UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMUNITY ONCOLOGY ALLIANCE,

Plaintiff,

v.

XAVIER BECERRA, Secretary of U.S. Department of Health and Human Services,

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

CHIQUITA BROOKS-LASURE, Administrator of the Centers for Medicare and Medicaid Services,

CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 23-cv-2168 (CJN)

MEMORANDUM OPINION

The Stark Law generally prohibits physicians from making referrals for designated health services to entities in which the physician has a financial stake. Community Oncology Alliance alleges that through its publication of certain Frequently Asked Questions, the government unlawfully extended this prohibition to physicians' mailing of prescription drugs to patients' homes. The Court previously determined that the Alliance was not entitled to preliminary injunctive relief against those FAQs, ECF No. 36, and now concludes on the merits that the FAQs rest on a correct interpretation of the Stark Law and its implementing regulations. The Court therefore grants Defendants' Motion to Dismiss and denies Plaintiff's Cross-Motion for Summary Judgment.

I. Background

A. Statutory and Regulatory Background

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq*. Through a series of legislative enactments commonly referred to as the "Stark Law," Congress has prohibited physicians from making referrals for designated health services payable by the Medicare program to entities in which they have a financial stake. *See* 42 U.S.C. § 1395nn, et seq. This prohibition is aimed at preventing Medicare abuse through self-dealing and the overutilization of health services. As relevant here, this includes the referral of out-patient prescriptions to pharmacies in which physicians have a financial interest. *See* 42 U.S.C. § 1395nn(a)(1)(A); *see also id.* § 1395nn(h)(6)(J); *see also* 42 C.F.R. § 411.351.[1]

Although the Stark Law is a broad and general prohibition against self-referrals, it does have exceptions. Under one, a physician may refer a patient to an entity with whom the physician has a financial relationship for "in-office ancillary services." 42 U.S.C. § 1395nn(b)(2). An "in-office ancillary service" is statutorily defined as a service, other than durable medical equipment, that is furnished by the referring physician (or her associates) in a building (i.e., "in-office") in which she provides care unrelated (or "ancillary") to the furnishing of "designated health services." *See id.* § 1395nn(b)(2)(a); *see also* §§ 1395nn(h)(1)(E)(6).

Congress empowered the Secretary of Health and Human Services to issue Stark exceptions for "any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." *Id.* § 1395nn(b)(4). Congress also

[1] The provision of out-patient prescription drugs is a type of designated health service. 42 U.S.C. § 1395nn(h)(6)(J).

gave the Secretary the authority to promulgate rules to delineate and clarify when and how the statutory exceptions to the Stark Law apply. *See id*. §§ 1302(a), 1395hh(a)(1).

Beginning in 1995, HHS exercised this authority regarding the in-office ancillary services exception. In defining *who* qualifies, HHS's regulations now explain that the exception is available to referring physicians, members of their practice group, and individuals supervised by those physicians. *See* 42 C.F.R. § 411.355(b)(1). In defining *where* the exception applies, the regulations contain fairly specific requirements regarding the types of locations that can satisfy the exemption. *See generally id*. § 411.355(b)(2). And in defining *what* services qualify for the exception, the regulations state that designated health services include outpatient prescription drugs, radiation therapy, durable medical equipment, and other items. *See id*. § 411.351. Lastly, with respect to where a service is "furnished," the regulations provide that a "designated health service is 'furnished' . . . in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules." *See id*. § 411.355(b)(5).

As a result, a physician generally does not run afoul of the Stark Law if she dispenses prescription drugs (such as certain cancer-treating drugs) to a patient in that physician's offices. The parties' disagreement is whether a physician may mail such drugs to her patients without violating the law.

