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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

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

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

8:19-cv-2105-DOC-(ADSx)

AMENDED APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date:	May 2, 2022
Time:	8:30 a.m.
Courtroom:	9D
Judge:	The Honorable David O. Carter
Trial Date:	July 12, 2022
Action Filed:	November 1, 2019

Defendants Rob Bonta, Ricardo Lara, Shelly Rouillard, and Tomás Aragón, filed an Application to Seal on February 25, 2022. ECF No. 126. The Court Granted Defendants' Application on March 1, 2022. ECF No. 137.

Due to inadvertence and mistake, Defendants' original Application and proposed order contained errors in the designation of which exhibits to the Declaration of Lisa Plank should be sealed. However, all of the Bates numbers for the sealed documents were included in the original Application.

Nevertheless, in an abundance of caution, Defendants hereby jointly apply and submit this Amended Application for Leave to File Under Seal:

- Documents titled "Premium Impacts of ESRD Patients in the Individual Market (Avalere)," produced in this action and designated Confidential by Plaintiff AKF pursuant to the protective order entered in these cases, and a spreadsheet of donation amounts by providers, Bates Nos. AKF-DOE-10130-10135, 10136, attached as Exhibits 2e and 2f to the Declaration of Lisa Plank.
- A document titled "FMC Insurance Counselor training program – undated 'Day 5' training," produced in this action and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, Bates Nos. FMC4921-4936, attached as Exhibit 4b to the Declaration of Lisa Plank.
- A document relating to "2018 Insurance Coordinator Goals," produced in this action and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, Bates No. FMC4940, attached as Exhibit 4c to the Declaration of Lisa Plank.
- A November 4, 2017 document relating to "Financial Coordinator Bonus Proposal," produced in this action and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, Bates Nos. FMC4941-4943, attached as Exhibit 4d to the Declaration of Lisa Plank.
- Unredacted versions of the 2018 and 2019 Donation Letters from Plaintiff DaVita to Plaintiff AKF specifying annual contribution and subsequent

increases to same, produced in this action and designated Confidential by Plaintiff DaVita pursuant to the protective order entered in these cases, Bates Nos. DAVITA 8273-8275, attached as Exhibit 5a to the Declaration of Lisa Plank.

- Pages 47, 48, 50-51, 63-64, 66, 69-70, 72, 119-120, 148 of the November 18, 2021 deposition of Steve Dover in these matters and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, attached as Exhibit 14b to the Declaration of Lisa Plank.
- Unredacted versions of the Memorandum of Points and Authorities in Support of Defendants' Motion for Summary Judgment as to the Doe Complaint, Portions of the Memorandum of Points and Authorities in Support of Defendants' Motion for Summary Judgment as to the Fresenius Complaint, and portions of the Statement of Undisputed Facts in support of both motions, all of which include references to information that Plaintiffs have deemed Confidential pursuant to the protective order entered in these cases.

This Amended Application for Leave to File Under Seal in Support of Defendants' Motions for Summary Judgment (Application) is brought pursuant to L.R. 79-5 et seq., Federal Rules of Civil Procedure, Rules 5.2 and 26(c), and the protective order for the Doe and Fresenius matters. The Application is accompanied by the concurrently-filed Declaration of S. Clinton Woods, a proposed order, the unredacted versions of documents proposed to be filed under seal, and the redacted versions of documents to be filed for public access as Exhibits to the Declaration of Lisa J. Plank.

Because all of the documents that Defendants seek to file under seal contain information previously designated as confidential by Plaintiffs pursuant to a protective order (ECF No. 70), this Application is made pursuant to the requirements under L.R. 79-5.2.2(b).

The stipulated protective order "provides protections for material including personally-identifiable information." ECF No. 70, 7:15-20. The protective order

states that good cause exists to protect confidential material of a "commercial, financial, technical, or proprietary nature." Id. at 3:23-24. The protective order further states that the parties must comply with L.R. 79-5.1 if they seek to file anything under seal" regarding material designated "confidential" in the order. Id. at 3:17. Local Rule 79-5.1 states that "[a] person seeking to have a case or document sealed must follow the procedures set forth below." L.R. 79-5.1. Parties seeking to file a document under seal must first obtain court approval via an Application for Leave to File Under Seal. L.R. 79-5.2.

This Application is subject to Local Rule 5-2.2(b) because Defendants are asking the Court to seal documents in a non-sealed civil case, and the proposed documents contain information previously designated as confidential by the Court in a protective order. ECF No. 70. Pursuant to Local Rule 79-5.2.2(b), Defendants request that the items identified above be filed under seal because the redacted information—specifically, documents produced and designated Confidential by Plaintiffs—are relevant to the determination of the concurrently-filed motions for summary judgment. Filing only redacted copies of the documents would obscure the factual information necessary to defeat some of Plaintiffs' claims, and moreover, the documents have been designated as confidential in their entirety pursuant to the protective order in place in this matter. ECF No. 70.

On Friday, February 18, 2022, counsel for Defendants met and conferred with counsel for Plaintiffs. On Wednesday, February 23, 2022, Defendants provided Plaintiffs with a copy of the instant Application consistent with the Court's Standing Order. Plaintiffs continued to assert confidential or highly confidential designation on the documents that remain the subject of this Application, and Defendants do not oppose those designations.

Plaintiffs contend that all commercially or competitively sensitive technical, financial or proprietary information should be filed under seal. This type of

information is included in the documents identified above and designated by Plaintiffs as confidential.

Defendants acknowledge that there is a strong presumption of public access in civil cases, and "[h]istorically, courts have recognized a 'general right to inspect and copy public records and documents, including judicial records and documents.'" Kamakana v. City and Cty. of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006) (citing Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 597 (1978)). Access to judicial records, however, is not absolute, and documents may be sealed for "important policy reasons." Id. Such important policy reasons exist in this case.

In an effort to uphold the sanctity of public access, Defendants have filed blank and redacted copies of the above-listed documents with the Declaration of Lisa Plank filed in support of their concurrently filed motions for summary judgment, along with partially-redacted versions of the supporting briefs, which substantively refer to information that Plaintiffs have designated confidential. It is Defendant's understanding that the proposed redactions are sufficient to allow these documents to be publicly filed because they redact all commercially-sensitive or personally identifiable information that the parties and the Court's previous protective order acknowledge is "confidential."

Accordingly, Defendants request that the documents identified above be filed under seal.

Dated: March 2, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
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R. MATTHEW WISE
Supervising Deputy Attorneys General
LISA PLANK
Deputy Attorney General

/s/ S. Clinton Woods
S. CLINTON WOODS
Deputy Attorney General
Attorneys for Defendants
Rob Bonta, et al.

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CERTIFICATE OF SERVICE

Case Name: ***Jane Doe, et al v. Xavier Becerra, et al.*** No. **8:19-cv-02105-DOC-(ADSx)**

I hereby certify that on March 3, 2022, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

- **AMENDED APPLICATION TO LEAVE TO FILE UNDER SEAL WITH REDACTED ATTACHMENTS**
- **[PROPOSED] ORDER GRANTING DEFENDANTS' AMENDED APPLICATION FOR LEAVE TO FILE UNDER SEAL**

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct and that this declaration was executed on March 3, 2022, at San Francisco, California.

Kazzi Figueroa-Lee
Declarant

Signature

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiffs,

v.

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Defendants.

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

[PROPOSED] ORDER GRANTING DEFENDANTS' AMENDED APPLICATION FOR LEAVE TO FILE UNDER SEAL

The Court, having reviewed the pleadings on file and considered the argument of counsel, and with good cause appearing, hereby orders the following documents be filed under seal pursuant to the Local Rule 79-5.2:

- Documents titled "Premium Impacts of ESRD Patients in the Individual Market (Avalere)," produced in this action and designated Confidential by Plaintiff AKF pursuant to the protective order entered in these cases, and a spreadsheet of donation amounts by providers, Bates Nos. AKF-DOE-10130-10135, 10136, attached as Exhibits 2e and 2f to the Declaration of Lisa Plank.
- A document titled "FMC Insurance Counselor training program – undated 'Day 5' training," produced in this action and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, Bates Nos. FMC4921-4936, attached as Exhibit 4b to the Declaration of Lisa Plank.
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- A November 4, 2017 document relating to "Financial Coordinator Bonus Proposal," produced in this action and designated Confidential by Plaintiff Fresenius pursuant to the protective order entered in these cases, Bates Nos. FMC4941-4943, attached as Exhibit 4d to the Declaration of Lisa Plank.
- Unredacted versions of the 2018 and 2019 Donation Letters from Plaintiff DaVita to Plaintiff AKF specifying annual contribution and subsequent increases to same, produced in this action and designated Confidential by Plaintiff DaVita pursuant to the protective order entered in these cases, Bates Nos. DAVITA 8273-8275, attached as Exhibit 5a to the Declaration of Lisa Plank.
- Pages 47, 48, 50-51, 63-64, 66, 69-70, 72, 119-120, 148 of the November 18, 2021 deposition of Steve Dover in these matters and designated Confidential by

Plaintiff Fresenius pursuant to the protective order entered in these cases, attached as Exhibit 14b to the Declaration of Lisa Plank.

- Unredacted versions of the Memorandum of Points and Authorities in Support of Defendants' Motion for Summary Judgment as to the *Doe* Complaint, Portions of the Memorandum of Points and Authorities in Support of Defendants' Motion for Summary Judgment as to the *Fresenius* Complaint, and portions of the Statement of Undisputed Facts in support of both motions, all of which include references to information that Plaintiffs have deemed Confidential pursuant to the protective order entered in these cases.

IT IS SO ORDERED.

Dated: _____

_____
The Honorable David O. Carter

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

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

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date: May 2, 2022
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: July 12, 2022
Action Filed: November 1, 2019

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INTRODUCTION

Assembly Bill 290, enacted by the California Legislature in 2019, addresses a troubling trend in the dialysis industry—a willingness among large providers to exploit the Affordable Care Act's reforms for their own benefit and to the detriment of their patients and the general public. Professing that their business practices are above reproach, Plaintiffs (and their provider partners) attribute AB 290's enactment to lobbying by "the commercial health insurance industry and its labor union allies," which "seek[] to pressure dialysis providers into unionizing their workforces." ECF No. 1 (Compl.), ¶ 11. But Plaintiffs' attempt at misdirection cannot paper over the overwhelming evidence that, at least since 2014, large providers—in particular, DaVita and Fresenius—have maximized their profits (and distorted the insurance risk pool) by steering end-stage renal disease (ESRD) patients who are eligible for Medicare or Medi-Cal into commercial insurance, and funneling money to Plaintiff American Kidney Fund (AKF) to cover the insurance premiums. This open secret within the industry has been the subject of numerous regulatory efforts at the federal and state level, challenged in lawsuits filed throughout the country, and widely covered in the media. Against this backdrop, AB 290 was enacted to protect patients from higher out-of-pocket costs, mid-year disruptions in coverage, and difficulty in obtaining life-saving kidney transplants and to protect the general public from soaring health care costs—in other words, to "alleviate [] to a material degree" "harms [that] are real." *See Edenfield v. Fane*, 507 U.S. 761, 771 (1993).

Plaintiffs challenge AB 290 on two grounds—that it is preempted by federal law and that it violates the First Amendment. Neither claim has merit.

