UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INTEGRITY SOCIAL WORK SERVICES, LCSW, LLC., a New York professional services limited liability company located at 46 Francesca Lane, Staten Island, NY 10303, Plaintiff, -against- ALEX M. AZAR, II, Secretary of the United States Department of Health and Human Services located at 200 Independence Avenue, S.W., Washington, DC 20201, and SAFEGUARD SERVICES, LLC., a Delaware limited liability company located at Suite 200, 1250 Camp Hill Bypass, Camp Hill, PA 17011 Defendants.	**OPINION AND ORDER** 20-CV-02770 (PK)

Peggy Kuo, United States Magistrate Judge:

Integrity Social Work Services, LCSW, LLC ("ISWS" or "Plaintiff") brought this action against Alex M. Azar II, in his official capacity as Secretary ("Secretary")[1] of the United States Department of Health and Human Services ("HHS"), and Safeguard Services LLC ("Safeguard," and collectively with the Secretary and HHS, "Defendants") for violations of ISWS's rights under the Fifth Amendment to the United States Constitution. (*See* "Compl.," Dkt. 1.)

Before the Court is Defendants' Motion to Dismiss.[2] ("Motion," Dkt. 28.) For the reasons below, the Motion is granted.

[1] Alex M. Azar, II was the Secretary at the time the Complaint was filed, but has since been replaced in that role.

[2] The parties consented to Magistrate Judge jurisdiction. (Dkts. 26, 27.)

BACKGROUND

I. Legal Background

A. Medicare

The Medicare program ("Medicare" or the "Program") provides health insurance to individuals over sixty-five years old, among others. *See* 42 U.S.C. §§ 1395 *et seq*. (the "Medicare Act" or the "Act"). The Center for Medicare & Medicaid Services ("CMS"), a component of the Department of Health and Human Services, administers Medicare. *See* 42 C.F.R. § 400.200.

1. Medicare Contractors

Congress provided for the use of private entities to aid in administering Medicare. *See* 42 U.S.C. §§ 1395kk-1, 1395ddd, 1395ff. Those entities include Medicare Administrative Contractors ("MACs"), which process and pay claims from healthcare providers for services to Medicare beneficiaries, *see* 42 U.S.C. § 1395kk-1(a)(4), Unified Program Integrity Contractors ("UPICs"), which "promote the integrity of the medicare program" by, among other things, reviewing provider activities, determining whether payments should not have been made, and recovering those payments, 42 U.S.C. § 1395ddd, and Qualified Independent Contractors ("QICs"), which review decisions by UPICs and MACs, including decisions to recover payments that should not have been made. *See* 42 U.S.C. §§ 1395ff(b)(1), 1395ddd(f)(2). CMS, pursuant to the Act, contracts with these types of entities.

2. Medicare Part B

Medicare Part B provides supplemental health insurance benefits for additional premiums, including for the type of services provided by Plaintiff. *See* 42 U.S.C. § 1395x; 42 C.F.R. Part 410. Except in limited enumerated circumstances, services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Services that are not reasonable and necessary, or are otherwise excluded from coverage, are not eligible for reimbursement by Medicare. *See id.*

Congress did not provide an all-encompassing definition of "reasonable and necessary," and thus the Secretary of HHS issues "comprehensive and intricate" regulations that "address[] matters such as limits on cost reimbursement, apportioning costs to Medicare services, and the specific treatment of numerous particular costs." *Shalala v. Guernsey Memorial Hosp.*, 514 U.S. 87, 96 (1995). These rules do not, however, address "every conceivable question." *Id.* at 96. As a result, the Secretary relies on both "formal regulations and (informal) instruction manuals and letters" when determining coverage of a particular service. *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006).

Among these rules are National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"). The Medicare Act expressly allows for the promulgation of NCDs and LCDs. 42 U.S.C. § 1395ff(f)(1) and (2). NCDs are "determination[s] by the Secretary with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(1)(B). LCDs are "determination[s] by a carrier [*i.e.*, a MAC][3] … respecting whether or not a particular item or service is covered" by Medicare in that MAC's service area. 42 U.S.C. § 1395ff(2)(B). NCDs are coverage decisions that are binding on both private contractors and administrative reviewers at CMS, including administrative law judges ("ALJs") and the Medicare Appeals Council, discussed further below. *See* 42 C.F.R. § 405.1060. LCDs are not binding on ALJs or the Council (*i.e.*, they are not binding on the government), but are entitled to "substantial deference." 42 C.F.R. § 405.1062(a). Through the creation of NCDs and LCDs in the Medicare Act, Congress expressly provided for private contractors to make limited coverage determinations.

3. The Initial Claims Process

Medical providers first file claims with a MAC, which determines coverage and the amounts payable, makes any payments due, and notifies the provider of the payment. 42 C.F.R. §§ 405.920,

[3] Medicare statutes and regulations refer to "carriers," but since October 1, 2005, the private entities that CMS contracts with to administer Medicare Part B have been known as MACs. (*See* Def. Mem. of Law at 3 n.3.)

405.921; *see also* 42 U.S.C. § 1395ff(a)(1). "The Medicare program processes over a billion claims each year." *Sahara Health Care, Inc. v. Azar*, 975 F.3d 523, 525 (5th Cir. 2020) (citation omitted). "As a general rule, MACs authorize payments on Part B claims 'immediately' upon receipt of a claim in order to facilitate claims processing and cash flow to Medicare providers; only later are these determinations audited." *Art of Healing Med., P.C. v. Burwell*, 91 F. Supp. 3d 400, 404 (E.D.N.Y. 2015) (citing cases).

4. Auditing and Recoupment

Under the Medicare Integrity Program created by Congress, UPICs review provider activities covered or potentially covered by Medicare, make "[d]eterminations as to whether payment should not be, or should not have been, made," and "recover[] payments that should not have been made." *See* 42 U.S.C. § 1395ddd(b). To conduct a "post-payment audit," UPICs generally first request "a probe sample of billings from a [provider] … in order to determine whether there is a likelihood of overpayment by Medicare." *I & R Med., P.C. v. Cochran*, No. 17-CV-6417 (ILG), 2021 WL 633781, at *2 (E.D.N.Y. Feb. 18, 2021) (quoting *Art of Healing Med.*, 91 F. Supp. 3d at 405) (omission supplied).

After this probe sample, UPICs may use statistical sampling and extrapolation to determine overpayment amounts. *See I & R Med.*, 2021 WL 633781 at *2 (quoting *Art of Healing Med.*, 91 F. Supp. 3d at 405). However, statistical sampling and extrapolation is only permissible where "the Secretary determines that (A) there is a sustained or high level of payment error; or (B) documented educational intervention has failed to correct the payment error." 42 U.S.C. § 1395ddd(f)(3). The Medicare Program Integrity Manual provides UPICs with guidance on determining whether "there is a sustained or high level of payment error." *See* Medicare Program Integrity Manual Ch. 8 § 8.4.1.4. If a provider determines that there is a high level of payment error based on one of several criteria listed in the Program Integrity Manual, including whether there is a "high error rate"—defined as "greater than or equal to 50 percent from a previous pre- or post-payment review"—it may conduct statistical sampling. *See* Medicare Program Integrity Manual Ch. 8 § 8.4.1.4. Alternatively, "[i]f the

contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed [in the Program Integrity Manual], it shall consult with [designated CMS employees] prior to creating a statistical sample and issuing a request for medical records from the provider/supplier." *See* Medicare Program Integrity Manual Ch. 8 § 8.4.1.4.

Once a UPIC determines that statistical sampling is appropriate based on the stated criteria or approval from CMS, the UPIC proceeds as follows:

> ... a statistically valid random sample ("SVRS") from the physician [is requested]. The SVRS is then extrapolated to the physician's total billing, in order to provide a reasonable approximation of the total overpayment when the quantity of billing is overly abundant. If, following an audit, [it is] determine[d] that an overpayment has been made, ... Medicare payments from the provider [may be offset or recouped].

See I & R Med., 2021 WL 633781 at *2 (quoting *Art of Healing Med.*, 91 F. Supp. 3d at 405) (alterations in *I & R Med.*). The Program Integrity Manual provides detailed guidance on statistical sampling methodology. *See* Medicare Program Integrity Manual Ch. 8 § 8.4.

If the UPIC determines through sampling and extrapolation that there has been an overpayment, the UPIC informs the MAC, which then issues a demand letter to the provider and undertakes recoupment or offsets future benefits against any overpayment amount. *See* Medicare Program Integrity Manual Ch. 8 § 8.4.7.1.; *see also* 42 C.F.R. §§ 405.921, 405.371. The MAC must explain its reasons for seeking recoupment or future offset and provide an opportunity for rebuttal. 42 C.F.R. §§ 405.373, 405.374.