B. Pandemic-Era Waivers

Congress has also granted the Secretary the authority to waive certain Medicare regulations during national emergencies. *See* 42 U.S.C. § 1320b-5(b). In March 2020, HHS did so in response to the COVID-19 pandemic. As relevant here, the Secretary issued Waiver no. 15, which suspended penalties for referrals that would otherwise violate the Stark Law, including "[t]he referral by a physician in a group practice for medically necessary designated health services

furnished by the group practice in a location that d[id] not qualify as a 'same building' or 'centralized building' for purposes of 42 CFR 411.355(b)(2)." *See generally* COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, available at https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf. The waiver thus expressly permitted the provision of "medically necessary" drugs and devices outside of a physician's office building, including by mail to a patient's home. *Id*. In HHS's view, this waiver, together with others, ensured that "sufficient health care items and services [we]re available to meet the needs of individuals in the emergency area enrolled in the Medicare, Medicaid, and CHIP programs." *Id*. They also protected "health care providers that furnish[ed] such items and services in good faith" and ensured that they could be reimbursed for their services. *Id*.

In September 2021, the Center for Medicaid and Medicare Services issued a document titled "Frequently Asked Questions." The FAQs explained that "[t]he 'location requirement' at 42 C.F.R. § 411.355(b)(2) would not be satisfied if a patient receives an item by mail outside the physician's office, as it would not be dispensed to the patient in the office." *See* ECF No. 1-1 at 9. On May 11, 2023, HHS declared the end of the COVID-19 public health emergency. The following week, HHS issued a second set of FAQs, explaining again that "[t]he location requirement would not be satisfied if a beneficiary received an item from the physician practice by mail (or otherwise) outside one of [the locations described in the regulation], as described in an FAQ posted in 2021 regarding this longstanding CMS policy." *See* ECF No. 1-2 at 15.

C. Procedural History

Community Oncology Alliance is a non-profit advocacy group representing community oncology practices across the United States. In July 2023 it filed this suit, alleging that the FAQs violated the Medicare Act and Administrative Procedure Act by changing physician obligations under federal law without undergoing formal notice-and-comment rulemaking. In particular, the

Alliance contends that even before the pandemic, HHS's regulations permitted physicians to mail prescription drugs directly to patients without running afoul of the Stark Law, and therefore the FAQs effected a substantive (and therefore improperly promulgated) change in those regulations. The Alliance also alleges that the FAQs violate the Tenth Amendment of the U.S. Constitution by preventing states from regulating how physicians may "dispense" cancer drugs to their patients.

The Alliance also moved to preliminarily enjoin HHS from "enforcing the FAQ regarding the location requirement of the In-Office Ancillary Services Exception against oncology practices and specialty practices involved in cancer care." *See* Mot. for Prelim. Inj., ECF No. 7-1 at 36. The Court denied that motion. *See* Mem. Op. Denying Prelim. Inj., ECF No. 36. The Court concluded that the Alliance had failed to demonstrate that its members were likely to suffer irreparable harm absent an injunction. *Id*. at 8–10. The Court also held that the Alliance had failed to demonstrate it was likely to succeed on the merits of either its regulatory claim because the FAQs were consistent with "the preexisting requirements of the Stark Law and its implementing regulations," *id*. at 11, or its Tenth Amendment claim, since the Stark Law and its implementing regulations did not interfere with the police power of states. *Id*.at 13. And, the Court held, the Alliance had not demonstrated that the public interest and balance of equities weighed in its favor. *Id*.

During this period, the parties also filed dispositive motions. *See* Defendants' Motion to Dismiss, ECF No. 21, and Plaintiff's Cross-Motion for Summary Judgment, ECF No. 29.

II. Analysis

A. APA and Medicare Act Claims

The primary issue presented by the parties' motions is whether the FAQs effected a substantive change to the Stark Law regulations. Under the Medicare Act, the Secretary of HHS must use formal rulemaking to establish a "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services." 42

U.S.C. § 1395hh(a)(2). The APA similarly requires formal rulemaking for legislative rules—i.e., rules that have "legal effect." *See* 5 U.S.C. § 553(b); *see also Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020). On the other hand, interpretive rules, general statements of policy, and rules of agency procedure do not need to undergo formal rulemaking. *See* 5 U.S.C. § 553(b)(3)(A).

The Court previously held that the Alliance had failed to demonstrate a likelihood of success on its claim that the FAQs changed the Stark regulations, and after considering the briefing and oral argument on the parties' dispositive motions, it again concludes that the FAQs are consistent with the Stark Law and its implementing regulations.

