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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.

XAVIER BECERRA, 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 SUSAN FANELLI, in her Official Capacity as Acting Director of the California Department of Public Health,

Defendants.

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

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Date: December 16, 2019
Time: 8:30 a.m.
Dept: 9D
Judge: The Honorable David O. Carter
Trial Date: n/a
Action Filed: 11/5/2019

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INTRODUCTION

The harms that Plaintiffs claim will flow from the California Legislature's passage of AB 290 are not harms inherent in the statute. Instead they flow entirely from an arbitrary decision by the American Kidney Fund (AKF)—backed by large dialysis companies that provide 80 percent of its funding—to cease supporting California patients with premium contribution payments effective January 1, 2020. AKF has made this decision even though AB 290 requires no action until July 1, 2020 at the earliest to ensure patient continuity of care; provides AKF with the option of tolling AB 290 after that date by seeking a revised opinion letter from the federal government; and includes other safe harbors designed by the Legislature to alleviate AKF's concerns. Whatever else Plaintiffs' papers show, one thing is clear: this is a self-manufactured dispute, one created entirely by the large dialysis providers and AKF, for reasons that remain elusive from the face of their complaints. This Court should decline Plaintiffs' invitation to enjoin an important state law, one designed to protect patients and reduce soaring health care costs, based on alleged injuries generated entirely by self-interested parties.

In enacting AB 290, the Legislature sought to protect patients on dialysis from higher out-of-pocket costs, mid-year disruptions in coverage, and difficulty in obtaining life-saving kidney transplants while also protecting the sustainability of risk pools in commercial insurance markets.[1] AB 290 contains provisions that prohibit organizations offering premium payment assistance to patients on dialysis (mainly AKF) from steering those patients toward a specific healthcare plan—particularly from steering patients eligible for Medicare or Medi-Cal (California's

[1] Plaintiffs are two individuals—Jane Doe and Stephen Albright—and two nonprofit corporations—the American Kidney Fund and Dialysis Patient Citizens, Inc. Plaintiffs have filed their motion in conjunction with the motion for preliminary injunction filed by the provider plaintiffs in *Fresenius Medical Care Orange County LLC v. Xavier Becerra*, case no. 8:19-cv-02130. Because much of plaintiffs' argument in these cases overlaps, the points made in this brief will also apply to the *Fresenius* motion and vice versa.

Medicaid) toward commercial premiums that might not be the best fit for their care needs.

Plaintiffs are not likely to succeed on the merits of their claims challenging AB 290. Plaintiffs assert that AB 290 is preempted by federal law. They contend that an Advisory Opinion issued in 1997 by the Department of Health and Human Services (HHS) Office of the Inspector General preempts AB 290. But that Advisory Opinion does not conflict with AB 290 and, in any event, it does not have the force of law for preemption purposes. Plaintiffs also contend that they cannot comply with both AB 290 and the Medicare Secondary Payer Act; they can. Plaintiffs' First Amendment claims are equally unlikely to succeed. They contend that AB 290's disclosure requirements violate their right to freedom of expression and association. But those disclosure provisions are economic regulations with only incidental burdens on speech. Plaintiffs also assert that the provision allowing AKF a grace period to seek an updated advisory opinion should it choose to do so violates AKF's right to petition by compelling it to request an opinion. AB 290 clearly makes requesting an updated opinion optional, not compulsory.

Plaintiffs attempt to demonstrate irreparable harm by attributing all of the negative effects that will result from AKF's decision to leave California to AB 290 itself. But the statute does not require AKF to leave the state. Furthermore, because AB 290 is not effective as to AKF until at least July 1, 2020, and longer if AKF seeks an updated Advisory Opinion, any irreparable harm that could truly be attributed to the state lacks the immediacy necessary for a preliminary injunction and is speculative, at best.

Aside from the lack of success on the merits and the failure to demonstrate irreparable harm attributable to the statute, the public interest weighs against preliminary injunctive relief because enjoining the statute would allow harms to patients across California to continue. Plaintiffs' request for a preliminary injunction should be denied.

BACKGROUND

I. THE AMERICAN KIDNEY FUND

The California Legislature passed AB 290 in response to the increased payment of health insurance premiums by healthcare providers and provider-funded groups for end-stage renal disease patients (ESRD). Assem. B. 290, Reg. Sess. (Cal. 2019-2020). The bill will impose requirements on "financially interested providers and entities that make third-party premium payments on behalf of health plan enrollees and insureds." Sen. Com. on Health, Analysis of Assem. Bill. No. 290 (2019-2020 Reg. Sess.) July 2, 2019 (Sen. Com. on Health Analysis) at 1. One such third-party payment provider is plaintiff AKF, a non-profit organization that pays insurance premiums for patients on dialysis that could not otherwise afford them. Complaint, Dkt. 1 at 4, 15. AKF receives roughly 80 percent of its funding from the two largest dialysis providers, DaVita and Fresenius. Declaration of Amie L. Medley (Medley Decl.), Ex. 1. Large dialysis providers such as DaVita, Fresenius, and U.S. Renal Care make up 77 percent of California's dialysis clinics. AB 290, Stats. 2019, ch. 862 (AB 290), § 1(h).