If immediate recoupment "would constitute a hardship" as defined by statute, providers may request an extended payment plan of six months to three years, although interest accrues during the repayment plan. 42 U.S.C. § 1395ddd(f)(1)(A). An "extreme hardship" may allow for a five-year repayment. 42 U.S.C. § 1395ddd(f)(1)(A).

5. Four-Step Administrative Appeals Process

Coverage determinations and determinations to recoup or offset overpayments are referred to as "initial determinations." Initial determinations may be appealed through a four-step process that involves MACs, QICs, Administrative Law Judges ("ALJs"), and an agency appeals board. After a final decision has been rendered by the agency, the matter may be raised in federal court.

STEP 1—Request for Redetermination: Providers that are "dissatisfied with an initial determination may request a redetermination by a contractor in accordance with" regulations. 42. C.F.R. § 405.940; *see also* 42 U.S.C. § 1395ff(a)(3). Redetermination requires an "independent review of an initial determination" by "[a]n individual [at a MAC] who was not involved in making the initial determination." 42 C.F.R. § 405.948. Recoupment pauses "upon receipt of a timely and valid request for a redetermination of an overpayment." 42 C.F.R. § 405.379(d)(1). Recoupment may resume if an overpayment decision is affirmed on redetermination, but pauses again if the provider requests a reconsideration. 42 C.F.R. §§ 405.389(d)(2), (3).

STEP 2—Request for Reconsideration: Providers "dissatisfied with that [re]determination, may request a reconsideration by a QIC [Qualified Independent Contractor] in accordance with" additional regulations. 42 C.F.R. § 405.960; *see also* 42 U.S.C. § 1395ff(b)(1). Reconsideration is "an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim." 42 C.F.R. § 405.968. Reconsideration must be completed within 60 calendar days unless an exception applies. 42 C.F.R. § 405.970. Recoupment pauses until a reconsideration decision is rendered. 42 U.S.C. § 1395ddd(f)(2)(A); *see also* 42 C.F.R. § 405.389(3). Once a reconsideration decision is rendered, however, recoupment resumes regardless of further appeals. 42 C.F.R. § 405.379(d)(5).

STEP 3—Request for Hearing: If a provider is "dissatisfied with a QIC's reconsideration, or if the adjudication period … for the QIC to complete its reconsideration has elapsed," the provider may then request a hearing before an Administrative Law Judge ("ALJ") at the Office of Medicare

Hearings and Appeals if the amount in controversy is at least $100. 42 C.F.R. §§ 405.1000, 405.1006; *see also* 42 U.S.C. § 1395ff(b)(1). The appellant may submit new evidence after the QIC reconsideration but before the hearing, and if there is good cause for submitting the evidence for the first time at this step of the appeals process, the ALJ may consider it. *See* 42 C.F.R. 405.1028(a)(1). The hearing before the ALJ may be in-person or remote. 42 C.F.R. § 405.1000(b). The ALJ must make a *de novo* determination based on the entire record, including the original record before the QIC, any new evidence submitted by the parties, and the hearing record. C.F.R. § 405.1000.

STEP 4—Request for Medicare Appeals Council Review: If an ALJ holds a hearing and issues a decision, and the provider is dissatisfied with *that* decision, the provider may request review by the Medicare Appeals Council. 42 C.F.R. § 405.1100; *see also* 42 U.S.C. § 1395ff(d)(2) (referring to the "Departmental Appeals Board"). The Medicare Appeals Council reviews the ALJ's decision *de novo*, but the provider is not entitled to a hearing before the Council. 42 C.F.R. § 405.1108(a). If the Council renders a decision, the Council's decision is the "final decision" of the Secretary and is subject to judicial review in federal district court. 42 C.F.R. § 405.1130; 42 U.S.C. § 1395ff(b)(1)(A); 42 U.S.C. § 405(g).

Bypass of Steps 3 and 4: The Act and regulations thereunder also provide for bypass of the ALJ hearing and Medicare Appeals Council review steps in the event of delay. With respect to bypass of Step 3, if an ALJ does not conduct a hearing and issue a decision within 90 days of a request for a hearing, the provider "may escalate the appeal" of the QIC's reconsideration to the Medicare Appeals Council. *See* 42 C.F.R. § 405.1016(c); *see also* 42 U.S.C. § 1395ff(d)(1), (d)(3). If a provider requests escalation and the Medicare Appeals Council does not decide an escalation request within 180 days, the provider "may request that the appeal … be escalated to Federal district court." 42 C.F.R. §§ 405.1132, 405.1100(d), 405.1106(b). The Council must then issue a decision or remand the case within five days of the request for escalation, or send a notice to the appellant "acknowledging receipt of the

request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame." 42 C.F.R. § 405.1132(a)(2). The appellant may then bring an action in federal district court within sixty days. *Id.* § 405.1132(b).

With respect to bypass of Step 4, if the Council fails to render a decision within 90 days after ALJ review, the provider may request escalation to federal court if the amount in controversy is at least $1,000. 42 C.F.R. § 405.1132; 42 U.S.C. § 1395ff(d)(3)(B). The Council again has five days to issue a decision, remand the matter to an ALJ, or send notice that it cannot render a decision. 42 C.F.R. §§ 405.1132(a)(2). The appellant has sixty days to bring an action in federal court. *Id.* § 405.1132(b).

If a provider successfully appeals and the overpayment decision is reversed, "the Secretary shall provide for repayment of the amount recouped plus interest." 42 U.S.C. § 1395ddd(f)(2)(B).

II. Factual Background

Except where otherwise noted, the following facts are taken from the Complaint.[4] Plaintiff is a New York professional services LLC based in Richmond County, New York. (Compl. ¶ 10.) It provides licensed clinical social work services to homebound Medicare and non-Medicare beneficiaries throughout New York City, including "in-home psychotherapy treatments and related mental health services," and it derives substantial revenues from Medicare. (*Id.* ¶¶ 2, 10, 33, 47; Plaintiff's Memorandum of Law in Opposition to Defendant's Motion to Dismiss, "Opp.," Dkt. 33 at 7.)[5] "ISWS has completed all necessary requirements to be a Medicare provider." (Compl. ¶ 10.)

[4] Defendants submitted three declarations with attached exhibits in support of their motion to dismiss providing additional facts regarding the payment to and recoupment from Plaintiff. (Dkts. 30-32.) Those exhibits consist of the underlying claims and overpayment and recoupment decisions referenced in the Complaint, as noted below.

[5] In the Complaint ISWS alleges that it predominantly or entirely serves Medicare beneficiaries (Compl. ¶¶ 2, 33, 47), but in its Opposition concedes that only about half of its revenues are from Medicare patients (*see* Opp. at 7).

Defendant Safeguard is a private contractor that provides services for HHS, including in this District. (*Id.* ¶ 12.) Defendant Safeguard is a UPIC. (*Id.* ¶ 6.)

Plaintiff provided psychotherapy services to Medicare patients from January 1, 2000 through February 8, 2018, and submitted Medicare claims to National Government Services ("NGS"), the MAC covering Plaintiff's region, which paid Plaintiff for claims submitted between January 1, 2017 and February 28, 2018. (*Id.* ¶ 34.)

On February 13, 2018, Plaintiff received a letter from Safeguard requesting medical records for ten patients to conduct a post-payment review. (*Id.* ¶ 35.) Based on Safeguard's review of Plaintiff's 51 claims for services provided to nine of those ten patients,[6] Safeguard determined that all of the claims should have been denied and Plaintiff had therefore been overpaid by $20,410.94. (Compl. ¶ 36; *see also* "First Notice," Ex. A to the Decl. of Matt Kochanski, Dkt. 30-1 at 2-4.) Based on that finding, Safeguard determined that ISWS's claims had a high level of payment error and that extrapolation was appropriate to determine the extent of overpayment. (*See id.* ¶ 45.)

On April 11, 2018 and May 17, 2018 Safeguard requested medical records from Plaintiff for 90 beneficiaries. (*Id.* ¶ 35; "Second Notice," Ex. B to the Decl. of Matt Kochanski, Dkt. 30-2 at 2-3.) Safeguard developed a statistically valid random sample of 101 claims for these 90 beneficiaries and determined that all 101 claims should have been denied. (Compl. ¶ 37; Second Notice at 3.) Safeguard then extrapolated from these claims and determined that Plaintiff had been overpaid $979,040.40. (Compl. ¶ 37; Second Notice at 13.)

On February 6, 2019, Safeguard sent Plaintiff copies of the two notices; the First Notice describing its review of the first ten claims Plaintiff submitted; and the Second Notice describing the statistically valid random sample methodology and the conclusion that Plaintiff had been overpaid by $979,040.40 from January 2, 2017 to January 23, 2018. (Compl. ¶¶ 36-37; First Notice; Second

[6] According to the First Notice, only nine of the initially provided records were reviewed. (First Notice at 3.)