Plaintiffs first allege that AB 290 is preempted by Advisory Opinion 97-1, an opinion issued by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) over two decades ago. But Advisory Opinion 97-1 cannot preempt AB 290 because it does not impose a mandate with

the force of federal law; it is merely a finding that the AKF's practices with respect to the payment of Medicare Part B and Medigap policies, as described in 1997, complied with the Health Insurance Portability and Accountability Act (HIPAA). Nor does AB 290 conflict with Advisory Opinion 97-1, which does not even address premium payments for commercial health insurance or group health plans.

Plaintiffs also allege that AB 290 is preempted by the Medicare Secondary Payer Act (MSPA). This claim fails as a matter of law because AB 290, which treats all ESRD patients equally, does not conflict with MSPA provisions that prohibit disparate treatment of patients based on their Medicare eligibility or their ESRD status.

Plaintiffs' assortment of First Amendment arguments fares no better. AB 290's steering prohibition is constitutionally sound: it does not restrict AKF from appropriately assisting patients, and it provides fair notice of the prohibited conduct. AB 290's reimbursement cap does not even implicate AKF's right of association because AKF has no First Amendment right to "amass funds" from dialysis providers. *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 892 (9th Cir. 2018). Nor do AB 290's disclosure provisions unlawfully coerce speech; they require only the truthful disclosure of "purely factual and uncontroversial information" about a patient's coverage options, AKF's compliance with AB 290's provisions, and the identity of patients receiving assistance from AKF. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). And the provision in AB 290 allowing AKF to request an updated advisory opinion from OIG does not violate AKF's right to petition, or any other First Amendment right, because it does not compel AKF to do anything at all.

This Court should reject Plaintiffs' attempt to upset the careful balance struck by the Legislature to protect vulnerable patients while preserving the ability of Plaintiff American Kidney Fund to provide financial assistance to patients in need. Because there is no genuine issue of material fact as to whether Plaintiffs'

constitutional rights were infringed, Defendants' motion for summary judgment should be granted.

BACKGROUND

I. THE DIALYSIS INDUSTRY'S SELF-FUNDED PRIVATE INSURANCE SCHEME

End-stage renal disease "is irreversible and permanent." Defendants' Statement of Uncontroverted Facts and Conclusions of Law (SUF) 1. ESRD patients require a kidney transplant or regular dialysis to survive. SUF 2. Recognizing the necessity and high costs of treatment, Congress permitted ESRD patients, regardless of age, to obtain Medicare coverage when it enacted the Social Security Amendments of 1972. SUF 3. Medicare covers a range of services to treat kidney failure, including transplant and dialysis services, along with other health care needs. SUF 4. Some patients may qualify for and receive coverage through both Medicare and Medi-Cal, California's Medicaid system. SUF 5.

In 2010, the Patient Protection and Affordable Care Act (ACA) enacted a set of reforms "to make health insurance more affordable and accessible to millions of Americans." SUF 6. One such reform, which took effect on January 1, 2014, "prohibited insurers . . . from imposing pre-existing condition exclusions" and required them "to guarantee the availability and renewability of non-grandfathered health plans to any applicant." *Id*. Under this "guaranteed issue" provision, among other ACA provisions, ESRD patients can no longer be denied coverage or charged higher premiums based on their health status. *See id.*

These provisions, together with the "higher reimbursement rates available through private coverage when compared to Medicare," "in effect created a financial incentive for dialysis facilities to leverage [the higher rates] by providing premium assistance to ESRD patients"—primarily through a third party entity, Plaintiff AKF—"and inappropriately steering them to purchase coverage in the individual market." SUF 7. HHS became concerned that health care providers

were "encouraging individuals to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patients." SUF 8. Based on this concern, the Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information on August 23, 2016, seeking public comment "about health care providers and provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates." SUF 9. In response, CMS received over 800 public comments from patients, providers, and other stakeholders. SUF 10.

These comments "documented a range of concerning practices, with providers and suppliers"—such as DaVita and Fresenius—"influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients." *Id.* In particular, commenters noted that patients "are sometimes specifically discouraged from pursuing Medicare or Medicaid" and "are unaware that a dialysis facility is seeking to enroll them in the individual market," and that facilities "retaliate against social workers who attempt to disclose additional information to consumers." SUF 11. Commenters agreed that these practices are fueled by a powerful incentive—the considerably higher rates that commercial coverage reimburses dialysis providers as compared to public coverage. SUF 12. Even more troubling, HHS's own data and the comments "suggest[ed] that this inappropriate steering of patients may be accelerating over time." SUF 13.

The comments also reflected three types of possible harms to patients: "[n]egatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage." SUF 14. In addition, comments "indicat[ed] that inappropriate steering practices"—which add ESRD patients to the individual market—"could have the effect of skewing the insurance risk pool." SUF 15.

In the face of such harms, "which go to essential patient safety and care in life-threatening circumstances," CMS issued an interim final rule establishing new standards for Medicare-certified dialysis facilities that pay premiums for individual market health plans, whether directly or through another entity. SUF 16. But shortly after that rule was issued, it was enjoined for failure to comply with Administrative Procedures Act requirements. SUF 17. That decision was not appealed.

II. CALIFORNIA'S EFFORTS TO REGULATE THE DIALYSIS INDUSTRY

In the absence of federal regulations addressing inappropriate steering of dialysis patients, states across the country, including California, took action. SUF 18.[1] In 2018, the California Legislature passed Senate Bill 1156, a predecessor to AB 290. SUF 19. But Governor Brown ultimately vetoed SB 1156 because it "would permit health plans and insurers to refuse premium assistance and to choose which patients they will cover." SUF 20.

The following legislative session, the Legislature considered AB 290, which included provisions addressing the reason for Governor Brown's veto. AB 290, § 3(m) (reaffirming obligations of health insurers, including the requirement not to "deny coverage to an insured whose premiums are paid by a third party"). Echoing CMS's concerns, the Legislature observed that "third-party payment arrangements have proliferated in recent years as a result of health care providers that have demonstrated a willingness to exploit the Affordable Care Act's guaranteed issue rules for their own financial benefit," which has the effect of "expos[ing] patients to direct harm." AB 290, §§ 1(b)-(c). The Legislature noted that this trend coincided with a rise in DaVita and Fresenius's "market dominance"—these companies now account for 92 percent of all dialysis industry revenue nationwide. *Id.*, § 1(g). The Legislature also embraced CMS's findings that "patients caught up in these

[1] As detailed in SB 1156's legislative record, these states include Delaware, Idaho, Louisiana, Minnesota, New Mexico, North Carolina, Oregon, and Washington. SUF 18.

schemes may face higher out-of-pocket costs and mid-year disruptions in coverage, and may have a more difficult time obtaining critical care such as kidney transplants." *Id.*, § 1(d). And the Legislature recognized that "[c]onsumers also pay higher health insurance premiums due to the distortion of the insurance risk pool" caused by inappropriate steering. *Id.*, § 1(e).

AB 290 approaches the problem at hand from at least three angles. First, AB 290's anti-steering provisions prohibit chronic dialysis clinics from "steer[ing], direct[ing], or advis[ing] a patient regarding any specific coverage program option or health care service plan contract"; require a "financially interested entity" that is making third-party premium payments to notify patients of alternative coverage options, including Medicare and Medicaid; and provide that financial assistance shall not be conditioned on use of any particular facility, healthcare provider, or coverage type. *Id.*, § 2(a), §§ 3(b)(3) & 3(b)(5).[2] Second, AB 290 caps the dialysis reimbursement rate for those patients receiving third-party premium assistance at the Medicare rate, or through an independent dispute resolution process. *Id.*, § 3(e).[3] Third, AB 290 requires that a financially interested entity providing premium assistance submit an annual statement of compliance with the law and disclose to health insurers the names of each insured patient who will receive premium assistance. *Id.*, § 3(c).[4]

[2] The provisions in Section 3 of AB 290 that were added to the Health and Safety Code were also added to the Insurance Code in Section 5 of the bill.

[3] This provision also prohibits providers from billing or seeking reimbursement from the insured patient for services, except for co-payments according to the patient's insurance plan contract. AB 290, § 3(e). Given that third party entities such as AKF often provide patients with debit cards that patients then use to pay their premiums, SUF 21, prohibiting providers from directly billing enrollees facilitates the identification of patients receiving premium assistance.

[4] Insurance companies are then required to report to the California Department of Managed Health Care or Department of Insurance, as applicable, the number of patients who received premium assistance, the identity of providers subject to the Medicare rate cap, and the identity of providers who failed to comply with the disclosure requirements. AB 290, §§ 3(j) & 5(j).

III. AKF'S PLAN TO LEAVE CALIFORNIA

Plaintiff AKF not only opposed AB 290, but notified the Legislature that it would "be forced to shut down in California if AB 290 is enacted" because, in its view, "AB 290 would take us outside the protection of our Advisory Opinion." RJN, Ex. 1.[5] That opinion, Advisory Opinion 97-1, issued by HHS's OIG in 1997 at AKF's request, concluded that AKF's practice of paying Medicare Part B and Medigap premiums for ESRD patients in financial need did not violate the federal prohibition against providing remuneration to Medicare-eligible individuals if such remuneration is likely to influence the individual's health care choices. SUF 63. OIG found it significant that AKF, rather than dialysis providers, determined which patients would receive AKF's Health Insurance Premium Program (HIPP) assistance and that HIPP assistance was available regardless of the patient's provider. SUF 64. AB 290 would have no impact on these aspects of HIPP. Advisory Opinion 97-1 also specifies that it is "case specific" and "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope." SUF 65.[6]

While AB 290 does not conflict with Advisory Opinion 97-1, the Legislature nonetheless made a concerted effort to accommodate AKF's concerns that AB 290 and Advisory Opinion 97-1 are incompatible. SUF 22. In particular, the Senate amended AB 290 so that it would not become operative as to financially interested entities covered by Advisory Opinion 97-1 until July 1, 2020—and any entity that

[5] California's Legislative Counsel concluded, in contrast, that based on the available facts, AKF "would remain in compliance with the arrangement approved in Advisory Opinion 97-1" if AB 290 were enacted and AKF "complies with the changes enacted by that bill." SUF 66.

[6] Much has changed since Advisory Opinion 97-1 was issued. Back then, ESRD patients generally lacked access to commercial insurance, and "less than ten percent" of donations to AKF were from companies that owned dialysis providers. SUF 67. But now, reforms under the ACA have made commercial insurance more widely available, and as AKF has expanded HIPP assistance to pay the premiums of commercially-insured patients, the contributions of "[l]arge dialysis companies" have grown to "more than 80 percent" of AKF's revenue. AB 290, § 1(h); *see also* Plank Decl., ¶ 5, Ex. 3.

requested an updated advisory opinion would be exempt until OIG issued an opinion confirming that AB 290 does not conflict with federal law. *Compare* RJN, Ex. 2, *with* AB 290, § 7. The Senate also amended the bill to ensure that AKF could continue to provide premium assistance to patients who were receiving assistance as of October 1, 2019, without complying with AB 290's requirements. *Compare* RJN, Ex. 2, *with* AB 290, §§ 3(d)(1)) & 5(d)(1).[7] Yet AKF maintained its plans to leave California at the end of 2019, despite these amendments largely delaying AB 290's implementation. SUF 71.

Governor Newsom signed AB 290 on October 13, 2019.

PROCEDURAL HISTORY

Plaintiffs filed their complaint on November 5, 2019. Days later, they filed a preliminary injunction motion, ECF No. 28, which Defendants opposed, ECF No. 46. On December 30, 2019, this Court granted Plaintiffs' motion, enjoining AB 290 in its entirety. ECF No. 58 at 17. After a delay due to the COVID-19 pandemic, proceedings restarted last fall. ECF No. 121.

