UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY, *et al.*,	
Plaintiffs,	
v.	**Case No. 16-cv-00157 (RMC)**
THOMAS E. PRICE, M.D., Secretary of the Department of Health and Human Services, *et al.*	
Defendants.	

MEMORANDUM OPINION

The case before the Court is an action brought by a collection of insurers operating under the UnitedHealthcare Insurance Company umbrella (United) which are participating in the Medicare Advantage Program. Under Medicare Advantage, insurers provide Medicare insurance coverage in lieu of the government itself. Defendants are (1) the Secretary for Health and Human Services in her official capacity; (2) the Centers for Medicare and Medicaid Services (CMS), a constituent agency of HHS, which administers the Medicare Advantage program; and (3) the United States of America. The Plaintiffs challenge a recent CMS rulemaking concerning the obligations of Medicare Advantage insurers.

Defendants have moved to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *See* Defs.' Mot. to Dismiss [Dkt 12] (Mot. to Dismiss). Plaintiffs have opposed, *see* Pls.' Opp. [Dkt. 14] (Opp.), and Defendants have replied, *see* Defs.' Reply [Dkt. 17] (Reply). Plaintiffs sur-replied, *see* Pls.' Sur-Reply [Dkt. 19] (Pls.' Sur-Reply), and Defendants sur-sur-replied, *see* Defs.' Sur-Reply [Dkt. 21] (Defs.' Sur-Reply).

Finally, Defendants submitted a Notice of Supplemental Authority [Dkt. 23], to which Plaintiffs have submitted a Response [Dkt. 24].

Despite the extensive briefing, the overarching questions before the Court can be summarized as follows: (1) Has CMS's new rule imposed a novel legal obligation on Plaintiffs, and, if so, (2) under the existing circumstances, may Plaintiffs challenge the rule in this Court without waiting for Defendants to bring an enforcement action? For the reasons stated below, the Court answers yes to both questions. It therefore concludes that Plaintiffs have standing and will deny Defendants' Motion to Dismiss. At this point, the merits are not addressed.

I. BACKGROUND

The Medicare Advantage (MA) program allows Medicare-eligible individuals to receive healthcare benefits through private insurance plans that have contracted with CMS. Compl. [Dkt. 1] ¶ 24. A Medicare Advantage insurer must provide, at a minimum, the same level of benefits provided by Medicare itself. *Id.* ¶ 26. Medicare Advantage insurers reimburse healthcare providers for services to Medicare beneficiaries covered by a Medicare Advantage insurer; the Medicare Advantage insurers are reimbursed themselves by CMS on a pre-set, per-member-per-month basis. *Id.*

Congress requires CMS to pay Medicare Advantage insurers in a manner that "ensures actuarial equivalence" between Medicare and Medicare Advantage plans. *Id.* ¶ 32, *see* 42 U.S.C. § 1395w-23(a)(1)(C)(i). To do this, CMS first calculates the average monthly expenditure for the average Medicare beneficiary. Compl. ¶ 30. However, because not all Medicare beneficiaries are the same, CMS then adjusts these baseline repayments according to the beneficiary profile of particular Medicare Advantage plans. *Id.* ¶ 32. To make these adjustments, CMS gathers demographic data as well as health history data, the latter of which are primarily provided to CMS by the Medicare Advantage insurer. *Id.* ¶ 33. Specifically, health

history data relies on specific diagnostic codes submitted by the healthcare providers to the Medicare Advantage insurers. *Id.* ¶ 34. These diagnostic codes can vary in granularity and content, and serve as a rough guide to what services have been provided by healthcare professionals to a patient. *Id.* The diagnostic codes are designated by healthcare providers to reflect patient conditions and medical needs and then sent to the Medicare Advantage insurers as part of the billing process. *Id*. The Medicare Advantage insurers compile these codes and submit them to CMS, which uses the data to make adjustments to its monthly payment based on the relative health of a particular Medicare Advantage insurer's enrollees. *Id.* In theory, if a Medicare Advantage insurer's enrollee had diagnosis codes that suggested a 20% higher annual coverage cost than the average Medicare beneficiary, the monthly payment to that Medicare Advantage insurer would be adjusted upwards to cover that cost. *Id.* ¶ 36.

