

1 JOSEPH N. AKROTIRIANAKIS (SBN 197971)  
*jakro@kslaw.com*

2 KING & SPALDING LLP  
633 West Fifth Street, Suite 1600  
3 Los Angeles, CA 90071  
Telephone: (213) 443-4355  
4 Facsimile: (213) 443-4310

5 MATTHEW M. LELAND (*pro hac vice*)  
*mleland@kslaw.com*

6 ASHLEY C. PARRISH (*pro hac vice pending*)  
*aparrish@kslaw.com*

7 KING & SPALDING LLP  
1700 Pennsylvania Avenue, NW  
8 2<sup>nd</sup> Floor  
Washington, DC 20006  
9 Telephone: (202) 737-0500  
Facsimile: (202) 626-3737

10 Attorneys for Plaintiffs  
11 JANE DOE, STEPHEN ALBRIGHT,  
AMERICAN KIDNEY FUND, INC.,  
12 AND DIALYSIS PATIENT CITIZENS, INC.

13 **UNITED STATES DISTRICT COURT**  
14 **CENTRAL DISTRICT OF CALIFORNIA**

16 JANE DOE, *et al.*,

17 Plaintiffs,

18 v.

19 ROB BONTA, in his Official  
Capacity as Attorney General of  
20 California, *et al.*,

21 Defendants.  
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**Case No. 8:19-cv-2105-DOC(ADSx)**

**PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' MOTION FOR  
SUMMARY JUDGMENT**

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1 **I. INTRODUCTION**

2 Since December 30, 2019, this Court has preliminarily enjoined Defendants from  
3 enforcing Assembly Bill 290 (“AB 290”). As the Court explained in its comprehensive  
4 opinion granting preliminary relief, AB 290’s “Steering Ban” and “Reimbursement  
5 Cap” likely violate the First Amendment. In addition, Plaintiffs will suffer irreparable  
6 harm if the law goes into effect. AKF will be forced to cease its operations in California  
7 and vulnerable ESRD patients will experience disruptions in their health care coverage,  
8 with many losing their health insurance entirely.

9 The same conclusions remain true after months of discovery. In its Motion for  
10 Summary Judgment, the State identifies no evidence of steering and no California  
11 patients who have been steered, let alone who have been harmed by steering. The State  
12 presents nothing that could warrant changing the Court’s preliminary injunction  
13 analysis, and it identifies no bases for granting summary judgment against Plaintiffs’  
14 First Amendment and federal preemption claims.

15 AB 290 tramples on Plaintiffs’ First Amendment rights in several ways. It  
16 contains content-based restrictions on Plaintiffs’ speech rights, including a prohibition  
17 on Plaintiff American Kidney Fund (“AKF”) “advising” patients regarding health  
18 insurance policies. Not only does the restriction control what AKF can and cannot say,  
19 it is also unconstitutionally vague, giving no notice as to what conduct might fall within  
20 its scope. In addition, AB 290 compels speech by forcing AKF to provide the names  
21 of all Health Insurance Premium Program (“HIP”) beneficiaries to private insurance  
22 companies. AB 290 also interferes with the constitutionally protected association  
23 between AKF and its donors by allowing insurers to sharply reduce reimbursement rates  
24 for a patient’s dialysis services when a service provider donates to AKF.

25 All these burdens on Plaintiffs’ First Amendment rights are subject to strict  
26 scrutiny, a standard the State makes no effort to meet. Instead, the State claims that AB  
27 290 regulates only commercial speech. But it cannot identify any law or evidence to  
28 support its assertion that AKF, a charity, “promotes” commercial insurance. More

1 fundamentally, the State has no credible evidence of the problems AB 290 purports to  
2 remedy, including patient “steering,” harm to patients, or distortion to the insurance  
3 market. Where the State cites anything, it amounts only to rumors or allegations  
4 directed at third parties. Such marginal “evidence” cannot justify AB 290’s heavy  
5 intrusions on AKF’s First Amendment rights under any standard of review.

6 AB 290 is also preempted by the federal Beneficiary Inducement Statute and the  
7 Medicare Secondary Payer Act (“MSPA”). If AKF were to comply with AB 290, HIPP  
8 would fall outside the scope of Advisory Opinion 97-1, AKF’s sanctioned safe harbor  
9 against penalties under the Beneficiary Inducement Statute. AKF thus faces impossible  
10 choices among complying with California law and risking federal sanctions; continuing  
11 to operate within its safe harbor and facing State sanctions; or ceasing the operation of  
12 HIPP altogether. That is a quintessential example of impossibility preemption. With  
13 little to say in response, the State repeats its erroneous argument from the preliminary  
14 injunction phase that Advisory Opinion 97-1, standing alone, cannot preempt AB 290.  
15 The State similarly lacks any meaningful response to Plaintiffs’ claim that AB 290  
16 interferes with Congress’s goals in enacting the MSPA.

17 Because the State’s case has not changed since this Court enjoined AB 290,  
18 Plaintiffs respectfully urge the Court to deny Defendants’ Motion for Summary  
19 Judgment and grant Plaintiffs’ Motion for Summary Judgment.

## 20 **II. ARGUMENT**

### 21 **A. AB 290 Violates AKF’s First Amendment Rights.**

22 AB 290’s provisions violate the First Amendment by compelling AKF to speak,  
23 mandating what the organization can say, and burdening its rights of association and  
24 petition. After extensive discovery, the State has no evidence of patient “steering,”  
25 rising healthcare costs, or other patient harm that AB 290 claims to remedy, and the  
26 State makes no showing that AB 290’s extreme provisions are the least restrictive means  
27 of accomplishing its purported goals.  
28



1 **1. AB 290 Violates AKF’s Right to Free Speech.**

2 **a. AB 290 Contains Content-Based Speech Restrictions.**

3 Because AB 290’s provisions “appl[y] to particular speech [due to] the topic  
4 discussed,” *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015), or else “[m]andat[e]  
5 speech that a speaker would not otherwise make,” *Riley v. Nat’l Fed’n of the Blind of*  
6 *North Carolina, Inc.*, 487 U.S. 781, 795 (1988), they are “content-based regulations,”  
7 *id.* Content-based speech restrictions are “presumptively unconstitutional.” *Reed*, 576  
8 U.S. at 163.

9 AB 290 controls the content of AKF’s speech in at least four ways, all of which  
10 are apparent from the statute’s plain text:

- 11 • sections 3(b)(4) and 5(b)(4) prohibit AKF from “steer[ing], direct[ing], or  
12 advis[ing]” any patient “into or away from a specific coverage program option or  
13 health care service plan contract” (the “Advising Restriction”);  
14 • sections 3(b)(3) and 5(b)(3) compel AKF to inform patients of “all available  
15 health coverage options”;  
16 • sections 3(c)(1) and 5(c)(1) require AKF to provide an annual statement to health  
17 care service plans certifying compliance with sections 3(b) and 5(b); and  
18 • sections 3(c)(2) and 5(c)(2) require AKF to disclose HIPP patient names to health  
19 insurers.