LEGAL STANDARD

Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). While the Court must draw all reasonable inferences in favor of the nonmoving party, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), Rule 56(c) "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

[7] In addition, the Senate amended AB 290 to delay implementation of the Medicare-linked reimbursement cap until January 1, 2022. *Compare* RJN, Ex. 2, *with* AB 290, §§ 3(d)(1)) & 5(d)(1).

ARGUMENT

I. AB 290 IS NOT PREEMPTED BY FEDERAL LAW

Plaintiffs' contention that Advisory Opinion 97-1 preempts AB 290 fails because the Advisory Opinion (1) does not have the force of federal law, and (2) does not conflict with AB 290. Nor is there a conflict between AB 290 and the Medicare Secondary Payer Act.

A. Advisory Opinion 97-1 Does Not Preempt AB 290

1. Advisory Opinion 97-1 Does Not Impose a Requirement with the Force of Federal Law

Advisory Opinion 97-1 examines AKF's practice in 1997 of paying premiums for Medicare Part B and Medigap policies using funds that were donated in part by dialysis companies and concludes that the arrangement as described did *not* fall within the HIPAA remuneration prohibition. SUF 63. Advisory Opinion 97-1 is therefore a finding that AKF's practices with respect to the payment of Medicare Part B and Medigap policies, as described in 1997, complied with HIPAA.[8] It imposes no legal obligations on AKF or any other entity. Nor does it immunize AKF from compliance with state law or purport to preempt state law.

Plaintiffs are thus incorrect to ascribe to Advisory Opinion 97-1 the mandate of federal law. It is black letter law that "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all . . . lack the force of law[.]" *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (agency memorandum and letter approving of state statutory scheme for Medicaid reimbursement were "opinion letters, not regulations with the force of

[8] At the time the Advisory Opinion was issued, patients with ESRD were usually unable to obtain commercial insurance because ESRD was an expensive pre-existing condition. SUF 68. Thus, AKF paid Medigap and Medicare Part B premiums for patients on dialysis. After the ACA was enacted in 2010, many more patients with ESRD were able to access commercial insurance because the ACA prohibits insurance companies from discriminating against patients with pre-existing conditions. SUF 69.

law"); *United States v. Mead Corp*., 533 U.S. 218, 233 (2001) (federal agency's "classification ruling" letters did not have the force of law when agency did not engage in notice-and-comment, and did not bind third parties).

Although "an agency regulation with the force of law can pre-empt conflicting state requirements," an agency action that was not the product of notice-and-comment rulemaking does not have the force of law and thus cannot, by itself, have preemptive effect. *Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009) (cleaned up); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (Ninth Circuit "declin[es] to afford preemptive effect to agency actions that do not carry the force of law under *Mead* and its progeny"). Accordingly, Advisory Opinion 97-1 does not have the force of federal law or regulation and cannot preempt AB 290.

2. Advisory Opinion 97-1 Does Not Conflict with AB 290

Even if Advisory Opinion 97-1 had the force of a federal statute or regulation, it would not preempt AB 290 because there is no conflict between the Opinion and the statute. First, the Opinion's conclusion that AKF's practice of paying Medicare Part B and Medigap premiums did not violate a federal prohibition does not immunize that practice as it existed in 1997—or AKF's current practices, which differ substantially—from the application of state consumer protection or insurance laws. States routinely prohibit conduct that is not prohibited under federal law, and nothing in the Opinion indicates that AKF *must* be permitted to pay Medicare Part B and Medigap premiums, such that AB 290 conflicts with the Opinion.

Second, by its own express terms, Advisory Opinion 97-1 only considers payments for Medicare Part B or Medigap premiums. SUF 65 (Opinion is "case specific" and "limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."). It does not discuss premium payments for commercial insurance or group health coverage. Thus, the Opinion's restrictions would apply only to payments for Medicare Part B or Medigap premiums, neither which fall within the

scope of AB 290. *See* AB 290, §§ 3(h)(3) & 5(h)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government [or] Medicare supplement coverage"). Moreover, the fact that other types of coverage options have been created since 1997 does not shift the scope of the Opinion because Advisory Opinion 97-1 is by its own terms limited to federal health care programs, and thereby expressly excludes programs such as Qualified Health Care Programs, Covered California, employer group plans, or private insurance. SUF 72.

Even if Advisory Opinion 97-1 could be construed to apply to premium payments for commercial health insurance and group health plans—and it cannot—it still would not conflict with AB 290. Nothing in AB 290 prevents AKF from using its funds in accordance with its charitable mission or restricts the kinds of patients AKF may help. AB 290 and Advisory Opinion 97-1 also both require that financial assistance not be conditioned on the use of a specific facility or health care provider. SUF 73; AB 290, §§ 3(b)(2) & 5(b)(2). The Opinion is also silent on disclosure of provider contributions to health plans or health insurance companies, and only requires that AKF not disclose a provider's contributions to other providers. AB 290's requirement that AKF disclose provider contributions to health plans or health insurance companies is thus consistent with the Opinion.

Plaintiffs will likely claim that because AB 290 requires AKF to disclose a HIPP recipient's identity to their insurer, the disclosure will lead the HIPP recipient to determine that their provider is a donor, and the recipient will then feel obligated to stay with their provider—a chain of events which they allege is contrary to Advisory Opinion 97-1. To be clear, a HIPP recipient is highly unlikely to learn of their dialysis providers' donor status because of AKF's disclosure. SUF 74. But even under Plaintiffs' theory, a HIPP recipient would only *potentially* learn that their provider is a donor *after* (1) picking a provider, (2) applying for and receiving HIPP, (3) obtaining dialysis, and (4) receiving a benefits statement. By then, the

HIPP recipient has already picked a provider without undue influence, as required by Advisory Opinion 97-1.

B. The Medicare Secondary Payer Act Does Not Preempt AB 290

Plaintiffs also inaccurately contend that AB 290 conflicts with requirements in the Medicare Secondary Payer Act (MSPA) that insurers treat ESRD and non-ESRD patients equally, such that payments for the same service cannot vary based on a patient's ESRD status. Plaintiffs rely on the "take into account" and "non-differentiation" provisions in the MSPA's ESRD sections. Neither provision preempts AB 290.

The "take into account" provision prohibits group health plans from "tak[ing] into account that an individual [with ESRD] is entitled to or eligible for [Medicare] benefits" for the first thirty months of eligibility. 42 U.S.C. § 1395y(b)(1)(C)(i). Similarly, the "nondifferentiation" requirement provides that group health plans "may not differentiate in the benefits [they] provide[] between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner" during the first thirty months of Medicare eligibility. *Id.* § 1395y(b)(1)(C)(ii). Prohibited "differentiation" includes "[i]mposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations" and "[p]aying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD . . . ." 42 C.F.R. §§ 411.161(b)(ii), (iv). The "pertinent inquiry' is "whether the plan's provisions 'result' in *different benefits for persons with ESRD*, not whether the plan's provisions disproportionately affect persons with ESRD or otherwise 'discriminate' against persons with ESRD." *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 674-75 (9th Cir. 2020).

Plaintiffs argue that AB 290 requires insurers to violate both of these provisions because a financially interested provider as defined by the statute would

receive different reimbursement—one amount for HIPP recipients (who necessarily have ESRD) and another amount for everyone else. But Plaintiffs do not—and cannot—show that AB 290 requires health plans to treat patients differently based on their Medicare eligibility or their ESRD status. Although treatments provided to HIPP recipients may be reimbursed at a lower rate, that is not a result of a patient's eligibility or non-eligibility for Medicare. The statute makes no distinction among patients based on their Medicare eligibility; a plan can "ignore[]" this factor. *Amy's Kitchen*, 981 F.3d at 670. Nor does the statute require differentiation between patients based on their ESRD status; a plan can "provide[] identical benefits to someone with ESRD as to someone without ESRD" and thus "not 'differentiate' between those two classes." *Id.* at 678. AB 290 comports with the MSPA.[9]

II. AB 290 DOES NOT VIOLATE PLAINTIFFS' FIRST AMENDMENT RIGHTS

A. AB 290's Steering Prohibition Neither Restricts Plaintiff AKF's Speech Nor Is Unconstitutionally Vague

AB 290 provides that a chronic dialysis clinic or financially interested entity cannot "steer, direct, or advise" a patient toward a specific coverage option or health care plan. AB 290, §§ 2(a), 3(b)(4). As shown below, this steering prohibition is constitutionally sound.

1. AB 290's Steering Prohibition Permissibly Regulates Commercial Speech

The steering prohibition regulates commercial speech. Under the governing test from *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), speech may be "characterized as commercial when (1) the speech is admittedly advertising, (2)

[9] On March 1, 2022, the Supreme Court will hear oral argument in *Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc.*, No. 20-1641, which addresses whether a group health plan that provides uniform reimbursement of all dialysis treatments nonetheless violated the MSPA's "take into account" and "nondifferentiation" provisions under a disparate impact theory. Because AB 290 does not require a plan to take any actions that would result in disparate treatment of or disparate impact on patients based on their Medicare eligibility or their ESRD status, Plaintiffs are unlikely to be able to salvage their preemption claim based on the Supreme Court's decision in *Marietta*.

the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger*, 463 U.S. at 66-67). While the combination of all of these characteristics strengthens the conclusion that the speech at issue is "properly characterized as commercial speech," it is not necessary for "each of the characteristics" to "be present in order for speech to be commercial." *Bolger*, 463 U.S. at 67 n.14.

The steering prohibition meets the latter two *Bolger* factors. It primarily regulates patient interactions with dialysis social workers and insurance counselors, who are tasked with helping patients "obtain insurance and apply for financial assistance," and who "may face a perceived or actual conflict of interest in doing so, since they may recommend insurance options that help patients remain on dialysis and maximize profits for the dialysis centers in which they work." SUF 23. The economic motive for these staff to promote a specific product—commercial insurance, for which "reimbursement rates [] are many times the cost associated with providing care"—is powerful. AB 290, § 1(g). Documents in the legislative record, including J.P. Morgan research reports, detail how critical commercial patients are to the providers' bottom line. SUF 24 (e.g., report describing the increase in "[i]nvestor concern regarding [DaVita's] commercial mix and earning power" in light of the probability that DaVita was "receiving more than its market share" of HIPP-supported commercial patients). So do the providers' communications with shareholders. SUF 25 (assurance from Fresenius CEO that loss of commercial payers in 2018 was "self-inflicted" and that the company would "sort through what needs to be done and get it fixed"). [redacted]. *See*, *e.g.*, SUF 26. The steering prohibition thus regulates a commercial transaction between patients and providers.

Because commercial speech is at issue, intermediate scrutiny applies: AB 290 must directly advance a substantial governmental interest and do so in a manner that is not more extensive than necessary. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Put another way, AB 290 must tackle harms that are "real" and must "in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. Indeed, AB 290 is tailored to address a practice with harms so compelling that the law would survive any level of scrutiny.

That practice—"encouraging," or steering "patients to enroll in commercial insurance coverage for the financial benefit of the provider"—is well documented. AB 290, § 1(c). In addition to the CMS record, *ante* Background I, the SB 1156 legislative record refers to a Washington Office of the Insurance Commissioner (OIC) order requiring DaVita "to immediately stop engaging in the business of unauthorized insurance via steering dialysis patients into higher reimbursing plans by offering to pay premiums." SUF 27. Washington OIC took enforcement action after learning that DaVita insurance coordinator Cary Ancheta had attempted "to sign up approximately 30 kidney dialysis patients, most of whom [we]re receiving Medicaid," onto commercial insurance. SUF 28. The order was rescinded by stipulation of the parties on the condition, among other requirements, that DaVita counselors "not ask or urge dialysis patients to enroll in any particular kind of insurance from any particular insurer" for a period of two years. SUF 29.

