JOSEPH N. AKROTIRIANAKIS (SBN 197971)
jakro@kslaw.com
KING & SPALDING LLP
633 West Fifth Street, Suite 1600
Los Angeles, CA 90071
Telephone: (213) 443-4355
Facsimile: (213) 443-4310

BOBBY R. BURCHFIELD (*pro hac vice*)
bburchfield@kslaw.com
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Washington, DC 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737

Attorneys for Plaintiffs
JANE DOE, STEPHEN ALBRIGHT,
AMERICAN KIDNEY FUND, INC.,
and DIALYSIS PATIENT CITIZENS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JANE DOE, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, *et al.*

Defendants.

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

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

Date: December 16, 2019
Time: 8:30 a.m.
Place: Courtroom 9D

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF CONTENTS

INTRODUCTION 1
BACKGROUND 1
A. AB 290 Does Not Address The "Problems" It Purports to Concern. 2
B. The State Misunderstands Advisory Opinion 97-1. 3
C. The State's Description of HIPP Is Inaccurate. 4
ARGUMENT 5
I. Plaintiffs Are Likely to Succeed on the Merits. 6
A. AB 290 Is Preempted by Federal Law. 6
1. AB 290 Is Preempted by the Beneficiary Inducement Statute. 7
2. AB 290 Pushes AKF's Program Outside of Advisory Opinion 97-1. 10
3. AB 290 Presents a Significant Obstacle to the Goals of the Medicare Secondary Payer Act. 13
B. AB 290 Tramples Plaintiffs' First Amendment Rights. 14
1. AB 290's Content and Speaker-Based Speech Restrictions Offend the First Amendment. 15
2. AB 290 Imposes Extreme Burdens on the Right of Association. 17
3. AB 290 Burdens the Right of Petition. 19
4. The Restrictions Cannot Pass Any Level of Scrutiny. 20
II. AB 290 Will Cause Immediate, Irreparable Harm. 21
III. The Equities and Public Interest Favor an Injunction. 25
CONCLUSION 25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF AUTHORITIES

Page(s)

Cases

Arizona Dream Act Coalition v. Brewer,
757 F.3d 1053 (9th Cir. 2014) 25

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 11

Beltran v. Myers,
677 F.2d 1317 (9th Cir. 1982) 23, 24

Bucklew v. Precythe,
139 S. Ct. 1112 (2019) 5

Christensen v. Harris Cty.,
529 U.S. 576 (2000) 10

Citizens United v. FEC,
558 U.S. 310 (2010) 20

Cline v. Hawke,
51 F. App'x 392 (4th Cir. 2002) 10

DaVita Inc. v. Amy's Kitchen, Inc.,
379 F. Supp. 3d 960 (N.D. Cal. 2019) 14

DaVita Inc. v. Marietta Mem'l Hosp. Employee Health Benefit Plan,
No. 2:18-CV-1739, 2019 WL 4574500 (S.D. Ohio Sept. 20, 2019) 14

Dialysis Patient Citizens v. Burwell,
No. 4:17-CV-16, 2017 WL 365271 (E.D. Tex., January 25, 2017) 2, 5

Disney Enters., Inc. v. VidAngel, Inc.,
224 F. Supp. 3d 957 (C.D. Cal. 2016) 6

Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 13

Harmon v. City of Santa Cruz,
271 F. Supp. 3d 1031 (N.D. Cal. 2017) 6

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Harris v. Bd. of Supervisors, Los Angeles Cty.,
366 F.3d 754 (9th Cir. 2004) 24

Hernandez v. Lynch,
No. EDCV 16-00620-JGB, 2016 WL 7116611 (C.D. Nov. 10, 2016) 23

Larkin v. Workers Comp. Appeals Bd.,
358 P.3d 552 (Ca. 2015) 18

Massachusetts v. Oakes,
491 U.S. 576 (1989) 6

Milavetz, Gallop & Milavetz v. United States,
559 U.S. 299 (2010) 15, 16, 20

Nat'l Renal All., LLC v. Blue Cross & Blue Shield of Ga., Ind.,
598 F. Supp. 2d 1344 (N.D. Ga. 2009) 14

National Institute of Family and Life Advocates v. Becerra (*NIFLA*),
138 S. Ct. 2361 (2018) 15, 16, 20, 21

Nken v. Holder,
556 U.S. 418 (2009) 25

PLIVA, Inc. v. Mensing,
564 U.S. 604 (2011) 8

Puente Arizona v. Arpaio,
821 F.3d 1098 (9th Cir. 2016) 6

Reed v. Town of Gilbert,
135 S. Ct. 2218 (2015) 20

Roulette v. City of Seattle,
97 F.3d 300 (9th Cir. 1996) 6

Sammartano v. First Judicial Dist. Court,
303 F.3d 959 (9th Cir. 2002) 13, 23

Santa Barbara Patients' Collective Health Co-op. v. City of Santa Barbara,
911 F. Supp. 2d 884 (C.D. Cal. 2012) 18

Santopietro v. Howell,
857 F.3d 980 (9th Cir. 2017) 17

Sorrell v. IMS Health Inc.,
564 U.S. 552 (2011) 17

South Pacific Trans. Co. v. Public Serv. Comm'n of Nev.,
909 F.2d 352 (9th Cir. 1990) 10

Teper v. Miller,
82 F.3d 989 (11th Cir. 1996) 10

Turner Broad. Sys., Inc. v. FCC,
512 U.S. 622 (1994) 20

United States v. Mead Corp.,
533 U.S. 218 (2001) 10

United Steelworkers of Am. v. Fort Pitt Steel Casting,
598 F.2d 1273 (3d Cir. 1979) 24

Wos v. E.M.A. ex rel. Johnson,
568 U.S. 627 (2013) 10

Zauderer v. Office of Disc. Counsel,
471 U.S. 626 (1985) 20, 21

Statutes

42 U.S.C. § 1320a-7d(b)(4) 9

42 U.S.C. § 1395y(b)(1)(C)(ii) 13, 14

42 U.S.C. § 1320a–7a(a)(5) 7

Other Authorities

42 C.F.R. § 411.161(b)(2)(iv) 14

42 C.F.R. § 1008.15(b) 20

42 C.F.R. § 1008.43 20

42 C.F.R. § 1008.45 4

81 Fed. Reg. 90211 (Dec. 14, 2016) 2

Advisory Opinion 97-1 .... *passim*
Assembly Bill 290 .... *passim*
CAL. CONST. art. IV, § 9(c) 22

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

INTRODUCTION

In their Motion and its supporting Points and Authorities,[1] Plaintiffs showed that Assembly Bill ("AB") 290 is preempted by the federal Beneficiary Inducement Statute, as interpreted in Advisory Opinion 97-1, and egregiously infringes Plaintiffs' First Amendment rights of speech, association, and petition. The State's multi-fold response tries to cast a renowned charity as a villain, ignores critical points (such as the Legislative Counsel's statement that AB 290 forces the American Kidney Fund outside the safe harbor of the Advisory Opinion), attempts to rewrite several of the most offensive provisions of AB 290, and confuses the factual record. With the effective date of AB 290 merely weeks away, a preliminary injunction against enforcement of these offensive provisions is urgently necessary.

