are "wildly underinclusive" to protect patients, thus casting doubt on whether the state has any legitimate interest in them. The Act imposes these restrictions on AKF, but not on insurance brokers, hospitals, physicians, or numerous other categories of individuals and entities that might come into contact

with ESRD patients. AKF receives no commission and has no financial interest in insurance policies. In stark contrast, the insurance industry, which aggressively supported AB 290, *does* have such a financial interest, but remains unrestricted by AB 290 and free to "steer, direct, or advise" patients in whatever manner it wants. In *NIFLA*, 138 S. Ct. at 2375, the Court rejected California's asserted interest in "providing low-income women with information about state-sponsored services" because the statute was "wildly underinclusive" to serve that interest; it did not include other clinics, for example. *Id*. at 2375 (citation omitted). As in *NIFLA*, "[s]uch '[u]nderinclusiveness raises serious doubts about whether the government is in fact pursuing the interest it invokes, rather than disfavoring a particular speaker or viewpoint." *Id.* 138 S. Ct. at 2376 (citation omitted).

If the goal is to combat rising health care costs, the Act's means of doing so are obtuse. By deterring donations to AKF, fewer patients will have the benefit of private insurance provided by HIPP and thus will be forced to participate in government programs (at greater cost to the taxpayers), and perhaps insurers will save money by covering fewer ESRD patients. Or perhaps the hope (however unlikely) is that providers, notwithstanding the Act, will continue to donate to AKF, the same number of patients will continue to participate in HIPP, the Act will reduce reimbursement by the insurers to the donating provider for treating HIPP beneficiaries, and insurers will again save money. Notably, the Act does not require the insurers to share any savings with policyholders. This is an approach to cost control only Rube Goldberg could understand. As the Court noted in *Nixon,* "[w]e have never accepted mere conjecture as adequate to carry a First Amendment burden." 528 U.S. at 392.

In short, no credible state interest can support AB 290's extensive assault on the First Amendment rights of the Plaintiffs.

B. AB 290 Will Cause Immediate, Irreparable Harm.

Plaintiffs' likelihood of success notwithstanding, final relief will come too

1 late. On January 1, 2020, AB 290 will begin to work severe and irreversible harm
2 to AKF and the vulnerable patients it supports, causing AKF to withdraw HIPP from
3 California.

4 To begin, AB 290 will deprive Plaintiffs of their First Amendment freedoms,
5 a loss that "unquestionably constitutes irreparable injury." *Manning v. Powers*, 281
6 F. Supp. 3d 953, 964 (C.D. Cal. 2017) (quoting *Elrod v. Burns*, 427 U.S. 347, 373
7 (1976)); *see also*, *e.g.*, *Sammartano v. First Judicial Dist. Court*, 303 F.3d 959, 973-
8 74 (9th Cir. 2002) (explaining irreparable harm follows if the plaintiff has raised "a
9 colorable First Amendment Claim"), *abrogated on other grounds by Winter*, 555
10 U.S. 7. Accordingly, the manifold constitutional harms laid out above themselves
11 justify preliminary injunctive relief. *See, e.g.*, *Weaver v. City of Montebello*, 370 F.
12 Supp. 3d 1130, 1138 (C.D. Cal. 2019); *Serv. Emps. Int'l Union v. City of L.A.*, 114
13 F. Supp. 2d 966, 975 (C.D. Cal. 2000).

14 In addition, and more importantly, implementation of AB 290 will
15 permanently upturn the lives of current AKF beneficiaries and substantially burden
16 future ESRD patients' access to life-saving dialysis and kidney transplants.
17 Plaintiffs Doe, Albright, and numerous members of DPC suffer constant anxiety
18 about their health care needs and expenses. Doe Decl. ¶ 17; Albright Decl. ¶ 13;
19 DPC Decl. ¶ 19. Losing AKF's assistance will make it impossible for them to afford
20 their current health insurance coverage. Doe Decl. ¶ 16; Albright Decl. ¶ 11; DPC
21 Decl. ¶ 15. As the result of even a short lapse in AKF's operations, Ms. Doe, Mr.
22 Albright, and many DPC members will see their health care needs come to dominate
23 their lives and livelihoods. Doe Decl. ¶ 16; Albright Decl. ¶¶ 11-14; DPC Decl.
24 ¶ 19. Some may even be delayed in receiving necessary kidney transplants as the
25 result of disruptions in their health insurance coverage. AKF Decl. ¶ 22; DPC Decl.
26 ¶ 18. These are precisely the types of hardship courts routinely avoid through
27 preliminary relief. *See M.R. v. Dreyfus*, 697 F.3d 706, 729, 732 (9th Cir. 2012);
28 *Harris v. Bd. of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004); *Lopez v. Heckler*,

