UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:	
Plaintiffs,	:	Civil Action No.: 17-2447 (RC)
v.	:	Re Document Nos.: 2, 17, 19
ERIC D. HARGAN, Acting Secretary, Department of Health and Human Services, *et al.*	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING DEFENDANTS' MOTION TO DISMISS; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION; AND DENYING MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

I. INTRODUCTION

This case represents a dispute between certain public and not-for-profit hospitals and the Department of Health and Human Services ("HHS") over the rates at which Medicare will begin reimbursing them for pharmaceuticals that they acquire through a federal program known as the 340B Program. Although the 340B Program has enabled eligible hospitals to purchase pharmaceuticals from manufacturers at discounts, Medicare has historically reimbursed those hospitals at rates that were significantly higher than acquisition costs. Healthcare providers, including Plaintiffs, claim that they have used this surplus to provide additional healthcare services to communities with vulnerable populations. But in 2017, the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS, issued a regulation which was designed to begin closing the gap between what hospitals were paying for drugs and the rates at which Medicare reimbursed those hospitals.

Plaintiffs in this action, three hospital associations and three of their member hospitals, contend that the Medicare reimbursement rate for 340B drugs is set by statute and that the Secretary exceeded his authority when he "adjusted" that statutory rate downward by nearly 30%. Compl. ¶¶ 47–49, ECF No. 1. In order to preserve the *status quo*, Plaintiffs now seek a preliminary injunction directing HHS and the Acting Secretary not to implement these provisions pending the resolution of this lawsuit and any appeal. Pls.' Mot. Prelim. Inj., ECF No. 2. In response, Defendants, HHS and the Acting Secretary, have opposed this motion and have themselves moved to dismiss the action pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. *See* Defs.' Mot. Dismiss, ECF No. 17. For the reasons stated below, the Court concludes that it lacks subject matter jurisdiction because Plaintiffs have failed to present any claim to the Secretary for final decision as required by 42 U.S.C. § 405(g). Accordingly, the Court grants Defendants' motion to dismiss and denies Plaintiffs' motion for preliminary injunction as moot.

II. BACKGROUND

A. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Pub. L. 102-585. This program was intended to enable certain hospitals and clinics "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384(II), at 12 (1992). To do this, it allowed participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from manufacturers. *See* 42 U.S.C. § 256b. Under this program, participating drug manufacturers agree to offer certain covered outpatient drugs to "covered

entities" at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. *See* 42 U.S.C. § 256b(a)(1)–(2).

B. Setting Medicare Reimbursement Rates for 340B Drugs

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. §§ 1395 *et seq.* Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* at § 1395c. Part B, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* at §§ 1395j, 1395k.

One component of Medicare Part B is the Outpatient Prospective Payment System ("OPPS"), which pays hospitals directly to provide outpatient services to beneficiaries. *See id*. at § 1395*l*(t). Under this system, hospitals are paid prospectively for their services for each upcoming year. As part of the annual determination of OPPS rates, CMS must also determine how much Medicare will pay for "specified covered outpatient drugs" ("SCODs"). *See id*. at § 1395*l*(t)(14). Importantly, some of these SCODs include outpatient drugs that hospitals purchase pursuant to the 340B Program.

Under the statutory scheme applicable here, Congress has authorized two potential methods of setting SCOD rates. First, if available, the payment rates must be set using "the average acquisition cost for the drug for that year." *Id.* at § 1395*l*(t)(14)(iii)(I). If that data is not available, however, then the payment rates must be set equal to "the average price for the drug in the year established under [certain other statutory provisions] . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* at § 1395*l*(t)(14)(iii)(II). For 2018, the applicable provision was 42 U.S.C. § 1395w-3a, which specified that the payment rate should be the "average sales price" for the drug plus six percent ("ASP + 6%"). *See id.* at § 1395w-3a(b).