Notice.)

On February 13, 2019, NGS sent Plaintiff a demand letter for the full overpayment amount. (Compl. ¶ 38.)

On March 11, 2019, Plaintiff submitted a Request for Redetermination to NGS. (*Id.* ¶ 39.) NGS upheld the overpayment determination. (*Id.*) Plaintiff alleges that "NGS essentially accepted Safeguard's determination at face value." (*Id.* ¶ 46.)

On June 14, 2019, Plaintiff filed a Request for Reconsideration with the appropriate QIC. (*Id.* ¶ 40.) The QIC also returned an unfavorable decision and found that Plaintiff had been overpaid. (*Id.*) Plaintiff alleges that "there is no evidence throughout the appeals process that ISWS's claims were reviewed by a reviewing profession[al] who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue pursuant to 42 U.S.C. § 1395ff(g)(4)(A)." (*Id.*) The letter informing Plaintiff of the unfavorable QIC determination states, "[a] panel of licensed health care professionals, including a physician, reviewed the documentation in this case and made these decisions." (Ex. E to the Decl. of Maria Ramirez, Dkt. 32-1 at 4.)

On October 7, 2019, Plaintiff submitted a Request for a Medicare Hearing with an ALJ. (Compl. ¶ 41.) As of the date of the Complaint on January 15, 2020, Plaintiff had not been provided with a hearing before an ALJ, and "believes that the earliest available hearing date is approximately three years from the date the request was made." (*Id.*)

Prior to the filing of the Complaint, Safeguard initiated recoupment of the overpayments to Plaintiff. (*Id.*) Plaintiff alleges that "[t]he delay in receiving an ALJ hearing is not merely a financial hardship for ISWS but will result in ISWS permanently closing its business before ISWS can be heard before an ALJ." (*Id.*) It is undisputed that Plaintiff has not sought to escalate its claim to the Medicare Appeals Council.

III. Procedural Background

Plaintiff filed the Complaint on January 15, 2020 in the District of Columbia, asserting a violation of Plaintiff's procedural due process rights (Count 1) and a violation of its substantive due process rights (Count 2). (Compl. ¶¶ 50-59.)

On its procedural due process claim, Plaintiff alleges that Defendants "summarily determined that ISWS's business was ineligible for Medicare payments without constitutional authority." (*Id.* ¶ 51.) It claims that Safeguard was "unconstitutionally delegated with regulatory, quasi-judicial, and judicial authority to deprive ISWS of its protected property and liberty interests, including its fundament[al] right to practice its profession" and "effectively took ISWS's business without an adequate hearing, which was ratified by the Secretary without conducting its own due diligence regarding the facts of the matter." (*Id.*) It also asserts that it has not been provided with "an adequate hearing" because "the delay in obtaining an ALJ hearing and the financial hardship of the recoupment process" will cause it to shut down its business before it can be heard by an ALJ. (*Id.* ¶ 52.)

On its substantive due process claim, Plaintiff alleges that Defendants "acted arbitrarily and capriciously by allowing a private contractor to determine that all claims submitted by ISWS during an 18-year period resulted in overpayment," thus "essentially forc[ing] ISWS out of business" and depriving it of its protected property and liberty interests "without an adequate hearing." (*Id.* ¶ 57.)

Plaintiff seeks a declaratory judgment that the procedures used to determine Plaintiff's overpayment were unconstitutional, and "that Defendants' use of private contractors to invalidate ISWS's entire business was unconstitutional…." (*Id.* ¶¶ 55,[7] 59.) It also seeks temporary suspension of the Medicare recoupment process and reinstatement of Plaintiff's payments until an ALJ hearing is provided. (*Id.* ¶¶ 55, 59.)

[7] There are two paragraphs numbered 55; citations to paragraph 55 in this Order refer to the last paragraph on page 13 of the Complaint.

On March 16, 2020, Defendants moved to dismiss or to transfer the case to this District for failure to comply with the Medicare Act's venue requirements. (*See* Dkt. 7.) Defendants argued that the case arises under the Medicare Act, and therefore venue is controlled by the Act's venue provision, 42 U.S.C. § 405(g), which supersedes the general venue provisions cited by Plaintiff in the Complaint. (*See* Dkt. 7 at 8-16.) Plaintiff argued in opposition that its claims did not arise under the Medicare Act, and even if they did, exceptions to the jurisdictional limits in the Act allowed Plaintiff to bring its claims pursuant to 28 U.S.C. § 1331 (*i.e.*, general federal question jurisdiction), and that the general venue provision applied. (Dkt. 8 at 6-9.)

On June 11, 2020, The Honorable Chief Judge Beryl A. Howell of the District of Columbia granted the motion to transfer, holding that Plaintiff's claims arise under the Medicare Act, and therefore the Medicare Act's venue requirement that claims made under the Act "shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business" applied. ("Venue Decision," Dkt. 11 at 10 (citing 42 U.S.C. § 405(g)).) The case was transferred to this District on June 23, 2020. (*See* Dkt. 12.)

Defendants filed the Motion on December 4, 2020, seeking to dismiss the case under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction and Rule 12(b)(6) for failure to state a claim. (Dkt. 28.) Plaintiff opposed the Motion on December 19, 2020 (Dkt. 33), and Defendants filed their reply on January 8, 2021. (Dkt. 34.)

LEGAL STANDARD

I. Rule 12(b)(1)

A defendant may move to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) where the court lacks subject-matter jurisdiction. "A Rule 12(b)(1) motion challenging subject matter jurisdiction may be either facial or fact based." *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56 (2d Cir. 2016). A facial challenge is based solely on the allegations in the complaint. *Id.* A fact-based challenge relies on

evidence outside the pleadings. *Id.*; *see also Makarova v. U.S.*, 201 F.3d 110, 113 (2d Cir. 2000) (court may rely on evidence outside the pleadings when evaluating a Rule 12(b)(1) motion) (citing *Kamen v. American Tel. & Tel. Co.*, 791 F.2d 1006, 1011 (2d Cir. 1986)). "A plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." *Makarova*, 201 F.3d at 113. A plaintiff may rest on the allegations in the complaint to sustain this burden. *See Carter*, 822 F.3d at 56.

II. Rule 12(b)(6)

To survive a Rule 12(b)(6) motion, a plaintiff's allegations must be supported by "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court accepts "all factual allegations in the complaint as true and draw[s] all reasonable inferences in favor of the plaintiff." *Hayles v. Aspen Properties Grp., LLC*, 782 F. App'x 3, 5 (2d Cir. 2019). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. "A complaint is properly dismissed where, as a matter of law, 'the allegations in a complaint, however true, could not raise a claim of entitlement to relief.'" *Hayles*, 782 F. App'x. at 5 (quoting *Twombly*, 550 U.S. at 558).

Courts generally "do not consider matters outside the pleadings" when evaluating a motion to dismiss under Rule 12(b)(6). *See Fillmore E. BS Fin. Subsidiary LLC v. Capmark Bank*, 552 F. App'x 13, 15 (2d Cir. 2014) (citation and quotations omitted). However, "[a] complaint is also deemed to include any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although not incorporated by reference, are integral to the complaint." *Cohen v. Rosicki, Rosicki & Assocs.*, P.C., 897 F.3d 75, 80 (2d Cir. 2018) (citation and quotations omitted).

DISCUSSION

I. Subject Matter Jurisdiction

Plaintiff asserts that this Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331.[8] (Compl. ¶¶ 13-15.)

Defendants argue that "the Medicare Act provides the sole avenue for judicial review of Medicare claims arising under the Act" and, therefore, the Court lacks federal question jurisdiction until Plaintiff exhausts its remedies under the Act.[9] ("Def. Mem. of Law," Dkt. 29 at 16 (quoting *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984)).)

The Medicare Act bars general federal question jurisdiction over claims arising under the Act. It states, "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h); 42 U.S.C. § 1395ii (applying 42 U.S.C. § 405(h)'s requirements to the Medicare Act). The Act requires that all claims arising under it "must proceed instead through the special review channel that the Medicare statutes create." *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 5 (2000). This "special review channel" provides for the four-step administrative review of overpayment and recoupment decisions (or bypass of the third and/or fourth steps) described *supra*, followed by judicial review of a "final decision" of the Secretary in federal district court. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 U.S.C. § 405(g). The Medicare Appeals Council's decision constitutes the "final decision" of the Secretary. *See* 42 C.F.R. § 405.1130.