AKF reported to the Senate Health Committee that in 2018, AKF provided premium payment assistance to 3,756 patients through a total of 4,367 policies. Sen. Com. on Health Analysis at 7. Of those policies, 1,447 were for commercial employer or COBRA coverage, 311 policies were other commercial policies, 1,154 policies were Medicare Part B (outpatient coverage and physician visits), 880 policies were Medigap (extra health insurance from a private company to pay health care costs not covered by Original Medicare), and 224 policies were Medicare Advantage (privately administered plans covering Medicare Part A (hospital coverage) and Medicare Part B). *Id*. AKF claims to operates under a 1997 Advisory Opinion from HHS's Office of Inspector General (OIG). *Id*. That Advisory Opinion found that AKF's practice of paying insurance premiums for Medicare Part B and Medigap policies for ESRD patients who could not afford

them did not violate HIPAA's prohibition on providing remuneration to individuals who are eligible for federal health care coverage such as Medicare or Medicaid if such remuneration is likely to influence the individual's health care choices. Plaintiff's Request for Judicial Notice (Plaintiff's RJN), Dkt. 29, Ex. 2. In that Advisory Opinion, the OIG found that AKF's arrangement did not constitute prohibited remuneration under the statute because the premiums were paid by AKF rather than directly by a dialysis provider. *Id.* at 6. The Advisory Opinion also found it significant that AKF, not the dialysis providers themselves, determined which patients would receive premium assistance and that AKF did not limit its charitable contributions only to premiums paid for patients treated by its donor companies. *Id.* Further, the Advisory Opinion concluded that AKF's arrangement did not influence a patient's provider choice, because patients applying for HIPP often already had selected a provider. *Id.* at 6-7. As an additional safeguard, dialysis providers would not advertise the availability of HIPP. *Id.*

II. PROBLEMS ADDRESSED BY AB 290

AB 290 was enacted against a backdrop of nationwide concern over dialysis providers and third-party payers inappropriately steering patients onto commercial insurance plans for their own—not the patient's—benefit. As noted in the legislative history of AB 290, in 2016, "the federal Department of Health and Human Services (HHS) had become concerned about the inappropriate steering of dialysis patients eligible for, or entitled to, Medicare or Medicaid into private plans by providers because of significantly higher reimbursement." Sen. Com. on Health Analysis at 5. The Centers for Medicare & Medicaid Services (CMS), a subdivision of HHS, issued a Request for Information (RFI) titled "Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans," which was published in the Federal Register on

August 23, 2016. 81 Fed. Reg. 57554, 57555 (Aug. 23, 2016).[2] In response, CMS received 800 public comments from patients, providers, health insurance companies, social workers and other stakeholders.[3] 81 Fed. Reg. 90214.

Based on these public comments, CMS found that "major non-profits that receive significant financial support from dialysis facilities will support payment of health insurance premiums only for patients currently receiving dialysis" and that "these non-profits will not continue to provide financial assistance once a patient receives a successful kidney transplant." 81 Fed. Reg. 90215. This can "cause significant issues for patients that cannot afford their coverage without financial support" and "is consistent with the conclusion that these third party payments are being targeted based on the financial interest of the dialysis facilities who contribute to these non-profits rather than the patients."[4] *Id.* A New York Times investigation in 2016 reached the same conclusion, reporting that "the charity has resisted giving aid to patients at clinics that do not donate money to the fund." Medley Decl., Ex. 1.[5] According to that investigation, a previous version of AKF's guidelines even said "clinics should not apply for patient aid if the company had not donated to the charity."[6] *Id.*

[2] Cited portions of the Federal Register are attached to Defendants' Request for Judicial Notice as Exhibits 2 & 3.

[3] Available at https://www.regulations.gov/docket?D=CMS-2016-0145.

[4] CMS promulgated guidance and a final interim rule, but the rule was invalidated by the United States District Court for the Eastern District of Texas, Case No. 4:17-cv-00016-ALM for failure to comply with the Administrative Procedures Act.

[5] Katie Thomas and Reed Abelson, *Kidney Fund Seen Insisting on Donations, Contrary to Government Deal*, N.Y. Times, Dec. 25, 2016, available at https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.

[6] Although news articles are generally hearsay, "[t]he urgency of obtaining a preliminary injunction necessitates a prompt determination" and so "[t]he trial court may give even inadmissible evidence some weight, when to do so serves the purpose of preventing irreparable harm before trial." *Flynt Distrib. Co. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984); *see also Ticketmaster L.L.C. v. RMG Techs., Inc.*, 507 F. Supp. 2d 1096, 1114 (C.D. Cal. 2007) ("[T]o the extent some of the newspaper articles may be offered for a hearsay purpose, the Court has wide latitude to consider such evidence in the preliminary injunction context.").

III. WHAT AB 290 DOES

Under AB 290, a financially interested entity making third-party premium payments must comply with several requirements, including "agree[ing] not to steer, direct, or advise the patient into or away from a specific coverage program option or health care service plan contract." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(4). The law requires financially interested entities, including organizations providing premium payment assistance, to provide that assistance for the full plan year and to notify the patient before an open enrollment period if that assistance is to be discontinued. *Id.* at (b)(1). It provides that financial assistance shall not be conditioned on eligibility for any particular surgery, procedure or device, or on use of any particular facility, healthcare provider, or coverage type. *Id.* at (b)(3) & (5). And it requires covered entities to inform applicants for premium assistance about all available health coverage options, including Medicare, Medicaid, individual market plans, and employer plans. *Id.* at (b)(3).

