

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CALIFORNIA LIFE SCIENCES
ASSOCIATION, et al.,

Plaintiffs,

v.

CENTER FOR MEDICARE AND
MEDICAID SERVICES, et al.,

Defendants.

Case No. 20-cv-08603-VC

**ORDER GRANTING MOTION FOR
PRELIMINARY INJUNCTION**

Re: Dkt. No. 27

The motion for a preliminary injunction is granted based on the government’s failure to complete the notice and comment procedures required by the Administrative Procedure Act. The government is enjoined from implementing the rule pending completion of those procedures. The recent ruling by Judge Catherine Blake thoroughly explains why the rule should be temporarily enjoined, and her reasoning is largely adopted here. *See Association of Community Cancer Centers v. Azar*, 2020 WL 7640818 (D. Md. Dec. 23, 2020). This ruling will highlight a few specific points:

1. Judicial review. As Judge Blake explains, the bars on judicial review contained in 42 U.S.C. §§ 405(g), (h) do not apply to this case. The defendants cite 42 U.S.C. § 1395ff(b), which incorporates the bars in section 405 into the Medicare statute, but that provision applies to appeals of initial determinations of benefits under part A and part B of subchapter XVIII (“Health Insurance for Aged and Disabled”). Section 1395ii similarly incorporates section 405(h) into the Medicare statute, but only “with respect to this subchapter”—subchapter XVIII. *See* 42 U.S.C. § 1395ii. Here, the plaintiffs challenge the government’s implementation of a model

under 42 U.S.C. § 1315a, which is in subchapter XI (“General Provisions, Peer Review, and Administrative Simplification”). Section 1320a-7 applies the bars on judicial review in section 405(h) to parts of subchapter XI, but not to section 1315a. *See* 42 U.S.C. § 1320a-7(f). Because the plaintiffs’ claims do not “arise under” any of the subchapters or sections subject to section 405’s bars on judicial review, the Court has jurisdiction over the claims. *See Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 976 (9th Cir. 2020).

In addition, the limits on judicial review contained in 42 U.S.C. § 1315a(d)(2) do not apply to the plaintiffs’ notice and comment claim because this claim is not inextricably intertwined with the substantive statutory claims. *Cf. Heckler v. Ringer*, 466 U.S. 602, 614 (1984). The alleged APA violation, and the relief sought for that violation, is very different from the alleged substantive violations and the relief sought for those.

2. Likelihood of success on the merits. The plaintiffs have demonstrated that they are very likely—indeed virtually certain—to prevail on their claim that the government violated the APA’s notice and comment requirements. As Judge Blake explains, the government’s argument that the good cause exception applies is flimsy; complying with the notice and comment requirements here would not interfere with the agency’s ability to carry out its mission, or cause real harm to life, property, or public safety. *See California v. Azar*, 911 F.3d 558, 575-77 (9th Cir. 2018); *East Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1278 (9th Cir. 2020). This would be true even if the government had not delayed so long in adopting the rule, but it is especially true in light of those delays. *See Azar*, 911 F.3d at 577; *Chamber of Commerce v. Department of Homeland Security*, 2020 WL 7043877, at *7-9 (N.D. Cal. Dec. 1, 2020).

In fact, it seems obvious—based on both common sense and the way the interim final rule is written—that the reasons the government offers for dispensing with the notice and comment requirements are contrived. The real reason is that the current presidential administration is in its waning days and would not have time to enact the policy if it adhered to these requirements. While there’s nothing unlawful per se about rushing to enact policy in the final days of a presidential administration (indeed, it’s a time-honored tradition), executive

branch officials may not circumvent clear legal requirements in the eleventh hour to achieve goals they couldn't accomplish in the normal course.

3. Irreparable harm. There is no dispute that some of the plaintiffs' members will suffer financial losses if the rule takes effect on January 1. While it's true that financial harm is typically not considered "irreparable," there is also no dispute that here the plaintiffs' members would be unable to recover their losses from the government should they ultimately prevail. Thus, by definition, the plaintiffs have demonstrated a likelihood of irreparable harm. *See City & County of San Francisco v. United States Citizenship & Immigration Services*, 981 F.3d 742, 762 (9th Cir. 2020); *East Bay Sanctuary Covenant*, 950 F.3d at 1280.

The government argues that even in cases where a plaintiff will ultimately be unable to recover financial losses, there is no irreparable harm unless the losses are "considerable" or would threaten to put the plaintiff out of business. This overreads Ninth Circuit law, and it confuses the irreparable harm inquiry with the next part of the preliminary injunction test, which relates to the balance of hardships. If a financial loss is irreparable but small, the plaintiff has checked the "irreparable harm" box, even if the size of the harm will make it more difficult to establish that the hardship to the defendant from an injunction is outweighed by the hardship to the plaintiff from the lack of an injunction. In any event, the plaintiffs here have demonstrated that the financial losses of their members would indeed be considerable. *See* Chen declaration ¶ 20; Hardy declaration ¶ 28.


4. Balance of hardships and the public interest. For the reasons explained by Judge Blake, the disruption and harm that would likely be caused by implementing the rule on January 1 is far greater than the harm that would result from delaying the rule until completion of the notice and comment process. *See generally* Chen declaration; Hardy declaration; *see also* Garthwaite declaration.

5. Scope of relief. For the reasons explained by Judge Blake, the only appropriate relief is to vacate the interim final rule pending completion of the notice and comment process. *See also East Bay Sanctuary Covenant*, 950 F.3d at 1282-84. After all, the agency itself declared that the

model would only be effective if it had a nationwide scope. *See* 85 Fed. Reg. 76180, 76188 (Nov. 27, 2020). It would thus be inappropriate—indeed counter to the purposes of the rule itself—to enjoin enforcement of the rule merely as to the plaintiffs in this case.

IT IS SO ORDERED.

Dated: December 28, 2020



VINCE CHHABRIA
United States District Judge