IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*, Defendant.	Civil Action No. 17-2645 (EGS)

DEFENDANT'S REPLY IN SUPPORT OF HIS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiff is evidently dissatisfied with the amount of money its members will be paid by Medicare for certain laboratory tests, and seeks to invalidate the fee schedule setting payment amounts for those tests, on the theory that the Secretary failed to collect the data used to establish the fee schedule from the right set of "applicable laboratories." Plaintiff faces three independent jurisdictional hurdles to its suit. It misjudges the height of each hurdle, and so fails to clear any of them.

First, there can be no plausible dispute that the data reporting requirements challenged here are integral to the "establishment of payment amounts," which is shielded from judicial review. Under consistent D.C. Circuit precedent, the reporting requirements are therefore barred from review as well. Second, although Plaintiff asserts that its members have incurred various economic and "competitive" injuries, it fails to support those assertions by reference to any specific facts showing a substantial probability that the Final Rule caused any such injuries. Nor does Plaintiff show that its requested relief, in the form of a revised rule, would redress any of those injuries. As a result, Plaintiff lacks standing. Third and finally, although Plaintiff argues that it has now satisfied the Medicare statute's exhaustion requirements, its attempt to do so comes far too late, some months after the filing of the Complaint in this case. The Court cannot excuse Plaintiff's clear failure to satisfy Medicare's jurisdictional requirements. For all of these reasons, the Court lacks subject matter jurisdiction.

Even if this Court reaches the merits, judgment should be entered for the Secretary. Plaintiff simply ignores the primary rationales for the challenged definition of "applicable laboratory" in the Final Rule. That is, the use of a National Provider Identifier ("NPI") was incorporated, in part, to clearly identify the entity that actually receives Medicare revenues, as demanded by the statute. Plaintiff does not dispute that absent an NPI, a laboratory receives no

Medicare revenues, nor does Plaintiff provide the Court with any more reasonable method to determine the Medicare payments received by a given laboratory. The Secretary's definition of an "applicable laboratory" to mean a laboratory that has been issued an NPI, and thus one that is treated by Medicare as receiving revenues, is entirely reasonable.

I. Review is Precluded by PAMA Section 216

The presumption in favor of judicial review "is just that—a presumption" and, "like all presumptions used in interpreting statutes, may be overcome by specific language or specific legislative history that is a reliable indicator of congressional intent." *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984)). Here, Plaintiff cannot circumvent the express bar on judicial review set forth by the specific language in 42 U.S.C. § 1395m-1(h)(1), precluding any review of "the establishment of payment amounts under this section."

As Defendant previously noted, section 1395m-1(a)(2) provides for the "[d]efinition of applicable laboratory" for purposes of the statute, and follows the heading: "Reporting of private sector payment rates *for establishment of Medicare payment rates*[.]" 42 U.S.C. § 1395m-1(a) (emphasis added). The "applicable laboratory" under this section reports "applicable information" to the Secretary, *id.* § 1395m-1(a)(3), who then calculates payment rates on the basis of that information, *id.* § 1395m-1(b)(2). Congress thereby confirmed that the definition of "applicable laboratory" is part and parcel of the "establishment of payment amounts" shielded from judicial review under section 1395m-1(h)(1). The express terms of the statute thus bar Plaintiff's challenge here.

The D.C. Circuit has consistently held that where an agency action is indispensable, integral, or inextricably intertwined with the unreviewable agency action, the former action is

shielded from review as well. *See, e.g., Fla. Health Sciences Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 519 (D.C. Cir. 2016). Plaintiff does not meaningfully dispute that the decision as to what data to collect, and from which sources, is integral to the "establishment of payment amounts" under the statute. *See* Pl. Combined Opp'n to Def.'s Mot. for Summ. J. & Reply in Supp. of Pl.'s Mot. for Summ. J. ("Pl. Opp'n.") at 8, ECF No. 29 ("Congress undoubtedly required the Secretary to take into account the collected market information when establishing payment amounts . . . ."). Indeed, Plaintiff's primary claim of injury to its members is that the "failure to collect accurate payment data will ultimately cause substantial harm to laboratories[,]" Pl. Opp'n. at 15, specifically because "the data-collection parameters imposed by the final rule are *destined* to lead to the Secretary establishing payment rates that are far below private-sector rates . . . ." Pl.'s Mot. for Summ. J. ("Pl. Mot.") at 3, ECF No. 13 (emphasis added). The clear aim of the instant suit is to enjoin these purportedly low payment amounts, and thereby aid Plaintiff's members. Plaintiff thus cannot plausibly claim that the definition of "applicable laboratory" is not integral to the establishment of payment amounts.