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[8] Plaintiff also invokes the Declaratory Judgment Act as a basis for jurisdiction, arguing, "[b]ecause jurisdiction is proper under 28 U.S.C. § 1331, jurisdiction is also proper under 28 U.S.C. §§ 2201 and 2202." (Opp. at 25; *see also* Compl. ¶ 17.) However, the Declaratory Judgment Act does not serve as an independent basis of jurisdiction. *See Anderson v. Sullivan*, 959 F.2d 690, 692 n.4 (8th Cir. 1992) (quoting the language of the Declaratory Judgment Act that begins, "In a case of actual controversy *within its jurisdiction*," and noting that § 2201 is not jurisdictional); *see also Chevron Corp. v. Naranjo*, 667 F.3d 232, 244 (2d Cir. 2012) (holding that the Declaratory Judgment Act does not create jurisdiction because "a declaratory judgment relies on a valid legal predicate.") In addition, Plaintiff has withdrawn its argument that jurisdiction is proper under 28 U.S.C. § 1332. (*See* Opp. at 5 n.1.)

[9] Defendants similarly argue that sovereign immunity limits jurisdiction over any suit against the federal government, and that the federal government has only waived sovereign immunity for claims arising under the Medicare Act to claims brought pursuant to the Medicare Act. (*See* Def. Mem. of Law at 15-16, "Reply," Dkt. 34 at 1-2.)

However, "[t]he Supreme Court has held that the 'final decision' requirement has two elements, one jurisdictional (non-waivable) and one prudential (waivable)." *Abbey v. Sullivan*, 978 F.2d 37, 43 (2d Cir. 1993) (citing *Bowen v. City of New York*, 476 U.S. 467, 483 (1986) and *Matthews v. Eldridge*, 424 U.S. 319, 328 (1974)). Thus, even if a claim arises under the Medicare Act, the Secretary or a federal court may waive the exhaustion requirement of Section 405(g). *Abbey*, 978 F.2d at 43.

Plaintiff contends that its claims do not "arise under" the Medicare Act because they do not challenge the underlying overpayment and recoupment decision. (Opp. at 12-14.) Even if its claims arise under the Act, Plaintiff argues that it is entitled to a waiver of the Act's exhaustion requirements or, alternatively, that the "no review" exception to the Act applies. (*Id.* at 14-24.) The Court considers these arguments in turn.

A. Whether Plaintiff's Claims Arise Under the Medicare Act

The phrase "claim arising under" is construed "quite broadly." *See Ringer*, 466 U.S. at 615 (citing *Weinberger v. Salfi*, 422 U.S. 749, 760-61 (1975)). A claim does not evade the channeling requirement of Section 405(g) merely because it seeks only injunctive or declaratory relief, or because it challenges a procedural rather than substantive requirement of the Medicare Act. *Ringer*, 466 U.S. 614-15. "[C]ourts should be wary of claims that are 'cleverly concealed claims for benefits'" in the guise of constitutional or statutory challenges, rather than express requests for benefits. *See Potts v. Rawlings Co., LLC*, 897 F.Supp.2d 185, 192 (S.D.N.Y. 2012) (citing *Uhm v. Humana, Inc.*, 620 F.3d 1134, 1131 (9th Cir. 2010)). All such challenges arise under the Medicare Act "irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by his non-discretionary application of allegedly unconstitutional statutory restrictions.'" *Illinois Council*, 529 U.S. at 11 (quoting *Weinberger*, 422 U.S. at 762).

In the Venue Decision, Judge Howell determined that Plaintiff's claims arise under the Medicare Act and therefore transferred the case to the Eastern District of New York. (Dkt. 11 at 6-

11.) Defendants argue that Judge Howell's finding that the claims "arise under" the Act is the law of the case and forecloses further examination of this issue. (Def. Mem. of Law at 16.) "The law of the case doctrine 'forecloses reconsideration of issues that were decided—or that could have been decided—during prior proceedings.'" *Doe v. E. Lyme Bd. of Educ.*, 962 F.3d 649, 662 (2d Cir. 2020) (quoting *United States v. Williams*, 475 F.3d 468, 471 (2d Cir. 2007)). "[T]he 'law of the case' doctrine [is] discretionary." *Furlong v. Shalala*, 238 F.3d 227, 235 n.4 (2d Cir. 2001). Here, it is not necessary to determine whether the law of the case doctrine applies because, for the reasons that follow, the Court reaches the same conclusion as Judge Howell.

Plaintiff argues that its claims do not "arise under" the Medicare Act because they do not challenge the underlying overpayment decision itself. (Opp. at 12-14.) Rather, Plaintiff claims a deprivation of its constitutionally protected property and liberty interests because the delay in providing an ALJ hearing, coupled with the ongoing recoupment process, will result in Plaintiff being forced out of business without an adequate hearing. (Compl ¶¶ 51-52, 57.) Plaintiff also alleges deprivation of these same interests due to the Secretary's unconstitutional delegation of authority to private contractors to "invalidate ISWS's entire business" through its benefits determinations. (Compl. ¶¶ 51, 57, 59.)

Although couched in constitutional terms and labeled as violations of "procedural" and "substantive" due process, Plaintiff's two-pronged Fifth Amendment challenge is at its core about Defendants' attempt to recoup Medicare payments from Plaintiff. These payments are a creation of the Medicare Act; thus, any entitlement to them—as well as any determination that they should be recouped—is grounded in the statute itself. Plaintiff's constitutional deprivation claims therefore derive from and are based on the Medicare Act. (*See* Venue Decision at 9) (any "protected interests in maintaining [Plaintiff's] business and earning a living" would "depend ultimately on payments made pursuant to the Medicare Act" because "[a]part from the unfavorable overpayment determination still

subject to administrative review, no separate liberty or property interest is at stake in this lawsuit.") (internal quotations omitted).) Indeed, Plaintiff concedes that the property and liberty interests at stake are "associated with its Medicare payments." (Compl. ¶ 53.) Any harm to Plaintiff flows from its deprivation of payments under the Act. Because "both the standing and the substantive basis for the presentation of [Plaintiff's] constitutional contentions" derive from the Act, *see Weinberger*, 422 U.S. at 761, Plaintiff's claims arise under the Medicare Act. Section 405(g)'s exhaustion requirement therefore applies and Plaintiff must follow the administrative appeals process set forth in the Act, unless there is a waiver of that exhaustion requirement.

B. Whether Plaintiff is Entitled to a Waiver of the Medicare Act's Exhaustion Requirement

If a claim is first presented to the Secretary, exhaustion may be waived, either by the Secretary or by a court. *Abbey*, 978 F.2d at 43. Because the Secretary has not waived exhaustion, the Court must therefore decide whether to apply a waiver.

In determining whether to apply judicial waiver, the court is guided by three factors: "(1) whether the claim is collateral to a demand for benefits; (2) whether exhaustion would be futile; and (3) whether the plaintiffs would suffer irreparable harm if required to exhaust their administrative remedies before obtaining relief." *Id.* at 44 (citing *City of New York v. Heckler*, 742 F.2d 729, 736 (2d Cir. 1984)). The factors "must be guided by the policies underlying the exhaustion requirement" using "judgment that weighs the utility of exhaustion against countervailing considerations like futility and irreparable harm." *Abbey*, 978 F.2d at 44 (internal quotations and citations omitted). "No one factor is critical," *City of New York*, 742 F.2d at 736, but "[e]xhaustion is the rule, waiver the exception," *Abbey*, 978 F.2d at 44.

1. Collateral Claims

Defendants argue that Plaintiff's constitutional claims are not collateral to its substantive claim for reinstatement of benefits, because those constitutional claims "are 'inextricably intertwined' with

its claims for the benefits that are the subject of the administrative overpayment proceedings." (Def. Mem. of Law at 21.)[10] Plaintiff counters that its claims are collateral because it "alleges that the Secretary's unconstitutional regulations deprived it of a meaningful forum to contest the overpayment amount." (Opp. at 15.)

A claim is collateral where it challenges administrative processes or regulations, rather than reimbursement decisions, and where it does not seek the same relief sought in the underlying administrative hearing. *See Bowen*, 476 U.S. at 483 (claims were collateral because "[t]he class members neither sought nor were awarded benefits in the District Court, but rather challenged the Secretary's failure to follow the applicable regulations.") A decision does not need to be "wholly collateral" to the claim for benefits as long as the court is "not asked to [and does not have to] rule on the merits of any of the underlying claims." *City of New York*, 742 F.2d at 737; *see also Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 501 (5th Cir. 2018) ("For a claim to be collateral, it must not require the court to 'immerse itself' in the substance of the underlying Medicare claim or demand a 'factual determination' as to the application of the Medicare Act.") (citation omitted).