Unfortunately, diagnostic codes in healthcare records are often miscoded, inappropriately added, or otherwise faulty. Medical professionals often cite incorrect diagnostic codes when preparing their billing, and Plaintiffs suggest that the error rate can be as high as 20%. *Id.* ¶ 38. In the past, neither CMS nor the Plaintiffs made efforts to review categorically the diagnostic codes assigned by healthcare providers to individual patients. *Id.* ¶ 40. As a result, CMS has treated the diagnostic codes as conclusively valid for its own payment purposes. *Id*. Regulations oblige Medicare Advantage insurers to certify "based on best knowledge, information and belief" that the information they provide to CMS, including the diagnostic codes included in the Medicare Advantage insurers' risk adjustment data, are "accurate, complete and truthful." *Id*. ¶ 41; 42 C.F.R. § 422.504(*l*)(2). However, Plaintiffs allege that neither this pre-existing regulation, nor any other regulation, has in the past obligated Medicare Advantage insurers to validate diagnostic codes independently. Compl. ¶ 42. They assert that Medicare

Advantage providers have not heretofor reviewed the underlying medical information from which particular diagnostic codes arose, and neither has CMS. *Id.* ¶ 42.

Nonetheless, it is widely known that the entry of diagnostic codes by medical professionals is often faulty. In order to adjust for mistakes—as well as fraud—CMS conducts what are known as Risk Adjustment Data Validation (RADV) audits. *Id.* ¶ 45. Every year, CMS selects a group of Medicare Advantage insurers for audit, *id.*, and reviews the underlying medical charts for a sample of each insurer's beneficiaries to determine whether the medical charts justify the diagnostic codes. *Id.* ¶¶ 46, 47. To the extent these adjustments result in a corrected risk score, monthly payments are adjusted accordingly. *Id.* ¶ 47. The results of these audits are extrapolated for Medicare Advantage insurers generally to calculate an average estimated error rate for the year. *Id.* ¶ 47. If the error rate is positive—if a Medicare Advantage insurer is being reimbursed for more services than were provided—the insurer is responsible for returning any overpayment to CMS. *Id.* ¶ 48.

In the past, CMS proposed requiring overpayment returns on an absolute basis, which would have meant that any errors found by an audit would be subject to return by the Medicare Advantage insurer if it resulted in an overpayment. *Id.* ¶ 49. Ultimately however, CMS included a "Fee-For-Service adjuster" (FFS adjuster) arising from CMS payments to Medicare beneficiaries, which reflects the expected error rate in the use of diagnostic codes relied upon by Medicare. The FFS adjuster reflects CMS's own estimate of the average error in diagnostic codes for its Medicare participants and essentially acts as a buffer for overpayments; Medicare Advantage providers are thereby only responsible for overpaying for any errors above and beyond CMS's own estimated error rate. Medicare Advantage plans run the risk of needing

to return overpayments if the diagnostic codes they submit are unusually error-prone compared to Medicare's reliance on diagnostic codes.

Plaintiffs state that the FFS adjuster works to counteract the fact that initial payments to Medicare Advantage insurers are based on a less precise set of data than that which is reviewed during an audit. Plaintiffs also state that the FFS adjuster was added at the urging of the American Academy of Actuaries to ensure that CMS would fulfill its statutory obligation to treat Medicare Advantage insurers with "actuarial equivalence."[1] *Id*. ¶ 50.

