UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RICU LLC, Plaintiff, v. **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,** *et al*., Defendants.	Case No. 21-cv-452 (CRC)

MEMORANDUM OPINION

In the spring of 2020, Congress passed a series of laws enabling the Department of Health and Human Services ("HHS") to temporarily extend Medicare coverage to a range of services, including critical telehealth services, in response to COVID-19. Exercising that authority, HHS promulgated an interim final rule that, among other things, added remotely-provided intensive care services to Medicare's eligibility list. Enter RICU LLC, which operates a network of intensive care doctors who live abroad but provide remote ICU services to patients in the United States. After HHS announced the interim rule, RICU inquired whether Medicare would now cover its services. HHS answered in the negative, reasoning that reimbursement for RICU's services remained barred by Medicare's longstanding prohibition on payments for services rendered outside the U.S. A protracted dialogue ensued, culminating in RICU filing this lawsuit and moving for a preliminary injunction. Finding that RICU failed to channel its reimbursement request through Medicare's mandatory administrative claims process and that it does not qualify for a narrow exception to the channeling requirement, the Court denies RICU's motion for a preliminary injunction and dismisses the case for lack of jurisdiction.

I. Background

A. Regulatory Background

In 1965, Congress passed the Social Security Amendments Act, commonly known as Medicare. Section 1862(a)(4) of the Act prohibited Medicare payments for services "not provided within the United States[.]" Pub. L. No. 89-97 § 1862(a)(4) (codified at 42 U.S.C. § 1395y(a)(4)); see also 42 C.F.R. § 411.9(a) ("Medicare does not pay for services furnished outside the United States."). Following the parties' lead, the Court will refer to this provision as the "foreign payments ban."

Fast forward 35 years. In an attempt to broaden Medicare's coverage of emerging telehealth services, Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Pub. L. No. 106-554 § 223 (codified at 42 U.S.C. § 1395m(m)), otherwise known as the Telehealth Statute. Section 1395m(m)(1) of the statute provides that HHS "shall pay for telehealth services that are furnished via a telecommunications system by a physician . . . to an eligible telehealth individual . . . notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary." Id. The statute defines "eligible telehealth individual" as a Medicare Part B beneficiary who "receives a telehealth service furnished at an originating site." Id. § 1395m(m)(4)(B). An "originating site," meanwhile, is a hospital, clinic, or other facility where the patient is located when the service is furnished. Id. § 1395m(m)(4)(C). By contrast, the location from which the telehealth physician provides services is referred to as the "distant site[.]" Id. § 1395m(m)(4)(A). Finally, § 1395m(m)(2)(A) provides that the Secretary shall pay the physician the amount he or she "would have been paid under this subchapter had [the] service been rendered without the use of a telecommunications system." HHS issued a Final

Rule implementing the Telehealth Statute on November 1, 2001. See 66 Fed. Reg. 55246 (codified at 42 C.F.R. § 410.78) ("Telehealth Rule").

Nineteen years later, Congress sought to expand public access to health services in response to the COVID-19 pandemic through a series of acts passed in the spring of 2020. See Coronavirus Preparedness and Response Supplemental Appropriations Act, Pub. L. No. 116-123, 134 Stat. 146 (Mar. 6, 2020); Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (Mar. 18, 2020); Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (Mar. 27, 2020). These statutes enabled HHS "to temporarily waive or modify the application" of Medicare requirements governing a range of services, including ICU-level telehealth care. 42 U.S.C. § 1320b-5(b)(8), (g)(1)(B). Pursuant to that authority, HHS promulgated an Interim Final Rule ("IFR") that, among other things, waived certain statutory requirements for Medicare reimbursement of telehealth care and expanded the list of telehealth services eligible for reimbursement. See 85 Fed. Reg. 19230, 19236 (Apr. 6, 2020).

The IFR became a final rule on December 28, 2020. See 85 Fed. Reg. 84472 (Dec. 28, 2020). It contains a sunset provision providing for removal of the added telehealth services at the end of 2021. Id. at 84517. However, the rule notes that HHS "could foresee a reasonable potential likelihood of clinical benefit . . . outside the circumstances of the [public health emergency] for COVID-19[.]" Id. at 84507.