That investigation also uncovered evidence provided by a former DaVita social worker of a DaVita PowerPoint presentation directing insurance counselors and social workers "to 'target' Medicaid eligible patients to get them to purchase commercial insurance." SUF 30. Known as "Medicaid Opportunity," this program, which began in 2015, was designed to increase the number of Medicaid patients enrolled in an individual market plan (paid for with HIPP assistance) as primary coverage. SUF 31. DaVita set about to discuss this "absolutely amazing opportunity" with "every single" patient on Medicaid. SUF 32. DaVita considered

this program a "true win-win situation" for patients and DaVita. SUF 33. DaVita's efforts to enroll patients in HIPP to facilitate the move to private primary insurance were meticulously tracked, and staff were urged to use "additional hours" to ensure that every patient was "educated" on HIPP availability. SUF 34.

While Plaintiffs are unwilling to publicly admit that they have engaged in patient steering, this practice has achieved notoriety in recent years. It has been the subject not only of federal rulemaking and state regulatory efforts, but of numerous lawsuits. One federal court, observing that DaVita's "own definition of 'steering' [] as legal communications with ESRD patients" was "a weak plausible alternative explanation as to the meaning of the statement that it 'does not steer,'" concluded that there was a "strong inference that [DaVita] made statements about steering and the source of [DaVita's] financial success with the intent to manipulate, deceive, or defraud." SUF 37 (*Peace Officers' Annuity and Benefit Fund of Ga. v. DaVita Inc.*, 372 F. Supp. 3d 1139, 1155 (D. Colo. 2019); *id.* at 1143, 1147 (denying DaVita's motion to dismiss securities fraud class action alleging that DaVita made false and misleading statements about steering patients toward private insurance and the impact on its performance)). Another federal court determined that it was "reasonable to infer . . . that the Medicaid Opportunity initiative was part of a

larger, systematic plan by DaVita's management to drive revenues and profitability through [DaVita's] AKF donations." SUF 38 (*In re DaVita Inc. v. Stockholder Derivative Litig.*, No. 17-152-MPT, 2019 WL 1855445, *14 (D. Del. Apr. 25, 2019); *id.* at *1, *12 (denying DaVita's motion to dismiss stockholder derivative action challenging specific Board decisions related to the Medicaid Opportunity initiative)).[10] This industry scheme has also been the focus of countless news articles and investigative journalism (*see*, e.g., SUF 39)[11] and even the report of a California-based House representative.[12]

As the old adage goes, where there's smoke, there's fire. There is ample evidence that when the Legislature turned its attention to regulating patient steering, it was dealing with a "real" problem. *See Edenfield*, 507 U.S. at 771.

And steering causes real harm. As described in the CMS record and the legislative findings, *ante* Background I and II, steering injures patients in at least three ways. First, patients steered into commercial insurance who would have been eligible for a kidney transplant under Medicare may be unable to demonstrate the financial means to care for a new kidney, given that HIPP assistance ends within months to a year of transplant. SUF 40 (e.g., public comment of Dr. Teri Browne, observing that the expected loss of HIPP assistance post-transplant "results in dialysis patients not being eligible to get listed for a kidney transplant"). This "threat of cessation of health insurance benefits" not only impairs transplant eligibility but "may induce some patients to remain on dialysis and never pursue

[10] Other similar lawsuits include *BlueCross and BlueShield of Fla. v. DaVita*, No. 19-cv-574 (M.D. Fla.), *see* Plank Decl., ¶ 17, Ex. 15, and *United States, ex. rel. Gonzalez v. DaVita Health Care Partners*, No. 166-cv-11840-NMG (D. Mass), *see* Plank Decl., ¶ 18, Ex. 16.

[11] *See also,* Carrie Arnold, *Kidney Dialysis is a Booming Business; Is It also a Rigged One?*, Scientific American, Dec. 14, 2020, available at https://www.scientificamerican.com/article/kidney-dialysis-is-a-booming-business-is-it-also-a-rigged-one1/ (last accessed Feb. 24, 2022); *Is Dialysis a Test Case of Medicare for All?*, Freakonomics Radio (Podcast), Apr. 7, 2021, available at https://freakonomics.com/podcast/dialysis/ (last accessed Feb. 16, 2022).

[12] *See* Plank Decl., ¶ 13, Ex. 11 (*Dying on Dialysis: Inside an Industry Putting Profits Over Patients, a report by the Office of Congresswoman Katie Porter*, July 15, 2021).

transplant." SUF 41. Second, patients steered into commercial insurance are saddled with high out-of-pocket expenses post-transplant when HIPP assistance ends, which may lead them to stop taking their immunosuppressant drugs, causing their transplant to fail. SUF 42 (e.g., observation of Dr. Browne that post-transplant patients who were steered into commercial insurance get "stuck" with "impossibly high premiums" they "cannot afford"). Third, and relatedly, patients who are unable to "make other arrangements" face mid-year disruptions in coverage, leading to similarly bad outcomes. SUF 43.

In addition to the harm to patients, steering raises health insurance premiums for a wide swath of the population because it "distort[s] [] the insurance risk pool." AB 290, § 1(e). Various researchers and other groups have examined the potential scope of the problem. SUF 44 (expert John Bertko projected a 5.3% premium increase in Covered California plans due to increase in ESRD enrollees, and cited Dr. Erin Trish's research letter estimating a 4.1% increase in individual market spending if 10% of non-aged Medicare enrollees with ESRD moved to the individual market); *id*. (Association of Health Insurance Plans provided examples of rise in insurance plan spending on ESRD services, including one plan's increase "from $1.7 million in 2013 to $36.8 million in 2015"); *id*. [redacted]. But the fact that an increase in commercially-insured ESRD patients results in higher insurance premiums for everyone in the market is not in serious dispute.

By placing guardrails on staff communications with patients, the steering prohibition "will in fact alleviate [these harms] to a material degree." *Edenfield*, 507 U.S. at 770. It "would remove a potential conflict of interest" from staff-patient interactions, providing the space for independent advocacy organizations, such as the Health Insurance Counseling and Advocacy Program (HICAP), to step in to "help patients navigate the complexities of their different insurance options."

SUF 45. And together with the disclosure requirements, the steering prohibition "[i]ncrease[]s transparency regarding coverage options and third-party premium payments," which "is important for patients to be able to make informed decisions and minimize their potential exposure to financial liabilities." SUF 46. This incremental, targeted approach directly advances California's substantial interest in protecting ESRD patients and the condition of the insurance risk pool without requiring more of Plaintiffs than is necessary to serve the law's purposes.

2. AB 290's Steering Prohibition Is Sufficiently Clear

AB 290's steering prohibition is also sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Edge v. City of Everitt*, 929 F.3d 657, 664 (9th Cir. 2019) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). A statute will generally survive a vagueness challenge so long as the speaker is not "compelled to steer too far clear of any forbidden area" of speech. *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 588 (1998) (internal quotation marks omitted). Indeed, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Edge*, 929 F.3d at 664 (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

Here, the terms "steer," "direct," and "advise" are not difficult to understand, particularly "when read in context with the entire provision." *Hunt v. City of Los Angeles*, 638 F.3d 703, 714 (9th Cir. 2011). The steering prohibition addresses the concerning practice of "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Its purpose is thus to "shield patients from potential harm caused by being steered into coverage options that may not be in their best interest." *Id.*, § 1(i). Taken together, the phrase "steer, direct, or advise" covers, in a comprehensive manner, the forms of encouragement prohibited by the statute. When "used in combination," these terms "provide sufficient clarity." *Edge*, 929 F.3d at 665 (quoting *Gammoh v. City of La*

Habra, 395 F.3d 1114, 1120 (9th Cir. 2005)). Providing factual information or answering questions about plan options is permissible; telling or prompting a patient to choose a certain option is not. In short, these terms are "reasonably ascertainable to a person of ordinary intelligence." *Id*. at 666.

B. AB 290's Reimbursement Cap Does Not Violate Plaintiff AKF's Right of Association

AB 290 caps the reimbursement rate for those patients receiving third-party premium assistance at the higher of the Medicare rate or a rate determined through an independent dispute resolution process. AB 290, § 3(e)(1). Plaintiffs suggest that this reimbursement cap "punishes" providers for donating to AKF, and thus "interferes with AKF's ability to associate freely with its major donors." Compl. ¶ 104. The Supreme Court has recognized that an individual's decision to make certain financial contributions, including political contributions, implicates "protected First Amendment interests." *McCutcheon v. FEC*, 572 U.S. 185, 196 (2014). But the Court has only recognized "the right of an individual to contribute, not the right of a[n] . . . organization to amass funds." *Interpipe*, 898 F.3d at 892 (citing *Buckley v. Valeo*, 424 U.S. 1, 21 (1976) (per curiam)). While AKF appears to assert that "the First Amendment right applies equally to the contributor *and* the recipient," the Court has never "establish[ed] an independent constitutional right of recipients to 'amass' funds." *Id.* AKF's argument, which "ignores this bedrock principle," *id.*, thus fails.

C. AB 290's Disclosure Provisions Do Not Unlawfully Compel Plaintiff AKF's Speech

AB 290 requires a financially interested entity like Plaintiff AKF to inform HIPP recipients of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, §§ 3(b)(3) & 5(b)(3). AB 290 similarly prohibits a financially interested entity from making a third-party premium payment unless it provides an annual statement

of compliance with the law and discloses to a health insurer the name of each insured patient who will receive premium assistance. *Id.*, § 3(c). These are some of the key provisions in AB 290 that "support[] transparency for ESRD patients" and "assist [patients] in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between AKF, dialysis providers, and private insurance companies." SUF 60. They are also the sort of disclosure requirements long held to be permissible under *Zauderer* and its progeny.

In *Zauderer*, the Supreme Court held that Ohio could require lawyers advertising contingency arrangements to disclose that clients might be liable for litigation costs if their cases were unsuccessful. 471 U.S. at 650-53. Noting the "material differences between disclosure requirements and outright prohibitions on speech," the Court recognized that there is only a "minimal" constitutionally protected interest in not providing "factual and uncontroversial information" to a consumer. *Id.* at 650, 651. The Court concluded that such disclosure requirements do not implicate First Amendment concerns as long as they "are reasonably related to the State's interest in preventing deception of consumers." *Id*. at 651.

Consistent with *Zauderer*, the Court has repeatedly acknowledged the government's authority to require disclosures of factual information that promote transparency. The Court has made clear that a requirement for fundraisers to "disclose unambiguously" their paid status "would withstand First Amendment scrutiny," *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 799 n.11 (1988); has upheld a federal statute requiring attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010); and has observed that a statutorily mandated disclosure of a film's connection to a federally registered agent of a foreign government would "better enable the public to evaluate the [film's] import," *Meese v. Keene*, 481 U.S. 465, 480 (1987). The

Court has also long recognized that requiring entities—including charitable organizations—to "report certain information" on a routine basis does not offend First Amendment interests. *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 637-38 n.12 (1980); *Riley*, 487 U.S. at 800 (same).

The Court's decision in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*) did not undermine this precedent. There, the Court held that the *Zauderer* standard applies only if the compelled disclosure involves "purely factual and uncontroversial" information. *Id.* at 2372. In so holding, the Court "d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Thus, "[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the disclosure is reasonably related to a substantial governmental interest and is purely factual and uncontroversial." *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019).