1 713 F.2d 1432, 1437 (9th Cir. 1983); *see also Beltran v. Myers*, 677 F.2d 1317, 1322
2 (9th Cir. 1982) ("Plaintiffs have shown a risk of irreparable injury, since
3 enforcement of the California rule may deny them needed medical care."); *United*
4 *Steelworkers of Am. v. Fort Pitt Steel Casting*, 598 F.2d 1273, 1280 (3d Cir. 1979)
5 (recognizing that "the possibility [of being] denied adequate medical care as a result
6 of having no insurance" is an irreparable injury).

7 Economic harms of this nature can support preliminary relief because of the
8 interim injury and because Plaintiffs are unable to recover damages from the state.
9 *Cal. Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 852 (9th Cir. 2009), *vacated*
10 *on other grounds by Douglas v. Indep. Living Ctr. of S. Cal.*, 565 U.S. 606 (2012).
11 Damages years from now could not make them whole anyway, *cf. Zepeda v. INS*,
12 753 F.2d 719, 727 (9th Cir. 1983) (recognizing the inadequacy of money damages
13 to retroactively cure a constitutional violation). Indeed, no form of relief could
14 restore Plaintiffs to their current position once AB 290 goes into effect. The need
15 for dialysis and maintaining adequate coverage for a transplant is ongoing and
16 cannot be put on hold.

17 **C. The Equities and Public Interest Favor an Injunction.**

18 Finally, the heavy support for preliminary relief has no counterweight. The
19 State will suffer no loss from preliminary relief, and the public will benefit from this
20 Court's maintenance of the status quo.

21 Although the balance of equities and the public interest are normally two
22 separate considerations, those considerations merge when an injunction would run
23 against the government. *See Nken v. Holder,* 556 U.S. 418, 435 (2009). And it is
24 always in the public interest to prevent state officials from breaking federal law and
25 violating constitutional rights. *E.g. Az. Dream Act Coalition v. Brewer*, 757 F.3d
26 1053, 1069 (9th Cir. 2014); *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012);
27 *Cal. Pharmacists*, 563 F.3d at 852–53; *cf. Rodriguez v. Robbins*, 715 F.3d 1127,
28 1145 (9th Cir. 2013) (the government "cannot suffer harm from an injunction that

1 merely ends an unlawful practice").
2 That is all Plaintiffs ask for here. Far from burdening the public, an injunction
3 would thus *serve* the public by protecting its most vulnerable members from illegal
4 privations. *See Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (recognizing the
5 public's interest in providing health care to the needy); *cf. Texas v. EPA*, 829 F.3d
6 405, 435 (5th Cir. 2016) (holding the public's immediate need for affordable
7 electricity paramount to the potential long-term benefits of a new government
8 policy). This Court has recognized the aptness of preliminary relief in similar
9 circumstances. *See, e.g.*, *Weaver*, 370 F. Supp. 3d at 1139; *Gebin v. Mineta*, 239 F.
10 Supp. 2d 967, 969 (C.D. Cal. 2002). It should reaffirm that principle here.

11 **CONCLUSION**

12 For the foregoing reasons, Plaintiffs urge this Court to enjoin the State from
13 implementing AB 290 while this lawsuit is pending.
14
15 DATED: November 8, 2019 KING & SPALDING LLP
16
17
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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

Case No. 8:19-cv-02105

DECLARATION OF HRANT JAMGOCHIAN IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

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

1 I, Hrant Jamgochian, declare as follows:

2 1. I am the Chief Executive Officer of Dialysis Patient Citizens ("DPC").
3 I am over 18 years of age. I have been the CEO of DPC since April 2011. I have
4 previously served as the Director of Health Policy for the United Way Worldwide,
5 as Director of Congressional and State Relations for the American Pharmacists
6 Association, and as Director of Field and State Operations for the American
7 Psychological Association. I have a Juris Doctorate (J.D.) from Catholic University
8 and a Master of Laws (LL.M.) in Global Health Law from Georgetown University
9 Law Center. I have personal knowledge of the facts set forth herein except as
10 otherwise stated. I could and would testify truthfully about the matters contained
11 herein.

12 **DPC's Mission Combatting End Stage Renal Disease**

13 2. DPC is a non-profit educational and social welfare organization
14 operating under section 501(c)(4) of the Internal Revenue Code. Our mission is to
15 improve the quality of life of patients with End Stage Renal Disease ("ESRD") and
16 chronic kidney disease ("CKD"). We empower patients with kidney disease through
17 a variety of advocacy and education efforts.