BACKGROUND

Plaintiffs Jane Doe, Stephen Albright, American Kidney Fund ("AKF"), and Dialysis Patient Citizens ("DPC") are, respectively, two End Stage Renal Disease patients who rely on grants from AKF to pay premiums for their health insurance coverage, a renowned and respected charity with the mission of fighting kidney disease, and a nonprofit dialysis patient advocacy group. Since 1997, AKF has operated its Health Insurance Premium Program ("HIPP") in strict compliance with the guidelines of Advisory Opinion 97-1, issued by the Office of Inspector General ("OIG") to confirm that, as operated, HIPP does not violate the Beneficiary Inducement Statute. In this case, Plaintiffs challenge AB 290 because it eliminates the safe harbor of the Advisory Opinion, severely represses Plaintiffs' exercise of their First Amendment rights, and will have the effect as of January 1, 2020, of rendering AKF unable to continue the HIPP in California. Each of Plaintiffs' factual predicates is supported by more than ample probative evidence.

---

[1] Notice of Motion and Motion for Preliminary Injunction ("Mot."), Dkt. No. 28.

A. AB 290 Does Not Address The "Problems" It Purports to Concern.

The State contends that AB 290 was "enacted against a backdrop of nationwide concern over dialysis providers and third-party payers inappropriately steering patients onto commercial insurance plans for their own—not the patient's—benefit." Opposition to Motion for Preliminary Injunction ("Opp."), Dkt. No. 46 at 4; *see* AB 290 § 1(i) (asserting that AB 290 is necessary to "protect the sustainability of the [commercial insurance] risk pools," "shield patients from potential harm," and "correct a market failure" favorable to providers).

This assertion lacks probative support. Nowhere in AB 290 itself, the California Senate Committee on Health Report, or the State's Opposition can be found any economic study to prove these claims.

Instead, like the Legislature, the State's brief relies most heavily on the record compiled by the Centers for Medicare and Medicaid Services ("CMS") for an interim final rule unrelated to AB 290, but also purporting to regulate charitable assistance programs, 81 Fed. Reg. 90211 (Dec. 14, 2016). Opp. 4–5. A federal district court enjoined that rule based, in part, on the weakness of the record on which it was based. *See Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *6 (E.D. Tex., Jan. 25, 2017). After the district court's ruling, the agency abandoned further litigation and has not attempted to re-issue the rule. Nor has the OIG taken any action to rescind or terminate Advisory Opinion 97-1 in light of any concerns expressed in the rulemaking. The State also cites to a 2016 newspaper article and a letter from a single Member of Congress, Opp. at 5, 10, both of which AKF contemporaneously rebutted as factually inaccurate. *See* Declaration of Don Roy, Jr. ("Roy Decl.") ¶¶ 15–17; Exhs. A–C.

Though AB 290 identifies "higher health insurance premiums" as one of the evils at which it is directed, *see* AB 290 § 1(e), the legislative record fails to quantify any increase causally related to HIPP, and AB 290 contains no provisions requiring health insurers to refund any purported savings due to the Act to policyholders.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

B. The State Misunderstands Advisory Opinion 97-1.

The State also misunderstands Advisory Opinion 97-1. *First*, the State claims that 97-1 "does not discuss premium payments for commercial insurance or group health coverage." Opp. at 11.[2] Although the OIG naturally focused its opinion on the Federal healthcare programs implicated by the Beneficiary Inducement Statute, the OIG also repeatedly acknowledged that HIPP supports a broader range of insurance types. *See, e.g.,* Plaintiffs' Request for Judicial Notice In Support of the Mot. ("RJN"), Dkt. No. 29-2, Exh. 2 at 21 ("[HIPP] provides financial assistance to financially needy ESRD patients for the costs of . . . health insurance premiums, *including* Medicare Part B and Medigap premiums." (Emphasis added.)).

Second, Advisory Opinion 97-1 is not a snapshot in time of HIPP, as the State implies. *See*, *e.g.*, Opp. at 9 ("The Advisory Opinion examines AKF's practice, in 1997, of paying premiums . . ."). Nor is the 2019 HIPP the "drastic[]" change of which Defendants complain. Opp. at 24; *see also id.* at 10, n.9 & n.10. When it requested the Advisory Opinion, AKF informed the OIG that "AKF proposes to expand significantly its patient assistance grants to financially needy ESRD patients . . . [and] [a]dditional funding will be donated primarily by the [dialysis provider] Companies." RJN, Exh. 2 at 22. Thus, although less than 10 percent of AKF's funding *in 1995* came from large dialysis providers, RJN, Exh. 2 at 21, AKF

---

[2] The State argues, in turn, that AB 290 does not implicate AKF's assistance of Medicare Part B or Medigap premiums. Opp. at 11. But even if AB 290 Secs. 3(d) and 5(d) exclude Medicare and Medigap from the law's disclosure requirements, the concern for patient inducement remains. For 10% of California HIPP recipients, AKF provides premium assistance for *both* private/commercial plans and Medicare or Medigap, and many more Medicare enrollees receive HIPP assistance for just their private/commercial plans. Roy Decl. ¶ 6; *see also, e.g.*, Declaration of Jane Doe ("Doe Decl."), Dkt. No. 26-2, ¶ 14 (noting enrollment in COBRA and Medicare). For any patient with both public and private insurance, knowledge about a provider's donation in support of the commercial plan may present concerns under the Beneficiary Inducement Statute.

specifically alerted the OIG that this was to change "significantly" and the OIG approved that change when it issued Advisory Opinion 97-1.

As the program has expanded in the intervening years—both in terms of participating donors and the tens of thousands of beneficiaries—AKF has *never* veered from the programmatic parameters of Advisory Opinion 97-1. *See* Roy Decl. ¶ 11. To do so risks severe legal, reputational, and financial harm. *Id.* ¶ 13.

Thus, Advisory Opinion 97-1 remains valid and authoritative today and will continue so long as AKF remains within its bounds and the OIG does not rescind or terminate it. *See* RJN, Exh. 2 at 26; *see also* 42 C.F.R. § 1008.45; Roy Decl. ¶ 11 ("HIPP was designed to comply with [Advisory Opinion 97-1], and we have followed it to the letter ever since.").

Indeed, over the intervening two decades since it issued Advisory Opinion 97-1, the OIG has continued to cite Advisory Opinion 97-1 favorably and follow its basic precepts. *See*, *e.g.*, Supplemental RJN, Exh. 4, Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries" (Aug. 2002); *id.*, Exh. 5, Advisory Opinion 03-3 (Feb. 2003). And the programmatic firewalls, approved by Advisory Opinion 97-1 for HIPP, have provided a framework for many other OIG-approved charitable assistance programs. *See*, *e.g.*, *id.*, Exh. 6, Advisory Opinion 14-11 (Dec. 2014) ("Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy patients, including Federal health care program beneficiaries, by contributing to independent, bona fide charitable assistance programs") (emphasis in original); *id.*, Exh. 7, Advisory Opinion 15-16 (Dec. 2015) (same); *id.*, Exh. 8, Advisory Opinion 15-17 (Dec. 2015).