AB 290's disclosure provisions meet this standard: they implicate commercial speech, are reasonably related to a substantial governmental interest, and are purely factual and uncontroversial. Like the steering prohibition, the disclosure provisions regulate the discussion of a specific commercial product—in particular, commercial insurance products—which Plaintiffs have an economic motive to promote. *Ante* Argument I.A. And like the steering prohibition, the disclosure provisions are reasonably related to California's substantial governmental interest in "shield[ing] patients from potential harm caused by being steered into coverage options that may not be in their best interest," AB 290, § 1(i); these provisions ensure that patients are informed of their coverage options and that health plans and insurers receive the information necessary for the law to be properly implemented.[13]

[13] Recall that third party entities such as AKF have at times provided patients with debit cards that patients then use to pay their premiums. *Ante* Background II,

The disclosed information is also "purely factual and uncontroversial," as that requirement was further defined in NIFLA. There, the Court specified that a purely factual statement was not uncontroversial where the statement "took sides in a heated political controversy." *CTIA*, 928 F.3d at 845 (citing *NIFLA*, 138 S. Ct. at 2372). The Court further required that the statement "relate to the product or service that is provided by an entity subject to the requirement." *Id.* (citing *NIFLA*, 138 S. Ct. at 2372). Here, the disclosure provisions require a financially interested entity to make truthful and neutral statements about a patient's health coverage options and receipt of premium assistance, *see* AB 290, §§ 3(b)(3), 3(c)—subjects that relate directly to the HIPP assistance that AKF provides patients. These "purely factual and uncontroversial" statements meet the *Zauderer* standard, and thus, permissibly regulate speech.

D. AB 290's Provision Allowing AKF to Request an Updated Advisory Opinion Does Not Abridge AKF's Right to Petition

Finally, Plaintiffs allege that Section 7 of AB 290, which allows AKF to request an updated advisory opinion, abridges its freedom to petition "by compelling AKF to file a petition it actually opposes." Compl. ¶ 105. This argument mischaracterizes Section 7. That section is not a "mandate," *see id.*; it merely provides AKF the *option* to request an updated advisory opinion. Without "a coerced nexus between the individual and the specific expressive activity," there is no First Amendment violation. *See Cal-Almond, Inc. v. U.S. Dep't of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993).

CONCLUSION

This Court should grant Defendants' motion for summary judgment.

n.2; SUF 21. The requirement for AKF to identify each patient for which it provides premium assistance ensures that health plans and insurers know when a Medicare-linked reimbursement rate applies—i.e., when section 3(e) is applicable.

Dated: February 25, 2022

Respectfully submitted,

ROB BONTA
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/s/ R. Matthew Wise

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Attorneys for Defendants Rob Bonta, et al.

SA2019106023

EXHIBIT 2e

Premium Impacts of ESRD Patients in the Individual Market (Avalere)

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 2f

American Kidney Fund Annual Contributions by Requested Providers [AKF-DOE-0010136]

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 4b

FMC Insurance Counselor training program

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 4c

2018 Insurance Coordinator Goals

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 4d

Financial Coordinator Bonus Proposal, November 4, 2017

FILED PROVISIONALLY UNDER SEAL

EXHIBIT 5a

DaVita 2018 and 2019 Donation Letters to AKF

DaVita

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Donation Adjustment Letter
November 8, 2019

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation Adjustment to American Kidney Fund

Dear Don:

DaVita Inc. (DaVita) supports the American Kidney Foundation (AKF) in its mission to improve the lives of those patients suffering from kidney disease. At the beginning of this year we determined an annual donation amount of [redacted] based on our estimate of the AKF's financial need. In June 2019, we contributed a one-time supplemental donation of [redacted] increasing our annual donation amount to [redacted]. In reviewing our contribution amount again, we have decided to modify the amount, such that the new annual donation amount will be [redacted], with [redacted] having been paid to date, [redacted] left to donate in monthly payments and a one-time supplemental donation of [redacted].

The Donation is not intended to induce the AKF to refer any beneficiaries to any particular provider for any particular treatment, including, but not limited to DaVita. The Donation is not in any way contingent upon the volume or value of any referrals and the Donation is not contingent upon the AKF's use of the Donation to support DaVita's patients or any individual or group of individuals identified by or associated with DaVita.
In making its Donation, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;
(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and
(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or the Donation made, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, Corporate Accounting
DaVita Inc.

DaVita

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Donation Adjustment Letter
June 25, 2019

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation Adjustment to American Kidney Fund

Dear Don:

DaVita Inc. (DaVita) supports the American Kidney Foundation (AKF) in its mission to improve the lives of those patients suffering from kidney disease. At the beginning of this year we determined an annual donation amount of [redacted] based on our estimate of the AKF's financial need. In reviewing our contribution amount, we have decided to modify the amount, such that the new annual donation amount will be [redacted], with [redacted] having been paid to date, [redacted] left to donate in monthly payments and a one-time supplemental donation of [redacted].

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In making its Donation, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;

(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and

(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or the Donation made, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, Corporate Accounting
DaVita Inc.

DaVita

32275 32nd Ave. S
Federal Way, WA 98001
Tel: (253) 272-1916
www.DaVita.com

Annual Donation Letter
November 27, 2018

American Kidney Fund
11921 Rockville Pike, Suite 300
Rockville, Maryland 20852

Attn: Don Roy

RE: Monetary Donation to American Kidney Fund

Dear Don:

This letter is to inform you that DaVita Inc. (DaVita) anticipates making donations in the amount of [redacted] to the American Kidney Fund (AKF) during the period of February 1, 2019 through January 31, 2020. This Donation is intended to help ensure that the AKF can continue to provide vital services to those suffering from kidney disease. DaVita's Donation will be made monthly. This letter in no way obligates DaVita to make any donations, and DaVita explicitly reserves the right to increase, decrease, or terminate its donation at any time.

The Donation is not intended to induce the AKF to refer any beneficiaries to any particular provider for any particular treatment, including, but not limited to DaVita. The Donation is not in any way contingent upon the volume or value of any referrals and the Donation is not contingent upon the AKF's use of the Donation to support DaVita's patients or any individual or group of individuals identified by or associated with DaVita.

In making its donations, DaVita understands that the:

(a) AKF has sole authority over its operations, including the choice of whether to market or provide its services to any individual or class of individuals;

(b) AKF's acceptance of the Donation does not obligate or otherwise influence the AKF to purchase, use, recommend or arrange for the use of any products of DaVita or any affiliate of DaVita; and

(c) AKF's determinations of patient eligibility for assistance are made solely on the AKF's good faith assessment of a patient's financial need and the AKF does not take the identity of a referring provider or the amount of any provider's donations into consideration when assessing patient applications or making grant determinations.

DaVita supports the AKF's mission to improve the lives of patients suffering from kidney disease. If you have any questions related to this letter or our anticipated Donation, please do not hesitate to contact me.

Sincerely,

Amanda Olson
Senior Director, General Accounting
DaVita Inc.

EXHIBIT 14b

Excerpts from transcript of deposition of Steve Dover taken on November 18, 2021

FILED PROVISIONALLY UNDER SEAL

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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

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

Plaintiffs,

v.

ROB BONTA, in his Official Capacity as Attorney General of California; RICARDO LARA in his Official Capacity as California Insurance Commissioner; SHELLY ROUILLARD in her official Capacity as Director of the California Department of Managed Health Care; and TOMAS ARAGON, in his Official Capacity as Director of the California Department of Public Health,

Defendants.

8:19-cv-2105-DOC-(ADSx)

DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

PROVISIONALLY REDACTED PURSUANT TO PENDING APPLICATION FOR LEAVE TO FILE UNDER SEAL

Date: May 2, 2022
Time: 8:30 a.m.
Courtroom: 9D
Judge: The Honorable David O. Carter
Trial Date: July 12, 2022
Action Filed: November 1, 2019

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

Pursuant to C.D. Cal. Local Rule 56-1, Defendants ROB BONTA, RICARDO LARA, SHELLY ROUILLARD, and TOMÁS J. ARAGÓN (Defendants) submit the following statement of uncontroverted facts and conclusions of law in support of their concurrently filed Motions for Summary Judgment in this action.

DEFENDANTS' STATEMENT OF UNCONTROVERTED FACTS

NO.	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
1.	End-stage renal disease "is irreversible and permanent."	Plank Decl., ¶ 2, Ex. 1c (CA1759).
2.	ESRD patients require a kidney transplant or regular dialysis to survive.	*Id.*
3.	Recognizing the necessity and high costs of treatment, Congress permitted ESRD patients, regardless of age, to obtain Medicare coverage when it enacted the Social Security Amendments of 1972.	*Id.*
4.	Medicare covers a range of services to treat kidney failure, including transplant and dialysis services, along with other health care needs.	*Id.*

5.	Some patients may qualify for and receive coverage through both Medicare and Medi-Cal, California's Medicaid system.	*See* Plank Decl., ¶ 2, Ex. 1c (CA1760).
6.	In 2010, the Patient Protection and Affordable Care Act (ACA) enacted a set of reforms "to make health insurance more affordable and accessible to millions of Americans." One such reform, which took effect on January 1, 2014, "prohibited insurers . . . from imposing pre-existing condition exclusions" and required them "to guarantee the availability and renewability of non-grandfathered health plans to any applicant." Under this "guaranteed issue" provision, among other ACA provisions, ESRD patients can no longer be denied coverage or charged higher premiums based on their health status.	*Id*.
7.	These provisions of the ACA, together with the "higher reimbursement rates available	Plank Decl., ¶ 8, Ex. 6 (Expert Report of Randolph Wayne Pate, JD, MPH (Pate Report), p. 5).

	through private coverage when compared to Medicare," "in effect created a financial incentive for dialysis facilities to leverage [the higher rates] by providing premium assistance to ESRD patients"—primarily through a third party entity, Plaintiff AKF—"and inappropriately steering them to purchase coverage in the individual market."	
8.	HHS became concerned that health care providers were "encouraging individuals to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patients."	Plank Decl., ¶ 2, Ex. 1c (CA1761).
9.	Based on this concern, the Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information on August 23, 2016, seeking public comment "about health care providers and	Plank Decl., ¶ 2, Ex. 1c (CA1753).

	provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates."	
10.	In response, CMS received over 800 public comments from patients, providers, and other stakeholders, which "documented a range of concerning practices, with providers and suppliers"—such as DaVita and Fresenius—"influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients."	Plank Decl., ¶ 2, Ex. 1c (CA1761).
11.	In particular, commenters noted that patients "are sometimes specifically discouraged from pursuing Medicare or Medicaid" and "are unaware that a dialysis facility is seeking to enroll them in the individual market," and that facilities "retaliate against social workers who attempt to	Plank Decl., ¶ 2, Ex. 1c (CA1765).

	disclose additional information to consumers."	
12.	Commenters agreed that these practices are fueled by a powerful incentive—the considerably higher rates that commercial coverage reimburses dialysis providers as compared to public coverage.	Plank Decl., ¶ 2, Ex. 1c (CA1761), Ex. 1d (CA2109).
13.	HHS's own data and the comments "suggest[ed] that this inappropriate steering of patients may be accelerating over time."	Plank Decl., ¶ 2, Ex. 1c (CA1765).
14.	The comments also reflected three types of possible harms to patients: "[n]egatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage."	Plank Decl., ¶ 1c (CA1762).
15.	Comments also "indicat[ed] that inappropriate steering practices"—which add ESRD	Plank Decl., ¶ 2, Ex. 1c (CA1773).

	patients to the individual market—"could have the effect of skewing the insurance risk pool."	
16.	In the face of such harms, "which go to essential patient safety and care in life-threatening circumstances," CMS issued an interim final rule establishing new standards for Medicare-certified dialysis facilities that pay premiums for individual market health plans, whether directly or through another entity.	Plank Decl., ¶ 2, Ex. 1c (CA1765).
17.	Shortly after that rule was issued, it was enjoined for alleged failure to comply with Administrative Procedures Act requirements. That decision was not appealed.	*See Dialysis Patient Citizens v. Burwell*, No. 4:17-cv-00016-ALM, 2017 WL 365271 (E.D. Tex. Jan. 25, 2017).
18.	In the absence of federal regulations addressing inappropriate steering of dialysis patients, states across the country, such as California, Delaware, Idaho, Louisiana, Minnesota, New Mexico, North	Plank Decl., ¶ 2, Ex. 1d (CA2595-2596).