B. RICU's Reimbursement Request

RICU is a telehealth company that provides critical care services—*i.e.*, services typically offered in a hospital's intensive care unit. See Rabinowitz Decl. ¶ 4. Physicians providing this type of care are known as "intensivists." Id. RICU contracts with about 60 intensivists who work outside the United States but have U.S. training and board certifications. Id. ¶¶ 8–10.

Since RICU's establishment in 2009, the company has grown at a rate of over 35% per year. Id. ¶ 34. RICU claims that its growth accelerated at the onset of the COVID-19 pandemic, but then "ground to a halt" after HHS issued the IFR and determined that RICU's services would remain ineligible for Medicare coverage. Id. ¶¶ 34, 38.

On April 22, 2020 (about two weeks after HHS issued the IFR), RICU's president, Seth Rabinowitz, emailed HHS's Centers for Medicare and Medicaid Services ("CMS") "seeking an urgent clarification" about the IFR's expanded coverage of telehealth services. See Compl. Ex. 2. The Acting Director of CMS's Chronic Care Policy Group, Jason Bennett, responded on June 1, 2020, informing Rabinowitz that following "an exhaustive review of the statute and regulations" CMS concluded that Medicare could not cover RICU's services. See Compl. Ex. 4. Bennett explained first that the IFR had no effect on the longstanding foreign payments ban, which "prohibits Medicare payment for services that are not furnished within the United States[.]" Id. He then noted that the 2001 Telehealth Rule "indicates that a telehealth service is furnished at the originating site and *also* at the distant site[.]" Id. (emphasis added). In other words, CMS took the position that RICU's doctors were providing telehealth services at two geographic locations: the U.S. location of the patient and the non-U.S. location of the RICU intensivist. CMS thus determined that payment for RICU's services was prohibited by the foreign payments ban. See id. ("Because the service is considered to be furnished at both sites, both sites are subject to the statutory payment exclusion that prohibits Medicare payment for services that are not furnished within the United States.").

Approximately three weeks later, CMS updated the FAQ page on its website to note that the IFR would not cover telehealth services provided by doctors located abroad. See CMS, COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing 73

(last updated on July 2, 2021), https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. The following month, the same page was updated again to elaborate on why such services are not covered, concluding that "a telehealth service is considered to be furnished at both the originating site and the distant site" and the Medicare laws "prohibit . . . payment for services that are not furnished within the United States." Id. at 82.

Meanwhile, Mr. Rabinowitz went about disputing the conclusions contained in Mr. Bennett's letter with increasingly senior CMS personnel. See Rabinowitz Decl. ¶¶ 30–31. On July 9, 2020, the Principal Deputy Administrator for CMS Operations and Policy, Kimberly Brandt, informed Rabinowitz that the "senior Medicare team and General Counsel's Office" had reviewed the issue and agreed with Bennett. Rabinowitz Decl. ¶ 30; Compl. Ex. 5; Compl. Ex. 7. Undeterred, Rabinowitz continued to dispute CMS's position and eventually secured a meeting with high-level CMS officials, which took place on October 14, 2020. Rabinowitz Decl. ¶ 31; Compl. Ex. 7. Following that meeting, CMS Principal Deputy Administrator Demetrios Kouzoukas sent Rabinowitz a letter that confirmed Bennett's and Brandt's conclusions and reiterated CMS's position that Rabinowitz's "request is inconsistent" with the statutory foreign payments ban. Compl. Ex. 7.

Approximately four months later, RICU filed the present complaint alleging that HHS's determination that reimbursement of its services is barred by the foreign payment ban was arbitrary and capricious and contrary to the Telehealth Statute. See Compl. ¶¶ 86–97 (Count I), 98–108 (Count II). Simultaneously, RICU sought a preliminary injunction "enjoining [defendants] from denying Medicare reimbursement for telehealth services on the basis of a physician's or practitioner's physical location outside of the United States at the time of service."

Mot. for Prelim. Inj. ("PI Mot.") at 40. HHS[1] opposed RICU's motion and moved to dismiss the complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6). See Def. Mot. to Dismiss & Opp. to Pl. Mot. ("Mot. to Dismiss"). The Court held a hearing on the motions on May 17, 2021, and they are ripe for the Court's resolution.