20 AKF has repeatedly shown that each of these provisions regulates AKF’s speech  
21 according to its content. *See* AKF Br. 9–10 (Dkt. 132); Mot. Prelim. Injunct. at 14–16  
22 (Dkt. 28); Prelim. Injunct. Reply at 15–17 (Dkt. 49). *First*, the Advising Restriction  
23 tells AKF what messages it can and cannot convey, a canonical example of a content-  
24 based regulation. *Reed*, 576 U.S. at 163. Moreover, the Advising Restriction is targeted  
25 at a particular group of disfavored speakers—AKF and dialysis providers—further  
26 demonstrating that its restrictions are content-based. *See Sorrell v. IMS Health Inc.*,  
27 564 U.S. 552, 564–66 (2011) (holding statute prohibiting sale of information to  
28 pharmaceutical marketers, but not to other parties, qualified as a content-based

1 restriction). *Second*, sections 3(b)(3) and 5(b)(3) force AKF to relay a state-preferred  
2 message about “all available health coverage options” it otherwise would not  
3 communicate because AKF does not discuss insurance options with HIPP beneficiaries  
4 at all. *Riley*, 487 U.S. at 795; *see also Nat’l Inst. of Family & Life Advocates v. Becerra*,  
5 138 S. Ct. 2361, 2371 (2018) (“*NIFLA*”) (finding statute that required clinics to  
6 “provide a government-drafted script about the availability of state-sponsored services”  
7 to be a content-based regulation); Dkt. 132-19 (Burton 2022 Decl. ¶ 39). *Third*, sections  
8 3(c)(1) and 5(c)(1) require AKF to certify to insurers its compliance with AB 290’s  
9 unconstitutional provisions, another example of compelled speech. *Riley*, 487 U.S. at  
10 795. *Fourth*, sections 3(c)(2) and 5(c)(2) compel speech because they force AKF to  
11 disclose the names of HIPP patients to health insurers. *Id.*

12 The State agrees that these provisions control the content of AKF’s speech and  
13 compel AKF to speak when it otherwise would not. *See* State Br. 14 (Dkt. 128-1)  
14 (acknowledging the Advising Restriction “regulates patient interactions”); *id.* at 20  
15 (acknowledging sections 3(b)(3) and 5(b)(3) “require[] . . . AKF to inform HIPP  
16 recipients of ‘all available health coverage options . . . .’”); *id.* at 6 (noting “AB 290  
17 requires that [AKF] submit an annual statement of compliance with the law and disclose  
18 to health insurers the names of each insured patient who will receive premium  
19 assistance”). Accordingly, AB 290 is constitutionally invalid and should be struck  
20 down unless the State can carry its burden under an appropriate level of scrutiny. *E.g.*,  
21 *Greater New Orleans Broad. Ass’n., Inc. v. United States*, 527 U.S. 173, 183 (1999)  
22 (“[T]he Government bears the burden of identifying a substantial interest and justifying  
23 the challenged restriction.”). As explained below, the State has not carried that burden.

#### 24 **b. AB 290 Is Subject to Strict Scrutiny.**

25 It is black-letter law that strict scrutiny applies to content-based restrictions. *E.g.*,  
26 *Reed*, 576 U.S. at 163; *R.A.V. v. City of St. Paul*, 505 U.S. 377, 395 (1992); *Simon &*  
27 *Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 115, 118  
28 (1991). To satisfy the strict scrutiny standard, the State must show that AB 290’s

1 restrictions “are narrowly tailored to serve compelling state interests.” *Reed*, 576 U.S.  
2 at 163; *see also United States v. Playboy Entm’t Grp., Inc.*, 529 U.S. 803, 813 (2000)  
3 (“If a less restrictive alternative would serve the Government’s purpose, the legislature  
4 must use that alternative.”). But the State makes no meaningful argument that AB 290  
5 can survive strict scrutiny; the words “strict scrutiny” do not even appear in its Brief.  
6 The State instead contends (erroneously) that AB 290’s provisions should be analyzed  
7 under a less demanding standard of review. *See* State Br. 8–9, 15, 20–21.

8 ***AKF’s Speech Is Not “Commercial Speech.”*** The State argues that AB 290  
9 regulates only “commercial speech” and therefore “intermediate scrutiny” applies.  
10 State Br. 8–9, 13–19. This attempt to lessen the State’s constitutional burden fails  
11 because AKF’s speech is not “commercial” in nature. Courts assess three components  
12 to determine whether speech is “commercial”: (1) whether “the speech is an  
13 advertisement,” (2) whether “the speech refers to a particular product,” and (3) whether  
14 “the speaker has an economic motivation.” *Hunt v. City of Los Angeles*, 638 F.3d 703,  
15 715 (9th Cir. 2011) (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66–67  
16 (1983)). The State must show a combination of these factors. *See Bolger*, 463 U.S. at  
17 66–67. “[T]he reference to a specific product does not by itself render [speech]  
18 commercial speech.” *Id.* at 66. Likewise, “economic motivation” is “insufficient by  
19 itself to turn . . . materials into commercial speech.” *Id.* at 67 (collecting cases). Even  
20 speech that appears “commercial” does not “retain[] its commercial character when it  
21 is inextricably intertwined with otherwise fully protected speech.” *Riley*, 487 U.S. at  
22 796 (internal quotation marks omitted).

23 The State effectively concedes that the first factor is not satisfied here. *See* State  
24 Br. 13. As for the second factor, the State argues that AKF “promote[s] a specific  
25 product,” “commercial insurance.” *Id.* at 14. But AKF does not discuss, let alone  
26 “promote,” commercial insurance. Less than one third of California HIPP patients are  
27 covered by commercial plans. Dkt. 132-19 (Burton 2022 Decl. ¶ 26). By contrast, more  
28 than 56 percent of HIPP recipients in California are covered by Medicare-related plans,

1 SUFCL ¶ 84, and an additional 16 percent are covered by COBRA plans, Dkt. 132-19  
2 (Burton 2022 Decl. ¶ 26). In any event, AKF provides no input to HIPP applicants  
3 about their insurance and does not advocate that HIPP patients keep or change their  
4 insurance, whatever their plan may be. SUFCL ¶¶ 74, 78. Indeed, to qualify for HIPP,  
5 applicants must prove that they *already* have insurance. SUFCL ¶ 73. And, as  
6 demonstrated by the individual Plaintiffs, AKF continues to provide HIPP assistance to  
7 patients who change their insurance coverage or dialysis provider. SUFCL ¶ 79.  
8 Plaintiff Jane Doe moved from a COBRA plan to a Medicare Advantage plan in the  
9 time since this litigation began, *compare* Dkt. 26-2 (Doe 2019 Decl. ¶ 9) *with* Dkt. 132-  
10 20 (Doe 2022 Decl. ¶ 13), and Plaintiff Stephen Albright left his wife’s commercial  
11 insurance plan for a Medicare Advantage plan, *compare* Dkt. 28-3 (Albright 2019 Decl.  
12 ¶ 9) *with* Dkt. 130-18 (Albright 2022 Decl. ¶ 13). As AKF’s CEO LaVarne Burton  
13 explained, AKF leaves “critical choices” about patients’ insurance coverage or dialysis  
14 provider in the “*patients’ hands.*” Dkt. 132-19 (Burton 2022 Decl. ¶ 23).

15 The State’s argument that AKF has an “economic motive” for its speech also  
16 fails. State Br. 14; *Hunt*, 638 F.3d at 715. Although AKF solicits charitable donations,  
17 that speech is not regulated by AB 290 and is not “commercial speech” in any event.  
18 *See Vill. of Schaumburg v. Citizens for a Better Env’t*, 444 U.S. 620, 632 (1980) (holding  
19 charitable solicitation “has not been dealt with in our cases as a variety of purely  
20 commercial speech”); AKF Br. 11–12. The State attempts to show that AKF has a  
21 “powerful” economic motivation, but the allegations detailed in its brief have no  
22 relevance to AKF. *See* State Br. 14 (discussing “how critical commercial patients are  
23 to the [*dialysis*] *providers’* bottom line” (emphasis added)); *id.* (discussing purported  
24 concerns of *DaVita* and *Fresenius* investors).

