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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.

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