	Carolina, Oregon, and Washington, took action.	
19.	In 2018, the California Legislature passed Senate Bill 1156, a predecessor to AB 290.	Plank Decl., ¶ 2, Ex. 1d (CA2482).
20.	Governor Brown vetoed SB 1156 because it "would permit health plans and insurers to refuse premium assistance and to choose which patients they will cover."	Plank Decl., ¶ 2, Ex. 1d (CA2585).
21.	Given that third party entities such as AKF often provide patients with debit cards that patients then use to pay their premiums, prohibiting providers from directly billing enrollees facilitates the identification of patients receiving premium assistance.	Plank Decl., ¶ 2, Ex. 1b (CA595).
22.	After AB 290 was signed by Governor Newsom in October of 2019, AKF planned to leave California at the end of 2019, despite a concerted effort by the Legislature to amend AB 290 to address AKF's concerns.	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-807).

23.	The steering prohibition in AB 290 primarily regulates patient interactions with dialysis social workers and insurance counselors, who are tasked with helping patients "obtain insurance and apply for financial assistance," and who "may face a perceived or actual conflict of interest in doing so, since they may recommend insurance options that help patients remain on dialysis and maximize profits for the dialysis centers in which they work."	Plank Decl., ¶ 10, Ex. 8 (Supplemental Expert Report of Amy D. Waterman, PhD (Waterman Supp. Report), p. 1); *see also* ¶ 8, Ex. 6 (Pate Report, p. 12).
24.	Documents in the legislative record, including J.P. Morgan research reports, detail how critical commercial patients are to Plaintiffs' bottom line.	Plank Decl., ¶ 2, Ex. 1d (CA2091, CA2101, CA2104); *see also id.*, ¶ 9, Ex. 7 (Expert Report of Amy D. Waterman, PhD (Waterman Report), pp. 3-4).
25.	Plaintiffs' communications with shareholders also indicate that commercial patients are critical to Plaintiffs' bottom line.	Plank Decl., ¶ 6, Ex. 4a (FMC3049-3050).
26.	[redacted]	*See*, *e.g.*, Plank Decl., ¶ 6, Ex. 4b (FMC4931).

	[redacted]	
27.	The SB 1156 legislative record refers to a Washington Office of the Insurance Commissioner (OIC) order requiring DaVita "to immediately stop engaging in the business of unauthorized insurance via steering dialysis patients into higher reimbursing plans by offering to pay premiums."	Plank Decl., ¶ 2, Ex. 1d (CA2596).
28.	Washington OIC took enforcement action after learning that DaVita insurance coordinator Cary Ancheta had attempted "to sign up approximately 30 kidney dialysis patients, most of whom [we]re receiving Medicaid," onto commercial insurance.	Plank Decl., ¶ 2, Ex. 1e (CA3072-3074, CA3171-3173 (transcript of Ancheta call)).
29.	The Washington OIC order was rescinded by stipulation of the parties on the condition, among other requirements, that DaVita counselors "not ask or urge	Plank Decl., ¶ 2, Ex. 1e (CA3097-3100).

	dialysis patients to enroll in any particular kind of insurance from any particular insurer" for a period of two years.	
30.	That investigation also uncovered evidence provided by a former DaVita social worker of a DaVita PowerPoint presentation directing insurance counselors and social workers "to 'target' Medicaid eligible patients to get them to purchase commercial insurance."	Plank Decl., ¶ 2, Ex. 1e (CA3072).
31.	Known as "Medicaid Opportunity," this program, which began in 2015, was designed to increase the number of Medicaid patients enrolled in an individual market plan (paid for with HIPP assistance) as primary coverage.	Plank Decl., ¶ 7, Ex. 5b (DAV14359 (WebEx presentation about Medicaid Opportunity program, and transcription presentation for the Court's convenience)); *id*., ¶ 16, Ex. 14a (Deposition of Corey Danko taken on November 11, 2021 (Danko Dep.) 111:15-113:15; Danko Dep. Ex. 3).
32.	DaVita set about to discuss this "absolutely amazing opportunity" with "every single" patient on Medicaid.	Plank Decl., ¶ 16, Ex. 14a (Danko Dep. 177:20-178:23).

33.	DaVita considered this program a "true win-win situation" for patients and DaVita.	Plank Decl., ¶ 16, Ex. 14a (Danko Dep. 182:24-183:3, 214:1-25).
34.	DaVita's efforts to enroll patients in HIPP to facilitate the move to private primary insurance were meticulously tracked, and staff were urged to use "additional hours" to ensure that every patient was "educated" on HIPP availability.	*Id.*, ¶ 16, Ex. 14a (Danko Dep. 207:13-24, Ex. 3, pp. 3-9).
35.	[redacted]	Plank Decl., ¶ 16, Ex. 14b (Deposition of Steve Dover taken on November 18, 2021 (Dover Dep.) 119:11-120:1); *id.*, ¶ 6, Ex. 4b (FMC4926); *see also id.*, ¶ 16, Ex. 14b (Dover Dep. 148:5-9).
36.	[redacted]	Plank Decl., ¶ 16, Ex. 14b (Dover Dep. 47:2-8, 48:6-18, 50:10-51:19, 63:6-24, 64:5-65:24, 66:1-67:4); *id.*, ¶ 6, Ex. 4b (FMC4940, FMC4941-4943); *see also id.*, ¶ 16, Ex. 14b (Dover Dep. 69:8-25, 70:5-14, 72:11-23).

	[redacted]	
37.	One federal court, observing that DaVita's "own definition of 'steering' [] as legal communications with ESRD patients" was "a weak plausible alternative explanation as to the meaning of the statement that it 'does not steer,'" concluded that there was a "strong inference that [DaVita] made statements about steering and the source of [DaVita's] financial success with the intent to manipulate, deceive, or defraud."	*Peace Officers' Annuity and Benefit Fund of Ga. v. DaVita Inc.*, 372 F. Supp. 3d 1139, 1143, 1147, 1155 (D. Colo. 2019).
38.	Another federal court determined that it was "reasonable to infer . . . that the Medicaid Opportunity initiative was part of a larger, systematic plan by DaVita's management to drive revenues and profitability through [DaVita's] AKF donations."	*In re DaVita Inc. v. Stockholder Derivative Litig.*, No. 17-152-MPT, 2019 WL 1855445, *14 (D. Del. Apr. 25, 2019); *id.* at *1, *12.
39.	This industry scheme to steer patients into private insurance has also been the focus of	Plank Decl., ¶ 2, Ex. 1d (CA2328-2329).

	countless news articles and investigative journalism.	
40.	Patients steered into commercial insurance who would have been eligible for a kidney transplant under Medicare may be unable to demonstrate the financial means to care for a new kidney, given that HIPP assistance ends within months to a year of transplant.	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, pp. 4-5); *id*., ¶ 2, Ex. 1c (CA1826-1829 (Browne letter)).
41.	This "threat of cessation of health insurance benefits" not only impairs transplant eligibility but "may induce some patients to remain on dialysis and never pursue transplant."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, pp. 3-4).
42.	Patents steered into commercial insurance are saddled with high out-of-pocket expenses post-transplant when HIPP assistance ends, which may lead them to stop taking their immunosuppressant drugs, causing their transplant to fail.	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, p. 5); *id*., ¶ 8, Ex. 6 (Pate Report, p. 16); *id*., ¶ 2, Ex. 1c (CA1826-1829).
43.	Patients who are unable to "make other arrangements" face mid-year disruptions in coverage,	Plank Decl., ¶ 9, Ex. 7 (Waterman Report, p. 5).

	leading to similarly bad outcomes.	
44.	Various researchers and other groups have examined the potential scope of the distortion to the insurance market caused by the scheme to steer patients into commercial insurance.	Plank Decl., ¶ 11, Ex. 9 (Expert Report of John Bertko, F.S.A., M.A.A.A. (Bertko Report), p. 7); *id*., ¶ 16, Ex. 14c (Deposition of John Bertko taken on January 13, 2022, 175:1-13); *id*., ¶ 12, Ex. 10 (Supplemental Expert Report of John Bertko, F.S.A., M.A.A.A. (Bertko Supp. Report), pp. 2-3); *id*., ¶ 2, Ex. 1c (CA1917-1938 (AHIP letter)), *id*., ¶ 4, Ex. 2c (AKF-DOE-10132).
45.	Placing guardrails on staff communications with patients by banning steering would alleviate these harms by "remov[ing] a potential conflict of interest" from staff-patient interactions, providing the space for independent advocacy organizations, such as the Health Insurance Counseling and Advocacy Program (HICAP), to step in to "help patients navigate the complexities of their different insurance options."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, p. 4); *id*., ¶ 9, Ex. 7 (Waterman Report, p. 6).

46.	Together with the disclosure requirements, the steering prohibition "[i]ncrease[]s transparency regarding coverage options and third-party premium payments," which "is important for patients to be able to make informed decisions and minimize their potential exposure to financial liabilities."	Plank Decl., ¶ 8, Ex. 6 (Pate Report, p. 23).
47.	Reimbursement rates for commercial coverage are considerably higher than for public coverage, and evidence in the CMS record shows that providers "therefore have much to gain financially (on the order of tens or even hundreds of thousands of dollars per patient) by making a relatively small outlay to pay an individual's premium to enroll in commercial coverage so as to receive a much larger payment for providing an identical set of health care services."	Plank Decl., ¶ 2, Ex. 1c (CA1761).

48.	Evidence in the CMS record also shows that Plaintiffs "[s]upport[] premium payments to facilitate enrollment of their patients in individual market coverage."	*Id.*
49.	The "only way" in which AKF can afford to pay the premiums of commercially-insured patients is for providers to pay their "fair share."	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-805); *see also id.,* ¶ 4, Ex. 2b (AKF-DOE-10060), *id.,* ¶ 2, Ex. 1c (CA1782-1806 (Blue Cross letter), CA1964-1972 (UHC letter)).
50.	For a time, AKF "request[ed] that [an] organization not refer [] patients to the HIPP program" "if [the] company [could] not make fair share contributions."	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-806), Ex. 2b (AKF-DOE-10060); *see also id.,* ¶ 4, Ex. 2c (AKF-DOE-10078), Ex. 2d (AKF-DOE-10097).
51.	[redacted]	Plank Decl., ¶ 4, Ex. 2f (AKF-DOE-10136).
52.	[redacted]	*Id.*

53.	[redacted]	*Id*.
54.	In November 2018, DaVita sent a letter informing AKF that it anticipated contributing [redacted] during the period of February 1, 2019, through January 31, 2020.	Plank Decl., ¶ 7, Ex. 5a (DAV8275).
55.	In June 2019, DaVita sent an "[a]djustment [l]etter" modifying its contribution to [redacted].	Plank Decl., ¶ 7, Ex. 5a (DAV8274).
56.	Later, in November 2019, DaVita sent a second adjustment letter further modifying its contribution to [redacted]	Plank Decl., ¶ 7, Ex. 5a (DAV8273).
57.	The very precise amounts of each contribution, as well as the periodic "adjustments," underscore the direct connection between Plaintiffs' annual "fair share" contribution amount and the premium assistance that AKF provides to their patients.	*See* Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-805).