Start with the statute. It contains a broad and general prohibition against physicians making referrals for designated health services to entities in which they have a financial stake. *See* 42 U.S.C. § 1395nn(a)(1)(A). The exceptions, including the in-office ancillary services exception, must be read in light of that general prohibition.

As for the in-office ancillary services exception itself, the statute exempts only health services furnished "*personally* by the referring physician, *personally* by a physician who is a member of the same group practice as the referring physician, or *personally* by individuals who are directly supervised by the physician or by another physician in the group practice." *See* 42 U.S.C. § 1395nn(b)(2)(A)(i) (emphasis added). The dictionary defines "personally" as "in person; through one's personal presence or action; by oneself." *See* OXFORD ENGLISH DICTIONARY, s.v. "personally (adv.), sense 1.b," March 2024.[2] The most natural reading of this statutory language,

[2] For example, when the Federal Rules of Civil Procedure explain that an individual in a foreign country (without an international agreement with the United States) may be served a copy of the complaint "personally," it clearly means that the plaintiff may serve defendant by giving her a copy of the complaint himself in person (so long as the country's laws do not forbit it). *See* Fed. R. Civ. P. 4(f)(2)(C)(i).

therefore, is that the exception applies to designated health services provided by a physician "in person."

HHS's regulations track this reading. With respect to *where* the exception applies, the regulations list specific "buildings" where a physician can furnish services and still satisfy the exception. *See* 42 C.F.R. § 411.355(b)(2). This list includes a "centralized building that is used by the group practice for the provision of some or all of the group practice's [designated health services]," *id*. § 411.355(b)(2)(iii), and a "centralized building that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services," *id*. § 411.355(b)(2)(ii). It also includes the same building where the referring physician is present and orders the service during a patient visit, provided she owns or rents an office in the building open at least 8 hours a week and she regularly practices medicine in the building 6 hours per week. *See id*. § 411.355(b)(2)(i)(C). And it includes the same building where services are furnished if the furnishing physician has an office open to her patients 35 hours a week and the physician practices medicine there at least 30 hours per week. *See id*. § 411.355(b)(2)(i)(A).

As to *who* qualifies for the exception, the regulations explain that designated health services must be furnished by either the referring physician, 42 C.F.R. § 411.355(b)(1)(i), a physician in the same group practice as the referring physician, *id*. § 411.355(b)(1)(ii), or an individual supervised by the referring physician or her practice group, *id*. § 411.355(b)(1)(iii). As to *what* services qualify, the regulations state that designated health services include outpatient prescription drugs, radiation therapy, durable medical equipment, and other items. *See id*. § 411.351.

Most important for the present dispute, the regulations also contain language concerning what it means to furnish a service. In particular, the regulations state that a "designated health

service is 'furnished' . . . in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules." *Id.* § 411.355(b)(5).

All of these regulations (like the statute itself) are quite consistent with the government's position that the in-office ancillary services exception does not apply when a physician mails a prescription drug to a patient's home. But, the Alliance points out, the regulations do state that a designated health service is furnished for purposes of the in-office ancillary services exception both "in the location where the service is actually performed upon a patient" *and* "where an item," such as a prescription drug, "is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules." *Id.* § 411.355(b)(5). Mailing prescription drugs to patients does meet Medicare payment and coverage rules. Thus, the Alliance argues, the in-office ancillary services exception is met anytime a prescription drug is mailed in a manner that satisfies Medicare payment and coverage rules—including from a doctor's office to a patient's home.