Within this context, Congress passed the Affordable Care Act (ACA) in 2010. Pub. L. No. 111-148, 124 Stat. 119 (2010). As relevant here, the ACA imposed an obligation on insurers that receive federal payments to report and return overpayments that the insurers discover on their own. *See* Pub. L. No. 111-148, § 6402, 124 Stat. at 755-56, codified at 42 U.S.C. § 1320a-7k(d)(1) (2012). This section of the ACA defines "overpayment" as "any funds that a person receives or retains under [Medicare] to which the person, after applicable reconciliation, is not entitled." *Id*. § 1320a-7k(d)(4)(B). It further requires that any "overpayment . . . be reported and returned [within] 60 days after the date on which the overpayment was identified." *Id*. § 1320a-7k(d)(2). Under the law, if a Medicare Advantage insurer fails to return an overpayment within 60 days of identifying it, that failure would render the insurer's initial but faulty claim for payment a violation of under the False Claims Act (FCA). *Id*. § 1320a-7k(d)(3)("Any overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title."); *see* False Claims Act, 31 U.S.C. § 3729 *et*

[1] While the full context of "actuarial equivalence" has not been discussed by the parties at this stage of the litigation, it presumably includes circumstances in which insurance companies process payments directly for Medicare.

seq. (2012). False Claims Act claims carry with them the potential for treble damages and civil penalties, and can result in disbarment from Medicare. *See* Compl. ¶ 58. Further, non-government *qui tam* plaintiffs may bring FCA claims in federal court. *Id.* ACA § 6402 lays out a basic statutory framework, but leaves several terms undefined. For example, it does not defined what "identified" means for triggering the 60-day clock, s*ee* Compl. ¶ 57, nor state explicitly whether "overpayments" are intended to incorporate an FFS adjustor threshold as do RADV audits.

In order to implement ACA § 6402, CMS issued a notice of proposed rulemaking in January 2014. Compl. ¶ 59; *see* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014). CMS proposed a new regulation, 42 C.F.R. § 422.326, titled "Reporting and Returning Overpayments," that was intended to "clarify the statutory definition of overpayment." 79 Fed. Reg. at 2055-56, 1996; *see* Compl. ¶ 59.

After engaging in notice and comment, CMS published the final rule in May 2014, which finalized 42 C.F.R. § 422.326 concerning overpayments (the CMS Rule). *See* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014). Under the CMS Rule, any inadequately documented diagnostic code not supported by underlying medical documentation will result in an overpayment. *Id*. at 29,921. Further, the CMS Rule specified that any overpayment would be considered "identified" when a Medicare Advantage insurer determined, or *should have determined* through reasonable diligence, that it had received an overpayment. *Id*. at 29,923. CMS further stated that reasonable diligence would require "at a minimum . . . proactive compliance activities conducted in good faith by qualified

individuals to monitor for the receipt of payments." *Id.* Plaintiffs allege that these obligations apply a negligence standard for purposes of False Claims Act liability. *See* Compl. ¶ 78. They allege further that this is a lower standard than that actually required by the FCA, which contains a recklessness standard. *Id.*; *see* False Claims Act, 31 U.S.C. § 3729(b) (defining "knowing" and "knowingly").

Plaintiffs also contend that the CMS Rule, which does not adopt the "FFS adjuster" buffer that exists in RADV audits, violates the statute's requirement that Medicare Advantage insurers be treated with "actuarial equivalence" to CMS and, instead, subjects them to a more searching form of scrutiny than CMS applies to its own enrollee data. Compl. ¶ 80. By requiring Medicare Advantage insurers to confirm diagnostic codes through review of underlying medical charts—while not conducting such reviews under Medicare proper—CMS allegedly will systematically underpay for beneficiaries' care to Medicare Advantage insurer plans compared to payments if that same beneficiary were in a traditional Medicare plan. *Id.* ¶ 81. Plaintiffs also argue that, by applying what amounts to a "negligence" standard of liability, the CMS Rule "cannot be squared with the language of the Act." *Id.* ¶ 78.

The merits of the case are not before the Court at this time. The present issue is whether the Plaintiffs, as Medicare Advantage insurers, have standing to challenge the CMS Rule.