C. The State's Description of HIPP Is Inaccurate.

Finally, the State misunderstands how HIPP operates. For example, AKF has *never* "inappropriately steer[ed] patients onto commercial insurance plans," let alone for its "own—not the patient's—benefit." Opp. at 4. To begin, AKF is a charity

with no financial interest in any insurance transaction. Further, patients come to the HIPP with their own insurance already in place—a prerequisite for them to even qualify for HIPP support—and support is in no way conditioned on their type of coverage. Roy Decl. ¶ 16.

The State also incorrectly asserts that AKF "will not continue to provide financial assistance once a patient receives a successful kidney transplant." Opp. at 5 (quoting the above enjoined rulemaking, 81 Fed. Reg. at 90215). To the contrary, "transplant patients will receive continued support following a transplant for the remainder of their full plan year and, at times when receiving the transplant at the end of their plan year, for a full additional plan year after their procedure." Roy Decl. ¶ 19. Indeed, when the court enjoined the CMS rule, it pointed out: "*Defendants have not provided a single example of a patient denied a kidney transplant because of charitable assistance*." *Dialysis Patient Citizens*, 2017 WL 365271, at *4 (emphasis added). As Plaintiff Jane Doe explains, HIPP is often essential for indigent patients to maintain insurance necessary for a transplant. *See* Doe Decl. ¶ 13.

ARGUMENT

By forcing AKF outside the safe harbor protections of Advisory Opinion 97-1, AB 290 exposes AKF to unacceptable risks of liability under federal law, and is thus preempted. It also infringes Plaintiffs' First Amendment rights. These harms are real, imminent, and supported by a detailed factual record. The State's suggestion that this lawsuit is a "facial challenge" subject to "disfavored" treatment and a heightened standard of review, Opp. at 8, is inaccurate and not supported by reference to Plaintiffs' briefing. *See id.* at 8–9. In fact, Plaintiffs *do not* challenge AB 290 in "all its applications" from a hypothetical posture. *Bucklew v. Precythe*, 139 S. Ct. 1112, 1127 (2019). Rather, Plaintiffs are challenging AB 290's application *to AKF and its activities* in California, on the ground that AKF cannot comply without unacceptably risking violation of federal law and compromising its

and the other Plaintiffs' First Amendment rights. *See, e.g.*, Mot. at 9 (focusing Plaintiffs' merits arguments on the ways in which "AB 290 conflicts with [AKF's] safe harbor in Advisory Opinion 97-1," "Congress's carefully calibrated structure for reimbursement of ESRD treatments," and "Plaintiffs' First Amendment rights to free speech, petition, and association"). Accordingly, this Court need not speculate on the ways in which AB 290 *might* be contrary to federal law or infringe constitutional rights—Plaintiffs have identified numerous concrete ways in which it does so.

Moreover, the courts' usual wariness of facial challenges is much less pressing for First Amendment challenges because vague and overbroad laws may chill protected expression. *See Massachusetts v. Oakes*, 491 U.S. 576, 581 (1989); *Roulette v. City of Seattle*, 97 F.3d 300, 303 (9th Cir. 1996). Thus, a speech-regulating statute with some "plainly legitimate sweep" may nonetheless fail a facial challenge under the First Amendment if "a [relatively] substantial number of its applications are unconstitutional." *Puente Arizona v. Arpaio*, 821 F.3d 1098, 1104 (9th Cir. 2016) (quoting *United States v. Stevens*, 559 U.S. 460, 473 (2010)).

Finally, and in any event, Plaintiffs need not "prove [their] case in full" to justify preliminary relief. *Harmon v. City of Santa Cruz*, 271 F. Supp. 3d 1031, 1041 (N.D. Cal. 2017) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). Rather, "[t]he purpose of a preliminary injunction is to preserve the status quo and the rights of the parties until a final judgment on the merits can be rendered." *Disney Enters., Inc. v. VidAngel, Inc.*, 224 F. Supp. 3d 957, 965 (C.D. Cal. 2016) (quoting *U.S. Philips Corp. v. KBC Bank N.V.*, 590 F.3d 1091, 1094 (9th Cir. 2010)). For the reasons given in their Motion and below, Plaintiffs have made that showing.

I. Plaintiffs Are Likely to Succeed on the Merits.

A. AB 290 Is Preempted by Federal Law.

AB 290 is preempted by federal law in two respects. *First*, by forcing AKF to operate outside of the careful guidelines of Advisory Opinion 97-1, AB 290 forces

AKF to choose between complying with California law and risking a violation of the federal Beneficiary Inducement Statute, 42 U.S.C. § 1320a–7a(a)(5), and leaving California entirely to avoid such a risk. *Second*, AB 290 poses an obstacle to achieving the purposes of the Medicare Secondary Payer Act ("MSPA"), because it interferes with the delicate shared public/private partnership Congress envisioned for ESRD patients, including by requiring that group insurers treat ESRD patients receiving HIPP premium assistance differently from those non-ESRD patients who receive no such assistance.

Instead of grappling with these issues, the State shadowboxes with arguments that Plaintiffs do not advance. In doing so, the State mischaracterizes HIPP and Advisory Opinion 97-1, and misstates AB 290's impact on both.

1. *AB 290 Is Preempted by the Beneficiary Inducement Statute.*

In the Motion, Plaintiffs established that AB 290 requires AKF to operate outside the safe harbor of Advisory Opinion 97-1. Most notably, AB 290 requires AKF to disclose the names of HIPP beneficiaries to insurers so that those insurers can then impose lower reimbursement rates on dialysis providers, an arrangement that will lead to patients knowing, though their billing statements, whether their particular provider has given to AKF. *See* Mot. at 10–11. That weakens the relevant "insulation so that the premium payments [will] not be attributed to [providers]," RJN, Exh. 2 at 24. AB 290 also requires AKF to treat different categories of HIPP beneficiaries differently. These requirements place AKF at grave legal risk under the Beneficiary Inducement Statute.[3]

Indeed, as Plaintiffs observed, the State's own Legislative Counsel Bureau reached the same conclusion: "the changes in the premium assistance program

---

[3] *See* 42 U.S.C. § 1320a–7a(a)(5) (providing for civil penalties against whomever "offers to or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid]").

required by AB 290 would remove the legal protection afforded by Opinion 97-1." RJN, Exh. 3 at 33; *see id.* (The "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."). Remarkably, the State never even acknowledges, much less denies, this pre-litigation admission from an authoritative State agency.[4]

In response to Plaintiffs' arguments about Advisory Opinion 97-1, the State contends, first, that Advisory Opinion 97-1 does not impose requirements with the force of federal law and thus cannot preempt AB 290. Opp. at 9–11. This argument is beyond odd, since the State recognizes just pages later, in connection with Section 7 of AB 290, that if AKF were to seek a new opinion from the OIG and if "that opinion says that AKF cannot comply with both AB 290 and federal law, [AB 290's] provisions *will never go into effect as to AKF at all*." Opp. at 22 (emphasis added); *see* AB 290 § 7. In other words, if AKF seeks a revised Advisory Opinion, AB 290 cannot go into effect unless and until the OIG changes the Advisory Opinion to accommodate AB 290. This concession confirms exactly what Plaintiffs have been saying: *as it stands now,* AB 290 is in irreconcilable conflict with Advisory Opinion 97-1 and only by improperly coercing AKF into seeking a change in that opinion can the State hope that AKF could comply both with the terms of a new Advisory Opinion and with AB 290. *See* pp. 19–20 below.