II. Legal Standard

"A preliminary injunction is an extraordinary remedy never awarded as of right." Winter v. NRDC, 555 U.S. 7, 24 (2008). To receive a preliminary injunction, the plaintiff must make four showings: "[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." Sherley v. Sebelius, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting Winter, 555 U.S. at 20). A preliminary injunction should not be granted "unless the movant, by a clear showing, carries the burden of persuasion." Protect Democracy Project, Inc. v. U.S. Dep't of Def., 263 F. Supp. 3d 293, 297 (D.D.C. 2017) (cleaned up) (Cooper, J.).

Under Rule 12(b)(1), plaintiffs bear the burden of proving by a preponderance of the evidence that the Court has subject matter jurisdiction to hear their claims. See Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992); see also, e.g., Biton v. Palestinian Interim Self-Gov't Auth., 310 F. Supp. 2d 172, 176 (D.D.C. 2004). When evaluating whether a plaintiff has carried that burden, the court must "assume the truth of all material factual allegations in the complaint and

[1] RICU named HHS, the Secretary of Health and Human Services, CMS, and the Administrator of CMS as defendants in this action. For ease of reference, the Court refers to defendants collectively as "HHS."

construe the complaint liberally, granting plaintiff the benefit of all inferences that can be derived from the facts alleged, and upon such facts determine [the] jurisdictional questions." Am. Nat'l Ins. Co. v. FDIC, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (cleaned up). At the same time, the factual allegations contained in the complaint "will bear closer scrutiny" on a Rule 12(b)(1) motion given the court's "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." Smallwood v. U.S. Dep't of Just., 266 F. Supp. 3d 217, 219 (D.D.C. 2017) (cleaned up) (Cooper, J.).

III. Analysis

Before considering the merits of RICU's claims, the Court must first assure itself of its jurisdiction.

A. Subject Matter Jurisdiction

RICU claims subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (authorizing jurisdiction over federal questions) and § 1346 (authorizing jurisdiction over claims against the United States). Compl. ¶ 17. As a general matter, 42 U.S.C. § 405(h) deprives courts of § 1331 or § 1346 jurisdiction over claims arising under the Medicare Act.[2] Section 405(g), however, provides an exception to that jurisdictional bar: parties may seek review of "any final decision of the [Secretary] made after a hearing to which he was a party" in federal district court. The Supreme Court has interpreted these provisions as requiring that "virtually all legal attacks" arising under the Medicare laws be "channel[ed] . . . through the agency." Shalala v. Ill. Council

[2] Section 405(h) strips courts of jurisdiction over claims arising under the Social Security Act. This provision, along with the exception provided in § 405(g), is applied to the Medicare Act via § 1395ii. See Am. Hosp. Ass'n v. Azar, 895 F.3d 822, 825 (D.C. Cir. 2018) ("American Hospital").

on Long Term Care, Inc., 529 U.S. 1, 13 (2000) ("Illinois Council"). The only exception is where application of the requirements "would mean no review at all." Id. at 17.

The Court first considers whether RICU has satisfied the Medicare channeling requirement before determining whether the Illinois Council exception applies.

1. Channeling

Channeling imposes two distinct burdens on plaintiffs seeking judicial review under the Medicare Act. *First*, plaintiffs must have "presented" the claim to the Secretary. American Hospital, 895 F.3d at 825. The presentment requirement is an "absolute prerequisite" to judicial review. Action All. of Senior Citizens v. Leavitt, 483 F.3d 852, 857–58 (D.C. Cir. 2007) ("Action Alliance I"). *Second*, plaintiffs must "fully exhaust all administrative remedies[.]" American Hospital, 895 F.3d at 826. The Court's analysis of whether RICU has satisfied § 405(g)'s channeling requirements begins and ends with presentment.

Presentment requires plaintiffs to submit their claim to the Secretary "in the context of a specific administrative claim for payment." Id. This prerequisite ensures that the Secretary has "an opportunity to rule on a concrete claim for reimbursement," meaning "a claim seeking *specific payments*," before being haled into federal court. Id. at 826 (emphasis added). Accordingly, in American Hospital, the D.C. Circuit rejected plaintiffs' argument that they had satisfied the presentment requirement by filing comments in opposition to the challenged regulation during the rule's notice-and-comment period. Id. The Circuit explained that § 405(g) requires plaintiffs to receive an "initial administrative determination in the *concrete setting of a specific reimbursement decision*" prior to bringing a challenge in federal court. Id. at 827 (emphasis added) (cleaned up).