18 3. ESRD is a chronic, painful, irreversible, and potentially fatal illness.
19 When a patient has ESRD, her kidneys are no longer capable of filtering waste and
20 toxins from her blood. ESRD is also associated with a host of comorbidities, most
21 notably diabetes, cancer, heart disease, and anemia. More than 700,000 people in
22 the United States have ESRD, and each year, there are more than 100,000 new ESRD
23 diagnoses in the United States.

24 4. To survive, an ESRD patient must either obtain a kidney transplant or
25 undergo dialysis. Dialysis is a medical process that filters waste and excess fluid
26 from a patient's blood. The typical dialysis patient requires three dialysis treatments
27 per week, each lasting four to five hours. Dialysis is the only way, absent a kidney
28 transplant, to keep an ESRD patient alive, and it exacts a tremendous toll. Dialysis

is expensive, stressful, and time-consuming. The demands of dialysis treatment mean that ESRD patients often have difficulty keeping their jobs. Further, the prevalence of depression or anxiety among ESRD patients is approximately four times higher than that of the general adult population.

5. DPC is a patient-led organization. Our by-laws require that the President, Vice President, and the majority of the Board of Directors to be current dialysis patients. DPC's membership is restricted to patients with kidney disease and their family members. We have more than 28,000 members nationwide and 4,587 members residing in California. Our 2016 Membership Survey found that 87% of our members with kidney disease are on dialysis and that 11% have received kidney transplants.

6. Our Membership Survey also found that the average DPC member with ESRD has been on dialysis for 6.7 years, and that 19% have been on dialysis for more than 10 years. One-third of our members who have not received transplants are on a transplant waiting list. The average waiting period for a DPC member to receive a kidney transplant is between three and seven years.

7. DPC is demographically diverse, as ESRD disproportionately afflicts racial minorities. Fifty-three percent of our members are white, 30% are African-American, and 4% are Hispanic.

8. Because dialysis patients must receive frequent, lengthy treatments, they have difficulty staying employed. Fifty-two percent of our members are retired, and another 26% are unemployed. As a result, a large portion of our members have very little income. Two-thirds of our members have received some form of financial assistance to help make ends meet.

9. Our members receive coverage from multiple sources, including Medicare, Medicaid, and private coverage. However, even with insurance, dialysis treatment is expensive. Accordingly, 23% of our members have received assistance from the American Kidney Fund ("AKF") to help them pay for their premiums,

including premiums for Medicare and Medicaid.

AB 290 Will Interfere with Congress's Objectives

10. During my work with DPC, I have become familiar with federal laws related to dialysis. Understanding these statutes is essential for DPC to conduct its mission and effectuate informed policymaking that best serves the needs of dialysis patients.

11. Some of the most important federal provisions related to dialysis are found in the Medicare Secondary Payer Act ("MSPA"). Based on my role with DPC and my legal training, I am familiar with the MSPA, its purposes, and its legislative history. Congress had three objectives when it enacted the MSPA. *First*, Congress designed the MSPA to allow a dialysis patient to keep her private insurance coverage if she elects to do so. Accordingly, there is no requirement that an ESRD patient must leave her health plan. (Doing so would, in fact, make receiving a kidney transplant more difficult if not impossible.) *Second*, Congress intended insurance providers to contribute to the cost of dialysis coverage. From 1973 until 1981, Medicare bore the entire burden of paying for dialysis for ESRD patients. The MSPA inverted this state of affairs by mandating that private insurers cover ESRD patients for the duration of the "coordination period," which was originally 12 months and is now 30 months. *Finally*, Congress sought to mitigate perverse incentives. Without the coordination period, unscrupulous insurers would be financially incentivized to allow patients with CKD to deteriorate to ESRD, thus foisting those patients and their costly dialysis needs onto Medicare. AB 290 will interfere with all three of Congress's objectives.

AB 290 Will Cause Irreparable Harm to DPC and Its Members

12. Based on my close working relationship with AKF and information I have learned from DPC members, I know AKF has already curtailed its charitable work to avoid liability under AB 290. Most notably, AKF has ceased providing new dialysis patients with premium assistance in California because the new grants