II. LEGAL STANDARD

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, a defendant can move to dismiss a complaint, or any portion thereof, for lack of subject matter jurisdiction in federal court. Fed. R. Civ. P. 12(b)(1). No action by the parties can confer subject matter jurisdiction on a federal court because subject matter jurisdiction is both a statutory requirement and an Article III requirement. *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir.

2003). The party claiming subject matter jurisdiction bears the burden of demonstrating that such jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); *see Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (noting that federal courts have limited jurisdiction and that "[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction"). When reviewing a motion to dismiss for lack of jurisdiction under Rule 12(b)(1), a court must construe the complaint liberally, giving the plaintiff the benefit of all inferences that can be derived from the facts alleged. *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). Nevertheless, "the court need not accept factual inferences drawn by plaintiffs if those inferences are not supported by facts alleged in the complaint, nor must the Court accept plaintiffs' legal conclusions." *Speelman v. United States*, 461 F. Supp. 2d 71, 73 (D.D.C. 2006).

III. ANALYSIS

Defendants have moved to dismiss, asserting that Plaintiffs lack both Article III and statutory standing to bring their suit before a court.

A. Article III Standing

Standing is part and parcel of Article III's limitation on the judicial power of the United States, which extends only to "cases or controversies." U.S. Const. Art. III, § 2. "No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). "The 'core component' of the requirement that a litigant have standing to invoke the authority of a federal court 'is an essential and unchanging part of the case-or-controversy requirement of Article III.'" *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). "At bottom, 'the gist of the question of standing' is whether petitioners have 'such

a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination.'" *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007) (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)). The strictures of Article III standing are by now "familiar." *United States v. Windsor*, 133 S. Ct. 2675, 2685 (2013). Standing requires (1) the plaintiff to have suffered an injury in fact that is both (a) concrete and particularized and (b) actual or imminent, as opposed to conjectural or hypothetical; (2) the injury to be traceable to the defendant's actions; and (3) the injury to be redressable by a favorable decision of the court. *See id.* at 2685-86 (citing *Lujan*, 504 U.S. at 559-62).

"The Supreme Court has stated that 'there is ordinarily little question' that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated." *State Nat. Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (quoting *Lujan*, 504 U.S. at 561-62). In *Big Spring*, the United States Circuit Court for the District of Columbia Circuit found that a bank subject to regulation by the Consumer Financial Protection Bureau had standing to bring a claim against the CFPB because CFPB regulations "impose[] disclosure requirements on institutions" such as the bank and the bank "must now monitor [a relevant part of its business], and the monitoring program causes it to incur costs." 795 F.3d at 53.

Plaintiffs have asserted that, as Medicare Advantage insurers, they are the intended objects of the CMS Rule and therefore have standing to challenge it.[2] Opp. at 19-21.

[2] In support of this position, Plaintiffs have predominantly cited cases dealing with the doctrine of ripeness. *See* Opp. at 19, 20 (citing, *inter alia*, *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272 (D.C. Cir. 2005). While the two are similar, it is important to emphasize that the doctrines are different, with separate analyses and occasionally different outcomes. *See AT&T Corp. v. FCC*, 349 F.3d 692, 702 (D.C. Cir. 2003) (finding Article III

The Court agrees that the text and character of the CMS Rule establish the kind of obligation contemplated by *Lujan* and *Big Spring*. The CMS Rule itself requires Medicare Advantage insurers to undertake "reasonable diligence" in certifying that diagnostic code information is supported by underlying medical charts. 42 C.F.R. § 422.326. In its response to notice and comment on the rule, the government stated that it expects "reasonable diligence" to require "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments." 79 Fed. Reg. at 29,923. Plaintiffs have alleged that the CMS Rule, effective since July 2014, imposes new "obligations" on Medicare Advantage insurers. *See* Compl. ¶ 9. The active obligation currently imposed by the CMS Rule on the Medicare Advantage insurers to engage in "proactive compliance activities" by "qualified individuals" falls squarely into the kind of regulation contemplated by *Lujan* and *Big Spring* to establish standing.