It is undisputed that RICU did not present its claim in the context of a specific reimbursement decision. To the Court's knowledge, no Medicare claim has ever been submitted for RICU's services. RICU instead argues that the presence of a specific payment decision is unnecessary to satisfy presentment under Action All. of Senior Citizens v. Sebelius, 607 F.3d 860 (D.C. Cir. 2010) ("Action Alliance II"). The Court disagrees.

RICU's reliance on Action Alliance II requires a brief segue into that decision's procedural history. The district court in Action Alliance I granted plaintiffs a preliminary injunction that barred HHS from seeking repayment of funds that it had overpaid the plaintiffs in Medicare benefits. Action All. of Senior Citizens v. Leavitt, 456 F. Supp. 2d 11, 24 (D.D.C. 2006), vacated, 483 F.3d 852 (D.C. Cir. 2007), remanded to 607 F. Supp. 2d 33 (D.D.C. 2009). On appeal, the Circuit vacated the preliminary injunction for lack of jurisdiction because plaintiffs had failed to satisfy the presentment requirement. Action Alliance I, 483 F.3d at 857–58. Following the Circuit's decision, plaintiffs' counsel sent "a separate letter from each of the plaintiffs" challenging HHS's attempt to recoup the amount it had overpaid each plaintiff. Action All. of Senior Citizens v. Johnson, 607 F. Supp. 2d 33, 37–38 (D.D.C. 2009), aff'd sub nom. Action All. of Senior Citizens v. Sebelius, 607 F.3d 860 (D.C. Cir. 2010)). On remand, the district court found that plaintiffs had thereby satisfied presentment and exercised jurisdiction. Id. at 38. On appeal a second time, the Circuit mentioned in a footnote that while its prior opinion found jurisdiction to be lacking, the plaintiffs had "since cured the jurisdictional defect." Action Alliance II, 607 F.3d at 862 n.1.

Based on this series of events, RICU contends that Action Alliance II held that a plaintiff need not present their claims to the Secretary in the context of a specific payment dispute to

satisfy presentment. Pl. Resp. at 7. But this argument is precluded by American Hospital, which the Circuit issued eight years after Action Alliance II. American Hospital explained:

> In Action Alliance [II], our entire discussion of presentment was a statement that the plaintiffs had "cured" their prior failure to present. Because we did not explain what constituted the cure, the decision has no precedential value on that specific point. In any event, the plaintiffs in Action Alliance [II] were embroiled with HHS in a specific payment dispute, which arose from the agency's efforts to recover Medicare payments erroneously made to them. The presentment "cure" presumably consisted of letters, sent to HHS on behalf of each plaintiff, invoking an alleged statutory right to a waiver. And the result was an agency decision denying the waivers.

American Hospital, 895 F.3d at 827 (cleaned up). Thus, in addition to declaring that Action Alliance II "has no precedential value" on this very issue, the Circuit explained that Action Alliance II did, in fact, involve "a specific payment dispute." Id.[3]

RICU presents no evidence of such a dispute here. Rather, it argues that it engaged HHS in a protracted discussion over the agency's determination, which involved a "robust," "exhaustive," "careful," and "complete" review of the relevant legal issues. Pl. Resp. at 8–9 (cleaned up). Perhaps. But presentment requires RICU to afford HHS "an opportunity to rule on a concrete claim for reimbursement" in the context of "a specific payment dispute[.]" American Hospital, 895 F.3d at 826–27 (cleaned up). It has not. RICU has thus failed to channel its claim, depriving this Court of jurisdiction absent an exception to that requirement.

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[3] RICU contends that "one panel of the D.C. Circuit cannot overrule a prior panel." Pl. Resp. at 10. But American Hospital did not purport to overrule a holding in Action Alliance II. Rather, it assessed whether the prior panel rendered a holding at all. RICU's argument that this assessment was erroneous is misplaced in this court, which is bound by Circuit precedent. See, e.g., Nichols v. Club for Growth Action, 235 F. Supp. 3d 289, 297 n.4 (D.D.C. 2017).