1 would not be "grandfathered" under the terms of AB 290. It is my understanding
2 that, by the end of the year, AKF must either provide premium assistance that
3 complies with the terms of AB 290 or else stop providing premium assistance in
4 California entirely.
5 13. If AKF stops providing premium assistance in California while this suit
6 is litigated, DPC and its members will be irreparably and irreversibly harmed.
7 14. It is imperative that ESRD patients have access to dialysis treatment, as
8 missing even one treatment can mean death. In my experience, providing patients
9 with affordable and reliable insurance coverage is the best way to ensure that they
10 receive the dialysis treatments they need at regular intervals. However, quality
11 health insurance coverage is expensive. The average annual premium for employer-
12 sponsored health insurance in 2019 was $7,188 for single coverage. Very few ESRD
13 patients are be able to pay for such coverage without assistance. Therefore, AKF's
14 premium assistance program is critical to ensuring dialysis patients have access to
15 the treatment they need. If AB 290 is allowed to go into effect while this lawsuit is
16 litigated, however, it will disrupt, or even terminate, the insurance coverage of many
17 of DPC's members.
18 15. Because many of DPC's members cannot afford their insurance
19 coverage without assistance from AKF, these patients will lose their current
20 insurance. DPC members who have private insurance coverage due to AKF's
21 assistance will no longer be able to afford that coverage. Upon losing AKF's
22 financial assistance, these members will be forced to shift to Medicare or Medicaid,
23 provided that they qualify for those programs and can afford to pay the associated
24 copayments. For DPC members who cannot afford to move to public insurance
25 options, the alternative is no insurance at all.
26 16. Based on my knowledge and experience, there are many reasons why
27 an ESRD patient could prefer to maintain commercial coverage rather than
28 immediately enroll in Medicare. For instance, Medicare does not offer coverage for

dependents, does not offer dental coverage, and does not have an out-of-pocket maximum. According to our Membership Survey, patients on Medicare were more than twice as likely to report having trouble getting the health care they wanted or needed compared with patients on private health insurance plans. We also found that Medicare beneficiaries were more likely to report difficulties in getting the specific medications they needed, more likely to report having difficulty getting answers to their questions, and more likely to experience delays in receiving care or treatment. For these reasons, DPC members strongly prefer to maintain their private insurance coverage when they can afford to do so. Likewise, a public insurance option like Medicare is far preferable to no insurance coverage at all.

17. Some DPC members may be able to afford their current insurance coverage, but only as a result of great personal financial sacrifice. As stated above, more than three-quarters of DPC's members are either unemployed or retired and thus have very low incomes. If forced to pay for their own insurance premiums without AKF's assistance, these DPC members would likely have to forego other essentials in order to continue receiving their dialysis treatments.

18. Further, dialysis patients who change insurance coverage frequently lose their places on kidney transplant waiting lists. Even in the best of circumstances, DPC members typically wait anywhere from three to seven years to receive a kidney transplant. If AB 290 is allowed to go into effect, it will jeopardize DPC members' access to life-saving kidney transplants through even further delay. These members will also be forced to spend even more time receiving dialysis treatment, and at great physical, financial, psychological, and emotional costs.

19. The effects of AB 290 will expand well beyond lost insurance coverage. From my experience at DPC, I know that our members suffer constant stress and anxiety about their health care needs and expenses. Many of our members have told me that paying for their dialysis treatments is already the largest source of stress and anxiety in their lives. AB 290 will only exacerbate the fears of DPC members due

to the uncertainty it will cause, to say nothing of the increased financial burdens it will place on them.

20. AB 290 will also have less immediate, but no less irreparable, long-term effects on DPC's members in California. In order to be economically viable, dialysis providers charge patients who have private insurance coverage higher rates than patients who have Medicare or another public insurance option. Based on my knowledge and experience, it would not be possible for dialysis providers to offer the level of access and quality of treatment that dialysis patients require if the dialysis providers received only the current Medicare reimbursement rate from all patients. But AB 290 will mandate that dialysis providers will receive only the Medicare reimbursement rate for most patients in California.

21. Based on my knowledge and experience, AB 290 will therefore force dialysis providers to close existing clinics. This will only worsen DPC members' access to dialysis treatment. The closure of even one dialysis clinic in California will have ripple effects on DPC's members and will burden them with additional costs, transportation time, anxiety, and uncertainty, as well as lowering the quality of care at the dialysis clinics that do remain open by foisting additional patients upon them.

22. Similarly, based on my knowledge and experience, AB 290 will discourage dialysis providers from opening new clinics in California. Because ESRD is becoming increasingly common due to the country's aging population, it is imperative that dialysis providers continue to open new clinics to meet the growing need for dialysis treatment. As stated above, there are more than 100,000 new ESRD diagnoses ever year in the United States. However, AB 290 will create an

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impediment to dialysis providers opening new clinics in California. This will further limit our members' access to critical dialysis treatment.