There is something to this argument, but it is not the most natural reading of the regulation. To be sure, dispense means "to mete out, deal out, distribute," *see* OXFORD ENGLISH DICTIONARY, s.v. "dispense (v.), sense 1.1.a," December 2023, which could include placing an item in the mail. But the regulation does not provide that an item is furnished just where it is "dispensed," but rather where it has been "dispensed *to* a patient." The prepositional phrase "to a patient" modifies "dispensed" such that an item is "dispensed" where it is received by the patient. *See* The Chicago Manual of Style § 5.177 ("[A] preposition may express a spatial relationship {to} {from} {out of} {into}.") (17th ed. 2017). The best reading of this language is that there is no dispensing to a patient until the item has been received by the patient; the act of dispensing to the patient therefore

occurs where the patient receives it. As a result, a prescription drug that is mailed to a patient at her home is not dispensed *to* that patient in the physician's office.[3]

Furthermore, the Alliance's proposed reading would render the location requirements in § 411.355(b)(2) of the regulation and the "personally" requirement in the statute either superfluous or incongruous. After all, it would have been unnecessary to enumerate the specific locations where the exception applies if the only real issue is whether Medicare payment and coverage rules are met. *See, e.g.*, *Pulsifer v. United States*, 601 U.S. 124, 143 (2024) ("When a statutory construction thus renders an entire subparagraph meaningless, this Court has noted, the canon against surplusage applies with special force.") (internal quotations omitted). And how is a prescription drug provided "personally" to a patient when it can be mailed? At a minimum, the Alliance's position is in significant tension with the exception applying only to "in-office" services performed "personally" by the physician or her associates.

For these reasons, the regulations do not extend the in-office ancillary services exception to the mailing of prescription drugs. The FAQs, therefore, did not change a "substantive legal standard," nor do they have a "legal effect" as cognizable under the APA. HHS was not required to promulgate the FAQs through notice-and-comment rulemaking.

B. Tenth Amendment

The Alliance also claims that the FAQs violate the Tenth Amendment of the U.S. Constitution by preventing states and their medical boards from "regulating how physicians may 'dispense' cancer drugs to their patients." Pl. Cross-Mot. for Summ. J., ECF No. 29 at 30. The

[3] The Alliance relies on the Controlled Substances Act's definition of "dispense," which includes "the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery." *Id*. (citing 21 U.S.C. § 802(10)). But that language does not answer the question of where a drug is dispensed "to a patient."

gravamen of this claim is that in states where mailing cancer medication is permitted, physicians will be stuck between a strict prohibition against mailing drugs by the federal government, on the one hand, and permission to do so by a state government, on the other. And since the regulation of medical practice falls within the police powers of states, the argument goes, that tension should be resolved in favor of the states. *Id*. at 29.

HHS argues that the Alliance lacks standing to pursue this claim. A plaintiff "must demonstrate standing for each claim he seeks to press and for each form of relief that is sought," *Davis v. FEC*, 554 U.S. 724, 734 (2008), and as HHS puts it, the Alliance "does not allege any facts plausibly stating that it or its members suffered a concrete, particularized injury in fact resulting from the alleged 'interference' in States' regulation of medical care." *See* Def. Mot. to Dismiss, ECF No. 21 at 30. According to HHS, neither the Stark Law nor the FAQs restrict the physicians' practice of medicine—they only place conditions on physicians seeking Medicare payments. *Id*. at 31.

The question of standing is a close one. The Court concludes that the Alliance has plausibly alleged that it and its members are harmed by the claimed conflict between the Stark Law (including the FAQs) and certain states' permissive mail-order prescription drug regimes. But even if the Alliance has standing, it has failed to state a claim. After all, Congress possesses broad power to "attach conditions on the receipt of federal funds," *see South Dakota v. Dole*, 483 U.S. 203, 206–12 (1987), including funds dispersed through Medicare. Accordingly, "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions that address the safe and effective provision of healthcare." *Biden v. Missouri*, 595 U.S. 87, 94 (2022). The Tenth Amendment is not violated when physicians seeking to receive

Medicare funds are subject to certain obligations under the Stark Law. Community Oncology's Tenth Amendment claim must therefore also be dismissed.

III. Conclusion

For the foregoing reasons, the Court **GRANTS** Defendants' Motion to Dismiss, ECF No. 21, and **DENIES** Plaintiff's Cross-Motion for Summary Judgment, ECF No. 29. An Order will issue contemporaneously with this Opinion.

DATE: August 30, 2024

CARL J. NICHOLS
United States District Judge