25 To the extent any of AKF’s speech might be deemed “commercial,” the State’s  
26 arguments still fail because AKF’s speech is “inextricably intertwined with otherwise  
27 fully protected speech.” *Riley*, 487 U.S. at 796. In *Riley*, the Supreme Court rejected  
28 the argument that intermediate scrutiny applied to a statutory requirement that

1 compelled fundraisers to disclose certain information while soliciting donations. *Id.* at  
2 795–96. The Supreme Court refused “to separate the component parts of charitable  
3 solicitations from the fully protected whole.” *Id.* at 796. Here, AB 290 imposes more  
4 numerous—and more restrictive—burdens on AKF’s speech, all of which are related to  
5 AKF’s charitable activities and mission. *See supra* pp. 3–4.

6 ***AB 290 Does Not Compel the Disclosure of “Purely Factual” or***  
7 ***“Uncontroversial” Information.*** The State argues that AB 290 is constitutional  
8 because it compels only the disclosure of “purely factual and uncontroversial”  
9 information in the context of commercial speech. State Br. 22 (quoting *NIFLA*, 138 S.  
10 Ct. at 2372). Because AKF’s speech is not “commercial,” this argument fails for the  
11 same reasons set out above. *See supra* pp. 5–7. But it is also independently wrong.  
12 The undisputed facts show that AB 290 *does not* compel the disclosure of “purely  
13 factual” or “uncontroversial” information. *First*, like the California statute struck down  
14 in *NIFLA*, AB 290 requires AKF to deliver a state-preferred message that “in no way  
15 relates to the services” AKF provides. *NIFLA*, 138 S. Ct. at 2372. *Second*, AB 290  
16 compels AKF to certify its compliance with other unconstitutional requirements—  
17 “anything but an ‘uncontroversial’ [or ‘purely factual’] topic.” *Id.* *Third*, AB 290  
18 requires AKF to disclose the names of its HIPP beneficiaries—information related to  
19 AKF’s charitable mission—to insurance companies, forced speech to which AKF  
20 strenuously objects. *See Riley*, 487 U.S. at 796–801 (finding statutory requirement that  
21 fundraisers disclose the percentage of collected funds given to charity to be a content-  
22 based regulation); Dkt. 132-19 (Burton 2022 Decl. ¶ 37).<sup>1</sup>

23 **c. AB 290 Fails Under Both Strict Scrutiny and Intermediate**  
24 **Scrutiny.**

25 The State argues that “AB 290 is tailored to address a practice with harms so

26 <sup>1</sup> Even if the Court determined that AB 290 compels only the disclosure of factual and  
27 uncontroversial information, the law’s disclosure requirements would fail the *Zauderer*  
28 standard of review for substantially the same reasons why those requirements fail strict  
and intermediate scrutiny. *See infra* pp. 7–10.

1 compelling that the law would survive any level of scrutiny.” State Br. 15. But the  
2 State has no evidence of this purported “practice” or the resultant “harms,” and,  
3 moreover, the State fails to show that AB 290 is properly tailored. To survive strict  
4 scrutiny, the State must show the restrictions “are narrowly tailored to serve compelling  
5 state interests.” *Reed*, 576 U.S. at 163. To survive intermediate scrutiny, the State must  
6 show “that the statute directly advances a substantial governmental interest and that the  
7 measure is drawn to achieve that interest.” *Sorrell*, 564 U.S. at 571–72. The State must  
8 also identify “an actual problem” and must “present more than anecdote and  
9 supposition” in support of its statute. *Playboy Entm’t Grp., Inc.*, 529 U.S. at 822. In  
10 addition, the State must have justification for its laws *before* enacting them—it “cannot  
11 impose [a speech restriction] and then hope a justification materializes in discovery.”  
12 *IMDb.com, Inc. v. Becerra*, 257 F. Supp. 3d 1099, 1102 (N.D. Cal. 2017), *aff’d*, 962  
13 F.3d 1111 (9th Cir. 2020). AB 290 fails under any standard of scrutiny.

14 ***No Evidence of Steering.*** The State argues that AB 290 is designed to eliminate  
15 the “steering” of dialysis patients into “commercial insurance coverage for the  
16 financial benefit of [dialysis] provider[s].” State Br. 15 (quoting AB 290, § 1(c)). But  
17 in the two years since the Court’s grant of a preliminary injunction, the State still has  
18 not come forward with credible evidence that AKF has “steered” dialysis patients. *See*  
19 *Doe v. Becerra*, Nos. SA CV 19-2105-DOC-ADS, SA CV 19-2130-DOC-ADS, 2019  
20 WL 8227464, at \*5 (C.D. Cal. Dec. 30, 2019) (“[T]he State has yet to identify a single  
21 California patient steered into a private insurance plan by a dialysis provider or third-  
22 party payer.”). The State has not identified a single California dialysis patient who was  
23 directed into a commercial insurance plan to their detriment. SUFCL ¶¶ 107, 116, 123;  
24 *see also* SUFCL ¶ 109 (no steps taken to identify “steered” patients). And it has no  
25 evidence that AKF or a dialysis provider influenced insurance coverage decisions by  
26 patients. SUFCL ¶¶ 110, 112, 117, 118. In fact, the State has not received even one  
27 *complaint* about steering. SUFCL ¶¶ 108, 113, 120.

28 Lacking evidence of steering in California, the State relies only on “anecdote and

1 supposition” to defend its statute. *Playboy Entm’t Grp.*, 529 U.S. at 822. Remarkably,  
2 the State even resorts to claiming that “where there’s smoke, there’s fire,” in an attempt  
3 to divert attention from the paucity of its evidence. State Br. 17. The State has all but  
4 admitted that it has not carried its burden.

5 The State relies primarily on (1) comments in response to a Center for Medicare  
6 and Medicaid Services (“CMS”) Request for Information (“RFI”) in connection with  
7 an interim rule that was enjoined by a federal court, and (2) a Washington investigation  
8 into the conduct of a single out-of-state employee of a dialysis provider. *Id.* at 15–16;  
9 *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at \*6 (E.D.  
10 Texas Jan. 25, 2017) (enjoining interim final rule and finding that “ESRD patients  
11 would also suffer irreparable injury were the Rule to go into effect”). Even if this  
12 evidence of out-of-state activities were relevant (and it is not), it would amount only to  
13 “handful of complaints” insufficient to justify AB 290’s restrictions. *Playboy Entm’t*  
14 *Grp.*, 529 U.S. at 821–22.

15 The State also cites inadmissible hearsay documents purporting to show that large  
16 dialysis providers encouraged patient steering. State Br. 15–16. But the materials do  
17 not concern activities in California or, for that matter, involvement in any steering by  
18 AKF. *See also* RSUF ¶¶ 30–36 (explaining why these facts are not uncontroverted).  
19 Accordingly, the documents are improper support for a motion for summary judgment  
20 and are insufficient to justify infringements on AKF’s speech. *See* Plaintiffs’  
21 Objections to Evidence ¶¶ 30–36 (explaining documents are inadmissible hearsay, lack  
22 foundation, and are irrelevant); Fed. R. Civ. P. 56(c)(2) (“A party may object that the  
23 material cited to support or dispute a fact cannot be presented in a form that would be  
24 admissible in evidence.”).