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

HRANT JAMGOCHIAN

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.* Defendants.	Case No. 8:19-cv-2105-DOC-ADS **DECLARATION OF LAVARNE A. BURTON IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION** Date: December 9, 2019 Time: 8:30 a.m. Place: Courtroom 9D

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

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

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

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

INTRODUCTION

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

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

1 opinion we obtained from the Office of the Inspector General ("OIG") of the
2 Department of Health and Human Services ("HHS"). Advisory Opinion 97-1
3 provides a safe harbor that allows us to operate this vital program without any chance
4 that we are violating federal law, which would pose great legal, financial, and
5 reputation risks to AKF.
6 6. We are a charity. We do what we do because we care about those who
7 suffer from kidney disease; not for profit, not for personal gain. We put 97 cents of
8 every dollar we receive into our programs, and for that, we have been lauded by
9 numerous charity publications and watchdogs. But it also means that we have zero
10 tolerance for risk with respect to our operations, particularly our financial assistance
11 operations. The very fact that we have engaged counsel to prosecute this litigation
12 on our behalf is an indication of how seriously we take this, though.
13 7. Advisory Opinion 97-1 is thus critical to our mission and our most
14 important financial assistance program, the Health Insurance Premium Program
15 ("HIPP"). We operate HIPP to the highest ethical standard. It focuses solely on the
16 financial neediness of ESRD patients who cannot afford the premiums of their health
17 insurance—the program is otherwise blind to any other consideration. But Advisory
18 Opinion 97-1 makes that high ethical standard a legal safe harbor. It ensures that
19 there is no risk that our financial assistance program will be viewed by the federal
20 government as providing impermissible remuneration under the Beneficiary
21 Inducement Statute to ESRD patients based on donations we receive from providers.
22 Without that assurance, we cannot operate HIPP.
23 8. Yet AB 290 requires us to breach the safeguards that Advisory Opinion
24 97-1 requires to maintain our safe harbor. California's Legislative Counsel has
25 acknowledged as much. If AB 290 goes into effect on January 1, 2020, AKF must
26 halt its financial assistance grants to low-income patients in California. Though AKF
27 is loath to exit California, it must consider the circumstances of the tens of thousands
28 of other HIPP grantees throughout the United States. Without the safe harbor

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

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

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

THE AMERICAN KIDNEY FUND AND ITS MISSION

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

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

1 providing disaster relief grants to ESRD patients who are affected by the wildfires.
2 And through HIPP, we provide grants to low-income people living with ESRD that
3 allow them to pay premiums on their existing health insurance, thus ensuring that
4 they have access to the dialysis, transplants, and the other health care that keeps them
5 alive.
6 13. AKF is one of the nation's top-rated nonprofits and invests 97 cents of
7 every donated dollar in programs, not overhead. Because of its transparency and
8 efficiency, AKF has held the highest 4-star (out of 4) rating from Charity Navigator
9 for 18 straight years and the Platinum Seal of Transparency from GuideStar. Only
10 a handful of the 9,000 charities evaluated by Charity Navigator have maintained a
11 4-star rating for this length of time.
12
THE CRITICAL ASSISTANCE PROVIDED BY HIPP

13 14. A silent killer, with no early signs or symptoms, kidney disease is one
14 of the top-ten leading causes of death in the United States. People confronted with
15 an ESRD diagnosis face life-altering challenges, including reduced ability to work
16 and care for themselves and their families, the significant burden of needing regular
17 dialysis treatment and other specialized health care, a decline in health and capacity
18 (including an increase in other significant health problems such as heart disease and
19 cancer), and the corresponding financial impact of living with and treating ESRD.
20 Without treatment—either dialysis or a transplant—ESRD is fatal. However,
21 transplants involve significant surgical and recovery complications, in addition to
22 delays due to a shortage of transplantable kidneys, meaning that many patients either
23 cannot receive one promptly or are not medically suitable at all. The end result is
24 that dialysis is often the only viable option for many ESRD patients.
25 15. By providing financial assistance to qualifying low-income patients
26 with kidney failure to help pay health insurance premiums, AKF allows these
27 patients to receive comprehensive medical care, including dialysis, medications, the
28

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

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

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

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

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

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HIPP SERVES THE MOST VULNERABLE

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

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

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

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

1 **HIPP ALLOWS ITS GRANTEES TO AFFORD THE COVERAGE BEST FOR THEM**

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

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

19 **HIPP IS VITAL FOR CALIFORNIA ESRD PATIENTS**

20 26. Nearly 95,000 Californians are living with ESRD. Of that group,
21 69,000 of them depend on dialysis to stay alive and over 25,000 have functioning
22 transplants.