During the legislative process, AKF commented on AB 290. On July 3, 2019, AKF President and CEO, LaVarne Burton, testified before the Senate Health Committee that AB 290 would take AKF outside the protections of Advisory Opinion 97-1.[7] Medley Decl., Ex. 2. This concern is also reflected in the Senate Health Committee bill analysis comments, which note that "AKF operates under OIG guidance issued in 1997, which indicates that, as described by AKF, the arrangement does not constitute a violation of HIPAA." Sen. Com. on Health Analysis at 7. In order to rectify and mitigate AKF's expressed concerns, the Senate proposed four amendments to either address compliance with Advisory Opinion 97-1 or delay AKF's timeframe for compliance to provide them additional time to adjust to AB 290's requirements.

[7] https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-health-committee-on-california-ab-290.html

First, the Senate amended section 1 of the bill to state that legislative intent was to grant "delayed implementation" to allow the "American Kidney Fund to request an updated advisory opinion from the United States Department of Health and Human Services Office of Inspector General for the purposes of protecting patients in California." *Compare* Assem. Bill No. 290 (2019-2020 Reg. Sess.) as introduced Jan. 28, 2019 (Jan. 28 Bill), *with* AB 290 at § 7.[8]

Second, the Senate amended the bill to state that if a financially interested entity covered by Advisory Opinion No. 97-1—like AKF—requested an updated advisory opinion before July 1, 2020, the effective date of AB 290 as to that entity would be tolled until OIG issues an advisory opinion stating that AB 290 does not conflict with federal law. *Compare* Jan. 28 Bill, *with* AB 290, § 7.

Third, to ensure continuity of care for patients on dialysis, the Senate amended the bill to ensure AKF could continue providing premium payment assistance for its existing patients under its existing arrangement. The amended bill exempts AKF from complying with AB 290 for those patients whose health insurance premiums were being paid by AKF or a similar nonprofit as of October 1, 2019. *Compare* Jan. 28 Bill, *with* AB 290, § 3, Cal. Health & Safety Code § 1367.016 (d)(1), § 5, Cal. Ins. Code § 10176.11(d)(1). This ensures that dialysis providers would continue to receive commercial reimbursement rates for those patients and AKF does not have to report information about these exempt patients to health insurance companies or health plans. *Id*.

Finally, the Senate amended the bill to delay implementation of the Medicare-linked reimbursement cap until January 1, 2022, giving providers and other financially interested entities around two years to adjust to the different reimbursement rates. *Compare* Jan. 28 Bill, *with* AB 290, § 3, Cal. Health & Safety Code § 1367.016 (d)(2); § 5, Cal. Ins. Code § 10176.11(d)(2).

[8] A comparison between AB 290 as introduced on January 28, 2019, and AB 290 as enacted on October 13, 2019 is attached to Defendants' Request for Judicial Notice as Exhibit 4.

IV. BACKGROUND OF THE CURRENT CASE

Plaintiffs filed the current case on November 5, 2019. The Complaint includes claims under the First and Fourteenth Amendments and the Supremacy Clause. Dkt. 1. Plaintiffs filed their motion for preliminary injunction, seeking to enjoin the implementation of AB 290 in its entirety, on November 8, 2019. Dkt. 30.

LEGAL STANDARD

To succeed in their motion for preliminary injunction, Plaintiffs must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction would be in the public interest. *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). Injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id*. at 22.

Plaintiffs seek to invalidate the enforcement of the entirety of AB 290 across California. Facial challenges to statutes are disfavored for a variety of reasons. They "often rest on speculation" resulting in a risk of "premature interpretation of statutes on the basis of factually barebones records." *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008) (citations omitted). Facial challenges also contradict the principle of judicial restraint that "courts should neither 'anticipate a question of constitutional law in advance of the necessity of deciding it' nor formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied.'" *Id.* Last, but not least, "facial challenges threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution." *Id*.

In light of all of the potential problems posed by facial challenges, "a plaintiff can only succeed in a facial challenge by 'establish[ing] that no set of circumstances exists under which the Act would be valid,' i.e., that the law is

unconstitutional in all of its applications." *Washington State Grange*, 552 U.S. at 449 (citing *U.S. v. Salerno*, 481 U.S. 739, 745 (1987)); *Morrison v. Peterson*, 809 F.3d 1059, 1064 (9th Cir. 2015). In considering a facial challenge to a statute, a court must "be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." *Washington State Grange*, at 450. Although Plaintiffs challenge the statute on its face, the Court cannot consider such challenges in the abstract.

ARGUMENT

I. PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THEIR CONSTITUTIONAL CLAIMS

A. AB 290 Is Not Preempted By Federal Law

Plaintiffs assert conflict preemption, under which "state laws are preempted when they conflict with federal law. This includes cases where 'compliance with both federal and state regulations is a physical impossibility,' and those instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (*Arizona II*) (citations omitted). "In preemption analysis, courts should assume that 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.'" *Id*. at 400 (citations omitted).

1. The Advisory Opinion Does Not Preempt AB 290

Plaintiffs contend that the Advisory Opinion preempts AB 290, because it is impossible to comply with both. This argument fails because the Advisory Opinion (1) does not have the force of federal law, and (2) does not conflict with AB 290.

a. The Advisory Opinion Does Not Impose a Requirement With the Force of Federal Law

The Advisory Opinion examines AKF's practice, in 1997, of paying premiums for Medicare Part B and Medigap policies, using funds that were donated in large

part by dialysis companies, concluding that the arrangement as described did *not* fall within the HIPAA remuneration prohibition.[9] Plaintiff's RJN, Dkt. 29, Ex. 2.