The Legislature recognized this very problem, but its effort to solve it by purporting to require AKF to seek a change in the Advisory Opinion does not cure the preemption problem. As Plaintiffs explained, Mot. at 12, the Supreme Court soundly rejected this approach in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011),

---

[4] As previously noted (Mot. at 11–12 n.4), the Legislative Counsel Bureau inexplicably concluded that AKF "would remain in compliance with the arrangement approved in Advisory Opinion 97-1," but this conclusion is unsustainable in light of its other determinations. RJN, Exh. 3 at 36. Even so, the Legislative Counsel Bureau conceded that AKF's compliance with the Advisory Opinion "would be a factual determination made by the OIG and could involve a consideration of facts not available to" the Legislative Counsel Bureau. *Id.* at 35.

1 stating "[t]he question for 'impossibility' is whether the private party could
2 independently do under federal law what state law requires of it." There, in the
3 context of Food and Drug Administration ("FDA") labeling requirements, the Court
4 rejected the State's precise theory:

> 5 We can often imagine that a third party or the Federal Government
> 6 might do something that makes it lawful for a private party to
> 7 accomplish under federal law what state law requires of it. In these
> 8 cases, it is certainly possible that, had the Manufacturers asked the FDA
> 9 for help, they might have eventually been able to strengthen their
> 10 warning label. Of course, it is also possible that the Manufacturers
> 11 could have convinced the FDA to reinterpret its regulations in a manner
> 12 that would have opened the CBE process to them. Following
> 13 [plaintiffs'] argument to its logical conclusion, it is also possible that,
> 14 by asking, the Manufacturers could have persuaded the FDA to rewrite
> 15 its generic drug regulations entirely or talked Congress into amending
> 16 the Hatch–Waxman Amendments.
>
> 17 If these conjectures suffice to prevent federal and state law from
> 18 conflicting for Supremacy Clause purposes, it is unclear when, outside
> 19 of express pre-emption, the Supremacy Clause would have any force.

20 *Id.* at 620–21.

21 *PLIVA*'s reasoning applies with full force here, and the State simply ignores
22 it. It also ignores that, under pertinent federal regulations governing Advisory
23 Opinions, AKF cannot seek the revised Advisory Opinion. *See* pp. 19–20 below.

24 More fundamentally, the State ignores that Advisory Opinion 97-1 is a
25 considered and authoritative statement of the views of the OIG, the agency
26 empowered to enforce the Beneficiary Inducement Statute, regarding the meaning
27 of that statute. *See* 42 U.S.C. § 1320a-7d(b)(4) ("Each advisory opinion issued by
28 the Secretary shall be binding as to the Secretary and the party or parties requesting

the opinion."). Advisory opinions would have little purpose otherwise.[5]

Through Advisory Opinion 97-1, the OIG has laid out the conditions under which HIPP does not trigger liability under the Beneficiary Inducement Statute. By forcing AKF outside of this safe harbor, AB 290 necessarily contravenes the OIG's deference-worthy views of the steps AKF must take to avoid risking liability under federal law.

The State attempts to refute preemption by relying on several decisions addressing not preemption, but *Chevron* deference to agency decision-making. *See Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (discussing "*Chevron*-style deference"); *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000) (also discussing "*Chevron*-style deference"); *United States v. Mead Corp.*, 533 U.S. 218, 233–34 (2001) (also discussing *Chevron* deference). Indeed, the word "preemption" does not even appear in either *Christensen* or *Mead*, and *Wos* actually held that a state statute *was preempted* by the federal Medicaid statute, thus undercutting the State's argument against preemption. *See Wos*, 568 U.S. at 644.

2. *AB 290 Pushes AKF's Program Outside of Advisory Opinion 97-1.*

As shown, Mot. at 10–11, AB 290 conflicts with Advisory Opinion 97-1 because it causes AKF to disclose which Providers support HIPP to beneficiaries and requires AKF to treat beneficiaries differently. The State's argument that

---

[5] Though the context is different, courts afford deference to agency advisory opinions when those opinions both construe the federal statute and opine that the statute preempts state law. *Cf. South Pacific Trans. Co. v. Public Serv. Comm'n of Nev.*, 909 F.2d 352, 356–59 (9th Cir. 1990) (holding that federal agency "Inconsistency Ruling" regarding preemption of state law was "deserving of substantial deference" and finding state law preempted); *Cline v. Hawke*, 51 F. App'x 392, 397 (4th Cir. 2002) (affording federal agency preemption letter *Skidmore* deference and holding state statute preempted on that basis); *Teper v. Miller*, 82 F.3d 989, 996-97 (11th Cir. 1996) (holding that "we are obliged to take the [the federal agency's] interpretation as more than merely convincing," such that "[a]ny residual ambiguity as to the [agency's] understanding of the preemptive effect of [the federal statute] on the Georgia statute is conclusively resolved by [the agency's] advisory opinions").

Advisory Opinion 97-1 does not conflict with AB 290, Opp. at 11–12, is both at odds with the pre-litigation statement of the Legislative Counsel and is predicated on a series of misunderstandings of both Advisory Opinion 97-1 and AB 290.

The State initially confuses matters by observing that Advisory Opinion 97-1 "does not discuss premium payments for commercial insurance or group health coverage." *Id.* at 11. But the Advisory Opinion plainly states that HIPP "provides financial assistance to financially needy ESRD patients for the costs of medicine, transportation, and health insurance premiums, including Medicare Part B and Medigap premiums." RJN, Exh. 2 at 21; *see id.* at 22 ("AKF proposes to expand significantly its patient assistance grants to financially needy ESRD patients for payment of medical insurance premiums through HIPP."). Nothing in the Advisory Opinion supports the State's crabbed reading.

The State next suggests that patients "would only *potentially* learn that their provider is a HIPP donor." Opp. at 12 (emphasis in original). The State recognizes that AB 290 will change HIPP patients' billing statements in ways that will disclose whether or not their provider gave to AKF. *See id.* For ESRD patients on dialysis, however, their medical bills for dialysis—the procedure that literally determines how and for how long they will live—are among, if not the, most important bills they receive. *See, e.g.*, Doe Decl. ¶¶ 16–17; Declaration of Stephen Albright ("Albright Decl."), Dkt. No. 28-3, ¶¶ 11–13. It is not, as the State claims, "purely speculative," Opp. at 12, to conclude that these patients will see what is plain before their eyes. Nothing requires this Court to ignore its "experience and common sense" when evaluating Plaintiffs' claims. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

The breach of the patient information firewall is not the only way in which AB 290 forces AKF outside of Advisory Opinion 97-1. AKF also committed to the OIG that "assistance [would be] available to all eligible patients on an equal basis." RJN, Exh. 2 at 21. Yet AB 290 creates tiers of California patients among those who

are "grandfathered," not grandfathered, and formerly grandfathered.[6] It also forces AKF to treat beneficiaries in California differently from those in other States. The State does not even discuss these breaches, even though they alone are sufficient for the OIG to rescind the Advisory Opinion. *See id.* at 8.