2. Illinois Council exception

RICU alternatively argues that it need not satisfy the presentment requirement because its claim falls within the Illinois Council exception to channeling. The Illinois Council exception derives from the Supreme Court's decision in Bowen v. Michigan Academy of Family Physicians, where the Court held that the plaintiff could seek judicial review of a Medicare Part B regulation where following § 405(h)'s channeling requirement would have resulted in "no review at all[.]" 476 U.S. 667, 680 (1986). The Court expounded on that exception in Illinois Council, explaining that "the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." 529 U.S. at 22–23 (emphasis in original). Consequently, the exception does not apply where requiring channeling would result in mere "postponement" and "added inconvenience or cost in an isolated, particular case." Id. at 22.

The D.C. Circuit has delineated the contours of the Illinois Council exception in two opinions with opposing outcomes: American Chiropractic, 431 F.3d 812 (D.C. Cir. 2005) and Council for Urological Interests v. Sebelius, 668 F.3d 704 (D.C. Cir. 2011) ("Urological Interests"). In American Chiropractic, an association of chiropractors sought judicial review of a Medicare rule permitting HMOs to require that patients receive a referral from a non-chiropractor before obtaining coverage for a chiropractor's services. 431 F.3d at 814–15. Although the association could not lodge a challenge itself, the Circuit declined to apply the Illinois Council exception because the claim could be brought by beneficiaries. Id. at 816–17. The Circuit reasoned that patients could see a chiropractor without the requisite referral, submit a claim for reimbursement, and have that claim denied by the HMO—thus "trigger[ing] the

administrative process[.]" Id.[4] The Illinois Council exception, the Circuit explained, applies only "when roadblocks practically cut off *any* avenue to federal court." Id. at 816 (emphasis added).

By contrast, Urological Interests applied the exception to a council of physician-owned medical equipment providers that challenged a regulation prohibiting it from receiving reimbursements in exchange for providing hospitals with surgical equipment. 668 F.3d at 705–06. It was undisputed that neither the council nor its members could lodge an administrative challenge, either directly or as an assignee of a beneficiary. Id. at 713. And though the council's claim could have been brought by its contracting hospitals, "several unique characteristics of the hospitals' relationship to the [c]ouncil and to the challenged regulations" rendered them "highly unlikely to do so[.]" Id. Specifically, the hospitals "resented" the council's role in its procedures and were eager to "reassert control" under the new regulations. Id. (cleaned up). Additionally, the regulations benefitted the hospitals financially by enabling them to purchase otherwise expensive surgical equipment at "fire-sale prices[.]" Id. (cleaned up). The Circuit concluded that "under the specific facts of [that] case," id. at 714, invocation of the channeling requirements "would have the practical effect of 'turn[ing] what appears to be simply a channeling

[4] The Circuit also noted that a chiropractor could lodge a challenge itself as an assignee of the patient's claim. Id. at 713. While the parties did not address the question in their briefs, the government represented at oral argument that a RICU physician could bring a claim as an assignee of a beneficiary's claim. Oral Arg. Tr. at 8:14–9:13. RICU did not dispute that its physicians could seek administrative review but asserted that hospitals lack "incentive . . . to assign the claims" to RICU's physicians. Id. at 27:16–19. The Court is not convinced. As explained below, RICU's own submissions in this case show that hospitals have strong incentives to seek reimbursement for its services. In any event, given the lack of briefing on this issue the Court declines to decide whether a RICU physician could pursue its claim as a beneficiary's assignee.

requirement into *complete* preclusion of judicial review,'" id. at 713 (quoting Illinois Council, 529 U.S. at 22–23) (emphasis in original).