The Advisory Opinion 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.[10] 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 provide no authority for the proposition that a finding that a particular course of action is consistent with federal law thus transforms the parameters of that course of action into affirmative requirements of federal law.

Plaintiffs are thus incorrect to ascribe to the Advisory Opinion the mandate of federal law. "Interpretations 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-

[9] In 1995, "less than ten percent" of donations received by AKF were from companies that own dialysis facilities. Plaintiff's RJN, Dkt. 29, Ex. 2. Currently, as stated in the AB 290's legislative findings, "[l]arge dialysis companies contribute more than 80 percent of the revenue to [AKF]." AB 290, § 1(h).

[10] 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. Medley Decl., Ex. 5 at 3. Thus, AKF paid Medigap and Medicare Part B premiums for patients on dialysis. After the Affordable Care Act (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. *Id*.; 42 U.S.C. § 18001.

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) (citations omitted); *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"). The Advisory Opinion does not have the force of federal law or regulation and cannot preempt AB 290.

b. The Advisory Opinion Does Not Conflict with AB 290

Even if the Advisory Opinion had the force of a federal statute or regulation, it still does not preempt AB 290 because there simply is no conflict between the Advisory Opinion and the statute. The Advisory Opinion only considers payments for Medicare Part B or Medigap premiums. Plaintiffs' RJN, Dkt. 29, Ex. 2. The Advisory Opinion does not discuss premium payments for commercial insurance or group health coverage. Even if the Advisory Opinion had the force of federal law, its requirements restrictions would apply only to payments for Medicare Part B or Medigap premiums, which do not fall within the scope of AB 290. *See* AB 290, § 3, Cal. Health & Safety Code § 1367.016(f)(3); Cal. Ins. Code § 10176.11(f)(2) (no application to "coverage of Medicare services pursuant to contracts with the United States government, Medicare supplement coverage").

And, even if the Advisory Opinion could be construed to apply to premium payments for commercial health insurance and group health plans, there is still no conflict with AB 290. Nothing in AB 290 prevents AKF from using its funds in accordance with its charitable mission and it does not restrict the kinds of patients AKF may help. AB 290 and the Advisory Opinion also both require that financial assistance may not be conditioned on the use of a specific facility or health care provider. Plaintiffs' RJN, Ex. 2 at 5-7; AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(2); § 5, Cal. Ins. Code § 10176.11(b)(2). Further, the Advisory Opinion is 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 Advisory Opinion.

Plaintiffs also claim that AB 290 requires AKF to disclose patients' identities to the "insurers of those patients for whom it provides premium assistance," which will lead to HIPP participants determining that their provider is a donor and feeling bound to stay with their provider, contrary to the Advisory Opinion. Mem., Dkt. 28, at 10. Under Plaintiffs' theory, HIPP participants would only *potentially* learn that their provider is a HIPP donor *after* a patient picks a provider, applies for and receives HIPP, obtains dialysis, and then receives a benefits statement. By then, the patient has already picked a provider without undue influence, as required by the Advisory Opinion. In addition, this concern is purely speculative, as Plaintiffs have not provided any evidence that HIPP participants are likely to examine their billing statements in order to determine whether their provider is a donor.[11]

c. The Court Should Not Presume a Conflict When AKF Can Forestall AB 290

Where there is "a basic uncertainty about what the law means and how it will be enforced," it would be "inappropriate to assume" that a state law "will be construed in a way that creates a conflict with federal law." *Arizona II*, 567 U.S. at 415 (citation omitted). Here, AB 290 explicitly provides a mechanism for regulated entities to receive a finding that compliance with AB 290 is consistent with federal law, before AB 290 will apply to those entities. AB 290, § 7.

[11] Plaintiffs also argue that AB 290 creates different classes of patients contending that it requires HIPP to treat California patients differently, as well as those patients in grandfathered plans, which would contradict the Advisory Opinion. Mem., Dkt. 28, at 10-11. It is not clear what portion of the Advisory Opinion Plaintiffs believe conflicts with AB 290 in this respect. To the extent Plaintiffs' contention is that the grandfathering provisions require differential treatment that is alleged to violate non-discrimination requirements in the Medicare Secondary Payer Act, that argument fails for the reasons discussed below.

Thus, "the nature and timing of this case counsel caution in evaluating the validity of" AB 290. *Id.* (citing *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960) ("To hold otherwise would be to ignore the teaching of this Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists")). "Well-established preemption principles favor upholding state law if it can plausibly coexist with the federal statute." *California Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1071 (9th Cir. 2019) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). Because the provisions of AB 290 that relate to the Advisory Opinion need not take effect, with respect to AKF or other entities covered by the Advisory Opinion, unless and until a federal agency has determined that compliance with AB 290 is consistent with federal law, there is no need to presume an irreconcilable conflict between the Advisory Opinion and AB 290.

2. AB 290 Does Not Conflict with the Medicare Secondary Payer Act

Plaintiffs 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]. Mem., Dkt. 28, at 14.