25 The State’s remaining examples of “steering” comprise only unsubstantiated  
26 claims and news reports. The States cites *allegations* pleaded in two securities cases.  
27 *See* State Br. 16–17 (citing *Peace Officers’ Annuity & Benefit Fund of Ga. v. DaVita*  
28 *Inc.*, 372 F. Supp. 3d 1139 (D. Colo. 2019) & *In re DaVita Inc. v. Stockholder*

1 *Derivative Litig.*, No. 17-152-MPT, 2019 WL 1855445 (D. Del. Apr. 25, 2019)). But  
2 “allegations are not evidence at the summary-judgment stage”—especially where, as  
3 here, the allegations come from *other cases*. *VBS Distrib., Inc. v. Nutrivita Lab ’ys, Inc.*,  
4 811 F. App’x 1005, 1011 & n.1 (9th Cir. 2020) (Bybee, J., concurring). The State also  
5 refers to (1) “countless” news articles (in actuality, a handful) purporting to show that  
6 dialysis providers have engaged in patient steering, and (2) a report authored by a single  
7 Congressional representative. State Br. 16–17. AKF has already debunked the claims  
8 made in the two *New York Times* articles, which are based on the factual  
9 misunderstandings of a small number of individuals and which fail to identify any  
10 “steering” in California. *See* AKF Br. 12–13; Dkt. 132-19 (Burton 2022 Decl. ¶¶ 44–  
11 45). The *St. Louis Post-Dispatch* article is insufficient for the same reasons. *See* Dkt.  
12 128-3 at 153. The *Scientific American* article and *Freakonomics Radio* podcast are even  
13 less relevant, as they contain no accusations of patient steering at all and they both post-  
14 date the enactment of AB 290. *See* State Br. 17 n.11. Moreover, Congresswoman  
15 Porter’s report merely recapitulates much of the “evidence” debunked above. *See* Dkt.  
16 128-4 at 197–202 (discussing *New York Times* article, securities lawsuits, CMS  
17 investigation, and former employee of dialysis provider’s testimony). Moreover, the  
18 Porter report was released *after* AB 290 was enacted, so the California legislature could  
19 not have considered it. *See IMDB.com, Inc.*, 257 F. Supp. 3d at 1102.

20 ***No Evidence of Other Harm.*** The State’s attempt to show evidence of other  
21 harms likewise fails. *See* State Br. 17–19. There can be no patient harm of any kind if  
22 there is no patient steering. *See supra* pp. 8–10; AKF Br. 12–14. Setting that aside, the  
23 State has no evidence of health care costs being impacted—the stated reason the  
24 legislature enacted AB 290. *See* AB 290 §§ 1(c)–(e), (h). Moreover, the State’s agency  
25 designees admit there is no evidence supporting any of AB 290’s legislative findings.  
26 SUFCL ¶ 114. They also admit that there is no evidence that Californians are paying  
27 higher insurance premiums due to “steering,” SUFCL ¶¶ 128, and that they conducted  
28 no analysis to determine how HIPP impacts insurance premiums, SUFCL ¶¶ 129.



1 Unsurprisingly, the State is aware of *no patients* who have been harmed by the alleged  
2 steering of ESRD patients. SUFCL ¶¶ 126–27.

3 Lacking evidence of steering, the State’s effort to prove harm through the  
4 opinions of John Bertko and Amy D. Waterman also fails. *See* State Br. 17–18. As this  
5 Court observed, if the harms AB 290 purports to remedy “were real, rather than  
6 speculative or conjectural, the State . . . would *already* understand and be able to  
7 demonstrate” such harms and would have no need for such reports. *Doe*, 2019 WL  
8 8227464 at \*5. At any rate, the expert reports fail on their own terms. Bertko repeatedly  
9 admitted that his opinions are inaccurate, misleading, and based on nothing but  
10 guesswork. RSUF ¶ 44. Moreover, Bertko’s entire analysis is predicated on the faulty  
11 assumption that “there was an increase in [ESRD] enrollees [in Covered California] . . .  
12 as a result of charitable premium assistance and steering.” Leland Decl. Ex. 59 (Bertko  
13 Dep. 188:9–12); *see also Doe*, 2019 WL 8227464, at \*5. Again, the State has no  
14 evidence of steering, much less steering into specific benefit programs. *See supra* pp.  
15 8–10; Leland Decl. Ex. 59 (Bertko Dep. 112:2–8) (expressing no opinion as to the  
16 existence or prevalence of patient steering). The relevant portions of Waterman’s  
17 analysis merely reiterate the legislature’s unsupported findings and comments made in  
18 response to CMS’s RFI. *Compare* State Br. 17–18 (claiming “steering injures patients  
19 in at least three ways”) *with id.* at 4 (discussing the “three types of possible harm”  
20 mentioned in CMS comments). Accordingly, her analysis fails for the same reasons.  
21 *See supra* pp. 8–10.<sup>2</sup>

22 ***AB 290 Is Not Narrowly Tailored.*** The State attempts to sidestep the issue of  
23 tailoring, arguing that “AB 290 is tailored to address a practice with harms so  
24 compelling that the law would survive any level of scrutiny.” State Br. 15. But the  
25 State fails to demonstrate that the statute is the “le[ast] restrictive alternative,” which is

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26 <sup>2</sup> Moreover, Waterman’s expert report is unreliable under the Federal Rules of Evidence  
27 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See* Motion  
28 to Exclude Expert Opinions and Testimony of Dr. Amy Waterman (Dkt. 146).

1 required to survive strict scrutiny. *Playboy Entm't Grp., Inc.*, 529 U.S. at 813. The  
2 State does not even show that AB 290 survives intermediate scrutiny—the standard that  
3 the *State itself* contends applies here. *See* State Br. 15 (arguing “intermediate scrutiny  
4 applies”); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447  
5 U.S. 557, 566 (1980) (holding “[the restriction must be] not more extensive than is  
6 necessary” to survive intermediate scrutiny).

7 Rather than make the required showing, the State merely argues that AB 290 will  
8 accomplish some of its stated goals, *see* State Br. 18, and then asserts that AB 290 does  
9 not “requir[e] more of Plaintiffs than is necessary” to achieve those goals, *id.* at 19. But  
10 the State could have accomplished its goals through any number of less restrictive  
11 alternatives. *See Doe*, 2019 WL 8227464, at \*6 (the Court discussing a less restrictive  
12 “targeted prohibition against steering” (citation omitted)); AKF Br. 14–15 (discussing  
13 the less restrictive alternative of relying on existing antifraud law to protect patients);  
14 SUFCL ¶ 130 (discussing State’s awareness of potential alternatives). The State’s  
15 failure to explain why these alternatives are insufficient provides an additional,  
16 independent reason to deny the State’s Motion—and to grant summary judgment for  
17 Plaintiffs. *See* AKF Br. 14–15.

## 18 **2. AB 290 Violates AKF’s Right of Association.**

19 The State argues that sections 3(e)(1) and 5(e)(1) (“the Reimbursement Penalty”)  
20 do not violate AKF’s right of association because, even though the provisions reduce  
21 insurance reimbursements for HIPP patients to the Medicare rate for dialysis providers  
22 that donate to HIPP, *see* AB 290 §§ 3(e)(1), 5(e)(1), AKF has no right “to amass  
23 funds.” State Br. 20 (quoting *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879,  
24 892 (9th Cir. 2018)).

25 This argument misses the point. As the State acknowledges, associations  
26 protected by the First Amendment can be formed by making financial contributions.  
27 *E.g.*, *McCutcheon v. FEC*, 572 U.S. 185, 203 (2014); *see also* State Br. 20 (conceding  
28 “certain financial contributions . . . implicate[] ‘protected First Amendment interests’”

1 (quoting *McCutcheon*, 572 U.S. at 196)). This protection extends to “charitable”  
2 activities. *Roberts v. U.S. Jaycees*, 468 U.S. 609, 626–27 (1984). The Reimbursement  
3 Penalty is thus unconstitutional because it “operate[s] as [a] disincentive[.]” for dialysis  
4 providers (and many of AKF’s 80,000 other donors) to associate with AKF, *Simon &*  
5 *Schuster*, 502 U.S. at 117; SUFCL ¶ 19; *see also Doe*, 2019 WL 8227464, at \*6 (finding  
6 the same).