The stakes of AB 290 could not be higher for AKF. If a party acts outside of the certifications it made during the advisory opinion process, that party will lose the protection of the advisory opinion it operated under, a consequence made clear by the OIG's recently rescission of Advisory Opinion 06-04. *See* Notice of Rescission of Advisory Opinion 06-04 (removing advisory opinion protection for charity providing co-payment support to Medicare patients via donations by pharmaceutical manufacturers).[7] In that rescission statement, OIG explained that the factual certifications made by the charity in requesting its advisory opinion "were material to [the OIG's] determination . . . that the arrangement interposed an independent, *bona fide*, charitable organization between donors and patients." *Id.* Once those certifications were gone, the OIG found that there was a "material[] increase[] [in] the risk that [the charity] served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from Requestor would be steered to federally reimbursable drugs that the manufacturer donor sold." *Id.* In light of these concerns, the OIG then rescinded Advisory Opinion 06-04 retroactively to the original date of its issuance. *Id.*

Unsurprisingly, the rescission proved catastrophic for the charity involved, which was forced to cease operating.[8] Here, it is not the State that will bear the

---

[6] *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).

[7] *See* Supp. RJN, Exhs. 9 (Notice of Rescission) and 10 (Advisory Opinion 06-04).

[8] *See* http://www.caringvoice.org/.

consequences of its gamble that AB 290 can coexist with federal law. It is AKF, a charitable organization which has everything—its 50-year reputation, finances, and mission—at stake, and those consequences are passed down to the patients throughout the country who rely on HIPP support for survival. The impossible dilemma that California has presented to AKF—asking it to adhere to an unconstitutional state law that would require taking potentially fatal risks under federal law—requires preemption.

3. *AB 290 Presents a Significant Obstacle to the Goals of the Medicare Secondary Payer Act.*

Plaintiffs also showed that AB 290 fails due to *obstacle* preemption because it creates a significant obstacle to achieving the goals of the Medicare Secondary Payer Act ("MSPA"). Mot. at 14; *see Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (finding preemption where the law creates an obstacle to the "accomplishment and execution of . . . important means-related federal objectives"). The State misconstrues this argument, contending that Plaintiffs have failed to show *impossibility* preemption. Opp. at 2 ("Plaintiffs also contend that they cannot comply with both AB 290 and the [MSPA]").[9] By misconstruing the argument, the State fails to rebut it.

The State also inaccurately describes how the MSPA interacts with AB 290 in two ways. *First*, according to the State, "AB 290 treats all patients with ESRD equally." Opp. at 15. But even if true, this assertion is irrelevant because the MSPA does not ask whether the insurer is differentiating among *ERSD* patients, but rather whether the insurer is differentiating between ESRD patients and *non-ESRD* patients. 42 U.S.C. § 1395y(b)(1)(C)(ii) (group health plans "may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage

[9] Indeed, no Plaintiff is a "group health plan" governed by the MSPA. *See* 42 U.S.C. § 1395y(b).

renal disease, the need for renal dialysis, or in any other manner"). In the MSPA, Congress recognized the high cost of dialysis and granted protection to ESRD patients to prevent insurers and others from discriminating against them. On its face, however, AB 290 treats ESRD patients receiving HIPP premium assistance differently from patients, including ESRD patients, who receive no assistance, requiring disclosure of HIPP recipients' names and imposing lower payment rates for treatments received by HIPP recipients. *See* AB 290 §§ 3(c), 3(e), 5(c), 5(e).

Second, the State misses the obstacle AB 290 poses to the MSPA. That obstacle results from AB 290's treatment of patients with ESRD (necessarily all HIPP recipients) differently from patients without ESRD—again reimbursing providers at lower rates for the provision of services for the former. AB 290 §§ 3(e), 5(e). This violates the MSPA's nondifferentiation requirements. 42 U.S.C. § 1395y(b)(1)(C)(ii); *see also* 42 C.F.R. § 411.161(b)(2)(iv). The violation is made clear by decisions cited *by the State*. *See, e.g.*, *Nat'l Renal All., LLC v. Blue Cross & Blue Shield of Ga., Ind.*, 598 F. Supp. 2d 1344, 1354 (N.D. Ga. 2009) ("Significant to the court's finding is the fact that there is no allegation that Blue Cross pays a different amount for dialysis treatment of non-ESRD patients than ESRD patients").[10]

B. AB 290 Tramples Plaintiffs' First Amendment Rights.

As explained in Plaintiffs' Motion, *see* Mot. at 14–22, AB 290 targets AKF with extensive, content-based speech mandates and restrictions, burdens its right to associate in pursuit of its mission of fighting kidney disease, and attempts to coerce it to file a petition with the OIG to obtain a new Advisory Opinion. The numerous burdens on protected speech and association strongly resemble, but are far more

[10] The State fails to note that two of the decisions it cites are on appeal. *See DaVita Inc. v. Marietta Mem'l Hosp. Employee Health Benefit Plan,* No. 2:18-CV-1739, 2019 WL 4574500 (S.D. Ohio Sept. 20, 2019), *appeal docketed*, 19-4039 (6th Cir., Oct. 23, 2019); *DaVita Inc. v. Amy's Kitchen, Inc.*, 379 F. Supp. 3d 960, 973 (N.D. Cal. 2019), *appeal docketed*, No. 19-15963 (9th Cir. May 6, 2019).

1 extensive than, those in *National Institute of Family and Life Advocates v. Becerra*
2 (*NIFLA*), 138 S. Ct. 2361 (2018), in which the Supreme Court reversed the denial of
3 preliminary relief against another California law, *see id.* at 2370. The more
4 extensive burdens here require preliminary injunctive relief.

5 **1. *AB 290's Content and Speaker-Based Speech Restrictions Offend the***
6 ***First Amendment.***

7 As shown, Mot. at 19, AB 290 compels AKF to "notify" each "enrollee" (§§
8 3(b)(1), 5(b)(1)), "applicant," and "recipient" (§§ 3(b)(3), 5(b)(3)), of "alternative
9 coverage options," and of "all available health coverage options, including but not
10 limited to, Medicare, Medicaid, individual market plans, and employer plans, if
11 applicable." As a matter of policy AKF does not currently provide this information.
12 AB 290 would require it to do so, however, but then would prohibit AKF from
13 "steer[ing], direct[ing], or advis[ing]" those persons to specific coverage options. *Id.*
14 § 2(a). AB 290 would also compel AKF to disclose to each insurer "the name of the
15 enrollee for each health care service plan contract" on whose behalf a premium
16 payment "will be made." *Id.* §§ 3(c)(2), 5(c)(2). It would compel AKF to provide
17 an annual statement to each insurer that it meets all the requirements set forth in §§
18 3(b) and 5(b).

19 The State cannot deny that these are restrictions on content or that they target
20 disfavored speakers. Instead, it tries to minimize their effect and equate them to
21 economic regulations and disclosure requirements. This effort fails.