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). However, "a health plan only violates this provision through disparate treatment based on Medicare eligibility—that is, when a group health plan treats those eligible for Medicare differently than those who are not." *DaVita, Inc. v. Marietta*

Mem'l Hosp. Employee Health Benefit Plan ("*Marietta Mem'l Hosp.*"), No. 2:18-CV-1739, 2019 WL 4574500, at *3 (S.D. Ohio Sept. 20, 2019).[12]

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. 42 U.S.C. § 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). Thus, "a health plan only violates this provision when it treats those with ESRD differently than those who do not have ESRD . . ." (i.e., disparate treatment). *Marietta Mem'l Hosp.*, 2019 WL 4574500, at *3–5.[13]

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

[12] *See also DaVita, Inc. v. Amy's Kitchen, Inc.*, 379 F. Supp. 3d 960, 973 (N.D. Cal. 2019) (finding that because those receiving dialysis treatment who are Medicare-eligible and those who are not are subject to the same provisions, the benefit plan did not violate the "take into account" provision); *Dialysis of Des Moines, LLC v. Smithfield Foods Healthcare Plan*, No. 2:18-CV-653, slip op. at 11–12 (E.D. Va. Aug. 5, 2019) ("[A] limitation on services is permitted so long as it is uniform, meaning that it applies to all plan enrollees regardless of Medicare eligibility or ESRD diagnosis."); *Nat'l Renal All., LLC v. Blue Cross & Blue Shield of Ga, Inc.*, 598 F. Supp. 2d 1344, 1354 (N.D. Ga. 2009) ("Plaintiffs have not demonstrated that Blue Cross's decision to lower reimbursement rates on dialysis treatment . . . constitutes 'taking into account' or 'differentiating' a level of coverage provided to those suffering from ESRD and those not.").

[13] *See also Dialysis of Des Moines*, slip op. at 11–12; *Amy's Kitchen*, 379 F. Supp. 3d at 973 ("[T]he applicable rates in Amy's Plan are set based on the fact of dialysis treatment, not the existence of ESRD."); *Nat'l Renal All.*, 598 F. Supp. 2d at 1354. ("Significant to the court's finding is the fact that there is no allegation that Blue Cross pays a different amount for dialysis treatment of non-ESRD patients than ESRD patients.").

necessarily have ESRD) and another amount for everyone else." Mem., Dkt. 28, at 14. But Plaintiffs do not—and cannot—allege 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. Nor does the statute differentiate between patients based on their ESRD status. AB 290 treats all patients with ESRD equally. Thus, consistent with the findings of numerous other federal courts in analogous cases, AB 290 does not violate the "take account" or "nondifferentiation" provisions of the MSPA. *See Marietta Mem'l Hosp.*, 2019 WL 4574500, at *3–5; *Amy's Kitchen, Inc.*, 379 F. Supp. 3d at 973; *Dialysis of Des Moines, LLC*, No. 2:18-CV-653, slip op. at 11–12; *Nat'l Renal All., LLC*, 598 F. Supp. 2d at 1354.

B. AB 290 Does Not Violate Plaintiffs' First Amendment Rights

1. The Requirement that AKF Inform Patients About Available Healthcare Plan Options Does Not Violate Its Free Speech Rights

AB 290 requires that financially interested entities like AKF inform the recipients of premium payment assistance of "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and employer plans." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(3), § 5, Cal. Ins. Code § 10176.11(b)(3). The Supreme Court has held that a speaker's First Amendment rights are "adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Milavetz, Gallop & Milavetz v. U.S.*, 559 U.S. 229, 250 (2010). That is the case here. In *Milavetz*, the Court considered a law that required attorneys advertising debt relief assistance to disclose that such relief would likely involve filing for bankruptcy. *Id.* The Court found that the required disclosures were "intended to combat the problem of inherently misleading commercial advertisements—

specifically, the promise of debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." *Id*. Simliarly, AB 290's requirement that AKF and other financially interested entities provide information to patients about their insurance options protects against patient steering by insuring that patients are informed about all of their options, not just the commercial insurance options that result in higher reimbursement rates for dialysis providers. Additionally, it is difficult to see how this requirement places a burden on AKF. Although AKF asserts that "[b]y policy and practice, AKF does not discuss coverage options with patients" but "simply pays for coverage submitted by the patients" (Mem., Dkt. 28, at 16), it does provide a list of the types of health care plans for which they offer premium payment assistance. Medley Decl. at Ex. 3 at 2.

Plaintiffs rely on *Nat'l Institute of Family and Life Advocates v. Becerra*, 138 S.Ct. 2361 (2018) (*NIFLA*), arguing that the disclosures required by AB 290 trigger the same level of First Amendment scrutiny as the required disclosure in that case. But the Court specifically explained in *NIFLA* that the required disclosure—the availability of publicly-funded reproductive healthcare services, including abortion—was not the type of "notice limited to purely factual and uncontroversial information" that it had previously upheld as a reasonable regulation of commercial speech. *Id*. at 2372 (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).) Furthermore, the Court in *NIFLA*, found it significant that the state could inform the target audience about available services "without burdening a speaker with unwanted speech." *Id*. at 2376. However, in the present case, the State has no way to identify patients receiving premium payment assistance from AKF because AKF often provides patients with debit cards that the patients then use to pay their premiums. Medley Decl., Ex. 4 at 15. Thus, the State cannot simply provide the information directly to patients who need it. AB 290's required disclosure of information about "all available health coverage options, including but not limited to, Medicare, Medicaid, individual market plans, and

employer plans" is much more akin to the disclosures at issue in *Zauderer* and *Milavetz* than those at issue in *NIFLA*. As such, the State must only show that the requirements are "reasonably related to the State's interest in preventing deception of consumers." The State has already done so. *Supra* pp. 4-5.