7 The lone case cited by the State is not on point. In *Interpipe*, the plaintiffs  
8 challenged an amendment to California’s labor code that limited the prevailing wage-  
9 credit employers could receive by donating to “industry advancement funds” (“IAFs”).  
10 898 F.3d at 883–84. One plaintiff, itself an IAF, argued that it “ha[d] a protected First  
11 Amendment right to receive the employee-subsidized funds[.]” *Id.* at 891 (emphasis  
12 omitted). The Ninth Circuit rejected that argument, noting that the statute did not  
13 “prevent[] employers (and employees for that matter) *from contributing* to [the  
14 plaintiff].” *Id.* (emphasis added); *see also id.* at 893 (the statute “leaves IAFs free to  
15 spend their funds on expressive activities however they wish without incurring a  
16 ‘penalty’ for doing so”). Here, by contrast, the purpose of the Reimbursement Penalty  
17 is to disincentivize dialysis providers from donating to AKF and, in turn, impede them  
18 from exercising their First Amendment right to donate to AKF.

19 The State does not appear to dispute that AB 290 violates AKF’s associational  
20 rights in at least two other ways. *Compare* State Br. 20 (arguing only that the  
21 Reimbursement Penalty does not violate AKF’s right of association) *with* AKF Br. 16  
22 (explaining that “AB 290 intrudes on AKF’s associational rights in *three ways*”  
23 (emphasis added)).<sup>3</sup> *First*, sections 3(b)(2) and 5(b)(2) of AB 290—which require AKF

24 \_\_\_\_\_  
25 <sup>3</sup> The State also does not contest that AKF is an “expressive association” that is fully  
26 protected by the First Amendment. *Boy Scouts of America v. Dale*, 530 U.S. 640, 648  
27 (2000); *see also Ams. for Prosperity Found. v. Bonta*, 141 S. Ct. 2373, 2376 (2021).  
28 Nor could it. It is undisputed that AKF is a 501(c)(3) nonprofit charity with the singular  
mission of combatting kidney disease through advocacy, education, research, and  
financial assistance. SUFCL ¶ 18; *see also Dale*, 530 U.S. at 648.

1 to “agree not to condition financial assistance on eligibility for, or receipt of, any  
2 surgery, *transplant, procedure, drug, or device*”—would transform the American  
3 *Kidney Fund* into an all-purpose medical charity. AB 290 §§ 3(b)(2), 5(b)(2) (emphasis  
4 added). In other words, these provisions would impermissibly require AKF to abandon  
5 its central mission—combatting kidney disease—in California. Dkt. 132-19 (Burton  
6 2022 Decl. ¶¶ 2, 14–15); *see U.S. Jaycees*, 468 U.S. at 622 (First Amendment protects  
7 “a wide variety of political, social, economic, educational, religious, and cultural  
8 ends”); *Santopietro v. Howell*, 857 F.3d 980, 989 (9th Cir. 2017) (same).

9 *Second*, the Patient Disclosure Mandate requires AKF to disclose the names of  
10 HIPP patients to health insurers. *See* AB 290 §§ 3(c)(2), 5(c)(2); *see also* AKF Br. 17.  
11 Such “compelled disclosure of affiliation with groups engaged in advocacy” restrains  
12 freedom of association. *Ams. for Prosperity*, 141 S. Ct. at 2382 (quoting *NAACP v.*  
13 *Alabama ex rel. Patterson*, 357 U.S. 449, 462 (1958)).

14 The State does not contest that the above restrictions are supported by the same  
15 rationales as the restrictions on AKF’s speech rights. *See* State Br. 20. Because AB  
16 290’s speech restrictions fail under both strict and intermediate scrutiny, the  
17 associational restrictions fail as well. *See supra* pp. 7–12; AKF Br. 12–15, 17.

### 18 **3. The Advising Restriction Is Void for Vagueness.**

19 The State asserts that the Advising Restriction is “[s]ufficiently [c]lear” to pass  
20 constitutional muster. State Br. 19. But The State’s crabbed reading only confirms the  
21 provision fails to give “ordinary people . . . fair notice of the conduct” it prohibits.  
22 *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018) (internal quotation marks omitted).

23 To make sense of the Advising Restriction, the State excises two of its three  
24 commands, interpreting the directive that AKF not “steer,” “direct,” or “advise” patients  
25 to mean only that AKF cannot “steer” patients. State Br. 19–20. That reading is at odds  
26 with the statute’s plain language, which sweeps much more broadly to prohibit  
27 “direct[ing]” and “advis[ing]” patients “into or away from” insurance options. AB 290  
28 §§ 3(b)(4), 5(b)(4); *see also Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 60 (2007)

1 (noting courts must “[g]ive effect, if possible, to every clause and word of a statute”  
2 (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)). The plain meaning  
3 of the word “advise” encompasses more than encouraging patients to enroll in  
4 commercial insurance coverage. See *Merriam-Webster’s Third New International*  
5 *Dictionary* 32 (2002) (defining “advise” as “to give information or notice to” or to  
6 “inform”); Dkt. 132-19 (Burton 2022 Decl. ¶ 38). In fact, even the State’s *own*  
7 *representatives* understand the Advising Restriction to encompass more than “steering”  
8 patients to commercial insurance plans. SUFCL ¶¶ 124–25.

9 Further, AB 290 does not define the terms “steer,” “direct,” or “advise,” leaving  
10 AKF to guess what speech is prohibited and what speech is permissible. See AB 290  
11 §§ 3(b)(4) & (h), 5(b)(4) & (h). Such indefinite language serves to “encourage[]  
12 arbitrary . . . enforcement,” a hallmark of unconstitutional vagueness. *Hill v. Colorado*,  
13 530 U.S. 703, 732 (2000); see also AKF Br. at 18 (collecting cases).

#### 14 **4. AB 290 Violates AKF’s Right to Petition.**

15 The State argues that AB 290 does not violate the right of petition because it does  
16 not “mandate” that AKF petition the government. State Br. 23. According to the State,  
17 section 7 merely provides “the option to request an updated advisory opinion.” *Id.*  
18 (emphasis omitted). But section 7 provides no “option” at all. Section 7 provides that  
19 “unless” AKF requests an updated opinion, AB 290’s unconstitutional and burdensome  
20 provisions “shall become operative” months or years earlier than they would otherwise.  
21 See also *supra* pp. 3–4 (discussing constitutional violations). AB 290 thus penalizes  
22 AKF based on how it chooses to petition the government, infringing on AKF’s First  
23 Amendment rights. See *Agency for Int’l. Dev. v. Alliance for Open Soc’y*, 570 U.S. 205,  
24 213–14 (2013); *Garrity v. New Jersey*, 385 U.S. 493, 497–98 (1967); see also *Wayte v.*  
25 *United States*, 470 U.S. 598, 610 & n.11 (1985) (“Although the right to petition and the  
26 right to free speech are separate guarantees, they are related and generally subject to the  
27  
28

1 same constitutional analysis.”).<sup>4</sup>

2 **B. AB 290 Is Preempted by Federal Law.**

3 AB 290 is preempted by federal law in two ways. *First*, it conflicts with the  
4 Beneficiary Inducement Statute, as that statute has been authoritatively construed by  
5 Advisory Opinion 97-1. *Second*, AB 290 is preempted by the Medicare Secondary  
6 Payer Act (“MSPA”) because it undermines Congress’ goal of ensuring that ESRD  
7 patients are not treated differently from other classes of patients. The State  
8 mischaracterizes—and fails to rebut—these two claims.