The Complaint asserts two counts. In its procedural due process claim, Plaintiff alleges that it was denied procedural due process because Safeguard has been unconstitutionally delegated authority to deprive Plaintiff of its protected property and liberty interests, the Secretary does not exercise proper oversight over Safeguard despite delegating authority to it, and Safeguard effectively took Plaintiff's business without an adequate hearing. (Compl. ¶¶ 51-53.) For its substantive due process claim, Plaintiff alleges that Defendants acted arbitrarily and capriciously by allowing a private

[10] Defendants also argue that even if Plaintiff's claims are collateral, the "exhaustion requirement should not be waived because there is no colorable constitutional claim." (Def. Mem. of Law at 21.) Defendants' argument collapses the jurisdictional question and the merits question. Courts considering similar claims have found jurisdiction, even where they have ruled against plaintiffs on the merits of their constitutional claims. *See, e.g.*, *Sahara*, 975 F.3d at 528 (citing *Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 505 (5th Cir. 2018)). Defendants' merits arguments are considered below.

contractor to deprive it of its constitutionally protected property and liberty right to practice its profession, and they did so without providing an adequate hearing. (Compl. ¶¶ 57-58.)

Insofar as Plaintiff's claims challenge the constitutionality of the Medicare administrative review process, and not the appropriateness of Safeguard's overpayment determination, they are collateral to the underlying claim for benefits. Indeed, Plaintiff's challenges to the procedures used to make the overpayment determination are quintessential collateral challenges. *See St. Francis Hosp. v. Sebelius*, 874 F. Supp. 2d 127, 133 (E.D.N.Y. 2012) (finding challenge collateral where it was to "the validity of the regulations and procedures themselves."); *City of New York*, 742 F.2d at 737 (claims that "Secretary unlawfully failed individually to assess claimants' residual functional capacity" were "substantially collateral" to claims for benefits); *cf. Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996) (finding claim not collateral where "Plaintiffs were not challenging the validity of agency regulations, but challenging the application of regulations to them.") Moreover, Plaintiff's request for a temporary suspension of the recoupment process and reinstatement of its payments pending an ALJ hearing does not render its claims non-collateral. Even if successful, a ruling on the collateral claims in Plaintiff's favor would not result in the automatic permanent restoration of benefits. Instead, Plaintiff requests that the Court "temporarily suspend the Medicare recoupment process and reinstate ISWS's payments until ISWS is provided with an ALJ hearing." (Compl. ¶¶ 55; 59.) Temporary suspension of recoupment and reinstatement of benefits does not preclude a waiver of the exhaustion requirement. *See Fam. Rehab.*, 886 F.3d at 503 ("plaintiffs may bring claims that sound only in constitutional or procedural law … and request that benefits be maintained temporarily until the agency follows the statutorily or constitutionally required procedures.") (citing *Matthews*, 424 U.S. at 330–32).

However, that portion of Plaintiff's procedural due process claim which argues that the Secretary does not exercise proper oversight over Safeguard despite delegating authority to it is not

collateral to its claim for benefits. Plaintiff's only factual allegation in support of its argument that the Secretary did not exercise proper oversight over Safeguard is the outcome of that process itself, *i.e.*, Safeguard's determination that Plaintiff was overpaid on its benefits claims. (*See* Compl. ¶¶ 42, 43, 45, 51; *see also* Opp. at 19 ("the fact that ISWS's claims were denied based upon standards clearly contradicted by the Secretary's guidance shows that the Secretary does not exercise proper oversight over Safeguard").) Plaintiff describes no procedural irregularities indicating lack of oversight, and the contradictions between the "Secretary's guidance" and the standards used by Safeguard are intertwined with Plaintiff's claims.

Bowen v. City of New York is instructive.[11] There, a class of plaintiffs argued that the Secretary of HHS "adopted an unlawful, unpublished policy under which countless deserving claimants were denied benefits." *Bowen*, 476 U.S. at 473. "[T]he District Court found a systemwide, unrevealed policy that was inconsistent in critically important ways with established regulations." *Id.* at 485. The policy did not "depend on the particular facts of the case before it; rather, the policy was illegal precisely because it ignored those facts." *Id.* Furthermore, the court did not order that class members be paid benefits, but rather that their cases be reopened for proper consideration under the applicable regulations. *Id.*

Here, by contrast, the Court can only evaluate the Secretary's failure to exercise proper oversight of contractors based on the particular facts of Plaintiff's underlying payment dispute. Since that determination would require the Court to evaluate whether Safeguard followed "the Secretary's guidance," it would require the Court to compare Safeguard's merits decision with the Secretary's rules and regulations applicable to Plaintiff's services. Plaintiff is essentially challenging the "application of regulations," rather than the "validity of agency regulations." *See St. Francis Hosp.*, 874 F.Supp.2d at

[11] *Bowen* was on appeal from the Second Circuit's decision in *City of New York v. Heckler*, 742 F.2d 729 (2d Cir. 1984), cited elsewhere herein.

133 (agency's "mere deviation from the applicable regulations … [is] fully correctable upon subsequent administrative review") (quoting *Bowen*, 476 U.S. at 484-85.) That would be precisely a determination on the underlying overpayment decision. And if the Court were to find that Safeguard did not follow the Secretary's guidance, "only essentially ministerial details will remain before [Plaintiff] would receive reimbursement." *See Ringer*, 466 U.S. at 615. Therefore, this portion of Plaintiff's procedural due process claim is not collateral to its claim for benefits.

2. Futility

Exhaustion is futile where it "would serve no legitimate purpose." *Abbey*, 978 F.2d at 45. The Second Circuit has found that there is "no legitimate interest to be advanced by requiring plaintiffs to travel through the administrative maze as a prerequisite of a judicial hearing" where "the administrative process cannot vindicate the procedural rights asserted in this litigation." *City of New York*, 742 F.2d at 737; *see also Mathews v. Diaz*, 426 U.S. 67, 76-77 (1976) (finding exhaustion futile where administrative process could not grant requested relief); *Jimmo v. Sebelius*, No. 5:11-CV-17, 2011 WL 5104355, at *8-9 (D. Vt. Oct. 25, 2011) (exhaustion was futile because successful result in administrative appeals "would not address the thrust of [plaintiffs'] Amended Complaint"); *cf. Washington v. Barr*, 925 F.3d 109, 119 (2d Cir. 2019) (exhaustion of Drug Enforcement Agency administrative review process not futile where plaintiffs could achieve change in classification of marijuana through administrative review process because agency possessed authority to make that change through administrative review).

Here, the next levels of Medicare reviewers cannot grant Plaintiff its requested relief—that is, changes to the statutorily prescribed administrative review process for recoupment of Medicare overpayments.[12] Resort to the administrative review process would therefore be futile. *See St. Francis Hosp.*, 874 F. Supp. 2d at 133 ("much of plaintiff's claims here hinge on questions of constitutional

[12] Plaintiff seeks this relief for all its claims, including those based on lack of oversight.

due process, and the constitutionality of a statute or regulation is generally considered 'a matter [] beyond [the Secretary's] jurisdiction to determine.") (quoting *Weinberger*, 422 U.S. at 765) (alterations in *St Francis Hosp.*).

3. Irreparable Harm

Irreparable harm is generally tied to deteriorating health due to deprivation of benefits or entitlements. *See, e.g.*, *Eldridge*, 424 U.S. at 331; *City of New York*, 742 F.2d at 736 (finding irreparable harm where administrative process "would likely trigger a 'severe medical setback'"). By contrast, the financial hardship claimed by providers seeking Medicare compensation does not constitute irreparable harm. *See, e.g., Pavano*, 95 F.3d at 151; *Abbey*, 978 F.2d at 46 ("[T]he expense and delay of completing the administrative process will not ordinarily justify waiver.") The "exacting standard for waiver [] is 'irreparable harm,' … not hardship." *Okocha v. Disman*, No. 11-CV-1854 (LTS)(JLC), 2012 WL 6860892, at *11 (S.D.N.Y. Oct. 1, 2012), *R&R adopted*, 2013 WL 163834 (S.D.N.Y. Jan. 15, 2013) (quoting *Pavano*, 95 F.3d at 150.)

Plaintiff argues that it is subject not to "mere inconvenience and expense resulting from protracted administrative proceedings," but rather that it will go out of business before the appeals process is completed. (Opp. at 21-22.) It also argues that even the offer of an extended repayment plan would increase the payment amount because it would have to pay interest. (Opp. at 22.) However, such financial harm—even one that poses an existential threat to Plaintiff's business—does not meet the exacting standard required for "irreparable harm."