58.	The arrangement between AKF and the providers is "a business strategy rather than a form of charity."	Plank Decl., ¶ 8, Ex. 6 (Pate Report, p. 8).
59.	By "eliminat[ing] preferentially high reimbursement rates for privately insured dialysis patients," the reimbursement cap removes an "incentive to keep patients on dialysis," and serves California's interest in "provid[ing] needed protections for kidney patients."	Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, p. 4).
60.	The provision in AB 290 that prohibits a financially interested entity like AKF from making a third-party premium payment unless it discloses to a health insurer the name of each insured patient who will receive premium assistance "supports transparency for ESRD patients" and "assist[s] [patients] in making informed decisions about how to finance their own care by removing potentially ethically compromising dynamics between	*Id.*

	AKF, dialysis providers, and private insurance companies."	
61.	Plaintiffs' interests do not align with those of their patients.	*See, e.g.*, Plank Decl., ¶ 10, Ex. 8 (Waterman Supp. Report, pp. 1, 2 (citing Paul J. Eliason, *How Acquisitions Affect Firm Behavior and Performance: Evidence From the Dialysis Industry*, Quarterly Journal of Economics (February 2020), https://doi.org/10.1093/qje/qjz034), 3-4).
62.	AKF not only opposed AB 290, but notified the Legislature that it would "be forced to shut down in California if AB 290 is enacted" because, as AKF President and CEO LaVarne Burton stated, "AB 290 would take us outside of the protections of our Advisory Opinion."	Request for Judicial Notice, Ex. 1 (excerpt from testimony of AKF President and CEO LaVarne Burton at July 3, 2019 California Senate Health Committee meeting).
63.	Advisory Opinion 97-1, issued by HHS's OIG in 1997 at AKF's request, concluded that AKF's practice of paying Medicare Part B and Medigap premiums for ESRD patients in financial need did not violate the federal	Plank Decl., ¶ 2, Ex. 1a (CA92).

	prohibition against providing remuneration to Medicare-eligible individuals if such remuneration is likely to influence the individual's health care choices.	
64.	OIG found it significant that AKF, rather than dialysis providers, determined which patients would receive AKF's Health Insurance Premium Program (HIPP) assistance and that HIPP assistance was available regardless of the patient's provider.	Plank Decl., ¶ 2, Ex. 1a (CA97).
65.	Advisory Opinion 97-1 specifies that it is "case specific" and "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."	Plank Decl., ¶ 2, Ex. 1a (CA99).
66.	California's Legislative Counsel concluded that based on the available facts, AKF "would remain in compliance with the	Plank Decl., ¶ 2, Ex. 1a (CA42).

	arrangement approved in Advisory Opinion 97-1" if AB 290 is enacted and AKF "complies with the changes enacted by that bill."	
67.	Much has changed since Advisory Opinion 97-1 was issued, as back then ESRD patients generally lacked access to commercial insurance, and "less than ten percent" of donations to AKF were from companies that owned dialysis providers.	Plank Decl., ¶ 2, Ex. 1a (CA94).
68.	At the time the Advisory Opinion was issued, patients with ESRD were usually unable to obtain commercial insurance because ESRD was an expensive pre-existing condition.	Plank Decl., ¶ 8, Ex. 6 (Pate Report, pp. 4-5).
69.	After the ACA was enacted in 2010, many more patients with ESRD were able to access commercial insurance because the ACA prohibits insurance companies from discriminating	*Id*.

	against patients with pre-existing conditions.	
70.	Reforms under the ACA have led to the expansion of AKF's HIPP assistance to pay the premiums of commercially-insured patients, and the contributions of "[l]arge dialysis companies" have grown to "more than 80 percent" of AKF's revenue.	AB 290, § 1(h); *see also* Plank Decl., Ex. 3 (AKF RFP Response 11).
71.	AKF maintained its plans to leave California at the end of 2019, despite amendments largely delaying AB 290's implementation.	Plank Decl., ¶ 4, Ex. 2a (AKF-DOE-807).
72.	The fact that other types of coverage options have been created since 1997 does not shift the scope of Advisory Opinion 97-1 because the Opinion is by its own terms limited to federal health care programs, and thereby expressly excludes programs such as Qualified Health Care Programs, Covered California, employer group plans, or private insurance.	Plank Decl., ¶ 2, Ex. 1a (CA96-98); *id*., ¶ 8, Ex. 6 (Pate Report, pp. 6-7).

73.	AB 290 and Advisory Opinion 97-1 both require that financial assistance not be conditioned on the use of a specific facility or health care provider.	Plank Decl., ¶ 2, Ex. 1a (CA96-98); AB 290, §§ 3(b)(2) & 5(b)(2).
74.	If AB 290 were to go into effect, a HIPP recipient would be highly unlikely to learn of their dialysis providers' donor status through the disclosure of information required of AKF by AB 290.	Plank Decl., ¶ 8, Ex. 6 (Pate Report, pp. 19-22).

CONCLUSIONS OF LAW

1. Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). While the Court must draw all reasonable inferences in favor of the nonmoving party, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), Rule 56(c) "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

2. Under the governing test from *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), speech may be "characterized as commercial when (1) the speech is admittedly advertising, (2) the speech references a specific product, and (3) the speaker has an economic motive for engaging in the speech." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106 (9th Cir. 2004) (citing *Bolger*, 463 U.S. at 66-67). While the combination of all of these characteristics strengthens the conclusion that the speech at issue is "properly characterized as commercial

speech," it is not necessary for "each of the characteristics" to "be present in order for speech to be commercial." *Bolger*, 463 U.S. at 67 n.14. The steering prohibition meets the latter two *Bolger* factors, and thus implicates commercial speech.

3. Because commercial speech is at issue, intermediate scrutiny applies: AB 290 must directly advance a substantial governmental interest and do so in a manner that is not more extensive than necessary. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Put another way, AB 290 must tackle harms that are "real" and must "in fact alleviate them to a material degree." *See Edenfield v. Fane*, 507 U.S. 761, 771 (1993). AB 290 meets this standard because it tackles harms that are real and alleviates them to a material degree. *Id*.

4. A statute will generally survive a vagueness challenge so long as the speaker is not "compelled to steer too far clear of any forbidden area" of speech. *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 588 (1998) (internal quotation marks omitted). Indeed, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Edge v. City of Everitt*, 929 F.3d 657, 664 (9th Cir. 2019) (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

5. AB 290's steering prohibition is sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Edge v. City of Everitt*, 929 F.3d at 664 (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). Here, the terms "steer," "direct," and "advise" are not difficult to understand, particularly "when read in context with the entire provision." *Hunt v. City of Los Angeles*, 638 F.3d 703, 714 (9th Cir. 2011). The steering prohibition addresses the concerning practice of "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Its purpose is thus to "shield patients

from potential harm caused by being steered into coverage options that may not be in their best interest." *Id.*, § 1(i). Taken together, the phrase "steer, direct, or advise" covers, in a comprehensive manner, the forms of encouragement prohibited by the statute. When "used in combination," these terms "provide sufficient clarity." *Edge*, 929 F.3d at 665 (quoting *Gammoh v. City of La Habra*, 395 F.3d 1114, 1120 (9th Cir. 2005)). Providing factual information or answering questions about plan options is permissible; telling or prompting a patient to choose a certain option is not. These terms are "reasonably ascertainable to a person of ordinary intelligence." *Id*. at 666.

6. AB 290's reimbursement cap does not burden Plaintiffs' right of association. As the Court posited at the outset of the case, it is merely "a restriction on economic activity or nonexpressive conduct" because Plaintiffs' donations are not an "expressive avenue by which providers join and support AKF's mission," but a quid pro quo arrangement that "secure[s] a later 'return on investment' in the form of higher private insurance reimbursements." *See* ECF No. 58 at 10-11; *cf. Lair v. Motl*, 873 F.3d 1170, 1172 (9th Cir. 2017) (upholding state law that regulated campaign contributions for the purpose of "combating quid pro quo corruption or its appearance"). Rather than burden Plaintiffs' expressive interests, the reimbursement cap regulates conduct that is not "actually under the aegis of the First Amendment." *See id.* at 11; *see also Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 892 n.11 (9th Cir. 2018) (observing that plaintiff bringing expressive association claim must show that the challenged law "regulates speech, not just conduct")

7. In *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626(1985), the Supreme Court held that Ohio could require lawyers advertising contingency arrangements to disclose that clients might be liable for litigation costs if their cases were unsuccessful. *Id.* at 650-53. Noting the "material differences between disclosure requirements and outright prohibitions on speech,"

the Court recognized that there is only a "minimal" constitutionally protected interest in not providing "factual and uncontroversial information" to a consumer. *Id.* at 650, 651. The Court concluded that such disclosure requirements do not implicate First Amendment concerns as long as they "are reasonably related to the State's interest in preventing deception of consumers." *Id*. at 651.

8. Consistent with *Zauderer*, the Court has repeatedly acknowledged the government's authority to require disclosures of factual information that promote transparency. The Court has made clear that a requirement for fundraisers to "disclose unambiguously" their paid status "would withstand First Amendment scrutiny," *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 799 n.11 (1988); has upheld a federal statute requiring attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010); and has observed that a statutorily mandated disclosure of a film's connection to a federally registered agent of a foreign government would "better enable the public to evaluate the [film's] import," *Meese v. Keene*, 481 U.S. 465, 480 (1987). The Court has also long recognized that requiring entities—including charitable organizations—to "report certain information" on a routine basis does not offend First Amendment interests. *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 637-38 n.12 (1980); *Riley*, 487 U.S. at 800 (same).

9. The Court's decision in *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*) did not undermine this precedent. There, the Court held that the *Zauderer* standard applies only if the compelled disclosure involves "purely factual and uncontroversial" information. *Id.* at 2372. In so holding, the Court "d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Thus, "[u]nder *Zauderer*, compelled disclosure of commercial speech complies with the First Amendment if the information in the

disclosure is reasonably related to a substantial governmental interest and is purely factual and uncontroversial." *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 845 (9th Cir. 2019).

10. AB 290 requires a financially interested entity like Plaintiff AKF to inform HIPP recipients of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, §§ 3(b)(3) & 5(b)(3). AB 290 similarly prohibits a financially interested entity from making a third-party premium payment unless it provides an annual statement of compliance with the law and discloses to a health insurer the name of each insured patient who will receive premium assistance. *Id.*, § 3(c).

11. AB 290's disclosure provisions meet the *Zauderer* standard: they implicate commercial speech, are reasonably related to a substantial governmental interest, and are purely factual and uncontroversial. Like the steering prohibition, the disclosure provisions regulate the discussion of a specific commercial product—in particular, commercial insurance products—which Plaintiffs have an economic motive to promote. The disclosed information is also "purely factual and uncontroversial," as that requirement was further defined in NIFLA. There, the Court specified that a purely factual statement was not uncontroversial where the statement "took sides in a heated political controversy." *CTIA*, 928 F.3d at 845 (citing *NIFLA*, 138 S. Ct. at 2372). The Court further required that the statement "relate to the product or service that is provided by an entity subject to the requirement." *Id.* (citing *NIFLA*, 138 S. Ct. at 2372). Here, the disclosure provisions require a financially interested entity to make truthful and neutral statements about a patient's health coverage options and receipt of premium assistance, *see* AB 290, §§ 3(b)(3), 3(c)—subjects that relate directly to the HIPP assistance that AKF provides patients. These "purely factual and uncontroversial" statements meet the *Zauderer* standard, and thus, permissibly regulate speech.