9 **1. The Beneficiary Inducement Statute and Advisory Opinion 97-1.**

10 Central to the preemption issues in this case are the Beneficiary Inducement  
11 Statute, its accompanying advisory opinion process, and Advisory Opinion 97-1. The  
12 federal statute penalizes any entity that knowingly “offers to or transfers remuneration  
13 to any individual eligible for [federal health care program] benefits,” with the intent to  
14 influence that individual’s choice of a health care provider. 42 U.S.C. § 1320a-7a(a)(5).  
15 The Beneficiary Inducement Statute provides that “remuneration” includes “transfers  
16 of items or services for free or for other than fair market value.” 42 U.S.C. § 1320a-  
17 7a(i)(6). The statute’s proper interpretation and implementation is a material focus of  
18 AKF’s compliance efforts. Dkt. 132-19 (Burton 2022 Decl. ¶¶ 31–35). AKF’s payment  
19 of premiums could be misconstrued as a prohibited offering of “remuneration” to  
20 influence ESRD patients’ choices regarding dialysis providers to those who support  
21 AKF, putting the charity at reputational and legal risk. Dkt. 132-19 (Burton 2022 Decl.  
22

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23 <sup>4</sup> The State’s throwaway argument that there is no “coerced nexus” between “the  
24 individual and the specific expressive activity” is a non sequitur. State Br. 23 (quoting  
25 *Cal-Almond, Inc. v. U.S. Dep’t of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993)). The  
26 “coerced nexus” test applies where the government compels parties to financially  
27 subsidize speech with which they disagree. *See, e.g., id.*; *United States v. Frame*, 885  
28 F.2d 1119, 1132–33 (3d Cir 1989), *rev’d on other grounds by Cochran v. Veneman*,  
359 F.3d 263 (3d Cir. 2004); *R.J. Reynolds Tobacco Co. v. Shewry*, 423 F.3d 906, 932  
(9th Cir 2005) (Trott, J., dissenting). It has no application here.

1 ¶ 36; AKF Br. 5–6).

2 Congress enacted procedures to help safeguard against this risk. Interested  
3 parties can seek an advisory opinion from the Department of Health and Human  
4 Services’ (“HHS”) Office of Inspector General (“OIG”)—the entity responsible for  
5 enforcing the Beneficiary Inducement Statute—on “[w]hether any activity or proposed  
6 activity constitutes grounds for the imposition of a sanction under [the Beneficiary  
7 Inducement Statute].” 42 U.S.C. § 1320a-7d(b)(2)(e). A favorable opinion acts as a  
8 “safe harbor” for the contemplated activity and is “binding as to [HHS] and the party or  
9 parties requesting the opinion.” 42 U.S.C. § 1320a-7d(a)(4)(A). But advisory opinions  
10 are limited to “the OIG’s opinion regarding the subject matter of the request based on  
11 the facts provided to the OIG.” 42 C.F.R. § 1008.43(b). A departure from those facts  
12 strips away the opinion’s protection. *See* 45 C.F.R. § 1008.45 (providing for rescission,  
13 termination, or modification of advisory opinions).

14 Advisory Opinion 97-1 has served as HIPP’s safe harbor under the Beneficiary  
15 Inducement Statute for 25 years.<sup>5</sup> The Advisory Opinion states that dialysis providers’  
16 donations to AKF do not constitute “remuneration” to an individual eligible for federal  
17 health care benefits because “the interposition of AKF, a bona fide, independent,  
18 charitable organization, and its administration of HIPP provides sufficient insulation so  
19 that the premium payments should not be attributed to the [provider] Companies.” Dkt.  
20 29 (RJN Exh. 2, at 24) (emphasis in original). “AKF will have absolute discretion  
21 regarding the use of provider contributions made to AKF,” *id.*, and “[donating]  
22 Companies will be free to determine whether to make contributions to AKF and, if so,  
23 how much to contribute,” *id.* at 22. What’s more, “AKF staff involved in awarding  
24 patient grants will not take the identity of the referring facility or the amount of any  
25

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26 <sup>5</sup> During this period, Congress amended the advisory opinion process to include  
27 additional definitions of remuneration. *See* 112 Stat. 2681–917; Pub. L. 106–554,  
28 § 5201(c). This reflects Congressional sanction and ratification of the advisory opinion  
process.

1 provider’s donation into consideration when assessing patient applications or making  
2 grant determinations.” *Id.*; Dkt. 132-19 (Burton 2022 Decl. ¶¶ 33–34). Advisory  
3 Opinion 97-1 also observed that any such risks are further attenuated by the fact  
4 “[a]ssistance is available to all eligible patients on an equal basis,” Dkt. 29 (RJN Exh.  
5 2, at 21, and an applying “patient will often have already selected a provider prior to  
6 submitting his or her application for assistance,” *id.* at 25. As a result, “AKF’s payment  
7 of premiums will expand, rather than limit, beneficiaries’ freedom of choice.” *Id.*

8 Since Advisory Opinion 97-1’s publication, AKF has not deviated from the  
9 program facts described to OIG, and OIG has not modified or revoked the Advisory  
10 Opinion since its issuance 25 years ago. Dkt. 132-19 (Burton 2022 Decl. ¶ 35).

## 11 **2. AB 290 Is Preempted by the Beneficiary Inducement Statute.**

12 There is a clear conflict between AB 290 and the Beneficiary Inducement Statute  
13 as it has been construed and implemented under Advisory Opinion 97-1. AB 290  
14 requires that AKF “disclose to health insurers the names of each insured patient who  
15 will receive premium assistance” in order to “cap[] the dialysis reimbursement rate for  
16 those patients . . . at the Medicare rate, or through an independent dispute resolution  
17 process.” State Br. 6 (citing AB 290 §§ 3(c), (e)). As the State well knows, this process  
18 will result in HIPP patients finding out whether their providers donate to AKF, as their  
19 billing statements will reflect this change. *See* Dkt. 29-2 (RJN Exh. 3, at 34–35)  
20 (California Legislative Counsel Bureau stating “a patient may receive a billing  
21 statement showing that the patient’s reimbursement rate had been lowered to the  
22 Medicare reimbursement rate”).

23 Such an arrangement would violate one of the key factual underpinning on which  
24 Advisory Opinion 97-1 is based. *See* Dkt. 29-2 (RJN Exh. 2, at 24) (“[AKF’s]  
25 administration of HIPP provides sufficient insulation so that the premium payments  
26 should not be attributed to the Companies.”). In turn, that would mean that Advisory  
27 Opinion would no longer serve as a safe harbor against the Beneficiary Inducement  
28 Statute. *See id.* at 26 (“This advisory opinion is limited in scope to the *specific*



1 arrangement described in this letter and has no applicability to other arrangements, even  
2 those which appear similar in nature or scope.” (emphasis added)).

3 AB 290 thus places AKF in an impossible position. As the Supreme Court has  
4 made clear time and again, “when it is ‘impossible for a private party to comply with  
5 both state and federal requirements,’” those State requirements must yield. *Merck*  
6 *Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (quoting *Mutual*  
7 *Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013)). AKF sought Advisory Opinion 97-  
8 1 precisely to avoid the risk of a violation of the Beneficiary Inducement Statute. *See*  
9 Dkt. 132-19 (Burton 2022 Decl. ¶ 31). But complying with AB 290 would require AKF  
10 not only to abandon the safe harbor offered by the Advisory Opinion, but also to do so  
11 on terms that AKF would have never adopted in the first place. Dkt. 132-19 (Burton  
12 2022 Decl. ¶ 36); *see* 42 U.S.C. §§ 1320a-7a(a)(5), 1320a-7a(i)(6) (prohibiting the  
13 giving of “remuneration”—which includes “transfers of items or services for free or for  
14 other than fair market value”—with knowledge that such giving is likely to influence a  
15 Federal health care program beneficiary’s choice of health care provider). Conversely,  
16 for AKF to continue to operate HIPP as it has done so—tightly adhering to the factual  
17 predicates laid out in Advisory Opinion 97-1—will necessarily breach AB 290.