22 *Compelled speech about healthcare options and names of beneficiaries*. The
23 State attempts to equate the compelled speech about "all available health care
24 options" and providing names of all beneficiaries to the insurers to efforts to combat
25 misleading attorney advertising about debt relief services. Opp. at 15 (citing
26 *Milavetz, Gallop & Milavetz v. United States*, 559 U.S. 299, 250 (2010)). This case
27 is very different from *Milavetz,* however. AKF does not advertise health coverages,
28 it receives no financial benefit from whichever coverage the patient chooses, and it

receives applications for benefits from patients who already have a policy in effect. As AKF President and CEO LaVarne A. Burton averred, "Patients choose their health insurance coverage *with no input from AKF*." Declaration of LaVarne Burton ("AKF Decl."), Dkt. No. 28-2, ¶ 41(h) (emphasis added).[11] A further difference between this case and *Milavetz* is that the attorney advertisers could stop advertising at any time and avoid regulation, whereas AB 290 *both* requires AKF to speak *and* tells it what it must say.

The State tries to distinguish *NIFLA* on the ground that, unlike *Milavetz* and this case, the information in *NIFLA* was not "purely factual and noncontroversial," Opp. at 16 (quoting *NIFLA*, 138 S. Ct. at 2372). The information in *NIFLA*, like that here, concerned state services, and like here some of the state programs were controversial (here, in their scope of coverage). The State also objects that it "has no way to identify patients receiving premium payments," and thus cannot notify them itself. Opp. at 16. Nor in *NIFLA* could the State know all women who might be pregnant. The Court's suggestion that the State could deliver its own message about alternatives did not imply that the message would be delivered on a person-to-person basis but rather as part of "a public-information campaign" or by posting "the information on public property near crisis pregnancy centers." 138 S. Ct. at 2376.

Restrictions on "advis[ing]" patients regarding insurance options. Having compelled AKF to deliver the State-preferred message to applicants regarding "all available health care options," AB 290 then prohibits AKF from "advising" them "regarding" those options. First, the State points to AKF's statement that it does not discuss coverage options with patients, Opp. at 17–18, but of course AB 290 would *force* it to do so. Next, the State attempts to rewrite the provision as limited to "curtailing the ability of financially interested entities to tell patients they should

[11] The State points to a page from AKF's website, Medley Decl. at Exh. 3 at 2, which generically lists the types of plans AKF helps to fund, such as "Commercial plans (including Marketplace plans)," "Employer group health plans," and "COBRA plans." This citation does not refute or minimize Ms. Burton's testimony.

choose one insurance option over another"—but that is a definition of "steering" or perhaps "directing," not "advising." In short, even if there were a justification for prohibiting AKF from "steering" or "directing," and Plaintiffs have shown there is not, the State has advanced no basis to preclude AKF from "advising" patients by providing potentially helpful information about the very complex maze of health coverage options. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577 (2011) (striking down limits on use of prescriber identifying information; "the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech.") (citation omitted). *See also* Reply Brief of Fresenius Plaintiffs at § I.A, *Fresenius Med. Care Orange Cty. v. Becerra et al.*, No. 8:19-cv-02130, Dkt. No. 51.

Certification of compliance with requirements. Having imposed extensive speech mandates and restrictions on AKF, sections 3(c)(1) and 5(c)(1) require AKF annually to certify compliance, not to the State, but to the "health care service plan" or "health insurer." It justifies this provision as "simply a mechanism to ensure compliance" with AB 290. Notably, each of the decisions cited by the State addresses reporting obligations to the government or to the public generally, not to a financially interested private party (here, the insurers who have a financial interest in minimizing reimbursement for dialysis, and who get a "bounty" for reporting violations).

2. *AB 290 Imposes Extreme Burdens on the Right of Association.*

Compounding the burden on Plaintiffs' First Amendment rights, AB 290 restricts their right of association in fundamental ways. Mot. at 19–20. The State suggests that AKF has no right of association with HIPP beneficiaries or providers. This is simply wrong. They are all joined in the fight against kidney disease, and that is why they are subject to AB 290's onerous terms. *See* AB 290 §§ 1(a), (h); *see also Santopietro v. Howell*, 857 F.3d 980, 989 (9th Cir. 2017) (First Amendment's association protections extend to the common "pursuit of a wide

1 variety of political, social, economic, educational, religious, and cultural ends."
2 (quoting *Roberts v. U.S. Jaycees*, 468 U.S. 609, 622 (1984)); *cf. Santa Barbara*
3 *Patients' Collective Health Co-op. v. City of Santa Barbara*, 911 F. Supp. 2d 884,
4 896 (C.D. Cal. 2012) (holding that restrictions on membership in a medical
5 marijuana collective infringed on the First Amendment right to association).

6 These restrictions on association are numerous. First, AB 290 requires AKF
7 to abandon its mission of fighting kidney disease and become an "all purpose"
8 medical charity. Section 3(b)(2) states that AKF must "agree not to condition
9 financial assistance on eligibility for, or receipt of, any surgery, transplant,
10 procedure, drug, or device." *See also* § 5(b)(2) (same). This language is clear: AKF
11 cannot focus HIPP on persons needing dialysis (a "procedure") or a kidney
12 "transplant." The State attempts to salvage the provision by creatively construing it
13 as intended "to prevent harmful practices such as withdrawing premium assistance
14 when a patient receives a kidney transplant." Opp. at 20. But that is simply not what
15 the statute says. When "interpreting a statute, we begin with its text"—"the ordinary
16 meaning of the language in question"—"as statutory language typically is the best
17 and most reliable indicator of the Legislature's intended purpose." *Larkin v.*
18 *Workers Comp. Appeals Bd.*, 358 P.3d 552, 555 (Ca. 2015). The Legislature could
19 very easily have written a provision that prohibited AKF from withdrawing
20 assistance following a transplant. And even if that were the intention, there is no
21 evidence (or logic) suggesting that HIPP interferes with access to kidney transplants.
22 Indeed, the evidence overwhelmingly shows that continuation of insurance
23 coverage, such as that provided by HIPP, is instrumental for patients to remain on
24 kidney transplant lists and that AKF continues premium assistance for a discrete
25 period after the transplant during the patients' recovery period. AKF Decl. ¶¶ 14,
26 19, 22, 27; Roy Decl. ¶ 7.

27 AB 290 also subjects any and all contributors to AKF, regardless of the
28 amount or intention, to a dramatic reduction in reimbursement. *See* §§ 3(h)(2)(A),

1 5(h)(1)(A) (defining "financially interested" provider); *see also* §§ 3(e)(1)–(2),
2 5(e)(1)–(2) (reimbursement reduction applies to any financially interested provider
3 that "has a financial relationship [such as by a donation] with the entity making the
4 third-party premium payment"). As shown, Mot. at 19–20, such a burden on
5 contributions directly impinges on the right of association. The State's response is
6 that the reimbursement reduction is "not a penalty imposed on dialysis providers
7 because of their financial support of AKF," but rather "a cap on commercial
8 insurance reimbursement rates." Opp. at 21. This explanation does not pass the
9 straight face test. Non-donor providers continue to receive higher reimbursement,
10 whereas only donor providers suffer the reduction as a direct consequence of their
11 donations.