C. The 2018 OPPS Rule

On July 13, 2017, CMS issued a proposed rule for OPPS rates for the Calendar Year 2018. *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33,558 (Jul. 20, 2017). In addition to updating the OPPS rates for 2018, CMS also proposed changing the way Medicare would pay hospitals for SCODs acquired through the 340B Program. *See id.* at 33,634. In its proposed rule, CMS noted that several studies in recent years had shown that the difference between the price that hospitals paid to acquire 340B drugs and the amount that Medicare reimbursed hospitals for those drugs was significant. *See id.* at 33,632–33. For example, in 2015, the Medicare Payment Advisory Commission ("MedPAC") estimated that, on average, "hospitals in the 340B program 'receive[d] a minimum discount of 22.5 percent of the [average sales price] for drugs paid under the [OPPS]," yet hospitals were being reimbursed at a rate of ASP + 6%. *Id.* at 33,632 (second alteration in original). The MedPAC report also observed drug spending increases correlated with hospitals' participation in the 340B Program. *Id.* Moreover, the number of hospitals participating in the 340B Program was only going higher. *Id.* at 33,633.

"Given the growth in the number of providers participating in the 340B program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, [CMS] believe[d] it [was] timely to reexamine the appropriateness of continuing to pay the current OPPS methodology of ASP + 6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates." *Id.* CMS also expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of

the Medicare payment rate for these drugs." *Id.* Specifically, CMS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id.*

Accordingly, CMS proposed lowering the Medicare payment rate for 340B Program drugs. CMS's goal was "to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals to stretch scarce resources while continuing to provide access to care." *Id.* CMS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug[s]." *Id.* at 33,634. For that reason, CMS believed it was appropriate to essentially estimate hospitals' acquisition costs based on hospitals' average discount under 340B. *See id.* Specifically, CMS proposed applying the average discount that MedPAC had estimated—22.5 percent of the average sales price. *See id.* CMS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent." *Id.*

CMS also stated its purported statutory basis for altering payment rates for 340B drugs. Specifically, CMS believed that this proposed change was within its authority "under section 1833(t)(14)(A)(iii)(II) [of] the Act [(codified at 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II))], which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug . . . as calculated and adjusted by the Secretary as necessary. *Id.* CMS conceded that it did not "have hospital acquisition cost data for 340B drugs" and, therefore, it was proposing to continue paying for the drugs under its authority at § 1395*l*(t)(14)(A)(iii)(II). *Id.* CMS proposed "exercise[ing] the Secretary's authority to adjust

applicable payment rate as necessary and, for separately payable drugs and biologicals . . . acquired under the 340B program, . . . adjust[ing] the rate to ASP minus 22.5 percent which [CMS] believe[d] better represents the average acquisition cost for these drugs and biologicals." *Id.*

The proposed rule, of course, solicited comment from the public and Plaintiffs in this case responded. Plaintiffs argued, among other things, that CMS, for various reasons, did not in fact, have the legal authority to change the 340B payment rates in the manner that CMS proposed and that adopting the nearly 30% reduction would severely impact covered entities' ability to provide critical healthcare programs to their communities, including underserved patients. *See* AHA Comments at 1–9, ECF No. 2-6; AAMC Comments at 3–6, ECF No. 2-7; AEH Comments at 3–13, ECF No. 2-8; EHMS Comments at 2–3, ECF No. 2-9; Henry Ford Comments at 1–3, ECF No. 2-10.

Nevertheless, on November 13, 2017, CMS adopted the payment reduction for 340B drugs that it had originally proposed. *See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 52,356, at 52,362 (Nov. 13, 2017). CMS did, however, respond to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. CMS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion to adjust payments for drugs, which it believed included an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. *Id.* CMS also disagreed with commenters that the authority to "calculate and adjust" drug rates as necessary is limited to "minor changes" and it saw "no evidence in the statute to

support that position." *Id.* at 52,500. Accordingly, CMS saw fit to use its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* Under this final rule, the change to 340B reimbursement rates is scheduled to go into effect on January 1, 2018. *Id.* at 52,356.

D. The Present Action

On November 13, 2017, Plaintiffs brought suit in this Court challenging the 340B provisions of the 2018 OPPS Rule under the Administrative Procedure Act ("APA"). *See* Compl., ECF No. 1. Plaintiffs allege, as they did in their comments, that the Secretary's nearly 30% reduction in the Medicare reimbursement rate for 340B drugs was "in excess of [his] authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)" and that it, therefore, violated the APA. Compl. ¶¶ 47–49. That same day, Plaintiffs also moved for a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure. *See* Pls.' Mot. Prelim. Inj. Plaintiffs specifically requested that this Court enjoin Defendants from implementing the new 340B provisions until this case has been fully adjudicated. *See* Pls.' Mot. Prelim. Inj. Defendants opposed Plaintiffs' motion and filed their own motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.[1] *See* Defs.' Mot. Dismiss. On December 21, 2017, the Court heard oral argument from the parties on both motions.