12. AB 290 does not abridge the right to petition. Plaintiffs allege that Section 7

of AB 290, which allows AKF to request an updated advisory opinion, abridges its freedom to petition "by compelling AKF to file a petition it actually opposes." Compl. ¶ 105. This argument mischaracterizes Section 7. That section is not a "mandate," *see id.*; it merely provides AKF the *option* to request an updated advisory opinion. Without "a coerced nexus between the individual and the specific expressive activity," there is no First Amendment violation. *See Cal-Almond, Inc. v. U.S. Dep't of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993).

13. AB 290 is not preempted by federal law. "[B]ecause the States are independent sovereigns in our federal system," preemption analysis must begin "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Plaintiffs have not demonstrated any actual conflict between a federal regulation and the steering prohibition. AB 290 can and should be interpreted in a manner consistent with federal law. *Cal. Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1071 (9th Cir. 2019) ("Well-established preemption principles favor upholding state law if it can plausibly coexist with the federal statute.")

14.*Doe* Plaintiffs' arguments regarding the preemptive effect of Advisory Opinion 97-1 fail because it is black letter law that "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all . . . lack the force of law[.]" *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 643 (2013) (agency memorandum and letter approving of state statutory scheme for Medicaid reimbursement were "opinion letters, not regulations with the force of law"); *United States v. Mead Corp.*, 533 U.S. 218, 233 (2001) (federal agency's "classification ruling" letters did not have the force of law when agency did not engage in notice-and-comment, and did not bind third parties). Although "an agency regulation with the force of law can pre-empt conflicting state

requirements," an agency action that was not the product of notice-and-comment rulemaking does not have the force of law and thus cannot, by itself, have preemptive effect. *Wyeth v. Levine*, 555 U.S. 555, 576, 580 (2009) (cleaned up); *see also Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (Ninth Circuit "declin[es] to afford preemptive effect to agency actions that do not carry the force of law under *Mead* and its progeny"). Accordingly, Advisory Opinion 97-1 does not have the force of federal law or regulation and cannot preempt AB 290.

15. *Doe* Plaintiffs' argument regarding the preemptive effect of Advisory Opinion 97-1 fail because there is no conflict between the Opinion and AB 290. The Advisory Opinion does not discuss premium payments for commercial insurance or group health coverage. Thus, the Opinion's restrictions would apply only to payments for Medicare Part B or Medigap premiums, neither which fall within the scope of AB 290. *See* AB 290, §§ 3(h)(3) & 5(h)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government [or] Medicare supplement coverage").

16. AB 290 does not conflict with the "take into account" provision or the "non-differentiation" provisions of the Medicare Secondary Payer Act. The "take into account" provision prohibits group health plans from "tak[ing] into account that an individual [with ESRD] is entitled to or eligible for [Medicare] benefits" for the first thirty months of eligibility. 42 U.S.C. § 1395y(b)(1)(C)(i). Similarly, the "nondifferentiation" requirement provides that group health plans "may not differentiate in the benefits [they] provide[] between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner" during the first thirty months of Medicare eligibility. *Id.* § 1395y(b)(1)(C)(ii). Prohibited "differentiation" includes "[i]mposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations" and "[p]aying providers and suppliers less for services furnished to individuals who

have ESRD than for the same services furnished to those who do not have ESRD . . . ." 42 C.F.R. §§ 411.161(b)(ii), (iv). The "pertinent inquiry' is "whether the plan's provisions 'result' in *different benefits for persons with ESRD*, not whether the plan's provisions disproportionately affect persons with ESRD or otherwise 'discriminate' against persons with ESRD." *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 674-75 (9th Cir. 2020). Plaintiffs do not—and cannot—show that AB 290 requires health plans to treat patients differently based on their Medicare eligibility or their ESRD status. Although treatments provided to HIPP recipients may be reimbursed at a lower rate, that is not a result of a patient's eligibility or non-eligibility for Medicare. The statute makes no distinction among patients based on their Medicare eligibility; a plan can "ignore[]" this factor. *Amy's Kitchen*, 981 F.3d at 670. Nor does the statute require differentiation between patients based on their ESRD status; a plan can "provide[] identical benefits to someone with ESRD as to someone without ESRD" and thus "not 'differentiate' between those two classes." *Id.* at 678. AB 290 comports with the MSPA.

17. *Fresenius* Plaintiffs' obstacle preemption argument assumes a conflict, not with a specific federal statutory provision or requirement, but with an alleged federal policy that Plaintiffs contend is broadly reflected in the Medicare Act, the Medicare Secondary Payer Act, and the ACA. Compl. ¶¶ 35, 130-133. These statutes purportedly embody a general federal policy of "ensuring ESRD patient access to care; protecting patient choice in insurance; and safeguarding the stability of the dialysis system by spreading the high costs of dialysis treatment among private and public insurers." Compl. ¶¶ 130-133. This argument fails because preemption cannot be based on an amorphous federal policy, even if such a policy existed. "Invoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law; a litigant must point specifically to 'a constitutional text or a federal statute' that does the displacing or conflicts with state law," or that authorizes an agency to do so. *Va.*

Uranium, Inc. v. Warren, 139 S. Ct. 1894, 1901 (2019) (lead opinion of Gorsuch, J) (cleaned up). Here, although the policy goals that Plaintiffs rely on might be consistent with various federal statutes, that does not mean that those goals have the *force* of any of those statutes. A federal policy, by itself, cannot preempt. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) ("The Supremacy Clause grants 'supreme' status only to the 'the *Laws* of the United States.'") (citing U. S. Const., Art. VI, cl. 2., emphasis in opinion); *Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357 (1986) (rejecting a federal agency's attempt to preempt based solely on its own determination that preemption would "best effectuate a federal policy").

18. *Fresenius* Plaintiffs' Contract Clause cause of action fails because the reimbursement cap does not "operate[] as a substantial impairment of a contractual relationship." *Gen. Motors Corp. v. Romein*, 503 U.S. 181, 186 (1992). The Contracts Clause does not trump the police power of a state to protect the general welfare of its citizens, a power which is paramount to any rights under contracts between individuals. *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 241 (1978). Plaintiffs have not shown impairment of any specific contractual right held by the providers that would not under normal circumstances be subject to regulation by the State.

19. No contract between a medical provider and an insurer can avoid the application of state law to the reimbursement rates provided. *See Campanelli v. Allstate Life Ins. Co.*, 322 F.3d 1086, 1098 (9th Cir. 2003) ("One whose rights, such as they are, are subject to state restriction, cannot remove them from the power of the State by making a contract about them.") That the insurance market is already heavily regulated by state and federal law weighs against any finding of impairment, much less substantial impairment. "In determining the extent of the impairment, a court must consider 'whether the industry the complaining party has entered has been regulated in the past." *Id*. at 1098. If the answer is yes, "then the

impairment is less severe because '[o]ne whose rights, such as they are, are subject to state restriction, cannot remove them from the power of the State by making a contract about them." *Id*.

20. Article III standing requires a party to show that (1) it has suffered a concrete and particularized "injury in fact" that is "actual or imminent" and not hypothetical; (2) the injury is "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court;" and (3) it is likely the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 409 (2013) ("possible future injuries that depend on a speculative chain of possibilities that may not occur are not sufficient").

21. *Fresenius* Plaintiffs' substantive due process claim fails because they cannot establish standing. Plaintiffs do not set forth specific facts demonstrating a concrete injury that is non-speculative or fairly traceable to AB 290 because their alleged injury stems from third-party AKF's threatened cessation of operations in California, not AB 290's provisions. *See, e.g.*, Compl. ¶¶ 106, 147-48. AB 290 does not compel AKF to stop providing assistance to ESRD patients in California. *Id*. ¶¶ 95, 98. Yet all of the alleged injuries are contingent on AKF's threatened departure from the state. *Id*. ¶¶ 106, 147. They depend on a "speculative chain of possibilities," and thus do not confer standing. *Clapper*, 568 U.S. at 411-12. Nor can Plaintiffs meet prudential standing requirements, *see Powers v. Ohio*, 499 U.S. 400, 410-413 (1991)—in particular, that their interests align with those of their patients.

22. *Fresenius* Plaintiffs' substantive due process claim also fails because the challenged provisions do not infringe on any fundamental right. Plaintiffs' assertion (Compl. ¶¶ 146, 149) that AB 290 interferes with a "fundamental right to lifesaving treatment"—a theory that is based on a dissenting opinion in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d

695 (D.C. Cir. 2007)—is incorrect as a matter of law. The range of liberty interests that substantive due process protects is narrow; "only those aspects of liberty that we as a society traditionally have protected as fundamental are included within the substantive protection of the Due Process Clause." *Mullins v. Oregon*, 57 F. 3d 789, 793 (9th Cir. 1995). The novel right asserted by Plaintiffs has never been recognized. Only "a clear showing of arbitrariness and irrationality" can overcome the presumption of legislative acts that do not impinge on fundamental rights. *Hodel v. Indiana*, 452 U.S. 314, 331-32 (1981).

23. *Fresenius* Plaintiffs' claim that AB 290 Section 3(i) violates their due process rights also fails, because the regulation does not penalize Plaintiffs for "the independent acts of others" and conduct they "had no ability to control." Compl. ¶¶ 158, 160. Instead, that section only allows for recovery of overpayments when a provider accepts a health plan's payment that exceeds the Medicare rate (or other applicable rate). All a provider would need to do to stay in compliance with this provision is decline to accept any overpayments from health plans for services to premium assistance recipients. Plaintiffs fail to establish a comprehensible basis for a claim their due process rights are denied by Section 3(i). *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976).

24. The Supreme Court has recognized that a per se taking occurs when an owner is deprived of "*all* economically beneficial uses" of the property, *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992), and when "a regulation results in a physical appropriation of property," *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). All other regulations of private property are governed by *Penn Central*'s balancing test, which considers (1) the character of the government action, (2) the economic impact of the regulation, and (3) the regulation's interference with reasonable investment-backed expectations. *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

25. *Fresenius* Plaintiffs' Takings Clause claim fails because none of the

Plaintiffs' purported harms constitute a taking. Any contention that the reimbursement cap—which has never taken effect—could be to blame for the closure of certain clinics or could "impos[e] significant economic losses" on Plaintiffs is highly speculative. This is not the sort of "'extraordinary case' in which a regulation permanently deprives property of all use." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 303 (2002). Nor does the reimbursement cap "seize a sum of money from a specific fund." *Ballinger v. City of Oakland*, __ F. 4th __, 2022 WL 289180, *4 (9th Cir. 2022). Plaintiffs' takings claim is thus subject to the *Penn Central* framework—which "aims to determine whether a regulatory action is functionally equivalent to the classic taking." *Bridge Aina Le'a, LLC v. Land Use Comm'n*, 950 F.3d 610, 630 (9th Cir. 2020) (internal quotation marks omitted). Absent evidence of such injury—which Plaintiffs have yet to produce—this claim rests on "speculative possibilities" that do not rise to the level of a taking. *See id.* at 634.

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