In an attempt to avoid this conclusion, Plaintiff strives mightily to distinguish this case from *Florida Health Sciences*, but in so doing misunderstands the holding of that case. There, the relevant statute barred review of the Secretary's "estimate" of uncompensated care provided by a hospital. *Fla. Health Sciences*, 830 F.3d at 518. The plaintiff argued that the court could review "the underlying data on which the Secretary relied, because an 'estimate' is not the same thing as the 'data' on which it is based." *Id.* In rejecting this argument, the D.C. Circuit explained that the test of judicial preclusion in the Medicare context is a simple one: whether a given agency decision was "'indispensable' or 'integral' to, 'inextricably intertwined' with, the unreviewable agency action." *Id*. at 519. (citation omitted). The court concluded that the

"underlying data here are 'indispensable'" to the Secretary's estimate, "[i]ndeed, the data are the entire basis for the estimate[,]" such that the bar on judicial review "expressly preclude[d]" the challenge. *Id.*

Ignoring this clear language, Plaintiff offers that the appropriate query should instead be whether "both decisions are so closely connected that they can be said to comprise the same agency action that Congress intended to exempt from judicial review." Pl. Opp'n. at 7-8. Plaintiff urges that the data-collection requirements, issued pursuant to notice-and-comment rulemaking, and the final issuance of the fee schedule, subject to separate public comment, are "separate agency action[s.]" *Id*. at 4. Plaintiff thus asserts that because the Secretary's collection of data and establishment of payment amounts do not constitute the "same agency action[,]" the collection of data is not shielded from review. *Id*. at 8.

Yet the D.C. Circuit explicitly rejected the same argument in *Florida Health Sciences*. The plaintiff there similarly argued that "the statute [] creates no bar to a court reviewing the Secretary's ultimate decision as to the amount of a hospital's DSH payment, but only her intermediate determination as to the estimate of a hospital's share of uncompensated care." *Fla. Health Sciences*, 830 F.3d at 521. In other words, the plaintiff argued that where only one specific decision was shielded from review, an entirely different agency decision could be challenged in court. But the D.C. Circuit held that this was a "distinction without a difference." *Id*. The Court explained: "[t]he dispositive issue is whether the challenged data are inextricably intertwined with an action that all agree is shielded from review, regardless of where that action lies in the agency's decision tree." *Id.*

The D.C. Circuit also disposed of the same argument in *Texas Alliance for Home Care Services*. In that case, the applicable Medicare statute barred review of "the awarding of

contracts." *Tex. All. for Home Care*, 681 F.3d at 410. But plaintiff there argued that it could challenge the "financial standards regulation[,]" which had been promulgated pursuant to notice-and-comment rulemaking, and which set forth the requirements for bidders concerning these Medicare contracts. *Id*. at 409. The court rejected the plaintiff's argument, noting that the statutory language broadly barred review of "the awarding of contracts," which inherently "require[d] the formulation and application of financial standards." *Id*. at 409-10. It was thus of no moment whether the awarding of contracts constituted the same agency action as the promulgation of the financial standards regulation (it did not); rather the question remained whether the standards regulation was "indispensable" to the subsequent awarding of contracts, itself shielded from review. *Id.* at 409. Because the standards regulation was indeed integral to the awarding of contracts, judicial review was similarly barred.[1]

Here, Plaintiff does not dispute that, like *Florida Health Sciences*, the collected payment information is generally the only data used to set forth the payment amounts in the new fee schedule. Nor does Plaintiff contest the fact that, like *Texas Alliance*, the establishment of Medicare payment amounts "require[d] the formulation and application" of the Secretary's Final Rule, also subject to notice-and-comment. *Id*. at 409-410. There can be no plausible dispute that the collection of payment data is "inextricably intertwined" with the establishment of payment amounts. *See Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1131 (D.C. Cir. 2017) (citing *Tex. All.*

[1] Plaintiff's argument that barring review here would raise "constitutional" concerns is unfounded. *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 681 n.12 (1986), cited for this proposition, states only that precluding all "constitutional claims" could raise these concerns. *Id.* Plaintiff raises no constitutional claims here. Nor is all review precluded of even statutory claims, as the Court may properly determine whether the Secretary's action was *ultra vires*, though Plaintiff has made no such showing here.