18 Section 7 of AB 290 recognizes this conflict. It provides that “[f]or financially  
19 interested entities covered by Advisory Opinion No. 97-1 issued by the [OIG] . . . this  
20 act shall become operative on July 1, 2020, unless one or more parties to Advisory  
21 Opinion 97-1 requests an updated opinion from [HHS OIG].” AB 290 § 7. That is  
22 strong evidence that the legislature recognized that AB 290 cannot be squared with the  
23 Beneficiary Inducement Statute.

24 More broadly, Section 7’s attempt to coerce AKF into obtaining a revised  
25 advisory opinion is both legally and practically wrongheaded. From the legal side,  
26 “[t]he question for ‘impossibility,’ is whether the private party could *independently* do  
27 under federal law what state law requires of it.” *PLIVA, Inc. v. Mensing*, 564 U.S. 604,  
28 620 (2011) (emphasis added). When confronted with a similar proposition in the drug-

1 labeling context, the Supreme Court explained precisely why it was invalid:

2 We can often imagine that a third party or the Federal Government *might*  
3 do something that makes it lawful for a private party to accomplish under  
4 federal law what state law requires of it. . . . Following [the plaintiffs']  
5 argument to its logical conclusion, it is also *possible* that, by asking, the  
6 Manufacturers could have persuaded the FDA to rewrite its generic drug  
7 regulations entirely or talked Congress into amending the Hatch-Waxman  
8 Amendments.

9 *Id.* at 620–21 (emphasis in original). That reasoning applies here. The mere possibility  
10 that AKF might persuade federal authorities to issue a new advisory opinion or  
11 otherwise forebear from sanctions under the Beneficiary Inducement Statute is  
12 insufficient to evade preemption. “[W]hen a party cannot satisfy its state duties without  
13 the Federal Government’s special permission and assistance, which is dependent on the  
14 exercise of judgment by a federal agency, that party cannot independently satisfy those  
15 state duties for pre-emption purposes.” *Id.* at 623–24.

16 Moreover, it is impractical for AKF to obtain a revised advisory opinion. There  
17 is no guarantee that AKF would receive an opinion sanctioning HIPP on the terms AB  
18 290 requires. Dkt. 132-19 (Burton 2022 Decl. ¶ 49). Further, AKF would face  
19 significant uncertainty while it waits for a revised advisory opinion. *Id.* Donations to  
20 AKF would decline precipitously as a result, leaving fewer funds to assist existing HIPP  
21 patients. *Id.* Moreover, AKF cannot certify in good faith, consistent with OIG’s  
22 advisory opinion regulations, that it will implement HIPP on the terms required by  
23 AB 290. *See* 42 C.F.R. § 1008.43.

24 The only way that AKF can avoid either violating AB 290 or risking crippling  
25 sanctions under the Beneficiary Inducement Statute is to halt operations in California.  
26 *Id.* ¶ 36. But that is no answer at all, neither for the gravely ill patients who rely upon  
27 AKF’s services nor for the principles underlying the law of preemption. *See Mutual*  
28 *Pharm.*, 570 U.S. at 488 (rejecting “‘stop-selling’ rationale” that would have found non-

1 preemption in case where private actor could halt selling affected product in State with  
2 conflicting law). As the Supreme Court has held, “if the option of ceasing to act  
3 defeated a claim of impossibility, impossibility pre-emption would be ‘all but  
4 meaningless.’” *Id.* (quoting *PLIVA*, 564 U.S. at 621).

### 5 **3. The State’s Arguments Are Irrelevant and Inaccurate.**

6 The State contends that “Advisory Opinion 97-1 does not preempt AB 290”  
7 because it “does not impose a requirement with the force of Federal law.” State Br. 9.  
8 But Plaintiffs do not argue that Advisory Opinion 97-1 carries preemptive force; that  
9 comes from the Beneficiary Inducement Statute, for which Advisory Opinion 97-1  
10 constitutes a safe harbor. *See* 42 U.S.C. § 1320a-7d(a)(1)(A). The State cannot dispute  
11 that the Beneficiary Inducement Statute has preemptive effect. *See Mutual Pharm.*, 570  
12 U.S. at 480 (“Even in the absence of an express pre-emption provision, the Court has  
13 found state law to be impliedly pre-empted where it is impossible for a private party to  
14 comply with both state and federal requirements.” (citation and internal quotation marks  
15 omitted)). Nor is the State correct that Advisory Opinion 97-1 lacks the force of federal  
16 law: it is binding on HHS. *See* 42 U.S.C. § 1320a-7d(b)(4) (“Each advisory opinion  
17 issued by the Secretary shall be binding as to the Secretary and the party or parties  
18 requesting the opinion.”).

19 Virtually all the State’s cited cases focus on the extent to which *Chevron*  
20 deference should be granted to various forms of agency decision-making. *See Wos v.*  
21 *E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (discussing “Chevron-style  
22 deference”); *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) (same); *United*  
23 *States v. Mead Corp.*, 533 U.S. 218, 233–34, 326 & n.17 (2001) (same). None of these  
24 cases speaks to preemption. Indeed, the State quotes *Wyeth v. Levine*, 555 U.S. 555  
25 (2009), for the proposition that “an agency regulation with the force of law can pre-  
26 empt conflicting state requirements.” *Id.* at 576.<sup>6</sup>

27 <sup>6</sup> The State attempts to distinguish *Wyeth* by arguing that “an agency action that was not  
28

1 The State also contends that “there is no conflict between” Advisory Opinion 97-  
2 1 and the AB 290, conflating the former with the Beneficiary Inducement Statute. State  
3 Br. 10. The State argues that there is no conflict because “Advisory Opinion 97-1 is by  
4 its own terms limited to federal health care programs, and thereby expressly excludes  
5 programs such as Qualified Health Care Programs, Covered California, employer group  
6 plans, or private insurance.” State Br. 11; *see id.* at 10 (“Advisory Opinion 97-1 only  
7 considers payments for Medicare Part B or Medigap premiums, . . . [and not]  
8 commercial insurance or group health coverage.”). The State is wrong on multiple  
9 levels. Advisory Opinion 97-1 explicitly recognizes that HIPP “provides financial  
10 assistance to financially needy ESRD patients for the costs of medicine, transportation,  
11 and health insurance premiums, *including* Medicare Part B and Medigap premiums.”  
12 Dkt. 29-2 (RJN Exh. 2, at 21) (emphasis added). This inclusive language does not *limit*  
13 HIPP to payments for Medicare Part B and Medigap premiums. Instead, it clarifies that  
14 Medicare Part B and Medigap are included among other insurance benefit programs  
15 that may be paid by AKF without violating the Beneficiary Inducement Statute. In fact,  
16 as OIG recognized, “[HIPP] [a]ssistance is available to all eligible patients on an equal  
17 basis.” *Id.* This would be impossible if HIPP did not include premium payments for  
18 patients enrolled in insurance other than Medicare and Medigap.

19 Nor does the Advisory Opinion restrict its analysis to federal health care  
20 programs. Rather, its analysis focuses on “offers or transfers [of] remuneration to any  
21

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22 the product of notice-and-comment rulemaking does not have the force of law and thus  
23 cannot, by itself, have preemptive effect.” State Br. 10. But the case does not stand for  
24 that proposition. The Supreme Court instead stated that it “ha[d] no occasion in th[at]  
25 case to consider the pre-emptive effect of a specific agency regulation bearing the force  
of law,” only a “preamble” that “d[id] not merit deference.” *Wyeth*, 555 U.S. at 580.

