

**\*\*This checklist is for educational purposes only. It is not intended to be legal advice.\*\***

**STARK GROUP PRACTICE/IN-OFFICE ANCILLARY SERVICES EXCEPTION**  
**AUDIT CHECKLIST**<sup>1</sup>

The Stark Law is a healthcare fraud and abuse law that prohibits physicians from referring patients for certain designated health services paid for by Medicare<sup>3</sup> to any entity in which they have a “financial relationship.” “**Designated Health Services**” or “**DHS**” are defined in 42 CFR §411.351, and include, but are not limited to, durable medical equipment (DME) and supplies, inpatient and outpatient hospital services, outpatient prescription drugs, clinical laboratory services, parenteral and enteral nutrients, equipment and supplies (PEN), certain therapy and imaging services, and certain prosthetic devices. Certain DHS categories are defined by a CPT / HCPCS Code List, which is updated and published annually by CMS. Qualifying as a group practice can be important for multi-physician practices to satisfy the in-office ancillary services exception to the Stark Law.

<b><u>GROUP PRACTICE DEFINITIONAL REQUIREMENTS</u></b>			
	<b><u>Requirement</u></b>	<b><u>Additional Description Surrounding Requirement</u></b>	<b><u>Element Satisfied?</u></b>
1. <i>At least two Members</i>	There are at least two physicians who are employed, <i>locum tenens</i> , on-call physicians or are owners of the group (“Members”). Questionnaire	Description: <i>To qualify as a group practice, a physician practice must have at least two Members (e.g., owners, employees, locum</i>	

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<sup>1</sup> The Stark Law Group Practice regulations can be found at 42 C.F.R. § 411.352.

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		<i>tenens)</i>	
2. <i>Single Legal Entity</i>	<ul style="list-style-type: none"> <li>• Is the group organized under a single legal entity (P.C., Corporation, etc) operating primarily for the purpose of being a physician group practice?</li> <li>• If no, is the reason for multiple entities because the Physician Practice is operating in contiguous states (though not necessarily all states in which Physician Practice operates contiguous to each other) that require such separation for licensing laws?</li> <li>• Is the group either owned or does the group own another medical practice, excluding subsidiary entities i.e., lab or other wholly owned subsidiaries?</li> </ul>	<p>Description: A group practice must be organized as a single legal entity or multiple entities for the purposes of operating in contiguous states that require separation for licensing laws.<sup>4</sup> A single legal entity may be organized or owned by another medical practice, provided that the other medical practice is not an operating physician practice. If a group practice otherwise qualifies as a single legal entity it may own subsidiary entities (such as a separately incorporated lab).</p>	<ul style="list-style-type: none"> <li>•</li> </ul>

<sup>4</sup> See 42 C.F.R. § 411.352(a) for specific requirements for multiple entities operating in contiguous states.

		<i>IDTF center).</i>	
3. <i>Full Range of Services</i>	Members of the group (as opposed to independent contractors) furnish substantially the full range of patient care services that the physician routinely furnishes through the use of shared office space, facilities, equipment and personnel.	Description: This element is meant to guard against situations, for example, where an employed physician only performs DHS services (such as cardiac stress tests and no other services) rather than all services the physician would typically furnish in his/her practice.	
4. <i>Substantially all Services</i>	Substantially all (75%) patient care services of the group's Members, in the aggregate, furnished through the group, billed under a billing number assigned to the group, and are the collections treated as receipts of the group.	Description: <i>Members must perform substantially all (75%) of the group's patient care services in the aggregate, and furnish the services through the practice, and bill under a billing number assigned to the group and treat such collections as receipt of the group.</i>	

5. <i>Physician Patient Encounters</i>	Members of the group personally conduct no less than 75% of the physician-patient encounters of the group practice.	Description: <i>Members of the practice, rather than independent contractors, personally conduct no less than 75% of the physician-patient encounters of the group practice.</i>	
6. <i>Unified Business</i>	The group's decision-making is centralized in a Body representative of the group that maintains effective control over the group's liabilities and assets.	Description: <i>A group must have a centralized decision making Body maintain effective control over the group's liabilities and assets and the practice must at a minimum have consolidated billing, accounting, and financial reporting.</i>	
7. <i>Distributions of Expenses and Income</i>	The group distributes overhead expenses and income according to methods determined prior to receipt of payment for the services giving rise to the overhead expense or producing the	Description: <i>A group must distribute overhead expenses and income according to methods determined prior to receipt of payment.</i>	

	Income.		
8. <i>Compensation</i>	Outside of compensation described below in #9, compensation paid to any Member of the group is not directly or indirectly based on the volume or value of the member's DHS referrals.	Description: <i>Outside of a profit share or productivity bonus, compensation paid to Members cannot directly or indirectly relate to the volume or value of DHS referrals.</i>	<i>See questions below on #9.</i>
9. <i>Special rules on Compensation</i>	<p>If a physician in the group<sup>5</sup> is paid a profit share or productivity bonus, the profit share or productivity bonus cannot directly take into account the volume or value of the physicians DHS referrals to the physician practice.</p> <ul style="list-style-type: none"> <li>A Productivity Bonus will be deemed <b>NOT</b> to <b>directly</b> relate to the volume or value of referrals of DHS if:</li> </ul>	Description: <i>A physician in the group practice may be paid a share of overall profits<sup>6</sup> of the group or a productivity bonus that does not directly relates to the volume or value of referrals of DHS. A productivity bonus or profit share cannot directly relate to the volume or value of the physician's DHS referrals. The Stark Regulations provide certain deeming provisions that, if followed, will allow a physician</i>	

		<i>practice certainty that the productivity bonus or profit share does not directly relate to the volume or value of DHS referrals.</i>	
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<sup>5</sup> A “Physician in the Group” includes Members plus independent contractors.