& Fla. Health Sciences). As a result, Plaintiff's challenge to the Final Rule, setting forth the requirements for data collection, is barred here.

A brief coda is warranted. Plaintiff repeatedly cites the fact that the new fee schedule was published some 17 months after the Final Rule challenged by Plaintiff. Pl. Opp'n. at 2, 4, 9. This fact is notable, but for a different reason than Plaintiff suggests. Indeed, the Secretary's Final Rule was issued on June 23, 2016, setting forth the definition of "applicable laboratory" challenged here. Some seventeen months later, the Secretary published the final payment amounts, on November 17, 2017. Plaintiff did not file the instant suit until December 11, 2017.

Why did Plaintiff file its Complaint when it did? The obvious answer, it would seem, is that Plaintiff and its members were dissatisfied with the payment amounts as established by the Secretary. But barred from directly challenging the "establishment of payment amounts," Plaintiff instead sought to circumvent that bar by attacking the Final Rule that was integral to establishing those payment amounts. Both common sense and binding precedent make clear that the Court should not permit this attempted end-run around a bar on judicial review.

II. Plaintiff Lacks Standing

Plaintiff fares no better in attempting to demonstrate standing here. As Defendant previously demonstrated, Plaintiff has pointed to no "specific facts," as required at the summary judgment stage, to show that the Secretary's definition of "applicable laboratory" actually caused fewer hospital laboratories to report than should have been required, which in turn caused Medicare payment amounts to be improperly lowered. Def.'s Cross-Mot. for Summ. J. & Opp'n to Pl.'s Mot. for Summ. J. ("Def. Cross-Mot.") at 22, ECF No. 27. But rather than submit any facts to support its claims of causation, Plaintiff initially argues that no such showing is necessary. Plaintiff urges that simply because "ACLA's members are the direct objects of the

Secretary's final rule, and because ACLA's members directly participated in the rulemaking process" they have standing.[2] Pl. Opp'n. at 11.

In fact, the cases cited by Plaintiff for support refute this contention. Although "[i]n many if not most cases the petitioner's standing to seek review of administrative action is self-evident; . . . When the petitioner's standing is not self-evident . . . the petitioner must supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review." *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002). Nor does Plaintiff provide support for the notion that participating in the rulemaking process alone somehow establishes standing. *Cf. Otay Mesa Prop., L.P. v. U.S. Dep't of the Interior*, 144 F. Supp. 3d 35, 57 (D.D.C. 2015) (holding only that plaintiff "has a personal stake in this matter and, thus, has constitutional standing"). The "immutable requirements of Article III" do not evaporate simply because a Plaintiff comments on, or is affected in some way by, an agency rule. *See Bennett v. Spear*, 520 U.S. 154, 162 (1997); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (setting forth the "irreducible constitutional minimum of standing"). Indeed, as Plaintiff later admits, it must show a "substantial probability," that the Final Rule will cause injury to its members. Pl. Opp'n. at 15. Plaintiff fails to satisfy this basic requirement.

Again, the Complaint's primary theory of injury is that, by failing to provide for the collection of payment data from more hospital laboratories, the Final Rule caused Medicare payment rates to be established that were too low, thereby harming the business of Plaintiff's members. Compl. ¶ 72(c)-(g). But to establish causation on this basis, Plaintiff must point to

[2] Defendant previously explained that Plaintiff lacks standing on its own behalf because it fails to allege any injury to its organization, and Plaintiff provides no response to this argument whatsoever. *See* Def. Cross-Mot. at 19-20. Plaintiff thus effectively concedes that it lacks standing to bring suit on its own behalf.

some specific fact showing that the Final Rule caused fewer hospitals to report than should have been required under a purportedly appropriate regulation, and that this underreporting affected the payment rates. In response, Plaintiff merely reiterates its previous statements, noting that there are some 7,000 hospital laboratories that bill under the Clinical Laboratory Fee Schedule ("CLFS") and claiming that "hospital laboratories typically receive higher commercial rates than other types of laboratories." Pl. Opp'n. at 14 (citation omitted). Yet, according to Plaintiff, how many hospital laboratories should have counted as an "applicable laboratory" under Section 216 of PAMA? That is, how many hospital laboratories could be said to receive a majority of Medicare revenues from the CLFS and Physicians Fee Schedule ("PFS"), and should therefore be required to report data? Plaintiff does not offer even a guess. And would this unknown number of laboratories have higher payment data sufficient to alter the fee schedule that was issued here? Again, Plaintiff does not say.