[1] On December 8, 2017, thirty-two not-for-profit state and regional hospital associations filed a consent motion for leave to submit a brief as *amici curiae* in support of Plaintiffs' motion for preliminary injunction and in opposition to Defendants' motion to dismiss. ECF No. 19. Because the Court does not reach the merits of Plaintiffs' claim, the Court finds it unnecessary to consider the amicus brief. Accordingly, the Court will deny the motion for leave.

III. ANALYSIS

The Court's analysis in this matter necessarily begins and ends with an inquiry into its own subject matter jurisdiction. On a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, it is the plaintiff's burden to establish that the court has subject matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). When considering whether it has jurisdiction, a court must accept "the allegations of the complaint as true." *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015) (citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)). However, a court may also "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Id.* (quoting *Herbert*, 974 F.2d at 197).

In this case, there is only one potential source of subject matter jurisdiction—42 U.S.C. § 405(g). "The Medicare Act places strict limits on the jurisdiction of federal courts to decide 'any claims arising under' the Act." *Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 122 (D.D.C. 2014) (citing 42 U.S.C. § 405(h)). Indeed, any such claim must be brought pursuant to 42 U.S.C. § 405(g) of the Social Security Act (which is made applicable to the Medicare Act by virtue of 42 U.S.C. § 1395ii) even if the claim has been framed as a challenge under other laws or the Constitution. *See* 42 U.S.C. § 405(h); *Heckler v. Ringer*, 466 U.S. 602, 615–16 (1984) ("§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act") (alterations in original); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("Parties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or

regulatory challenge.") (per curiam). A claim arises under the Medicare Act when its provisions provide "both the standing and the substantive basis" for the complaint. *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975). Because Plaintiffs' sole claim is substantively based on the Medicare Act, judicial review may occur only if § 405(g)'s jurisdictional requirements are satisfied. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 122 ("As all of [plaintiff]'s claims are substantively based in the Medicare Act, satisfaction of the Act's conditions regarding judicial review is required.")

Section 405(g) permits judicial review only "after [a] final decision of the [Secretary] made after a hearing to which he was a party." 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976). Thus, § 405(g) speaks in terms of both "ripeness" and "exhaustion." And while these are familiar concepts in the administrative law context, the Supreme Court has been clear that the requirements under § 405(g) represent an even more exacting standard. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. at 12 ("the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'. . . ."). Indeed, while ordinary administrative law doctrines might permit judicial review under various exceptions, the Medicare Act "demands the 'channeling' of virtually all legal attacks through the agency." *Id.*

The Supreme Court has defined two elements that a plaintiff must establish in order to satisfy § 405(g). First, there is a non-waivable, jurisdictional "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328. "Absent such a claim there can be no 'decision' of any type," which "is clearly required by the statute." *Id.* Thus, the D.C. Circuit has previously described the presentment requirement as an "absolute prerequisite" to review and has found jurisdiction to be lacking where a plaintiff "proceeded

directly to district court, seeking a preliminary injunction barring HHS . . . from implementing [a] new rate reduction." *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1129–30 (D.C. Cir. 1992). The second element is a waivable "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Eldridge*, 424 U.S. at 328. Unlike the first element, however, a plaintiff may be excused from this obligation when, for example, exhaustion would be futile. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992); *Nat'l Ass'n. for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) ("Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with the other factors . . . ."). Together, § 405(g)'s two elements serve the practical purpose of "preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Salfi*, 422 U.S. at 765; *see also Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13 (§ 405(g)'s requirements "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts . . . ."). In this case, Plaintiffs argue that they have satisfied the presentment requirement and that they should be excused from the exhaustion requirement. *See* Pls.' Reply at 14–17, ECF No. 20.

The Plaintiffs' problem, however, is that they have not yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision. Indeed, the Rule that sets the reimbursement rates at issue and which might form the basis of reimbursement claims that they might submit someday in the future has not yet gone into effect. The Supreme Court addressed similar circumstances in *Heckler v. Ringer*, 466 U.S. 602 (1984).