Applying these two decisions here, the Court begins with the undisputed fact that RICU cannot bring an administrative challenge directly because it is not a Medicare enrolled supplier.[5] See Rabinowitz Decl. ¶ 22. While this factor inches this case closer to Urological Interests, the caselaw is clear that the Illinois Council exception is concerned with situations where channeling would effectively bar the *claim*—not the *claimant*—from federal court. As emphasized in American Chiropractic and reiterated in Urological Interests, "the Illinois Council exception is not intended to allow [§] 1331 federal question jurisdiction in every case where [§] 405(h) would prevent *a particular individual or entity* from seeking judicial review." 668 F.3d at 711 (emphasis added); see also Colo. Heart Inst., LLC v. Johnson, 609 F. Supp. 2d 30, 37 (D.D.C. 2009) ("[p]laintiffs' lack of a direct avenue to administrative review through an assignment does not mean that they could not get their *claim* heard") (emphasis in original); accord Sensory Neurostimulation, Inc. v. Azar, 977 F.3d 969, 983 (9th Cir. 2020) (agreeing with American

[5] It is also undisputed that no third-party has yet mounted an administrative challenge to a denial of RICU's services. RICU contends the lack of any third-party challenge renders this case akin to Urological Interests, where the Circuit observed that the absence of such a challenge for three years "confirm[ed]" that hospitals had "little incentive" to bring a claim. 668 F.3d at 713. The lack of challenge in this case does not move the needle. For starters, HHS promulgated the IFR in April 2020 and addressed the application of that rule to RICU's services over the course of the following summer and fall. And as RICU argues elsewhere, HHS's application of the IFR to its services is a "sub-regulatory policy," the implementation of which has been in flux amidst the pandemic and change in administrations. See Pl. Resp. at 36–37 (explaining why RICU declined to seek a preliminary injunction until ten months after announcement of the IFR). Moreover, even if the Court *were* to start the clock at the moment that HHS issued the IFR—that is, *months before* Rabinowitz met with senior CMS officials to discuss Medicare coverage of its services—the timespan in this case would still be approximately two years shy of that in Urological Interests. Little (if anything) can be read into the lack of a third-party challenge to date.

Chiropractic that the exception does not apply when "another party can bring the same claim through the existing administrative channel[] and is sufficiently incentivized to do so"); Fam. Rehab., Inc. v. Azar, 886 F.3d 496, 505 (5th Cir. 2018) (noting that channeling is required "so long as there potentially [are] other parties with an interest and a right to seek administrative review") (cleaned up); cf. P.R. Ass'n of Physical Med. & Rehab., Inc. v. United States, 521 F.3d 46, 49 (1st Cir. 2008) (finding exception inapplicable where third parties have "ample economic incentive to frame and support a test case").

Here, it is undisputed that RICU's partnering hospitals can bring an administrative challenge to HHS's determination that RICU's services are not reimbursable. RICU responds that the hospitals present an inadequate proxy because they lack incentive to bring such a claim. Pl. Resp. at 14–17. But RICU's complaint and supporting declaration tell a different story. According to Mr. Rabinowitz, RICU's president, RICU's client hospitals "continue[] to inquire about whether there is any hope" that its services might be covered. Rabinowitz Decl. ¶ 37. Other clients are "concern[ed]" and "perplexed" by the prospect of continued exclusion. See id. ¶ 40 (attesting that hospital representatives have indicated "concern . . . that RICU's services will continue to be excluded from payment."); Compl. ¶ 84 (same); Rabinowitz Decl. ¶ 37 (attesting that hospital system leadership is "perplexed as to why CMS would exclude RICU's services during a public health emergency"). Unlike in Urological Interests, where the interests of the plaintiffs and their potential proxies were structurally opposed, RICU's proxies have expressed a strong interest in seeking Medicare reimbursement for its services. And not only are the interests of RICU's *current* clients aligned with RICU's on this issue, but its prospective clients, too, have "inquired on sales calls with RICU as to whether the hospital will be able to bill for RICU's services[.]" Rabinowitz Decl. ¶ 39.