In sum, Plaintiff provides the Court with no basis to find a substantial probability that the agency's definition of "applicable laboratory" (1) caused fewer numbers of hospital laboratories to report, and (2) thereby resulted in lower payment amounts than would have been established otherwise. Plaintiff thus fails to establish causation on this ground. *See, e.g., Ass'n of Flight Attendants-CWA, AFL-CIO v. U.S. Dep't of Transp.*, 564 F.3d 462, 469 (D.C. Cir. 2009) (holding that "[w]ithout some underlying factual basis for attributing" alleged injury to agency action, "rather than to other factors—we cannot accept these statements as anything other than conclusory and therefore inadequate"); *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 670 (D.C. Cir. 1996) ("Most, if not all, of the individual links in the chain alleged by appellants depend on some allegation that cannot be easily described as true or false; as noted, we routinely refuse to permit such predictive assumptions to establish standing.")

Likely recognizing these deficiencies, Plaintiff in its response brief places great emphasis on a separate theory of competitor standing. Pl. Opp'n. at 13. This doctrine recognizes that there are circumstances where economic actors 'suffer an injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition' against them." *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010) (citation omitted). However, "the basic requirement common to all [competitor standing] cases," is that the challenged government regulation has caused "an actual or imminent increase in competition, which increase . . . will almost certainly cause an injury in fact." *Id*. at 73. As the D.C. Circuit has explained, "[t]he nub of the 'competit[or] [*sic*] standing' doctrine is that when a challenged agency action authorizes allegedly illegal transactions that *will almost surely* cause petitioner to lose business, there is no need to wait for injury from specific transactions to claim standing." *El Paso Nat. Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995)) (emphasis added). By contrast, courts routinely reject claims to competitor standing that are "conjectural" or fail to demonstrate that an agency decision "will almost surely" cause a plaintiff competitive injury. *DEK Energy Co. v. FERC*, 248 F.3d 1192, 1196 (D.C. Cir. 2001) (quoting *El Paso Nat. Gas*, 50 F.3d at 27); *see also United Transp. Union, v. ICC*, 891 F.2d 908, 912 n.7 (D.C. Cir. 1989) (assessing competitor standing, court need not "accept allegations founded solely on the complainant's speculation").

In light of these strict standards, Plaintiff's theory of competitor standing also fails. Plaintiff has not alleged any specific facts to show that its members compete against those hospital laboratories that allegedly should have been required to report, or that those hospital laboratories will gain some sort of a market advantage, such that ACLA's members "will almost surely" suffer some type of competitive injury. *See DEK Energy*, 248 F.3d at 1196; *Delta Air Lines, Inc. v. Export-Import Bank*, 85 F. Supp. 3d 250, 266 (D.D.C. 2015) (no competitor

standing where "numerous factual questions remain unresolved and undeveloped, many of which are necessary for determining if and how Plaintiffs might suffer an injury-in-fact from the [agency's] allegedly wrongful conduct").

Nor does Plaintiff explain how the reporting requirements could cause an "actual or imminent increase in competition[.]" *Sherley*, 610 F.3d at 73. Rather, Plaintiff argues only that, because of the Final Rule, its members that were required to report private-payor data had "expenses and labor [costs] that competitors affiliated with hospital laboratories did not share." Pl. Opp'n. at 14. However, the basis of Plaintiff's injury in this context is not its own member's compliance costs,[3] but rather that certain competitors allegedly do not share those costs, thereby causing harm to Plaintiff's member businesses in some way. Plaintiff fails to explain how the absence of compliance costs for certain hospital laboratories could cause an "increase in competition[.]" *Sherley*, 610 F.3d at 73. Indeed, Plaintiff fails to provide specific facts or even allege that, because certain hospital laboratories may not have to report data, Plaintiff's members will lose market share, lose business, or indeed suffer any specific "competitive injury." *Cf.* Decl. of Dermot Shorten ¶ 30, ECF No. 1-3 (speculating that other laboratories "received a competitive advantage"). Absent a concrete and particularized "competitive injury," Plaintiff cannot establish standing on a competitor theory of standing and fails to do so here.