In *Ringer*, the plaintiff had not presented an actual claim, but was instead "seeking to establish a right to future payments" on a potential future claim. *Id.* at 621. The Court held that allowing an anticipatory challenge to the Secretary's policy choice in the absence of a specific claim "would be inviting [claimants] to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court." *Id.* Thus, "[b]ecause [the plaintiff] ha[d] not given the Secretary an opportunity to rule on *a concrete claim for reimbursement*, he ha[d] not satisfied the nonwaivable exhaustion requirement of § 405(g)." *Heckler v. Ringer*, 466 U.S. 602, 622 (1984) (emphasis added); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("anticipatory challenges to the lawfulness of a provision that might later bar recovery of benefits must proceed 'through the special review channel that the Medicare statutes create.'" (quoting *Ill. Council*, 529 U.S. at 5)).

Plaintiffs argue, however, that they have met the presentment requirement because they "submitt[ed] detailed comments during the notice-and-comment process for the 340B Provisions of the OPPS Rule." Pls.' Reply at 14. But comments submitted in a rulemaking are not individualized, "concrete claim[s] for reimbursement," as courts routinely require to satisfy presentment. *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary."). Not surprisingly then, the few Courts that have specifically considered arguments like those espoused by Plaintiffs have generally found that the submission of letters and comments that are divorced from discrete claims for reimbursement are insufficient for purposes of § 405(g). For example, in *National Association for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103 (D.D.C. 2015), another court in this District held that the presentment requirement was not satisfied when the

plaintiffs "submit[ed] comments to the agency and [] me[t] with agency officials to voice disagreement with [a particular] rule" because "an association may not challenge the constitutionality of Medicare regulations in the abstract on the basis that its members are likely to confront those regulations in the future." *Id.* at 109 n.1 (citing *Ill. Council*, 529 U.S. at 5); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x at 3 (holding that plaintiff's "letter to the PRRB requesting a jurisdictional ruling" did not satisfy the presentment requirement because "[t]he Medicare Act [] requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim"); *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiffs]'s self-described 'detailed critiques of the [agency action] . . . [were] insufficient to establish presentment.").

Plaintiffs do not cite any authority in this Circuit or elsewhere in which a court has found the submission of comments in response to an agency's request for notice and comment on a proposed regulation satisfies 405(g)'s presentment requirement. *See* Hr'g Tr. at 21:22–22:4 (Dec. 21, 2017) (admitting that Plaintiffs have not seen any "circuit case that specifically finds that commenting in a notice-and-comment period satisfies the presentment requirement"). Nevertheless, Plaintiffs attempt to bolster their argument with two cases that they claim support their position. First, Plaintiffs point to *Mathews v. Eldridge*, 424 U.S. 319 (1976), where the Supreme Court held that the plaintiff's failure to "raise with the Secretary his constitutional claim" was "not controlling." *Id.* at 329. But in that case, even though the plaintiff had not presented his precise constitutional argument to the Secretary, there had been a "'final decision' by the Secretary with respect to the [plaintiff's] claim of entitlement to benefits." *Id*. Indeed, the Court found that the named plaintiff, "[t]hrough his answers to the state agency questionnaire,

and his letter in response to the tentative determination that his disability had ceased, had specifically presented the claim that his benefits should not be terminated because he was still disabled." *Id.* Moreover, "[t]his claim was denied by the state agency and its decision was accepted by the [Social Security Administration]." *Id.* Thus, despite not presenting a particular constitutional argument to the Secretary, the plaintiff in *Eldridge*—unlike the Plaintiffs here—*had* submitted a claim for definite benefits, which the Secretary had denied. Thus, *Eldridge* does not lend support to Plaintiffs' position that comments made during the rulemaking process alone may satisfy § 405(g)'s presentment requirement.