2. AB 290's Prohibition on Steering, Directing, or Advising Patients Regarding Insurance Options Is Not Unconstitutionally Vague

As discussed in further detail in Defendants' opposition to the preliminary injunction motion filed in *Fresenius, et al. v. Becerra, et al.*, 8:19-cv-02130, the meaning of AB 290's prohibition on steering, directing, or advising patients "into or away from a specific coverage program option or health care service plan contract" is sufficiently definite to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited" and will not compel speakers "to steer too far clear of any forbidden area" of speech. *Edge v. City of Everett*, 929 F.3d 657, 665 (9th Cir. 2019). The phrase "steer, direct, or advise" in the context of AB 290 is not difficult to ascertain—the Legislative findings highlight concerns over "[e]ncouraging patients to enroll in commercial insurance coverage for the financial benefit of the provider." AB 290, § 1(c). Plaintiffs rely on *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), arguing that AB 290's prohibition on steering, directing, or advising patients toward or away from a particular insurance option has the effect of preventing one type of speaker from communicating with a particular audience "in an effective and informative manner." Mem., Dkt. 28, at 18. It does not; nothing in AB 290 prohibits a financially interested entity from communicating factual information to its patients.

AKF's argument that the steering provision "restricts AKF's freedom to inform patients, for example, of Medicare costs and deductibles, or to state its view that particular types may better fit a patient than other plan types, or to "advise patients about the availability of better, more appropriate, or less expensive coverage" undercuts their statement on the previous page of their brief that "[b]y

policy and practice, AKF does not discuss coverage options with patients" but "simply pays for coverage submitted by the patients." Mem., Dkt. 28, at 16. It also undercuts AKF's claim that "HIPP patients . . . come to the program only *after* they have qualified for and obtained health insurance of their choosing." Compl., Dkt. 1, at 16. Furthermore, curtailing the ability of financially interested entities to tell patients they should choose one insurance option over another is precisely the point of the statute, in light of documented concerns that these entities are inappropriately steering patients toward insurance options that benefit their major donors—the dialysis providers. AB 290, § 1(h); 81 Fed. Reg. 90217.

3. AB 290's Requirement of an Annual Statement Certifying Compliance Does Not Violate the First Amendment

AB 290 requires that a financially interested entity "shall not make a third-party premium payment" unless it "[a]nnually provides a statement to the health care service plan that it meets the requirements set forth in subdivision (b)" and "[d]iscloses to the health care service plan, prior to making the initial payment, the name of the enrollee for each health care service plan contract on whose behalf a third-party premium payment described in this section will be made." AB 290, § 3, Cal. Health & Safety Code § 1367.016(c)(1); Cal. Ins. Code § 10176.11(c)(1). Plaintiffs contend that each of these requirements violates their First Amendment right to be free from compelled speech.

It is not unusual for charitable organizations to be subject to reporting or certification requirements. *See, e.g.*, *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 637-38 n.12 (2019) (noting that "Illinois law . . . requires charitable organizations to register with the State Attorney General's Office and to report certain information about their structure and fundraising activities"); *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 800 (1988) (noting that the State may "publish the detailed financial disclosure forms it requires professional fundraisers to file."). AB 290's required compliance

statement is just such a requirement. It does not force AKF "to endorse a pledge or motto contrary to their deeply-held beliefs," a sign of impermissible compelled speech. *Beeman v. Anthem Prescription Mgmt., Inc.*, No. EDCV 04-407-VAP (SFLx), 2007 WL 8433882 at *5 (C.D. Cal. May 7, 2007). It is simply a mechanism to ensure compliance with the statutory requirements of AB 290.

Likewise, the requirement that financially interested entities disclose to insurers the names of patient enrollees receiving premium payment assistance does not violate the First Amendment. Plaintiffs offer no authority for the proposition that a statutory requirement that a financially interested entity paying premiums on a patient's behalf has a constitutional right not to disclose the identities of those patients to the insurer.[14] But like the required compliance statement, the disclosure of patient names does not involve any compelled message. The disclosure of patient names is necessary to the functioning of the statute; health plans will only know whether the reimbursement cap applies if they know which patients are receiving premium payment assistance. The provision will also help ensure that patients receive complete information about their insurance options and can choose the best insurance for their care needs.

Plaintiffs also assert that the compliance statement and patient disclosure requirements are content-based regulations subject to strict scrutiny because the regulations apply only to financially interested entities as defined by statute. The logical extension of this argument is that states could not regulate any specific industry or group of economic actors if any kind of reporting or disclosure were required. That is obviously not the case. *See, e.g., SEC v. Tex. Gulf Sulphur Co.*, 401 F.2d 833 (2d Cir. 1968) (regulating the exchange of information about

[14] AB 290 specifies that its provisions do not "supersede or modify any privacy and information security requirements and protections in federal and state law regarding protected health information or personally identifiable information, including, but not limited to, the federal Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 300gg)." AB 290, § 3, Cal. Health & Safety Code § 1367.016(n); § 5, Ins. Code § 10176.11(n).

securities); *Mills v. Elec. Auto-Lite Co.*, 396 U.S. 375 (1970) (requirements relating to corporate proxy statements).