The government responds that Plaintiffs argue for *per se* standing. *See* Reply at 5-8. That phrase never appears in Plaintiffs' briefs nor in any case Plaintiffs cite. While the government cites multiple cases involving, *inter alia*, gun owners, passport holders, and Sierra Club members, none of these cases is inconsistent with, or otherwise challenges, the general framework relating to regulated entities, as articulated in *Lujan* and *Big Spring*. *See* Reply at 5-7 (citing *Parker v. District of Columbia*, 478 F.3d 370 (D.C. Cir. 2007)(gun owners); *Zivotofsky v.*

---

standing but dismissing for lack of ripeness). While the Court understands the parties to be contesting Plaintiffs' Article III standing, it finds that the matter is ripe for review. "The Supreme Court's landmark decision in *Abbott Laboratories* largely resolved the ripeness issue for many challenges to agency action. There, the Supreme Court ruled that affected parties could challenge agency regulations in pre-enforcement suits. The Supreme Court explained that regulated parties generally need not violate a law in order to challenge the law." *Big Spring*, 795 F.3d at 53-54 (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-53 (1967)). Such is the case here.

Sec'y of State, 444 F.3d 614 (D.C. Cir. 2006)(passport holders); *Sierra Club v. EPA*, 292 F.3d 895 (D.C. Cir. 2002)(Sierra Club members)). The Court therefore construes the government's argument as challenging the sufficiency of Plaintiffs' allegations of harm. *See* Reply at 7 ("[Plaintiffs have not even offered factual allegations that could be backed up with evidentiary submissions . . . ."). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presume that general allegations embrace those specific facts that are necessary to support the claim.'" *Lujan* 504 U.S. at 561 (1992) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 883-889 (1990)). It is only at the summary judgment stage that "the plaintiff can no longer rest on such 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts,'" *Lujan*, 504 U.S. at 561. Plaintiffs have alleged that they are Medicare Advantage insurers and that the CMS Rule is actively in effect. Compl. ¶¶ 1, 9. The agency's own interpretation of the CMS Rule requires Medicare Advantage insurers to engage in "proactive compliance activities" sufficient to validate medical care with diagnostic codes. 79 Fed. Reg. at 29,923. *Lujan* does not require the Court to demand an in-depth accounting of the cost of compliance activities when the CMS Rule itself requires affirmative compliance efforts on its face. Plaintiffs have adequately pled injury-in-fact.

Because the CMS Rule's affirmative obligations establishes an injury-in-fact upon Plaintiffs, the Court now must consider the remaining two components of Article III standing. The Court concludes that Plaintiffs have met their burden. The Court has found injury through the compliance obligations imposed on the Plaintiffs by the CMS Rule. While the parties veer repeatedly into territory that might be better understood as addressing the merits of the Complaint or whether Plaintiffs have been injured at all, their arguments about traceability and redressability essentially collapse into one question: Did the CMS Rule impose a novel legal

obligation on Plaintiffs or simply restate pre-existing obligations? If it is the latter, then Plaintiffs' injury is not fairly traceable to the CMS Rule. Similarly, any injury could not be redressed because the preexisting obligations would still require Plaintiffs to carry out the same activities.

The government asserts that Medicare Advantage insurers are otherwise obligated to exercise "due diligence" and undertake "good faith efforts" to certify that the information they submit to CMS is accurate. Mot. to Dismiss at 15-16 (citing 42 C.F.R. § 422.504(*l*)(2)). The government also argues that 42 C.F.R. § 422.503(b)(4)(vi) requires Medicare Advantage insurers to adopt and implement effective compliance programs to ensure fraud detection and reporting accuracy. *Id*. It scorns Plaintifs' argument as an attempt to get paid for erroneous entries. *See, e.g.,* Mot. to Dismiss at 1.