26 The State’s reliance on *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. 2015), also  
27 fails. State Br. 10. That case involved a Food and Drug Letter “couched in tentative  
28 and non-committal terms” that “d[id] not promise that the FDA w[ould] not enforce its  
existing regulation.” *Reid*, 780 F.3d at 965. Advisory Opinion 97-1 is not so limited.

1 individual eligible for benefits [Federal health care programs (including Medicare or  
2 Medicaid)].” *Id.* at 23 (alterations in original; citation and quotation marks omitted).  
3 That language includes more than Medicare and Medigap programs. The State cites  
4 nothing that supports its contrived Medicare-and-Medigap limitation. If HIPP had  
5 exceeded the factual predicates of the Advisory Opinion, as the State contends, then  
6 OIG could have modified or rescinded the Opinion. OIG has done no such thing. That  
7 is strong evidence that the State is wrong. Dkt. 132-19 (Burton 2022 Decl. ¶ 46).

8 The State also contends that the requirements of AB 290 do not conflict with the  
9 factual predicates on which Advisory Opinion 97-1 based its application of the  
10 Beneficiary Inducement Statute. *See* State Br. 11–12. That is plainly incorrect. The  
11 entire basis of Advisory Opinion 97-1 is that AKF’s careful administration of HIPP  
12 “provides sufficient insulation so that . . . premium payments should not be attributed  
13 to [donating] Companies.” Dkt. 29 (RJN Exh. 2, at 24). The State itself has repeatedly  
14 acknowledged that AB 290 will alter this arrangement, as the California Legislative  
15 Counsel Bureau also recognized before the legislature enacted AB 290. *See* Dkt. 29-2  
16 (RJN Exh. 3, at 34–35) (acknowledging “it may be possible . . . for a patient to infer  
17 that the patient’s provider has donated [to AKF]”). The State recognizes the point in its  
18 summary judgment brief, although it asserts—without support or citation—that patients  
19 making a deduction is “highly unlikely.” State Br. 11–12. At core, the State cannot  
20 deny that AB 290 will change the factual arrangement contemplated in Advisory  
21 Opinion 97-1. That is decisive because the Advisory Opinion states that it “is limited  
22 in scope to the specific arrangement described [within it] and has no applicability to  
23 other arrangements, even those which appear similar in nature or scope.” Dkt. 29-2  
24 (RJN Exh. 2, at 26). And, as noted above, there is no guarantee that OIG would permit  
25 HIPP to operate on the terms that AB 290 demands.

26 The State’s arguments on this issue ring hollow for two additional reasons. *First*,  
27 the State’s own agency has admitted that the risk of patient deduction under AB 290 is  
28 ultimately a “determination made by the OIG,” not the State of California. Dkt. 29-2

1 (RJN Exh. 3, at 35). *Second*, the fact that section 7 of AB 290 would halt the operation  
2 of the statute pending AKF’s effort to obtain a new advisory opinion establishes that  
3 the State does see a conflict.

4 **4. AB 290 Is Preempted by the Medicare Secondary Payer Act.**

5 AB 290 also conflicts with the MSPA, 42 U.S.C. § 1395y(b). The MSPA, “as  
6 the name suggests, designate[s] Medicare as the secondary payer in certain  
7 circumstances when both Medicare and a non-Medicare entity have independent duties  
8 to pay for a covered person’s healthcare costs.” *DaVita Inc. v. Virginia Mason Mem’l*  
9 *Hosp.*, 981 F.3d 679, 684 (9th Cir. 2020). Beginning in the late 1980s, however,  
10 “Congress added many provisions that go well beyond simply requiring plans to make  
11 primary payments.” *Id.* at 693. Among these was a requirement that “plans may not  
12 treat persons with ESRD differently even if they are not enrolled in Medicare.” *Id.* As  
13 the Ninth Circuit has observed, “some persons with ESRD never go on Medicare, and  
14 nearly everyone with ESRD is ineligible for Medicare during their first three months of  
15 treatment.” *Id.* The statute and its implementing regulations thus require that group  
16 insurers treat ESRD patients the same as non-ESRD patients, and that plans cannot pay  
17 providers less for the same service for individuals with ESRD than without. 42 U.S.C.  
18 § 1395y(b)(1)(C)(i); 42 C.F.R. § 411.161(b)(2)(iv); SUFCL ¶¶ 48–49. This  
19 arrangement is critical because dialysis is a costly service and Medicare reimbursement  
20 rates are often well below private insurance reimbursement rates. *See Virginia Mason*  
21 *Mem’l Hosp.*, 981 F.3d at 683–84.

22 Accordingly, AB 290 “present[s] an obstacle to the variety and mix of [regulatory  
23 approaches]” selected by Congress in the MSPA and should be preempted. *Geier v.*  
24 *Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000). Dialysis providers that contribute to  
25 AKF become “financially interested” entities under AB 290, *see* AB 290, §§ 3(h)(2)(A),  
26 5(h)(1)(A), and are thus subject to the reduced reimbursement rate for all ESRD patients  
27 on dialysis that are also HIPP recipients, *see id.* §§ 3(e), 5(e). By mandating reduced  
28 reimbursement rates for ESRD patients benefitting from HIPP, AB 290 draws a sharp

1 and impermissible distinction between ESRD patients and those suffering from acute  
2 kidney injuries or other illnesses. This runs entirely counter to the MSPA’s protection  
3 of patients with ESRD.

4 The State resists this result by claiming that “[a]lthough treatments provided to  
5 HIPP recipients may be reimbursed at a lower rate, that is not a result of a patient’s  
6 eligibility or non-eligibility for Medicare.” State Br. 13. For this, the State relies on  
7 the statement in *DaVita Inc. v. Amy’s Kitchen, Inc.* that the “pertinent inquiry” [is]  
8 whether the plan’s provisions ‘result’ in different benefits for persons with ESRD, not  
9 whether the plan’s provisions disproportionately affect persons with ESRD or otherwise  
10 ‘discriminate’ against persons with ESRD.” 981 F.3d 664, 674–75 (9th Cir. 2020).

11 As *Amy’s Kitchen* observes, however, the MSPA has two different requirements:  
12 *first*, a group health plan may not “take into account” a person’s eligibility for Medicare  
13 due to ESRD (42 U.S.C. § 1395y(b)(1)(C)(i)); *second*, a plan may not “differentiate in  
14 the benefits it provides between individuals having [ESRD] and other individuals  
15 covered by [the] plan on the basis of the existence of [ESRD], the need for renal dialysis,  
16 or in any other manner” (*id.* § 1395y(b)(1)(C)(ii)). See *Amy’s Kitchen*, 981 F.3d at 668.  
17 Plaintiffs seek preemption under the latter and, on that ground, *Amy’s Kitchen* does not  
18 speak to whether AB 290 is preempted by the MPSA. *Id.* at 667 (“DaVita brought this  
19 action, arguing that the Plan’s dialysis provisions violate (1) the Medicare as Secondary  
20 Payer provisions . . . of the Social Security Act, (2) the Employee Retirement Income  
21 Security Act of 1974 . . . , and (3) state law”). As with other of its arguments, the State  
22 simply does not engage with Plaintiffs’ claim.

### 23 **III. CONCLUSION**

24 Plaintiffs respectfully request that the Court deny Defendants’ Motion for  
25 Summary Judgment and instead grant Plaintiffs’ Motion for Summary Judgment.

26 Dated: March 25, 2022

By: /s/ Joseph N. Akrotirianakis  
JOSEPH N. AKROTIRIANAKIS  
Attorneys for Plaintiffs