12 AB 290 interferes with AKF's association with HIPP beneficiaries, including
13 Plaintiffs Doe and Albright, by requiring AKF to reveal confidential information
14 about HIPP beneficiaries, and restricting communications among them. The State
15 inaccurately contends that AKF has no associational rights with HIPP beneficiaries,
16 notwithstanding that they are unified in their efforts to fight kidney disease. Finally,
17 AB 290 burdens the right of HIPP beneficiaries to associate with the providers of
18 their choice by reducing the reimbursement rates payable on their behalf to any
19 provider that donates to AKF.

20 **3. *AB 290 Burdens the Right of Petition.***

21 As shown, Mot. at 20–21, Section 7 of AB 290 pressures AKF to file a petition
22 with the OIG for a new Advisory Opinion. That provision embodies a recognition,
23 which the State's Opposition strongly confirms, that AB 290 is preempted by federal
24 law, and can become effective only if Advisory Opinion 97-1 is set aside. The State
25 rejoins that the Section 7 petition is but an "option," not "coercion." Opp. at 22–23.
26 If AKF does not file the petition, however, it will be subject to an array of speech
27 and financial burdens. It is fiction to suggest that the petition is merely an option
28

when AB 290 creates such clear detriment to not filing—leaving AKF with no choice but to leave California.

The State also denies that the content of the petition would constitute compelled speech, because, it says, "AKF could phrase the request as seeking a finding that 'complying with the requirements of AB 290 would require it to violate federal law." Opp. at 23. But under the regulations governing Advisory Opinions, AKF cannot do that. AKF must certify under 42 C.F.R. § 1008.43 that it in good faith intends to follow AB 290's scheme. AKF cannot and will not make that certification. *See* Mot. at 13; AKF Decl. ¶ 49. Moreover, the advisory opinion process is not designed to require the OIG to opine on whether a state law forces violation of federal law. *See* 42 C.F.R. § 1008.15(b) ("Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.").

4. *The Restrictions Cannot Pass Any Level of Scrutiny.*

Restrictions, like the ones here, that target both the content of speech and particular speakers are subject to strict scrutiny. *See, e.g.*, *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226–27 (2015) (content restrictions); *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 658 (1994); *see also Citizens United v. FEC*, 558 U.S. 310, 340 (2010) ("Speech restrictions based on the identity of the speaker are all too often simply a means to control content."). Notably, the State makes no effort to justify the restrictions under strict scrutiny, nor could it. It cites no *compelling interest* to justify the restrictions, and makes no effort to defend them as *narrowly tailored.*

Instead, the State contends the restrictions are "reasonably related" to achieving a State interest. Opp. at 15. This is the same lenient standard the State advocated—unsuccessfully—in *NIFLA*.[12] Because, just as here, those restrictions

[12] In *NIFLA*, the State relied on *Zauderer v. Office of Disc. Counsel*, 471 U.S. 626 (1985), on which *Milavetz* relied, 559 U.S. at 249–50. *See NIFLA*, 138 S. Ct. at 2372 (explaining that the Supreme Court "ha[s] applied a lower level of scrutiny to laws that compel disclosures in *certain contexts*," including commercial

1 were content-based and directed at a particular group, the Supreme Court held that
2 each restriction could not survive even the modest scrutiny the State seeks here. *See*
3 *NIFLA*, 138 S. Ct. at 2375 ("[T]he licensed notice cannot survive even intermediate
4 scrutiny."); *id.* at 2377 (Even under the more lenient *Zauderer* standard, the
5 unlicensed notice "imposes a government-scripted, speaker-based disclosure
6 requirement that is wholly disconnected from California's informational interest.").
7 And, the Court noted in *NIFLA*, the restrictions were "wildly underinclusive" to
8 serve the State's purported interest in informing low income women about
9 pregnancy-related services. 138 S. Ct. at 2375. Likewise here, AB 290 targets a
10 renowned charity with extensive compelled disclosures and speech restrictions, but
11 leaves the financially interested health insurance industry free to "steer, direct, and
12 advise" as its profit motive demands.

13 Finally, as shown, the evil at which the statute is addressed does not exist.
14 Beneficiaries come to AKF with policies in hand; AKF does not steer them to
15 particular policies. AKF Decl. ¶¶ 12, 16, 25; Roy Decl. ¶ 16. Moreover, the effect
16 of the 1,758 commercial policies funded by HIPP, Opp. at 3, on the massive
17 California insurance market is *de minimis*. And the prospect of any substantial
18 impact of AB 290 on the California insurance market is both speculative and
19 illusory. Mot. at 22. Considered against the sweeping restrictions on speech and
20 association, these purported interests simply do not carry sufficient weight.

21 **II. AB 290 Will Cause Immediate, Irreparable Harm.**

22 As shown, AB 290 puts AKF at unacceptable risk of violating the Beneficiary
23 Inducement Statute, and immediately infringes Plaintiffs' First Amendment rights.
24 The result is that AKF cannot continue to offer HIPP in California. The State
25 responds by arguing that (1) there is no emergency because, except for the "anti-
26 steering provisions" applicable to the Provider Plaintiffs, AB 290 does not go into
27 effect on January 1, 2020, *see* Opp. at 23–24, and that (2) AB 290 will not irreparably
28

advertisements stating "the terms under which . . . services will be available" (emphasis added, quoting *Zauderer*, 471 U.S. at 651)).

harm AKF, its donors, and its HIPP beneficiaries, *see* Opp. at 24. Neither point is persuasive.

Contrary to the State's assertion, AB 290 begins to inflict injury on Plaintiffs on January 1, 2020. *See* CAL. CONST. art. IV, § 9(c) ("[A] statute enacted at a regular session shall go into effect on January 1 next following a 90-day period from the date of enactment . . . ."). *First*, because AB 290—and AKF's own charitable commitments—require AKF to "provide assistance" for a "full plan year," *id.* §§ 3(b)(1), 5(b)(1), Roy Decl. ¶¶ 7, 21, any policies AKF places after January 1, 2020 must continue in effect for the entire plan year, beyond July 1, 2020. *Second*, under the Act's "grandfathering" provisions, any patients who receive HIPP assistance from AKF as of *October 1, 2019* and change health insurance plans after *March 1, 2020* are covered by the Act.[13] *See* AB 290 §§ 3(d)(2), 5(d)(2). Thus, although Section 7 of AB 290 states that "Sections 3 to 6" of the Act "become operative on July 1, 2020," AB 290 § 7, policies placed into effect long before that become immediately subject to the Act. *Third*, AB 290 immediately deters providers from donating to AKF. The State cannot deny that any provider who donates any amount to AKF at any time enters into a "financial relationship" and is thus subject to the draconian reduction in reimbursement. *See* AB 290 §§ 3(e)(1)–(2), 5(e)(1)–(2). Since AB 290 places no time restriction on those donations, the immediate and intended effect will be for providers to cease donating to AKF.

