Patterson Belknap

Litigation Alert
April 10, 2026

Ninth Circuit Finds First Amendment Right to Donate to Patient Assistance Charities, With Possible Impact on Enforcement of Federal Anti-Kickback Statute

Last week, the Ninth Circuit issued a published decision striking down California's Assembly Bill 290 ("AB 290") on First Amendment grounds. *See Fresenius Med. Care Orange Cnty., LLC v. Bonta*, No. 24-3654 (9th Cir. Apr. 7, 2026). Its central holding was that providers of medical services have a protected First Amendment right to make donations to patient assistance charities that engage in expressive activity, even if those donations are driven by commercial self-interest. Although the case did not directly involve the federal Anti-Kickback Statute ("AKS")—or any federal statute—it arguably calls into question the constitutionality of AKS proceedings often brought against pharmaceutical manufacturers that make analogous donations to patient assistance charities out of alleged self-interest.

AB 290, the California statute at issue in *Fresenius*, imposed various restrictions and requirements that burdened the ability of dialysis clinics to contribute to patient assistance charities. Among other things, the statute capped the rate at which clinics that donate to charities could be reimbursed by insurers; required charities offering insurance premium assistance to disclose their patients to insurers; and prohibited charities from conditioning their grants of assistance on "on eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." The statute's stated goals were "to protect the sustainability of [insurance] risk pools," "shield patients from potential harm caused by being steered into coverage options that may not be in their best interest," and "correct a market failure that has allowed large dialysis organizations to use their oligopoly power to inflate commercial reimbursement rates and unjustly drive up the cost of care."

Certain dialysis clinics sued the State of California in federal court, joined by two patients and a patient assistance charity called the American Kidney Fund (the "Fund"). The plaintiffs asserted that AB 290 violated their First Amendment rights of association and speech. The district court found certain parts of the statute unconstitutional but upheld others, and the parties cross-appealed. The Ninth Circuit struck down the statute in full, finding that most of its provisions violated the First Amendment, and that the remaining provisions were not severable from the unconstitutional ones.

As an initial matter, the Ninth Circuit held that the clinics' donations to the Fund were fully protected by the First Amendment. This was because, in addition to assisting dialysis patients with their insurance premiums, the Fund "engage[d] in various protected activities, including educational and lobbying efforts on behalf of Americans [with kidney disease]." The Fund therefore qualified as an "expressive association." From there, it was a quick step to finding the clinics' contributions constitutionally protected, since "the First Amendment does not only protect the rights of expressive associations; it also protects the rights of donors to those expressive associations." Laws that substantially burden donors' rights to contribute to such associations are therefore "subject to 'exacting scrutiny.'"

The Ninth Circuit rejected California's argument that only "charitable contributions that are *primarily* expressive in nature" receive this "exacting" First Amendment protection—and that the clinics' contributions to the Fund were motivated primarily by economic self-interest, not "expressive" goals. The district court had largely accepted that argument, finding the clinics' donations to the Fund "transactional" rather than "expressive," since they were a form of

"quid pro quo arrangement that 'secure[s] a later return on investment in the form of higher private insurance reimbursements.'" The Ninth Circuit disagreed. In its view, it did not matter whether the clinics' contributions were intended to support the Fund's expressive mission or to advance the clinics' own economic self-interest. It was enough to trigger full First Amendment protection that the Fund, to whom the donations were directed, engaged in *some* expressive conduct—*i.e.*, that the Fund's activities were "expressive *at all*."

Having found that "exacting scrutiny" applies, the Ninth Circuit concluded that most of AB 290's provisions restricting donations could not meet that test, which requires that the provisions be "narrowly tailored" to an "important governmental interest." California's stated interest in preventing "unjust enrichment" was insufficient: while the clinics were admittedly "enriched by their financial relationship with [the Fund]," this enrichment was not "unjust" absent "evidence" of resulting "patient harm," which California had not adduced.

The Ninth Circuit gave more credence to California's stated interest in "preventing distortion to insurance risk pools," but ultimately found it insufficient as well. Although there was some evidence that the clinics' donations could have such a distortive effect, the challenged restrictions were not "narrowly tailored" to the goal of preventing risk-pool distortion. For one thing, there were "many alternative measures" the State could take to accomplish the same goal without targeting protected First Amendment activity—*e.g.*, "directly regulat[ing] insurance premiums or reimbursement rates" across the board, "provid[ing] subsidies," or "creat[ing] incentives for additional competitors to enter the dialysis market." For another thing, AB 290's restrictions were "overbr[oad]," as they were triggered by "*any* donation from *any* health care provider," whether or not they plausibly implicated the stated concerns.

Next, the Ninth Circuit found unconstitutional AB 290's provision barring charities from conditioning their grants of assistance on a patient's "eligibility for, or receipt of, any surgery, transplant, procedure, drug, or device." This restriction violated the Fund's "First Amendment right to expressive association: [its] right to associate with whom it chooses"—in this case, "patients [with a particular kidney disease] undergoing dialysis." Citing Supreme Court precedent recognizing the Boy Scouts' right to exclude a gay scoutmaster, the Ninth Circuit found that the Fund was "protect[ed] against ... forced inclusion of ... unwanted person[s]" in its "financial assistance" program. The court rejected California's argument that this provision was justified by its interest in "protecting vulnerable [patient] populations" from "abusive practices," again finding a lack of narrow tailoring to this goal.