Parties also dedicate part of a reply, a sur-reply and a sur-sur-reply to the Ninth Circuit decision *United States ex rel Swoben v. United Healthcare Ins. Co.*, No. 13-56746 (9th Cir. Aug. 8, 2016). *Swoben*, a non-controlling case in this Circuit, is of limited use because it does not involve any Rule 12(b)(1) standing issue, does not concern the CMS Rule, and involved a defendant Medicare Advantage insurer that allegedly concealed coding information. *See Swoben*, slip op. at 15. *Swoben* held that a *qui tam* plaintiff could state a cognizable claim under Rule 12(b)(6) that a Medicare Advantage insurer who concealed and otherwise failed to report faulty diagnostic codes failed to exercise due diligence as required by 42 C.F.R. § 422.504(*l*)(2). The government points to *Swoben* as evidence that the Plaintiffs have a pre-existing obligation to exercise due diligence and therefore cannot show redressability. *See* Reply at 15. *Swoben* is not the droid the Secretary is looking for.

The CMS Rule requires Medicare Advantage organizations to undertake "reasonable diligence" which the agency explains requires "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments." 79 Fed. Reg. at 29,923. While the Secretary points to other requirements that Plaintiffs must exercise "due diligence," CMS has pointed to no other regulation where the statute has been interpreted to apply such a standard, either to CMS or to Medicare Advantage insurers. In essence, the Secretary would have the Court find that the CMS Rule's insistence on "proactive compliance activities," under pain of a False Claims Act suit provable by negligence alone, is meaningless. It is not; it imposes (for good reason or not) new obligations. Plaintiffs have established Article III standing.

B. Statutory Standing

A federal court must assure itself of both constitutional and statutory subject matter jurisdiction. Typically, when a plaintiff seeks redress for an issue involving a federal law, 28 U.S.C. § 1331 confers subject matter jurisdiction on district courts to hear that case. *See* 28 U.S.C. § 1331 (2012) (conferring jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States"). However, Congress has from time to time restricted this general grant of jurisdiction. One such instance is the Medicare Act, which incorporates certain jurisdictional restrictions originating in the Social Security Act, to which Medicare was an addition.

The mechanisms providing for administrative review are complicated. Certain provisions of the Social Security Act provide for administrative review of proceedings. *See* 42 U.S.C. § 405 (2012). In particular, § 405(b) allows an aggrieved party with a dispute under the Social Security Act to bring such grievances in an administrative hearing before an SSA Administrative Law Judge and then to the Commissioner of Social Security. Section 405(g)

provides for judicial review of a § 405(b) hearing. Finally, § 405(h) states that it provides the exclusive path to bring any complaints under the Social Security Act: "No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No 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).

Section 405 does not apply "on its own terms" to Medicare, *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 680 (1986), but Congress has extended these provisions to claims arising under the Medicare Act. At 42 U.S.C. § 1395ii, Medicare incorporates most provisions of § 405 *mutatis mutandis* into the Medicare Act, although not §§ 405(b) and 405(g). *See* 42 U.S.C. § 1395ii ("[S]ubsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter . . . ."). The Medicare statute does provide that certain categories of disputes must be channeled through the procedures set forth in §§ 405(b) and 405(g); for example, § 1395ff(b)(1) allows beneficiaries dissatisfied with a benefit determination to challenge that determination through a hearing as provided in § 405(b). *See* § 1395ff(b)(1). Where a § 405(b) hearing is available, or an administrative procedure is otherwise provided, § 405(h) makes that procedure the exclusive avenue for aggrieved parties to challenge a CMS decision. Accordingly, "§ 405(h)[] channels most, if not all, Medicare claims through" administrative procedures before they may be brought into a federal court. *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 8 (2000).