4. AB 290 Does Not Violate AKF's Right of Association

AB 290 requires financially interested entities such as AKF to "agree not to condition financial assistance on eligibility for, or receipt of, any surgery, transplant, procedure, drug or device." AB 290, § 3, Cal. Health & Safety Code § 1367.016(b)(2); § 5, Cal. Ins. Code § 10176.11(b)(2). AKF argues that this restriction would prevent it from providing HIPP assistance limited to patients on dialysis or those who within the past year have received a kidney transplant. Mem., Dkt. 28, at 19. But AB 290 does not prohibit AKF from limiting its assistance to those patients diagnosed with ESRD. Instead, it is designed to prevent harmful practices such as withdrawing premium payment assistance when a patient receives a kidney transplant. AB 290, § 1(c) and (d); *see also* 81 Fed. Reg. 90215 ("Documents in the record show that these non-profits will not continue to provide financial assistance once a patient receives a successful kidney transplant, nor will the non-profit cover any costs of the transplant itself, living donor care, post-surgical care, post-transplant immunosuppressive therapy, or long-term monitoring"). The statute would require organizations who offer premium payment assistance to pay those premiums no matter which course of treatment is best for a patient suffering from ESRD, not only when the insurance purchased with those premiums is used to cover dialysis treatment to the benefit of AKF's major donors.

Plaintiffs assert that AB 290 "burdens AKF's right to associate with patients by imposing mandatory and prohibitory speech restrictions on how AKF communicates with them, and by requiring AKF to disclose their identities, along with their medical and financial status, to the insurance companies." Mem., Dkt. 28, at 20. And Plaintiffs argue that "the Act burdens the right of patients to associate with the dialysis providers of their choice" by "allowing more generous reimbursement for providers who do not donate to AKF than for providers that do."

Id. But the cases out of which the right to expressive association grew "protect[ed] 'freedom of association *for the purpose of advancing ideas and airing grievances*.'" *Whalen v. Roe*, 429 U.S. 589, 604 (1977) (emphasis added); and *Nat'l Ass'n for Advancement of Colored People v. State of Ala. ex rel. Patterson*, 357 U.S. 449, 462 (1958). In fact, courts have held that "the relationship between an individual patient and doctor is not the kind of association whose communications are protected by the First Amendment right to freedom of association." *Conant v. McCoffey*, No. C 97-0139 FMS, 1998 WL 164946, at *3 (N.D. Cal. Mar. 16, 1998); *see also Behar v. Pa. Dep't of Transp.*, 791 F. Supp. 2d 383 (M.D. Pa. 2011) (doctor's "association with a patient is an association in the broadest sense [but] it is not the type of association protected by the First Amendment.") A different conclusion is not warranted as to the association between AKF and patients, which facilitates the association between patients and dialysis providers through the payment of money to fund insurance premiums.

As discussed in further detail in the opposition to the preliminary injunction motion filed in *Fresenius v. Becerra*, Plaintiffs' argument that AB 290 permits more generous reimbursement for providers who do not donate to AKF than for providers that do is incorrect. AB 290's reimbursement limit is not a penalty imposed on dialysis providers because of their financial support of AKF. Instead, it is a cap on commercial insurance reimbursement rates for dialysis care provided to patients who receive premium payment assistance from an entity in which the dialysis provider has a financial stake.

5. AB 290 Does Not Violate AKF's Right to Petition by Compelling It to Seek an Updated Advisory Opinion

In response to AKF's expressed concerns that compliance with AB 290 would require it to run afoul of Advisory Opinion 97-1, the Legislature added a provision to the bill specifically to "allow the American Kidney Fund to request an updated advisory opinion" from the OIG. AB 290, § 1(j). That provision not only allows a

grace period until July 1, 2010 for AKF to request an updated advisory opinion, but also states that if AKF does so, the sections of AB 290 that would impose requirements on AKF, including offering HIPP assistance for an entire plan year and disclosing the identities of patients to the patients' insurers, will only become operative relative to AKF "upon a finding by the [OIG] that compliance with those sections by a financially interested entity does not violate the federal laws addressed by Advisory Opinion 97-1." AB 290, § 7. In other words, if AKF requests an updated OIG advisory opinion, certain provisions of AB 290 will not go into effect for AKF until the OIG issues an opinion, and if that opinion says that AKF cannot comply with both AB 290 and federal law, those provisions will never go into effect as to AKF at all.

AKF asserts a novel argument that the provision allowing them to seek an updated advisory opinion from the OIG violates its First Amendment rights by compelling it to exercise its right to petition. As an initial matter, AKF offers no authority demonstrating that the courts have ever found a cognizable cause of action for forced or compelled petition under similar circumstances, or recognized the theory at all under the First Amendment. Instead, AKF cites *Wayte v. United States*, 470 U.S. 598, 610 n.11 (1985) for the general proposition that "the right to petition and the right to free speech . . . are related and generally subject to the same constitutional analysis." Mem., Dkt. 28, at 21. Even assuming that a theory of compelled petition is cognizable, it is not the case that AB 290 compels AKF to seek an updated advisory opinion. AKF argues that AB 290 "attempts to force AKF to submit a petition advocating a result it vigorously opposes." Mem., Dkt. 28 at 21. AB 290 does no such thing. It provides the option for AKF to request an updated advisory opinion on the question of whether, by complying with AB 290's requirements, it would be violating federal law. It does not mandate that AKF do so. "Both the right to be free from compelled expressive activity and the right to be free from compelled affirmation of belief presuppose a coerced nexus between the

individual and the specific expressive activity." *Cal-Almond, Inc. v. U.S. Dept. of Agric.*, 14 F.3d 429, 435 (9th Cir. 1993). No such coercion is at issue here.