Perhaps recognizing this alignment of interests, RICU retreats to arguing that hospitals lack incentive to pursue an administration challenge because the final rule contains a sunset provision that would likely precede any resolution. RICU has submitted no evidence indicating that any hospital has voiced this concern. To the contrary, the Rabinowitz declaration and the complaint state that representatives from "several large hospitals" are "concern[ed] that HHS may eventually approve tele-ICU services *permanently* but that RICU's services will continue to be excluded from payment." Compl. ¶ 84 (emphasis added); see also Rabinowitz Decl. ¶ 40 (same). RICU itself adopted this position in its motion for a preliminary injunction. See, e.g., PI Mot. at 19 (arguing that "HHS telehealth services approved under the Telehealth Waiver are *likely to become permanently reimbursable* under Medicare even after the pandemic subsides") (emphasis added); id. at 36 ("[t]he government has stated its expectation that *expanded telehealth services will continue* beyond the COVID-19 pandemic") (emphasis added); accord 85 Fed. Reg. at 84507 (indicating that parties can request "permanent changes to the Medicare telehealth services list").

RICU further contends that hospitals lack sufficient incentive because they have reimbursable alternatives. See Pl. Resp. at 14; Rabinowitz Decl. ¶ 42. To support this contention, RICU cites to Mr. Rabinowitz's attestations that "some existing clients have decreased the amount of services" they procure from RICU because of HHS's Medicare determination, see Rabinowitz Decl. ¶¶ 36–38, and that "RICU's competitors that provide tele-ICU services using doctors located in the United States enjoy a substantial competitive advantage over RICU" under the new regulatory regime, id. ¶ 41. But this is a thin reed, as clients that have *reduced* RICU's services nonetheless have a financial incentive to seek

reimbursement for that portion they retain.[6] It is thinner still when viewed alongside the remaining allegations in the Rabinowitz declaration and the complaint. RICU's filings indicate that its client hospitals have "always been extremely satisfied with RICU's services and the quality of the RICU physicians." Id. ¶ 37. And these same clients have *always* paid for RICU's services without reimbursement because they have never been eligible for Medicare coverage. If RICU's clients have a demand for its services at non-reimbursable prices, they plainly have an incentive to continue receiving those services at a fraction of the cost.

In any event, RICU's filings do not permit an inference that ready substitutes exist for its tele-ICU services. Aside from generally raising the specter of reimbursable competition and alleging that *two* of the company's more than 250 clients have indicated that they will turn to competitors, RICU has submitted no evidence that any other telehealth company offers comparable telecommunications capabilities. This absence of proof may be explained by the significant barriers to entry identified in RICU's complaint. See id. ¶¶ 16–17; Compl. ¶ 5. For instance, RICU states that it made a "substantial financial investment" into building a robust proprietary technology system that "uses a global private network of dedicated T1 lines . . . and employs varying combinations of highly sophisticated data accelerators and compressors" to provide a "sophisticated" and "highly reliable telecommunications system[.]" Rabinowitz Decl. ¶ 17. This investment was necessary, RICU explains, to "gain the trust of hospitals," id. ¶ 16,

[6] Urological Interests provides a helpful point of contrast. See 668 F.3d at 713. The plaintiffs there challenged a regulation that would make it cheaper for hospitals to buy surgical equipment. Id. (cleaned up). Here, too, the underlying regulation saves hospitals money by expanding the list of services for which hospitals can bill Medicare. But unlike in Urological Interests, the plaintiff is not opposing a rule that would save hospitals money. Instead, RICU is arguing that the rule's scope should be *expanded* so as to also permit hospitals to bill Medicare for its services. In this respect, the interests of RICU and its proxies are aligned.

when entering this emerging field. With this technology, RICU has grown into "one of the nation's largest inpatient telehealth companies" and now services over 250 hospitals and is accessible to 35 million Americans. Id. ¶ 6. Notwithstanding these sworn statements, RICU now argues that *no* hospital will file a claim for its services. Instead, RICU argues, the company's vast network of clients will simply abandon RICU's trusted technology (amidst a shortage in the precise type of care that RICU offers) because those services *remain* ineligible for Medicare. No such inference is supported by these facts.

This case is thus distinguishable from Regeneron Pharmaceuticals, Inc. v. HHS, 510 F. Supp. 3d 29 (S.D.N.Y. 2020), on which RICU relies. There, drug manufacturer Regeneron challenged the recently enacted "most favored nation" rule, which caps Medicare reimbursement for certain drugs based on the lowest price for which it is sold internationally. Id. at 35–36. Under the most favored nation rule, the reimbursement rate providers could receive for Regeneron's drug fell below their acquisition costs, meaning providers could not administer the drug without taking a financial loss. Id. at 40. Regeneron sought judicial review through the Illinois Council exception on the ground that the potential proxies for its claim—providers—lacked the financial incentives to bring a challenge. Id. at 44. In support of this argument, Regeneron averred that providers could readily turn to one of two available substitutes for its drug that were unaffected by the rule. Id.