Plaintiff also argues that bypassing the third and fourth levels of administrative appeal would require it to "forfeit its right to fully develop an administrative record for judicial review" (*Id.*) However, this argument goes to the merits of its due process claim and does not support its allegation

of irreparable harm.[13]

With the exception of Plaintiff's arguments concerning the Secretary's alleged lack of oversight, Plaintiff's claims are collateral to its claims for benefits, and exhaustion would be futile. Although Plaintiff has not shown irreparable harm, that failure does not preclude a waiver of exhaustion. *City of New York*, 742 F.2d 736 ("No one factor is critical.") Waiver is therefore appropriate for the collateral portions of Plaintiff's claims. *See, e.g.*, *Sahara*, 975 F.3d at 528 (citing *Family Rehab., Inc.*, 886 F.3d at 504) (finding subject matter jurisdiction over similar allegations); *Accident, Inj. & Rehab., PC v. Azar*, 943 F.3d 195, 200-01 (4th Cir. 2019) (same).

C. No Review Exception

Notwithstanding the Court's finding that Plaintiff's argument regarding the Secretary's lack of oversight is not collateral, that portion of Plaintiff's procedural due process claim may still be heard if it qualifies for the "no review" exception to exhaustion.

The "no review" exception only applies "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19. The "no review" exception does not apply where following the Medicare administrative appeals process would result in "added inconvenience or cost in an isolated, particular case," but rather where "hardship likely found in many cases turns what appears to be simply a channeling requirement into a *complete* preclusion of judicial review." *Id.* at 22-23 (citing *McNary v. Haitian Refugee Center, Inc.,* 498 U.S. 479, 496-97 (1991)) (emphasis in *Illinois Council*); *see also Fox Ins. Co v. Sebelius*, 381 F. App'x 93, 97 (2d Cir. 2010) (provider's "claimed financial harm does not constitute the circumstances in which CMS's actions and their effects on [the provider] are subject to 'no review at all'" because provider "had the opportunity to avail itself of its administrative remedy, and it has now done so."). The

[13] In any event, as discussed below, Plaintiff has an opportunity to "create [its] record at the QIC stage and thereafter escalate [its] claims to the courts within a period of months." *See Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016).

exception does not apply where the administrative agency lacks the authority to adjudicate a constitutional claim if the statute eventually provides for review in a federal court that can decide the constitutional issue. *See Illinois Council*, 529 U.S. at 23; *see also, e.g.*, *Elgin v. Dep't of Treasury*, 567 U.S. 1, 16-21 (2012) (requiring channeling of review of constitutional challenge to employment decision through the administrative review of the Civil Service Reform Act even where administrative agency could not resolve constitutional issue in favor of employee); *see also Avon Nursing & Rehab. v. Azar*, 410 F. Supp. 3d 648, 654 (S.D.N.Y. 2019), *rev'd on other grounds,* 995 F.3d 305 (2d Cir. 2021) (finding no-review exception did not apply where "Plaintiffs' arguments … conflate their opportunity to obtain certain types of relief with the availability of judicial review."); *cf. Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708-11 (D.C. Cir. 2011) (applying no-review exception because association of doctor-owned equipment providers could not bring any challenge whatsoever to Medicare rules through the administrative process and no parties eligible to bring such a challenge had a sufficient interest to do so).

Because Plaintiff "is indisputably eligible to bring an administrative challenge to the post-payment review process challenged in the case," (Venue Decision at 14), and thereafter seek judicial review of any remaining constitutional challenge to the Secretary's alleged lack of oversight, the "no review" exception does not apply.

Accordingly, the Court lacks subject matter jurisdiction over the portion of Plaintiff's procedural due process claim that alleges that the Secretary does not exercise proper oversight of its contractors. The Court has jurisdiction over the remainder of Plaintiff's claims.

II. Failure to State a Claim

Defendants argue that even if Plaintiff is entitled to a waiver of the exhaustion requirement, the Complaint does not state a claim to relief in either Count I for denial of procedural due process, or in Count II for denial of substantive due process. They contend that Plaintiff does not have a

viable constitutional claim because it does not assert a protected property or liberty interest, delegation to contractors is constitutional, and the process provided by the Medicare Act and implementing regulations is constitutionally adequate. (Def. Mem. of Law at 22-28.)

Plaintiff does not separately argue that it has stated a claim to relief that is plausible on its face and sufficient to withstand a motion to dismiss under Rule 12(b)(6). However, it has made various statements in its arguments for waiver of exhaustion that it has a "colorable constitutional claim." (Opp. at 15, 18.) Accordingly, the Court construes those statements as Plaintiff's opposition to Defendants' Rule 12(b)(6) challenge. In the Complaint and its Opposition, Plaintiff alleges that it has genuine property and liberty interests, delegation to contractors is constitutionally impermissible, delegation to Safeguard denies it due process because Safeguard has a financial incentive to be overly aggressive in recouping overpayments, and the Secretary does not provide sufficient oversight of the private contractors.

A. Count I—Procedural Due Process

"To plead a violation of procedural due process, a plaintiff must plausibly allege that he was deprived of property without constitutionally adequate pre- or post-deprivation process." *J.S. v. T'Kach*, 714 F.3d 99, 105 (2d Cir. 2013). "In order to do this, a plaintiff must 'first identify a property right, second show that the [government] has deprived him of *that* right, and third show that the deprivation was effected without due process." *Id.* (alteration and emphasis in original). *See also Kampfer v. Argotsinger*, 856 F.App'x 331, 334 (2d Cir. 2021) (quoting and citing *T'Kach*).

"Although the Constitution protects property interests, it does not create them. 'Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law—rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.'" *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998) (quoting *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972)).

Despite Plaintiff's citation to *Furlong* for the existence of a protected property interest here, the Second Circuit has not decided the question of whether Medicare providers have a protected property interest in Medicare payments subject to recoupment. (Opp. at 17.) In *Furlong*, the Second Circuit found that the plaintiffs "demonstrated a cognizable property interest" in a particular reimbursement *rate* for services that the parties agreed were reimbursable by Medicare. 156 F.3d at 393, 396 ("We have previously held that professionals who provide services under a federal program such as Medicaid or Medicare have a property interest in reimbursement for their services at the 'duly promulgated reimbursement rate.'") (quoting *Oberlander v. Perales*, 740 F.2d 116, 120 (2d Cir. 1984)). *Furlong* did not examine whether medical providers have a property interest in reimbursement for services that have been deemed *ineligible* for payment and subject to recoupment. Thus, however instructive *Furlong* may be, it does not squarely address the issue here.

District courts across the country are split on whether Medicare providers have a protected property interest in Medicare payments subject to recoupment. Several courts have found that the Medicare Act does create such a property right. *See, e.g.*, *Accident, Injury & Rehab., PC v. Azar*, No. 4:18-CV-2173 (DCC), 2018 WL 4625791, at *7 (D.S.C. Sept. 27, 2018); *Adams EMS, Inc. v. Azar*, No. H-18-1443, 2018 WL 3377787, at *4 (S.D. Tex. July 11, 2018); *Family Rehab., Inc. v. Azar*, No. 3:17-CV-3008-K, 2018 WL 3155911, at *4-5 (N.D. Tex. June 28, 2018). Other courts have found that no such property interest exists. *See, e.g.*, *Alpha Home Health Solutions, LLC v. Sec'y of United States Dep't of Health & Human Servs.*, 340 F. Supp. 3d 1291, 1303 (M.D. Fla. 2018); *Sahara Health Care, Inc. v. Azar*, 349 F. Supp. 3d 555, 572 (S.D. Tex. 2018); *PHHC, LLC v. Azar*, No. 1:18-CV-1824, 2018 WL 5754393, at *10 (N.D. Ohio Nov. 2, 2018); *In Touch Home Health Agency, Inc. v. Azar*, 414 F. Supp. 3d 1177, 1189-90 (N.D. Ill. 2019).

Without deciding whether such a property interest exists, the Court assumes for purposes of the Motion that Plaintiff does have a protected property right, and that it was deprived of that right

when it became subject to recoupment of overpayments made to it. Nevertheless, because the Court finds that the Secretary's delegation of responsibility to Safeguard was not improper, and that the administrative review process is constitutionally adequate to protect any property right, Plaintiff fails to state a claim for a violation of procedural due process.

1. Delegation By the Secretary Was Proper

Plaintiff contends that delegation to private contractors of "regulatory, quasi-judicial, and judicial authority to deprive ISWS of its protected property and liberty interests" is constitutionally impermissible. (Compl. ¶ 51.) Plaintiff also alleges that Safeguard has payment incentives that "necessarily make[] its interests adverse to Medicare providers." (Opp. at 18-19; Compl. ¶¶ 27, 43.)

The delegation that Plaintiff argues is improper was expressly authorized, and at least in part mandated, by Congress. *See* 42 U.S.C. § 1395u(a) ("The administration of this part *shall* be conducted through contracts with medicare administrative contractors under section 1395kk-1") (emphasis added); 42 U.S.C. § 1395kk-1 ("The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all the functions described" in other parts of the Act); 42 U.S.C. § 1395ddd(a) ("There is hereby established the Medicare Integrity Program … under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities, or otherwise, to carry out the activities described" in the Act). That delegation includes reviews of provider activities and "[d]eterminations as to whether payment should not be, or should not have been, made … and recovery of payments that should not have been made." 42 U.S.C. § 1395ddd(b).