<sup>6</sup> “Overall profits” is defined as profits derived from DHS payable by Medicare or Medicaid or profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians.

	<ol style="list-style-type: none"> <li>1. The bonus is based on the physician' total patient encounters or wRVUs;</li> <li>2. The bonus is based on the allocation of the physician' compensation attributable to services that are not DHS payable by any Federal health program or private payor;</li> </ol> <p><b><u>OR</u></b></p> <ol style="list-style-type: none"> <li>3. Revenues derived from DHS are less than 5% of the group' total revenues AND the allocation of the DHS revenues to each physician constitutes 5% or less of his or her total compensation from the group.</li> </ol> <ul style="list-style-type: none"> <li>• A Profit Share will be deemed NOT to directly relate to the volume or value of DHS referrals if: <ol style="list-style-type: none"> <li>1. The group's profits are divided per capita;</li> <li>2. Revenues derived from</li> </ol> </li> </ul>		
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	<p>DHS are distributed based on the distribution of the group practice's revenues attributable to services that are not DHS payable by any FHCP program or private payor; <b><u>OR</u></b></p> <p>3. Revenues derived from DHS are less than 5% of the group's total revenues AND the allocation of the DHS revenues to each physician constitutes 5% or less of her total compensation from the group.</p>		
<b><u>IN-OFFICE ANCILLARY SERVICES EXCEPTION (IOASE) REQUIREMENTS</u></b>			
<i>1. Performance/ Supervision Test</i>	<p>DHS Services are furnished by:</p> <ol style="list-style-type: none"> <li>1. The referring physician or a Member of the same group practice; <b><u>or</u></b></li> <li>2. Supervised by the referring physician or another "physician in the group practice"</li> </ol>	<p>Description: <i>Supervision must meet the supervision requirements for Medicare coverage for the specific type of DHS services. If for example, the DHS is an MRI, Medicare conditions coverage would require that the supervising physician be in the office suite and immediately available to direct and assist the MRI technologist.</i><sup>2</sup></p>	
<i>2. Location Test</i>	The IOASE requires that the DHS be	<p>Description: <i>A group will only need to navigate the "same building" test if it is sharing its DHS facilities with</i></p>	•

<sup>2</sup> See 42 CFR §410.32.



	<p>furnished<sup>3</sup> in one of two locations:</p> <ol style="list-style-type: none"> <li>1. For group practices, in space owned by the practice or in space leased by the practice on an exclusive 24/7 basis for a term of at least 6 months and used exclusively by the practice; <b>or</b></li> <li>2. The same building where the referring physician or a member of his group practice furnishes physician services unrelated to DHS.</li> </ol>	<p><i>another DHS supplier. The “same building” test does not require the practice to maintain a full-time office providing some non-DHS physician services in the same building where its DHS facility is located, but if the office is not full-time, additional and technical limitations will apply.<sup>4</sup></i></p>	
3. <i>Billing Test</i>	<p>The IOASE requires that the DHS be billed by, or under the billing number assigned to the physician performing or supervising the services, the physician’s group practice, or an entity wholly owned by the physician or his or her group practice.</p>	<p><i>Description: The billing test also allows a group practice to engage an independent third party billing company acting as an agent of the group practice, under a billing number assigned to the group practice and consistent with Medicare rules on reassignment. The Billing Test does not require that the group have a single billing number.</i></p>	
4. <i>The Notice Requirement</i>	<p>To the extent the DHS referral is for an MRI, CT, or PET service which falls under the Stark Law definition of “radiology and certain other imaging services,” the referring physician must provide the patient, at the time of the</p>	<p><i>Description: If there are 5 or less alternative suppliers of the imaging service within a 25-mile radius of the physician’s office location at the time of the referral, the notice must list all of them; if there are more than 5</i></p>	

<sup>3</sup> “Furnished” means 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.

<sup>4</sup> Detailed technical requirements are noted at 42 CFR §411.355(b)(2)(i)(B)-(C).

	<p>referral, a written notice that the patient may receive the same imaging services from an alternative supplier.</p>	<p><i>alternative suppliers, the notice must list at least five of them, and the practice is not required to list the 5 that are closest to the office location making the referral.</i></p> <p><i>It is important to note that the term “suppliers” is a Medicare term of art that does not include hospitals and other institutional providers.</i></p>	
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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

COMMUNITY ONCOLOGY ALLIANCE,

*Plaintiff,*

v.

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

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.*

**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.<sup>1</sup>

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

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<sup>1</sup> 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.<sup>2</sup> The most natural reading of this statutory language,

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<sup>2</sup> 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 forbid 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.<sup>3</sup>

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

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<sup>3</sup> 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

  
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CARL J. NICHOLS  
United States District Judge