Neither does AB 290 force AKF to convey any specific message if it requests an updated advisory opinion. AKF could phrase the request as seeking a finding that "complying with the requirements of AB 290 would require it to violate federal law." Compelled speech occurs when "an individual is obliged personally to express a message he disagrees with, imposed by the government." *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550, 557 (2005). That is not the case here.

II. PLAINTIFFS FAIL TO DEMONSTRATE ANY IRREPARABLE HARM CAUSED BY AB 290 RATHER THAN BY THE PROVIDERS AND AKF'S DECISIONS

Plaintiffs paint a dire picture in their brief and declarations of the effects that will result if AB 290 goes into effect on January 1, 2020, including the loss of premium payment assistance, due to AKF's decision to leave the State of California. But most provisions of the statute—including the cap on reimbursements to private insurers or health care plans for treatments provided to patients receiving premium assistance from a financially interested entity—will not go into effect until at least January 1, 2022, and may be delayed further if AKF seeks an updated opinion from the OIG by July 1, 2020. AB 290, § 7. In fact, the only provision that will go into effect as of January 1, 2020 is the patient steering prohibition. Furthermore, patients who were receiving HIPP assistance before October 1, 2019 are grandfathered such that AKF may continue paying their premiums and the dialysis providers may continue receiving reimbursement at the non-Medicare rate. AB 290, § 3, Cal. Health & Safety Code § 1367.016(d)(1) & (2); Cal. Ins. Code § 10176.11(d)(1) & (2). The alleged harms Plaintiffs assert are not so imminent to support a preliminary injunction, or AKF's decision to vacate the California market. Additionally, nothing in AB 290 requires AKF to cease making premium payments on behalf of patients on dialysis it has already been serving effective January 1, 2020. AB 290 does not apply to third-party premium

payments for Medigap coverage or for Medicare coinsurance costs at all. AB 290 only applies when commercial insurance is involved. AKF has articulated no rational reason connected to AB 290 to withdraw funding from those patients it serves who are enrolled in government insurance programs.

Despite all of these mechanisms built into AB 290 to encourage AKF to continue providing premium assistance in California, AKF has stated that it will be leaving the state entirely—cutting off all funding to patients it currently serves in California—as of January 1, 2020. Leaving the state rather than taking advantage of provisions is a decision AKF is making to the detriment of the patients it serves. The harm AKF asserts is of its own making, not a result of AB 290.

AKF makes much of the harm it will suffer from losing the "safe harbor" provided by Advisory Opinion 97-1. But circumstances have changed drastically since the 1997 Advisory Opinion, which stated that it was "[b]ased on the information provided" and was "limited to the facts presented." *Id*. at 1. In 1995, "less than ten percent" of donations received by AKF were from companies that own dialysis facilities. Plaintiff's RJN, Ex. 2 at 3. Currently, as stated in the AB 290's legislative findings, "[l]arge dialysis companies contribute more than 80 percent of the revenue to [AKF]." AB 290, § 1(h). At the time the opinion was issued, most ESRD patients were only able to obtain coverage through Medicare, and as such, would rely on AKF for Medicare Part B (outpatient coverage and physician visits) and Medigap coverage (extra health insurance from a private company to pay health care costs not covered by Original Medicare). Upon implementation of the Affordable Care Act, many ESRD patients were able to enroll in private insurance plans, since insurance companies could no longer deny coverage based on preexisting conditions. 42 U.S.C. § 18001.

The irreparable harms described in Plaintiffs brief will result from AKF's own decision to exit the State of California—a decision that is in no way required by

AB 290. AKF should not be permitted to obtain an injunction of an important state statute by threatening the dialysis care of vulnerable patients within the state.

III. ENJOINING AB 290 WOULD NOT BE IN THE PUBLIC INTEREST

The last two preliminary injunction factors under the *Winter* test—the balance of hardships and the public interest—weigh in favor of denying Plaintiff's request for a preliminary injunction. *Winter*, 555 U.S. at 20. "When the government is a party, these last two factors merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (citing *Nken v. Holder*, 556 U.S. 418 (2009)).

The State of California and its citizens have an interest in laws that protect California patients and to ensure that commercial insurance remains affordable. AB 290 is designed to "shield patients from potential harm caused by being steered into coverage options that may not be in their best interest." AB 290, § 1(i). Furthermore, "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1301 (2012). As both the California Legislature and CMS have found, the proliferation of third-party payment arrangements since the enactment of the Affordable Care Act has exposed patients on dialysis to direct harm and caused health care and insurance premium costs to escalate. AB 290, § 1(c)-(e); 81 Fed. Reg. 90214, *et seq*. If AB 290 is enjoined, these practices will continue and patients will continue to have their care compromised and costs increased. It is squarely within California's traditional police powers to regulate arrangements between dialysis providers and third-party premium payers in order to protect its citizens from these ill effects. *See Cal. Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1064 (9th Cir. 2019).

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for preliminary injunction should be denied.

Dated: November 25, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

Case Name: **Jane Doe, et al v. Xavier Becerra, et al.** Case No.: **8:19-cv-2105-DOC-(ADSx)**

I hereby certify that on November 25, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DEFENDANTS' OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

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 the foregoing is true and correct and that this declaration was executed on November 25, 2019, at Los Angeles, California.

Colby Luong	/s/ Colby Luong
Declarant	Signature

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