Because the Medicare Act expressly provides for delegation, the Court construes Plaintiff's challenge as a facial attack on the constitutionality of the Medicare Act's delegation to private contractors of initial overpayment and recoupment determinations and the first two stages of the appeals process. Plaintiff argues that it states "a colorable constitutional claim" in that "[t]he Fifth

Amendment's Due Process Clause prohibits federal lawmakers from delegating regulatory authority to a private entity." (Opp. at 18.) However, Plaintiff cites to no relevant case law in support of this contention. The cases it does cite—*Carter v. Carter Coal Co.*, 298 U.S. 238 (1936) and *Ass'n of Am. Railroads v. United States Dep't of Transportation*, 896 F.3d 539 (D.C. Cir. 2018) ("*Am. Railroads IV*")—are inapposite.

In *Carter*, the Supreme Court considered legislation that allowed the majority of coal producers and miners to set maximum hours and minimum wages that controlled rates for their competitors, who would suffer the "hazard of enforcement of the drastic compulsory provisions of the act" if they refused to submit. 298 U.S. at 310-11. The Court found the legislation unconstitutional, stating,

> The power conferred upon the majority is, in effect, the power to regulate the affairs of an unwilling minority. This is legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business.

Id. at 311. The holding in *Carter* was not broadly that any delegation of regulatory power to a private entity is improper. Rather, the court emphasized that it found delegation of this nature to a *competitor* to be "clearly arbitrary." *Id.* There is no allegation that the private contractors to whom the Secretary delegates responsibilities under the Medicare Act are Plaintiff's competitors, or that they are even in the same business as Plaintiff of providing medical services to Medicare beneficiaries.

Plaintiff acknowledges that "private entities performing inherently government functions may be delegated with rulemaking authority," but "they may not be competitors in the field they are regulating." (Compl. ¶ 43.) Plaintiff argues that "Safeguard competes with other UPIC companies for CMS contracts while developing policies and standards for auditing Medicare providers. Accordingly, Safeguard has an incentive to implement aggressive collection and auditing policies that only it can provide in order to obtain CMS contracts." (*Id.*) This is not the type of competitor regulation that caused the court concern in *Carter*. Safeguard was not put in a position to regulate its

competitors, *i.e.*, other UPIC companies, nor was a competitor medical provider given authority to regulate Plaintiff.

Plaintiff also cites to *Am. Railroads IV* for the proposition that "[t]o establish a due process violation, the Court must find (1) a self-interested private party (2) given power by Congress to regulate other private parties who may have adverse interests." (Pl. Opp. at 18 (citing *Am. Railroads*, 896 F.3d at 545).) However, in that case, the D.C. Circuit reaffirmed a prior holding (from *Ass'n of Am. R.R. v. Dep't of Transp.*, 821 F.3d 19 (D.C. Cir. 2016) ("*Am. Railroads III*")) that the 2008 Rail Act unconstitutionally delegated authority to Amtrak because "(1) [] Amtrak was economically self-interested in and competing with the freight railroads as to the content of [certain] metrics and standards, and (2) the 2008 Rail Act endowed Amtrak with the power to regulate those competitors." *Am. Railroads IV*, 896 F.3d at 545 (citing *Am. Railroads III* at 31). *Am. Railroads IV* concerned the provisions of the 2008 Rail Act that granted Amtrak and the Department of Transportation's Federal Railroad Administration (the "Administration") the ability to jointly develop metrics and standards for railroads. *Am. Railroads IV* at 542. In the event of disagreement between Amtrak and the Administration, the Rail Act provided for arbitration that would resolve the disagreement and bind the government. *Id.* The issue was not whether Amtrak could regulate other private parties with adverse interests, but whether the Rail Act "empowered Amtrak to impose on its competitors rules formulated with its own self-interest in mind, without the controlling intermediation of a neutral federal agency." *Id.* at 545. The D.C. Circuit found that the binding-arbitration provision in the 2008 Rail Act impermissibly gave Amtrak "independent regulatory muscle and disarmed the Administration" and concluded that removing that provision would be an appropriate remedy to cure the constitutional defect. *Id.* at 545, 551 (remarking that *Am. Railroads III* "specifically noted that a number of arrangements by which regulatory measures were imposed through the 'joint action of a self-interested group and a government agency' had passed constitutional muster.")

Plaintiff's formulation of the rule attributed to *Am. Railroads* is actually a direct quote from *Agendia, Inc. v. Azar*, 420 F.Supp.3d 985, 992 (C.D. Cal. 2019), a case not cited by Plaintiff, but whose holding contradicts Plaintiff's argument. *Agendia* involved a clinical laboratory's challenge to the constitutionality of the Secretary's delegation of authority to MACs to issue LCDs. The district court there, citing to Supreme Court and Third Circuit decisions, concluded that "Congress may delegate regulatory authority to a private party when there is agency authority and supervision over the activities of those parties." *Agendia*, 420 F.Supp.3d at 993 (citations omitted). *Agendia* therefore held that the Medicare Act's delegation of authority to MACs to issue Local Coverage Determinations was constitutional because the government ultimately "'has authority and surveillance over the activities' of the MACs." *Id.* at 994 (quoting *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399 (1940)) ("Even assuming that [the MAC] is self-interested in a way that may affect their decisions in creating LCD and other programs and policies, the Court finds there is sufficient independent check on the MACs through the claims appeal process that was fully utilized here.") This portion of the district court's decision in *Agendia* was recently affirmed on appeal by the Ninth Circuit, which held that delegation of authority to create LCDs to MACs does not violate the constitution because MACs "'function subordinately' to the Secretary." *Agendia Inc. v. Becerra*, 4 F.4th 896, 902-03 (9th Cir. 2021) (quoting *Sunshine*, 310 U.S. at 399).

The Second Circuit has acknowledged the necessary role that private contractors play in the administration of Medicare. *See, e.g.*, *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 73 (2d Cir. 1998) ("The carriers and fiscal intermediaries that administer the millions of Medicare claims filed annually are indispensable components of the governmental program and are in a unique position to combat the drain on public resources caused by fraudulent claims.") While the Act allows contractors to issue LCDs, make initial payment determinations, and make overpayment and recoupment decisions, those decisions are subject to review by government actors. *See, e.g.*, 42 C.F.R. § 405.1062(a) (LCDs not

binding on the government); 42 C.F.R. §§ 405.1000, 405.1006; *see also* 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. § 405.1100; *see also* 42 U.S.C. § 1395ff(d)(2) (providing for *de novo* review of contractor payment and recoupment determinations by agency ALJs and the Appeals Council).

Because MACs and UPICs do not compete with Medicare providers and because the Act expressly provides for oversight and review of their determinations through the *de novo* administrative review process, delegation of responsibilities to them does not run afoul of any anti-delegation doctrine. Plaintiff's allegation that private contractors have an incentive to deny claims, standing alone within the statutory and regulatory framework of the Medicare Act, is insufficient to create an unconstitutional delegation. Accordingly, Plaintiff's improper delegation arguments fail to state a valid constitutional claim.

2. Delay in ALJ Hearing

Plaintiff alleges that the Secretary's failure to provide it with a prompt ALJ hearing deprived it of due process because by the time it receives a hearing, it will be driven out of business by the ongoing recoupment process. (Compl. ¶ 52.)

In evaluating the constitutional adequacy of the procedures here, pursuant to *Matthews v. Eldridge*, 424 U.S. 319, 335 (1976), the "court must consider '(1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedures used and the probable value of additional or substitute procedural safeguards; and (3) the fiscal and administrative burdens that the additional or substantive procedures entail.'" *Furlong*, 238 F.3d at 236 (quoting *Isaacs v. Bowen,* 865 F.2d 468, 476 (2d Cir.1989)).