Plaintiffs also place heavy reliance on *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009), but it too offers limited support to Plaintiffs' position. In that case, two organizations and one recipient of Medicare benefits sought to challenge the Secretary's decision to recover refunds that HHS had erroneously issued to Medicare beneficiaries. After filing their complaint, plaintiffs sought, and were granted, a preliminary injunction. *See Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 854 (D.C. Cir. 2007). The Secretary challenged that injunction in several respects on appeal, but he did not contest subject matter jurisdiction until the D.C. Circuit itself raised the issue *sua sponte* and requested supplemental briefing. *See id.* at 856. Ultimately, the Circuit held that the district court did not have jurisdiction to consider plaintiffs' claims or to issue the preliminary injunction because the plaintiffs had not adequately presented their claims to the Secretary for a final determination. *See id.* It then remanded the case to the district court. *Id.* at 861.

Following the D.C. Circuit's opinion, the plaintiffs sent letters to the agency setting forth their various legal arguments and requesting that it accord the affected Medicare beneficiaries with certain relief. *Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–38; *see also* Joint

Appendix at A-130, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). The agency responded by denying the plaintiffs' requests and explaining its rationale. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–40. On remand, the Secretary argued that the two association plaintiffs did not satisfy the presentment requirement because the letters were from the associations rather than their members. *See id.* at 38–39. The Secretary did not argue, however, that presentment must be accomplished, if at all, through a formal submission of a concrete claim. *See* Defs.' Mot. Dismiss at 21–23, *Action All. of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009) (No. 06-1607), ECF No. 49. And the district court did not address this issue on its own. Rather, the district court held that associations may present claims on behalf of their members and concluded, without explanation, that the organizations' letters satisfied § 405(g)'s presentment requirement. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 40. The district court then proceeded to consider the merits of plaintiffs' claims, but ultimately sided with the Secretary and granted his motion to dismiss. *See id.* at 42.

Plaintiffs then appealed the district court's decision. The Secretary did not cross-appeal on the jurisdictional issue and, in fact, conceded that the Circuit "ha[d] jurisdiction to address the issues presented in th[e] appeal." *See* Appellee's Brief at 11 n.2, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). And while the Secretary did present an abbreviated version of the argument made to the trial court, the Secretary still did not argue that the generalized nature of the letters in anyway made them deficient. *See id.* After reviewing the case, the D.C. Circuit affirmed the judgment of the district court and observed in a footnote that, while presentment had at one time precluded judicial review of their claims, "[p]laintiffs ha[d] since cured the jurisdictional defect." *See Action All. of Senior Citizens v. Sebelius*, 607 F.3d

860, 862 n.2 (D.C. Cir. 2010). But like the district court, the Court of Appeals did not offer any explanation as to why generalized letters satisfied the presentment requirement. *See id.* at 862.

Given the lack of any substantive discussion on the issue of whether generalized letters may suffice for purposes of presentment by either the defendant Secretary, the district court, or the Court of Appeals, at least one court has questioned the precedential value of *Action Alliance* in that regard. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("The lack of explanation in both cases is likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in Action Alliance, and the Court therefore questions the precedential value of those opinions."); *see also Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) ("When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed."); *Ticor Title Ins. Co. v. FTC*, 814 F.2d 731, 749 (D.C. Cir. 1987) ("[I]t is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists." (citing *Pennhurst State Sch. & Hospital v. Halderman*, 465 U.S. 89, 119 (1984))). This Court too believes that *Action Alliance*'s value on this underdeveloped issue is doubtful. In any event, there is a meaningful difference between the letters at issue in *Action Alliance* and the comments that Plaintiffs submitted in this case. Indeed, in *Action Alliance,* the associations' letters concerned specific claims that *had already accrued to individuals* and thus "were closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 (quoting *Ringer*, 466 U.S. at 622). By contrast, even though Plaintiffs' comments in this case criticized the proposed 2018 OPPS Rule, they were not advancing any specific, concrete claims for reimbursement.

Thus, they cannot satisfy the presentment requirement of § 405(g). *See id.* ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiff]'s self-described 'detailed critiques of the [agency action]' . . . [were] insufficient to establish presentment."); *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary.").

In conclusion, Plaintiffs' failure to present any concrete claim for reimbursement to the Secretary for a final decision is a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g). As a result, the Court must necessarily dismiss Plaintiffs' action for want of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss (ECF No. 17) is **GRANTED**; Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**; and the Motion for Leave to File Brief as *Amici Curiae* (ECF No. 19) is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: December 29, 2017

RUDOLPH CONTRERAS
United States District Judge