Moreover, to the degree that there is any uncertainty regarding the effective date of AB 290, AKF must err on the side of caution to protect its ability to fulfill its nationwide half-century-old charitable mission. Indeed, even under the State's interpretation of the Act, if a patient receiving HIPP assistance before October 1, 2019 changes insurance after March 1, 2020, AKF must comply with the disclosure

[13] The State notes that patients receiving HIPP assistance as of October 1, 2019 will be grandfathered, Opp. at 23, but neglects to mention that if those patients change insurance after March 1, 2020, AKF must "comply with the disclosure requirements" as to those patients nonetheless. AB 290 §§ 3(d)(2), 5(d)(2).

1 requirements as of July 1, 2020 at the latest for the rest of that plan year.[14] *See* Opp.
2 at 23. AKF cannot withdraw assistance from HIPP beneficiaries after January 1,
3 2020 without violating AB 290 because AKF must provide coverage for a "full plan
4 year" AB 290 §§ 3(b)(1), 5(b)(1). In turn, AKF cannot comply with the disclosure
5 requirements because doing so removes AKF from the safe harbor of Advisory
6 Opinion 97-1, *see* pp. 7–12 above.

7 Therefore, AKF must cease operations in the state as of January 1, 2020 if AB
8 290 goes into effect. To do anything else risks liability under AB 290 and running
9 afoul of the protection of Advisory Opinion 97-1. This is not the self-inflicted
10 wound that the State intonates—the harm AKF seeks to avoid is solely and directly
11 attributable to the State. *See Hernandez v. Lynch*, No. EDCV 16-00620-JGB (KKx),
12 2016 WL 7116611, at *29 n.30 (C.D. Nov. 10, 2016) (rejecting argument that
13 plaintiffs' harm was "self-inflicted" and a result of plaintiffs' choices because the
14 unconstitutional practices plaintiffs alleged were ultimately "attributable to
15 [d]efendants"). AKF consistently represented to the State during the legislative
16 process that compliance with AB 290 takes it outside Advisory Opinion 97-1's safe
17 harbor, Roy Decl. ¶ 23, and the Legislative Counsel itself concluded as much. *See*
18 RJN, Exh. 3 at 33 (noting that AB 290 "remove[s] the legal protections afforded by
19 Opinion 97-1").

20 Plaintiffs will suffer immediate and irreparable harm in two ways. *See* Mot.
21 at 22–24. To begin, "a colorable First Amendment claim" alone is "sufficient" to
22 demonstrate irreparable harm. *Sammartano v. First Judicial Dist. Court*, 303 F.3d
23 959, 973–74 (9th Cir. 2002), *abrogated on other grounds by Winter*, 555 U.S. 7.

24 Moreover, the conflict between AB 290 and federal law means that AKF
25 cannot continue to operate in California, thereby doing lasting and irreversible
26 damage to AKF and the patients, such as Plaintiffs Doe and Albright, that it serves.
27
28

[14] As shown, the State cannot require AKF to petition OIG, and especially cannot require AKF seek a determination that "complying with the requirements of AB 290 would require it to violate federal law." *See* above, pp. 19–20; Mot. at 23.

See Beltran v. Myers, 677 F.2d 1317, 1322 (9th Cir. 1982), above pp. 12–13. Patients who lose HIPP assistance will likely be unable to afford their current health insurance. Doe Decl. ¶ 16; Albright Decl. ¶ 11; DPC Decl. ¶ 15. This fact alone suffices to show irreparable injury. *See* Mot. at 23; *Beltran*, 677 F.2d at 1322 (showing irreparable injury where "enforcement of the California rule may deny them needed medical care"); *United Steelworkers of Am. v. Fort Pitt Steel Casting*, 598 F.2d 1273, 1280 (3d Cir. 1979) ("[T]he possibility [of being] denied adequate medical care as a result of having no insurance [is an irreparable injury]"). But it is hardly the only injury vulnerable ESRD patients will incur. Plaintiffs and other ESRD patients will also be subjected to increased anxiety about their medical expenses and, in some cases, will have life-saving kidney transplants delayed or possibly denied altogether. Mot. at 23; Doe Decl. ¶ 17; Albright Decl. ¶ 13; DPC Decl. ¶¶ 18–19, AKF Decl. ¶ 22. These harms are especially acute given the nature of ESRD and the demographics it afflicts. ESRD has no early signs or symptoms, AKF Decl. ¶ 14, Roy Decl. ¶ 16, and disproportionately afflicts historically marginalized racial and ethnic minorities, AKF Decl. ¶ 23. More than 80% of dialysis patients are unemployed. AKF Decl. ¶ 21. And because the need for dialysis treatment is ongoing, no retroactive relief could ever restore Plaintiffs once their treatment is jeopardized.

The State does not meaningfully contest *whether* these harms will occur, or even dispute that a preliminary injunction avoids them. Instead, it merely avers that these harms are "not so imminent" as to warrant preliminary relief. Opp. at 23. But thousands of dialysis patients will be without premium assistance the moment AKF is forced to leave California on January 1, 2020. And in any event, there is no requirement that a court consider *only* the most immediate effects in determining whether an injury is irreparable. *See, e.g.*, *Harris v. Bd. of Supervisors, Los Angeles Cty.*, 366 F.3d 754, 757, 766–67 (9th Cir. 2004) (upholding finding of irreparable injury where the harm would be felt over a "two-year period"). Plaintiffs have

1 carried their burden of demonstrating irreparable harm.

2 **III. The Equities and Public Interest Favor an Injunction.**

3 As shown, *see* Mot. at 24–25, the final two *Winter* factors weigh heavily in
4 Plaintiffs' favor. When the State is the opposing party in a preliminary injunction
5 motion, the last two *Winter* factors merge. *See Nken v. Holder*, 556 U.S. 418, 435
6 (2009). "[I]t is clear that it would not be equitable or in the public's interest to allow
7 the state . . . to violate the requirements of federal law, especially when there are no
8 adequate remedies available." *Arizona Dream Act Coalition v. Brewer*, 757 F.3d
9 1053, 1069 (9th Cir. 2014). That is exactly the case here. AB 290 violates the First
10 Amendment and requires AKF to engage in activities that run afoul of Advisory
11 Opinion 97-1's guidelines. For these reasons, AB 290 compels AKF to leave
12 California and consequently threatens the continued availability of ESRD treatment
13 to some of the most vulnerable members of society. The State has advanced no
14 cogent countervailing concerns to offset these imminent injuries. Only a preliminary
15 injunction can avoid this disastrous outcome.

16 **CONCLUSION**

17 For the foregoing reasons and those stated in Plaintiffs' Motion for
18 Preliminary Injunction, Plaintiffs urge this Court to enjoin the State from
19 implementing AB 290 while this lawsuit is pending.

20

21 DATED: December 2, 2019 KING & SPALDING LLP

22

23 By: */s/ Joseph N. Akrotirianakis* ______
24 JOSEPH AKROTIRIANAKIS
25 BOBBY R. BURCHFIELD

26 Attorneys for Plaintiffs
27 JANE DOE, STEPHEN ALBRIGHT, AMERICAN KIDNEY FUND, INC.,
28 and DIALYSIS PATIENT CITIZENS, INC.