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

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

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

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

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

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

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

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

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

THE IMPORTANCE OF ADVISORY OPINION 97-1 FOR HIPP

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

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

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

1 We explained that the program was entirely need-based and that we would not treat
2 patients differently depending on who their provider was.
3 37. The resultant opinion, Advisory Opinion 97-1, was the first of its kind
4 and remains in effect and is published on the OIG's website at:
5 https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/.
6 38. In that opinion, the OIG reviewed the information provided and
7 concluded that continuation of AKF's operating procedures in an expanded HIPP
8 program—one which would allow dialysis providers to donate to the program—
9 would enhance patient choice with regard to dialysis providers and ensure that
10 provider contributions would not be used to influence patients.
11 39. The OIG ultimately concluded that "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 Companies. The Companies who contribute to AKF will not be assured that the
15 amount of HIPP assistance their patients receive bears any relationship to the amount
16 of their donations. Indeed, the Companies are not guaranteed that beneficiaries they
17 refer to HIPP will receive any assistance at all. . . . Simply put, AKF's payment of
18 premiums will expand, rather than limit, beneficiaries' freedom of choice."
19 40. Advisory Opinion 97-1 identified the key aspects of AKF's operation
20 of HIPP that prevented the program from constituting impermissible renumeration:
21 a. AKF is an independent 501(c)(3) organization.
22 b. Providers are not required to contribute to HIPP in order for their
23 patients to receive assistance.
24 c. AKF has complete discretion to determine applicant eligibility, based
25 on AKF-established criteria of financial need.
26 d. Patients are not informed whether their provider contributes to HIPP.
27 e. Patients' applications and HIPP grants are treated equally, without
28 regard to considerations such as their dialysis provider.

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

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

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

a. All contributions to HIPP are always voluntary.

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

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

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

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

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

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

our beneficiaries are enrolled in government health insurance programs.

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

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

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

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

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

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

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

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

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

AB 290 DIRECTLY THREATENS AKF AND HIPP

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

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

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

1 46. Conversely, patients will be made aware that their dialysis providers
2 contribute to AKF when the insurers implement reduced reimbursement rates
3 following the receipt of patient names. That means that a key firewall of Advisory
4 Opinion 97-1—whereby patients are not informed of whether their particular
5 provider donated to AKF—will be removed by AB 290.
6 47. Thus, when AB 290 takes effect on January 1, 2010, AKF will begin to
7 accrue obligations under that Act that will directly undermine the safe harbor of
8 Advisory Opinion 97-1. For instance, AB 290 and AKF's own HIPP policy obligate
9 us to provide premium assistance for a full plan year, which will trigger AB 290's
10 unconstitutional reporting obligations. Unless AB 290 is enjoined prior to its
11 effective date, AKF will have to cease operating HIPP in California.
12 48. California was well aware of this when it enacted AB 290. Not only
13 did we inform legislators of this possibility, but California's own Legislative
14 Counsel concluded that AB 290 would require AKF to exit the safe harbor created
15 by Advisory Opinion 97-1. Indeed, the strongest evidence of California's awareness
16 of this risk is found in AB 290 itself, as the law has a provision that delays some of
17 its implementation if AKF seeks a revised advisory opinion from OIG.
18 49. Yet this is wholly inadequate. To obtain a new OIG opinion that
19 accounts for AB 290, we would have to certify in good faith that we will actually
20 pursue such a program if given authorization. This is something that we cannot do,
21 particularly given that the advisory opinion process can take years and leave HIPP
22 in limbo. More fundamentally, it would be irresponsible of AKF to put at risk our
23 existing nationwide arrangement simply to accommodate an unconstitutional and ill-
24 conceived law such as AB 290. After all, there is no guarantee that the OIG would
25 reach a favorable conclusion.
26 50. Nor does AB 290 stop with requiring AKF to operate outside the
27 boundaries of Advisory Opinion 97-1. It also forces us to change our behavior with
28 respect to the patients we support. As I explained above, patients apply to HIPP with