On the other hand, the Ninth Circuit found no problem with AB 290's requirement that patient assistance charities like the Fund "inform [patients] of all available health coverage options." This disclosure requirement did not burden expressive association but merely required charities to convey "factual and uncontroversial information" to patients. However, this disclosure requirement could not be severed from the statute's unconstitutional provisions, so the entire statutory scheme was deemed invalid.

Fresenius raises questions going beyond California's AB 290. In particular, the federal government has long taken the position that the AKS prohibits anyone from knowingly paying any remuneration to anyone else, as long as the payment is subjectively intended, in any material part, to induce the purchase of a federally reimbursable product or service.[1] As relevant here, the government maintains that pharmaceutical companies' donations to patient assistance charities that help Medicare patients afford the companies' own

[1] *See* 42 U.S.C. § 1320a-7b(b)(2); *Pharm. Coalition for Patient Access v. United States*, 126 F.4th 947 (4th Cir. 2025); *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, 42 F.4th 67 (2d Cir. 2022).

medications may violate the AKS on this basis, unless the donors and charities comply with detailed restrictions on how assistance programs may be structured, what conditions and drugs they may cover, and what information may be shared between the donor and the charity.[2] The government maintains that donations that run afoul of these restrictions pose a "heightened risk of fraud and abuse," including by "steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs."[3] Accordingly, the government (either acting directly, or through *qui tam* relators) has brought enforcement proceedings against pharmaceutical companies for making charitable donations that fail to comply with these restrictions.[4]

Previous First Amendment challenges to such AKS proceedings have not succeeded—largely on the ground that donations to patient assistance charities are supposedly unprotected "conduct," not protected speech or association.[5] But these decisions are difficult to reconcile with *Fresenius*'s reasoning. After all, the charities in these pharmaceutical cases likely engaged in at least *some* expressive conduct, such as patient advocacy and lobbying, alongside their provision of financial assistance to patients. And, under *Fresenius*, that fact alone should render the manufacturers' donations protected by the First Amendment's right of association, irrespective of their subjective intent in making those donations.

The question would then become whether the AKS's provisions are narrowly tailored to a sufficiently important government interest—and it is debatable whether they are. Again, as interpreted by the government, the AKS prohibits *anyone* from paying *anything* to *any* third party, as long as that payment is intended in *any* material part to induce the purchase of a federally reimbursable product or service. Under *Fresenius*'s reasoning, such a sweeping prohibition may be found overbroad, rather than directly targeted to the particular ills the government claims that it is seeking to prevent (*e.g.*, distortion of pharmaceutical prices and resulting economic harm). Moreover, as in *Fresenius*, there are any number of more direct ways the government could attack these perceived problems without barring pharmaceutical companies from donating to charities.

Manufacturers that contribute or desire to contribute to patient assistance charities should closely monitor whether California seeks rehearing or certiorari in *Fresenius*; the result of those proceedings, if any; and whether other courts follow the Ninth Circuit's lead. If so, the AKS enforcement landscape could shift substantially.

---

[2] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120, 31120 (May 30, 2014); Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

[3] 70 Fed. Reg. at 70625.

[4] *See, e.g.*, *U.S. v. Regeneron Pharms., Inc.*, No. 20-CV-11217, 2020 WL 7130004 (D. Mass. Dec. 4, 2020); *Humana Inc. v. Mallinckrodt Ard LLC*, No. 19-CV-6926, 2020 WL 3041309 (C.D. Cal. Mar. 9, 2020); *U.S. ex rel. Strunck v. Mallinckrodt Ard LLC*, No. 12-175, 13-1776, 2020 WL 362717 (E.D. Pa. Jan, 22, 2020); *U.S. ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647 (D.S.C. 2019); *U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032 (C.D. Cal. 2016).

[5] *See, e.g.*, *Regeneron*, 2020 WL 7130004, at *17 (finding that manufacturer's donations to a patient assistance charity were "conduct," and that "[a] pharmaceutical manufacturer has no First Amendment right to pay kickbacks intended to induce prescriptions and purchases of its drugs"); *Pharm. Coalition for Patient Access v. United States*, 2024 WL 187707, at *21 (E.D. Va. Jan. 17, 2024) (stating that "[c]ommunicating with charities about ... spending on specific drugs may be protected speech, but making donations to induce claims for one's own drugs ... is not").

This alert is for general informational purposes only and should not be construed as specific legal advice. If you would like more information about this alert, please contact one of the following attorneys or call your regular Patterson contact.

Jonah M. Knobler	212.336.2134	jknobler@pbwt.com
William F. Cavanaugh	212.336.2793	wfcavanaugh@pbwt.com
Joshua A. Goldberg	212.336.2441	jgoldberg@pbwt.com
Lauren Schorr Potter	212.336.2117	lspotter@pbwt.com

To subscribe to any of our publications, call us at 212.336.2000, email mktg@pbwt.com or sign up on our website, https://www.pbwt.com/subscribe/.

Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036–6710
212.336.2000
www.pbwt.com