However, not all claims that can conceivably arise under the Medicare Act are necessarily afforded an administrative hearing. *Illinois Council* recognized that direct judicial

review is not foreclosed to plaintiffs where it would mean "no review at all." 529 U.S. at 20-21. "No review at all" means one of two things: Firstly, when there is literally no avenue for judicial review, because no prior administrative route for reviewing a claim exists; and, secondly, where a claim is foreclosed as a practical matter because the likelihood of severe sanctions for noncompliance is so great that it serves to "deny review in practice." *Id*. at 20-22. For sanctions to be so great as to deny review in practice, they must go beyond the typical burdens associated with administrative review, such as "occasional individual delay related hardship." *Id.* at 13, 22-23 ("[W]e do not hold that an individual party could circumvent [the Medicare Act's] channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case."). Further, the fact that a particular plaintiff may not have an avenue to challenge a particular regulation is not sufficient to escape § 405(h) where other, similarly-motivated plaintiffs may have an avenue of appeal. *See Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 817 (D.C. Cir. 2005) (finding no standing where theoretical plaintiffs could obtain administrative review even though that option was not available to plaintiffs before the court).

There is no direct appeal process that allows these Plaintiffs to challenge the promulgated CMS Rule on their own initiative, under § 405(b) or otherwise. Further, CMS does not bring enforcement actions; if it determines that Plaintiffs have received an overpayment, Plaintiffs have no opportunity to challenge that determination directly.[3] If an overpayment is discovered, Plaintiffs have two options: (1) repay the overpayment, at which point there is no further review; or (2) withhold the overpayment, which, per the CMS Rule, violates the

[3] The same, of course, applies in situations where the Plaintiffs discover an overpayment themselves.

regulation and triggers liability under the False Claims Act after 60 days. Either the Office of the Inspector General (OIG) for Health and Human Services could bring an enforcement action against Plaintiffs under its own authority found in 42 U.S.C. § 1320a-7a, or a *qui tam* action could be brought by a private plaintiff.[4]

Plaintiffs raise several theories as to why such a situation does not preclude judicial review now. They assert that (1) an OIG enforcement action brought under § 1320a-7a is not a proceeding under the Medicare Act, and therefore § 405(h) would not apply; (2) an OIG enforcement action would not provide an avenue for administrative review of the CMS Rule; and (3) the penalty for the Plaintiffs is so great that it is the "practical equivalent of a total denial of judicial review" under *Illinois Council*. *See* Opp. at 35-45; *Illinois Council*, 529 U.S. at 20.

As to the first point, Plaintiffs assert that an OIG enforcement action, brought under its own governing procedures found in § 1320a-7a, is not a proceeding under § 405(b) and therefore not subject to § 405(h). *Id.* at 37. In their view, § 405(h) applies only in conjunction with §§ 405(b) and 405(g), citing as support the D.C. Circuit's statement in *Council for Urological Interests* that "section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims." *Council for Urological Interests v. Sebelius*, 668 F.3d. 704, 708 (D.C. Cir. 2011).

However, the Court reads *Illinois Council* to apply to proceedings under § 1320a-7a for two reasons. First, *Illinois Council* explicitly identifies § 1320a-7a as part of the "special review system" through which "§ 405(h) channels most, if not all, Medicare claims." 529 U.S.

[4] This issue has not been discussed by the parties, but to the extent Plaintiffs are publicly-traded companies, they would also presumably face possible SEC scrutiny, which has previously brought enforcement actions predicated on behavior that potentially violated the False Claims Act. *See, e.g., SEC v. RPM Int'l, Inc.*, No. CV 16-1803 (ABJ), 2016 WL 7388284, at *1 (D.D.C. Dec. 20, 2016).

at 8. Second, *Illinois Council* states that § 405(h) would not apply where "application of § 405(h) would not simply channel review through the agency, but would mean no review *at all*." *Id*. at 19 (emphasis added). OIG enforcement procedures would ultimately end in judicial review of some kind, suggesting that, under the reasoning of *Illinois Council*, § 405(h) would still apply.