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

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

CONCLUSION

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

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

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

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

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

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

DECLARATION OF PLAINTIFF STEPHEN ALBRIGHT IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

Date: December 9, 2019
Time: 8:30 AM
Place: Courtroom 9D

1 I, Stephen Albright, declare as follows:
2 1. I am 54 years old and currently reside in Costa Mesa, California. I am
3 a plaintiff in the above-captioned lawsuit.
4 2. I have personal knowledge of the facts set forth herein. If asked to do
5 so, I could testify truthfully about the matters contained herein.
6 3. I was born in Orange County and have lived here for most of my life.
7 My significant other is 54 years old and moved to Orange County in 1990. We
8 consider Orange County our home, and together we have developed deep roots in
9 this community.
10 4. Things have become very difficult for us over the past several years. In
11 2011, I was diagnosed with polycystic kidney disease, a disorder in which the
12 kidneys develop fluid-filled cysts which prevent them from filtering waste products
13 from the blood. For several years, I was able to manage my diagnosis with the help
14 of my doctor, but my condition nonetheless deteriorated.
15 5. In 2017, I was diagnosed with renal failure. In order to deal with that
16 diagnosis, I had to commence dialysis. I was initially on hemodialysis—a form of
17 dialysis which involves blood filtering through a machine—for six months.
18 Unfortunately, that treatment proved ineffective because of blood clotting issues. As
19 a result, I had numerous health complications, including ulcers and fatigue, which
20 left me unable to work.
21 6. In 2018, I eventually transitioned to peritoneal dialysis, in which the
22 body's abdominal lining is used to carry out the necessary filtering. I have been on
23 that form of dialysis since my transition, with much better results. Indeed, I have
24 been able to work four days a week (32 hours total) while being on dialysis.
25 7. Nonetheless, my life remains extremely challenging. To remain alive,
26 I must dialyze every single night. That means I have to hook up to my machine and
27 bags at around 9:00 p.m. each night and carry out dialysis until 5:00 a.m. or 6 a.m.
28 the following morning. It is difficult to sleep while undergoing dialysis, as the

machine can emit alarms, the fluid bags required as part of the process are heavy and intrusive, and I often experience cramping. In addition to my required dialysis routine, I take over 30 pills a day: 11 in the morning, 7 at night, and 5 with each meal. These medications are essential for dealing with the comorbidities that arise from kidney failure, as well as the side effects of dialysis. Even with my dialysis and medication, I still have a host of health complications. For example, over the course of July, August, and September, I suffered from anemia and sudden weight loss, which left me weakened. Incidents like that are not uncommon in my life.

8. Dealing with my disease is also logistically challenging. One day a month, I have to stay home to wait for my 30-day supply of dialysis materials. (The delivery consists of twenty-pound boxes that take up a great deal of space.) Of course, there are also numerous visits with doctors. I try to schedule them for Wednesdays, the day I take off during the week, but sometimes I am unable to obtain an appointment on that day. I am fortunate that my employer has been willing to provide me with a flexible schedule. I ultimately hope that I will be able to obtain a kidney transplant, but for the time being, I remain in the evaluation phase for that procedure.

9. The medical costs of my condition are very high. For example, some of my medications individually cost $1,000 for a single month's supply. Because my condition limits my ability to work to part-time employment, I am ineligible for healthcare through my employer, and my significant other and I obtain my primary insurance through her employer and use Medicare as my secondary insurance. The premiums we pay for my insurance are expensive in light of our modest means: $436 a month on our primary insurance and $1,200 a year for Medicare.

10. The American Kidney Fund has provided critical assistance by paying the premiums on both my primary insurance and Medicare. That financial assistance is absolutely essential for us. Even with the American Kidney Fund's help, our finances are very tight. If California Assembly Bill 290 were to go into effect in

1 January 2020 and the American Kidney Fund can no longer providing us with
2 financial assistance, our situation will become dire.
3 11. My significant other and I have discussed our options if the law goes
4 into effect and none of them are good. My significant other would likely have to
5 move us to a primary health insurance plan with less coverage, but lower premiums.
6 Such a move, however, would expose us to higher out-of-pocket costs and could also
7 leave us uncovered for certain health events. We have also investigated Medi-Cal
8 as an option, but do not see that as a realistic option because our incomes are just
9 slightly too high. We are indeed needy, but we are not yet at the extremely low
10 levels required for Medi-Cal. It is unclear whether the new law will eventually force
11 us into that scenario. It is a possibility that fills us with dread.
12 12. We also cannot seriously contemplate leaving the State of California
13 and moving to another state to reduce my healthcare costs. Even leaving aside that
14 Orange County is our home, the truth is that we have no realistic options. I am in
15 my mid-50s and suffer from renal disease. I do not think that I would be able to
16 obtain a new job or be retrained for another line of work. It is also doubtful that my
17 significant other could obtain a job with similar health benefits.
18 13. Though life was difficult before Assembly Bill 290, I now suffer from
19 severe anxiety contemplating what my significant other and I will have to try to do
20 to make ends meet. My anxiety adds additional problems, including trouble
21 sleeping, and I must take anxiety medication so that I do not worsen my other health
22 problems. Come January 2020, I have no idea what we will do if the American
23 Kidney Fund is no longer able to provide the financial assistance that we rely upon
24 so much.
25 14. The simple truth is that Assembly Bill 290 will put me at immediate
26 risk of real health and financial harm if it takes effect.
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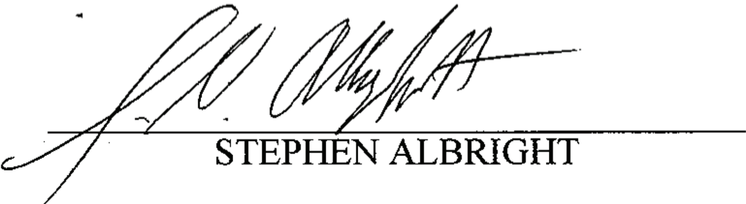
28