The Fourth and Fifth Circuits have recently considered similar allegations regarding the constitutionality of Medicare overpayment and recoupment procedures in light of delays in ALJ review, analyzed those allegations under the *Eldgridge* factors, and held that the procedures pass constitutional muster. *See Sahara,* 975 F.3d at 530; *Accident, Inj. & Rehab.*, 943 F.3d. Both courts

rejected the plaintiffs' arguments that an ALJ hearing provides indispensable procedural protections, instead concluding that, given the limited additional procedural mechanisms available at an ALJ hearing and the limited ability for additional factfinding, ALJ hearings would provide little additional protections. *Sahara*, 975 F.3d at 531-532; *Accident, Inj., & Rehab.*, 943 F.3d at 204. Both Circuit Courts held that the first two levels of administrative review, combined with *either* ALJ and Appeals Council review *or* bypass of those levels of review through escalation, provided the plaintiffs with sufficient procedural protections. *Sahara*, 975 F.3d at 532-33 ("Sahara received some procedure, chose to forego additional protections, and cannot demonstrate the additional value of the hearing it requests."); *Accident, Inj., & Rehab.*, 943 F.3d at 204-05 ("At bottom, while [plaintiff] has elected not to avail itself of the escalation procedure in favor of pursuing delayed ALJ review, it cannot complain that its election denies it due process. Because the escalation procedure is specifically made part of the process to ensure a timely post-deprivation review *in a court of law*, [plaintiff] cannot succeed on its procedural due process claim." (emphasis in original))[14]

The Court finds these decisions persuasive. Here, the first and third *Eldridge* factors weigh in favor of Plaintiff. Plaintiff's private interest is substantial, regardless of whether Medicare accounts for half, most, or all of its revenues, and that private interest "outweighs the government's interest in efficient recoupment administration." *See Sahara*, 975 F.3d at 529. But the first two layers of Medicare administrative review provide substantial protections and allow providers to develop a complete record for judicial review. For example, on redetermination, Medicare regulations direct providers to "include any evidence that the party believes should be considered by the contractor when making its

[14] Neither the *Sahara* nor the *Accident, Inj., & Rehab* plaintiffs challenged the constitutionality of the first two steps of the recoupment process. 975 F.3d at 532 ("Sahara does not allege that the recoupment procedure itself is structured in an unconstitutional way"); 943 F.3d at 203 ("[plaintiff] does not contend that HHS failed to follow the specified administrative process or that the process itself is unconstitutional.") Plaintiff here does challenge the constitutionality of the process, but, for the reasons above, the Court finds those challenges unconvincing.

redetermination," and require an individual from the contractor not involved in the initial determination to review "any additional evidence the parties submit or the contractor obtains on its own." 42 C.F.R. §§ 405.946, 405.948. Similarly, reconsideration by a QIC is "an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim." 42 C.F.R. § 405.968. The provider may again submit comprehensive evidence, including evidence that was missing in the redetermination. 42 C.F.R. § 405.966. The QIC conducting the reconsideration must "review[] the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own." 42 C.F.R. § 405.968(a)(1). Determinations of whether a service was reasonable and necessary "must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable." 42 C.F.R. § 405.968(a)(1). These procedures allow for the development of a full record of all the facts before recoupment begins.

The Act then allows for recoupment, but provides *either* two more layers of administrative review by an ALJ and the Appeals Council followed by judicial review, 42 C.F.R. §§ 405.1000, 405.1006; 42 C.F.R. § 405.1100; 42 U.S.C. § 1395ff(b)(1), (d)(2); 42 C.F.R. § 405.1130; 42 U.S.C. § 405(g), or bypass of the administrative reviews to federal court, 42 C.F.R. §§ 405.1132, 405.1100(d), 405.1106(b), 42 U.S.C. § 1395ff(d)(3)(B).[15] On either path, the next levels of appeal have complete

[15] Plaintiff cites to *A1 Diabetes & Med. Supply v. Azar*, 937 F.3d 613, 618-20 (6th Cir. 2019) for the propositions "that administrative review at the third and fourth levels are not necessary" and that escalation "would restrict the district court's review to the written administrative record." (Opp. at 20.) *A1 Diabetes* does not support Plaintiff's argument. The Sixth Circuit did not make those holdings, and instead remanded the case to the district court for additional findings on key questions surrounding the plaintiff's requested relief, the additional procedural protections that would be available in an ALJ hearing, and the additional factual development plaintiff would give up if it pursued escalation in lieu of administrative exhaustion. *A1 Diabetes*, 937 F.3d at 618-21.

records on which to evaluate the earlier administrative decisions.

These procedures provide Plaintiff with pre-deprivation opportunity to be heard, post-deprivation review, and the possibility of correcting any errors, which together reduce the risk of erroneous deprivation of any interest Plaintiff has in Medicare reimbursements subject to recoupment. Moreover, the procedures provide the ability to bypass up to two levels of administrative review in the event of delay, thus hastening judicial review of overpayment determinations. These procedures satisfy due process, and, therefore, Plaintiff's procedural due process claim fails under Rule 12(b)(6).

B. Count II—Substantive Due Process

Plaintiff alleges that Defendants acted "arbitrarily and capriciously by allowing a private contractor to determine that all claims submitted by ISWS during an 18-year period resulted in overpayment." (Compl. ¶ 57.) It contends that Safeguard's actions "essentially forced ISWS out of business and effectively deprived ISWS of its fundamental right to practice its profession." (*Id.*) Defendants argue that these allegations fail to state a claim to relief. (Def. Mem. of Law at 23-24.)

The Due Process Clause provides substantive "protection against arbitrary [government] action." *Kia P. v. McIntyre*, 235 F.3d 749, 758 (2d Cir. 2000) (quoting *Cty. Of Sacramento v. Lewis*, 523 U.S. 833, 845 (1998) (alteration in *Kia P.*)) To plead a substantive due process violation, a plaintiff must show (1) a valid property or liberty interest and (2) infringement upon that interest in an arbitrary or irrational manner. *See Kampfer*, 856 F.App'x at 334 (quoting *Royal Crown Day Care LLC v. Dep't of Health & Mental Hygiene of City of N.Y.*, 746 F.3d 538, 545 (2d Cir. 2014)). "Arbitrary or capricious" conduct does not satisfy this standard. *Natale v. Town of Ridgefield*, 170 F.3d 258, 263 (2d Cir. 1999). Instead, the denial of a protected interest "must have occurred under circumstances warranting the labels 'arbitrary' and 'outrageous.'" *Id.* at 262 (2d Cir. 1999) (citing *Cty. of Sacramento*, 523 U.S. 833 (1998)). "Substantive due process standards are violated only by conduct that is so outrageously arbitrary as to constitute a gross abuse of governmental authority." *Natale*, 170 F.3d at 263.

Even if Plaintiff has "protected property and liberty interests in providing psychotherapy services to elder homebound patients," (*see* Compl. ¶ 57), for the reasons above, the Secretary's delegation of administrative responsibility to private contractors, subject to government oversight and district court review, was neither arbitrary nor outrageous. *See, e.g.*, *Pani*, 152 F.3d 73. Nor is the process to contest an overpayment or a recoupment decision arbitrary, outrageous, or even inadequate.

Count II of the Complaint alleging a violation of substantive due process therefore fails to state a claim to relief.

III. Leave to Amend

Requests to amend a complaint are governed by Rule 15 of the Federal Rules of Civil Procedure, which provides that once the period to amend as a matter of course has passed, "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). Rule 15 also states that "the court should freely give leave when justice so requires." *Id.*; *see also Pinyuk v. CBE Grp., Inc.*, No. 17-cv-5753 (RRM)(CLP), 2019 WL 1900985, at *2 (E.D.N.Y. Apr. 29, 2019) ("Rule 15 expresses a strong presumption in favor of allowing amendment"). Leave to amend may be denied "for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *Id.* An amendment is not futile when it would make a complaint "sufficient to withstand a motion to dismiss under Rule 12(b)(6)." *Kassner v. 2nd Ave. Delicatessen Inc.*, 496 F.3d 229, 244 (2d Cir. 2007); *see also IBEW Local Union No. 58 Pension Trust Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 389 (2d Cir. 2015) ("[T]he standard for denying leave to amend based on futility is the same as the standard for granting a motion to dismiss.") The determination of whether to grant or deny leave to amend "is within the sound discretion of the district court." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007).

Plaintiff proposes to amend its complaint "to include facts demonstrating that it has a property

interest in the receipt of Medicare payments," to "add facts demonstrating that exhaustion would [be] futile," and to "include facts showing irreparable harm would result if it was required to exhaust its administrative remedies." (Opp. at 25.) These proposed amendments would not cure the deficiencies identified above. The Court already held that exhaustion would be futile, and even if Plaintiff has a property interest in the receipt of Medicare payments or if it would suffer irreparable harm, it still fails to state a claim to relief. These proposed amendments would do nothing to show that the Act or the Secretary's implementation of it denies Plaintiff procedural or substantive due process. As such, amendment would be futile and leave to amend is denied.

CONCLUSION

For the reasons above, Defendant's Motion is GRANTED. The portion of Plaintiff's procedural due process claim that seeks relief based on the Secretary's lack of oversight is dismissed pursuant to Rule 12(b)(1), and the remainder of Plaintiff's procedural due process claim and its substantive due process claim are dismissed pursuant to Rule 12(b)(6). The Clerk of the Court is respectfully directed to close this case.

SO ORDERED:

Peggy Kuo

PEGGY KUO
United States Magistrate Judge

Dated: Brooklyn, New York
September 30, 2021