As described above, RICU's filings demonstrate that its services are not so easily substituted.[7] RICU touts the qualitative benefits of its services to its client hospitals. See, e.g., Rabinowitz Decl. ¶¶ 8, 10, 17–19, 41; Compl. ¶ 30. And it repeatedly emphasizes that these services are all the more valuable given the ongoing shortage of intensivists nationwide. See Compl. ¶¶ 47–60. Indeed, RICU's filings point out that even *without* Medicare reimbursement, the company retains a competitive edge on U.S.-based telehealth services because its intensivists can cover U.S. night shifts while working a daytime schedule. Rabinowitz Decl. ¶ 41; Compl. ¶ 30. This unique aspect of RICU's business model "decreas[es] fatigue and improve[s] physician performance, which, in turn, result can improve patient outcomes" as compared to the U.S.-based competition. Compl. ¶ 30; see also Rabinowitz Decl. ¶ 19 (noting that, unlike tele-ICU intensivists located in the U.S., "RICU's intensivists can cover U.S. night shifts while on a daytime schedule—a significant benefit that can improve patient care"). The Illinois Council exception exists for those claims where practical barriers transform the channeling requirements into "*complete* preclusion of judicial review." Urological Interests, 668 F.3d at 708 (quoting Illinois Council, 529 U.S. at 23) (emphasis in original). Even accepting RICU's allegations to be true and drawing all inferences in its favor, the company has not carried its burden to establish the presence of such barriers here.

In sum, RICU represents that it has lost only a portion of its business to reimbursable telehealth companies; that it has expended substantial resources creating a robust proprietary

[7] This case differs from Regeneron for another reason. Because Regeneron first sold its drug to wholesalers that then resold it to hospitals and providers, the court observed that the company lacked any "direct link" to the providers that might channel its claim. 510 F. Supp. 3d at 44. By contrast, RICU contracts directly with the hospitals that can channel its claim. See Rabinowitz Decl. ¶ 21 (averring that RICU maintains "direct contracts with hospitals and hospital systems" in addition to "contracts with third-party intermediaries").

telehealth infrastructure, which has helped the company gain the trust of hospitals across the country; that hospitals nationwide desperately need the precise type of telehealth service that RICU provides;[8] that RICU offers better patient outcomes than the reimbursable competition; and that both current and potential client hospitals have expressed strong interest in receiving Medicare reimbursement for its services. Accepting these representations precludes any inference that RICU's 250 client hospitals are so lacking in incentives to seek reimbursement for its services that applying the presentment requirement would turn "what appears to be simply a channeling requirement into *complete* preclusion of judicial review." Urological Interests, 668 F.3d at 714 (quoting Illinois Council, 529 U.S. at 22–23) (emphasis in original). Consequently, the Illinois Council exception is unavailable.

[8] RICU claims that the circumstances surrounding COVID-19 render hospitals less likely to mount an administrative challenge because "they are in a constant state of triage, determining the best methods for treating COVID-19 patients." Pl. Resp. at 15. This argument cuts both ways. The public health crisis both decreases hospital capacity and increases the value of RICU's services, as RICU points out repeatedly in its papers. See, e.g., Compl. Ex. 3 (informing CMS that RICU's physicians "are desperately needed at this time" and that there is "no doubt" that increasing hospital access to RICU physicians will "save lives"). Additionally, it bears repeating that RICU's current clients have *always* relied on its services without reimbursement. It belies common sense that these hospitals now lack the capacity to mount an administrative challenge but can instead shop around for a reimbursable replacement of RICU's "proprietary technology [that] expands the reach of tele-ICU capabilities and maximizes the number of patients who can receive critical care." Compl. ¶ 26.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendants' Motion to Dismiss, deny Plaintiff's Motion for a Preliminary Injunction, and dismiss the case. A separate Order shall accompany this Memorandum Opinion.

CHRISTOPHER R. COOPER
United States District Judge

Date: August 20, 2021