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



STEPHEN ALBRIGHT

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Case No. 8:19-cv-02105

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

1 On December 9, 2019, the motion of Plaintiffs Jane Doe, Stephen Albright,
2 American Kidney Fund, Inc. (“AKF”), and Dialysis Patient Citizens, Inc. (“DPC”)
3 came on regularly for hearing.
4 After full consideration of all arguments of counsel and all points and authorities
5 filed in support of, and in opposition to, the Motion, and GOOD CAUSE THEREFOR
6 APPEARING, IT IS HEREBY ORDERED:
7 **A.** The Motion is GRANTED.
8 **B.** The Court makes the following statement of reasons pursuant to Federal
9 Rule of Civil Procedure 65(d)(1).
10 Statement of Reasons
11 The Court has the power to enjoin enforcement of state laws that conflict with
12 federal law and deprive rights protected under the Constitution of the United States.
13 Preliminary injunctive relief is appropriate where a plaintiff demonstrates that (1) she
14 is likely to succeed on the merits; (2) she is likely to suffer irreparable harm in the
15 absence of preliminary relief; (3) the balance of equities tip in her favor; and (4) the
16 injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S.
17 7, 20 (2008).
18 Here, Plaintiffs have established each of these factors favor preliminary
19 injunctive relief. First, Plaintiffs are likely to succeed on the merits of their claims
20 because California Assembly Bill 290 (“AB 290”) conflicts with federal health care law
21 and deprives AKF, DPC, and the individual patient Plaintiffs, Jane Doe and Stephen
22 Albright, of First Amendment rights to expression and association. Plaintiffs have
23 shown a likelihood of success on their claims that AB 290 violates Plaintiffs’
24 constitutional rights and is preempted by federal law. The California law makes it
25 impossible for AKF to comply with the mandates of Advisory Opinion 97-1 and
26 frustrates Congress’s objective of ensuring ESRD patients’ access to needed medical
27 care. The law also runs afoul of the First Amendment in several respects, including its
28 unjustified compelled speech mandates and its chilling of Plaintiffs’ protected

expression and associational rights. These manifold defects make it likely that the Court will ultimately declare AB 290 invalid and permanently enjoin its enforcement.

Second, Plaintiffs will suffer irreparable injury absent preliminary relief because AB 290's mandates would chill protected expression, inhibit AKF's charitable mission, and ultimately force AKF to stop providing premium assistance in California. The deprivation of constitutional rights—even for a brief period—always constitutes irreparable harm. In addition, AKF's inability to continue offering premium assistance in California under AB 290 will cause extreme hardship to the Patient Plaintiffs and others that rely on AKF to help finance their medical needs. Both AKF and its beneficiaries will thus suffer unrecoverable financial losses as well as irreversible disruptions in access to needed treatment.

Lastly, Plaintiffs have shown that the equities and public interest favor preliminary relief because both considerations cut in favor of the protection of constitutional rights and against the implementation of invalid and superseded state laws. Any countervailing hardship to the State is negligible—if it exists at all. Indeed, the State has the same interests as the public in this case, and the public has a clear interest in preventing State officials from violating supreme federal law and constitutional rights.

C. The Court therefore enters a preliminary injunction as follows:

Defendants Xavier Becerra, Ricardo Lara, Shelly Rouillard, and Sonia Angell, each in his or her official capacity, are immediately enjoined from enforcing or otherwise implementing California Assembly Bill 290. *See* Act of Oct. 13, 2019, ch.

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1 862, 2019 Cal. Stat. ___ (2019) (to be codified at Cal. Health & Safety Code §§ 1210,
2 1367.016, 1385.09 and Cal. Ins. Code §§ 10176.11, 10181.8).
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4 **IT IS SO ORDERED.**
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DATED: ________________	________________ THE HONORABLE DAVID O. CARTER UNITED STATES DISTRICT JUDGE

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