While the Court is satisfied that an OIG enforcement action could constitute a review pathway, the more difficult question is whether it would constitute a review pathway *for the CMS Rule at issue*, which is the crux of Plaintiffs' second argument. OIG has in fact promulgated its own, separate rule concerning overpayments, titled "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules," 81 Fed. Reg. 88,334 (Dec. 7, 2016) (OIG Rule).[5] The OIG Rule defines OIG's procedures for enforcing the reporting and return requirements of overpayments. The OIG Rule refers to the similar CMS Rule, stating "[i]n the context of Parts C and D, CMS has interpreted the meaning of 'overpayment,' and we are required to apply the same meaning in an enforcement action against a Part C plan or Part D plan sponsor." 81 Fed. Reg. at 88,344. Despite this language, in many instances OIG otherwise disclaimed responsibility for interpreting the CMS Rule. For example, OIG has refused to state that good faith compliance with the CMS Rule would necessarily mean a Medicare Advantage insurer is complying with the OIG Rule. *Id.* OIG also states that its own rulemaking "did not propose to interpret the CMS final rule concerning Part C plans," and that commenters' concerns with CMS's definitions are "outside the scope of [OIG's] rulemaking." *Id*. While the government has asserted in brief that OIG has

[5] This rule was in the process of notice-and-comment when the parties submitted their briefs; the government submitted a Notice of Supplemental Authority [Dkt. 23], to which the Plaintiffs responded [Dkt. 24], when the final OIG Rule was promulgated.

applied CMS regulations in the past, *see* Reply at 22 n.12, the text of the OIG Rule and OIG's statements on the OIG Rule indicate that CMS's definitions and the appropriateness thereof would be beyond the scope of any OIG enforcement proceeding.

Accordingly, it cannot be said that an independent enforcement proceeding brought by OIG would serve as a vehicle for Plaintiffs to challenge the CMS Rule. Given the differences between the CMS Rule and the OIG Rule, and the fact that they were promulgated by different agencies within HHS, it is difficult to discern how judicial review of an OIG enforcement action would encompass an APA-like review of the CMS Rule. OIG warns explicitly that the OIG Rule is not intended to interpret the CMS Rule; thus, it is exceedingly doubtful that any judicial review of the OIG Rule would provide an occasion to review the CMS Rule under the APA. The Court concludes that an OIG enforcement action could provide for judicial review of *a* rule, that is, the OIG Rule, but it would not provide judicial review of the CMS Rule at issue here.

As a result, an OIG enforcement action would not serve as an administrative mechanism resulting in judicial review under *Illinois Council*. Neither party suggests a different path for review. Accordingly, as a legal matter, § 405(h) cannot be applied to the CMS Rule, as to do so would leave Plaintiffs with no judicial review of the CMS Rule at all.

Even if there were a legal avenue that would result in judicial review of the CMS Rule, the associated penalties would render such a path practicably foreclosed. Plaintiffs are facing a much different set of circumstances than hardship caused by the typical delays associated with administrative review. *See Illinois Council*, 529 U.S. at 13. If Plaintiffs fail to remit timely an overpayment, they face exposure to an OIG enforcement action and False Claims Act liability. In other words, to challenge the CMS Rule administratively, Plaintiffs first would

have to facially commit "fraud" without correction because correction to avoid possible civil penalties and disbarment from Medicare could moot any challenge to the CMS Rule. Further, this conundrum presents a systematic risk for all Medicare Advantage insurers that might want to challenge the CMS Rule. The costs associated with such action would be inherently more burdensome than the costs associated with a typical delay in resolving a Medicare payment dispute.

The stated purpose of requiring administrative review is not served by such a procedural quagmire. Channeling claims through CMS "assures the agency greater opportunity to apply, interpret or revise policies, regulations or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case." *Id.* Both CMS and the OIG have engaged in rulemaking without addressing the issue posed by Plaintiffs' suit.

Because the Court sees no viable path for administrative review of the CMS Rule, and because the CMS Rule systematically places such heavy burdens that any review would be practicably foreclosed, the Court finds that § 405(h) does not preclude judicial review at this time.

CONCLUSION

Plaintiffs have established both Article III and statutory standing to bring their suit challenging the CMS Rule. The Court therefore will deny Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction Under 12(b)(1). A memorializing Order accompanies this Memorandum Opinion.

Date: March 31, 2017

/s/
ROSEMARY M. COLLYER
United States District Court