Plaintiff also pays short shrift to the third standing requirement, that the "relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged by the plaintiff." *Fla. Audobon Soc'y*, 94 F.3d at 663-64. As the D.C. Circuit has highlighted, "[t]he key word is 'likely.'" *West v. Lynch*, 845 F.3d 1228, 1235 (D.C. Cir. 2017) (citation

[3] Plaintiff does not claim that, were it successful here, its members would not have to report data to the Secretary. The compliance costs of Plaintiff's members, standing alone, thus cannot constitute a redressable injury.

omitted). Lest there be any doubt, Plaintiff's Complaint and Proposed Order both request relief in the form of an injunction of the new CLFS "until such time as the Secretary has made appropriate revisions to [the] final rule." Compl. Prayer for Relief (C); Proposed Order at 2, ECF No. 13-1. Plaintiff must therefore show that such relief is likely to result in a greater number of hospital laboratories reporting data to the agency, such that either (1) the fee schedule would contain higher payment rates, and/or (2) the reporting requirements would eliminate the injuries of increased "competition" of which Plaintiff complains. Yet Plaintiff has failed to even suggest any "appropriate revisions" the Secretary could make, and more importantly, how those revisions would provide Plaintiff with its sought relief.

Accordingly, Plaintiff asks that the Court speculate that if it were to strike down the Secretary's Final Rule, and the agency were to implement some unspecified "appropriate" definition of "applicable laboratory," this action would likely redress Plaintiff's injuries. Of course, "[w]hen conjecture is necessary, redressability is lacking." *West*, 845 F.3d at 1237. Plaintiff has not come close to showing that some unknown "appropriate" future rulemaking would redress its alleged injuries, and the basis for that claim, and accordingly lacks standing. *See, e.g.*, *Franklin v. Massachusetts*, 505 U.S. 788, 802 (1992) (plurality) (finding no standing where Plaintiffs had "neither alleged nor shown" that injuries would be redressed if agency had used "some other source of 'more accurate' data"); *Nat'l Law Ctr. on Homelessness & Poverty v. Kantor*, 91 F.3d 178, 183 (D.C. Cir. 1996) (finding no standing where Plaintiffs "do not present an alternative approach that . . . promises any significantly different result").

III. Plaintiff Has Failed to Exhaust Administrative Remedies

Plaintiff's suit should be dismissed for a third independent reason: it failed to satisfy the requirements of presentment and exhaustion under the Medicare statute. The Secretary's

opening brief explained in detail that the presentation of a concrete claim for benefits is an "absolute" jurisdictional "prerequisite" to judicial review under the Medicare statute and cannot be excused due to futility. *See Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 857 (D.C. Cir. 2007). Defendant also cited consistent holdings by courts in this circuit reasoning that letters or rulemaking comments "are not individualized, 'concrete claims for reimbursement,' as courts routinely require to satisfy presentment." *Am. Hosp. Ass'n v. Hargan* , No. 17-2447 (RC), 2017 WL 6734176, at *6 (D.D.C. Dec. 29, 2017) (citation omitted); Def. Cross-Mot. at 26.

In response, Plaintiff cites one footnote in which the D.C. Circuit has "suggested that submitting a letter to the agency is sufficient to satisfy the jurisdictional presentment requirement." Pl. Opp'n. at 17 (citing *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010)). Plaintiff rightly does not rely heavily on this single footnote, given that the court in *Action Alliance* provided no "substantive discussion on the issue of whether generalized letters may suffice for purposes of presentment . . . ." *Am. Hosp. Ass'n*, 2017 WL 6734176, at *7. Accordingly, "*Action Alliance's* value on this underdeveloped issue is doubtful." *Id.*; *see also Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014) (noting that the "Court therefore questions the precedential value" of *Action Alliance*). In addition, the letters at issue in that case "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. Hosp. Ass'n*, 2017 WL 6734176, at *7 (citing *Am. Orthotic & Prosthetic*, 62 F. Supp. 3d at 123). Here, by contrast, the letters and comments from Plaintiff to the agency concerned general grievances about how the Secretary would gather data in order to establish payment rates. Such prospective, informal complaints do 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." *Three Lower Ctys. Cmty. Health Servs., Inc. v. HHS*, 317 F. App'x 1, 2 (D.C. Cir. 2009) (per curiam).

Plaintiff appears to recognize that its failure to present an administrative claim renders this Court without subject matter jurisdiction, and now belatedly alleges that "one of ACLA's members has already submitted its objections to the Secretary's administrative contractor in the context of specific claims for payment." Pl. Opp'n. at 17. Plaintiff contends that "the presentment requirement is therefore satisfied and there is no bar to judicial review." *Id.* Not so.

Plaintiff's Attachment A is purportedly a letter from one of Plaintiff's members, seeking administrative adjudication of certain claims for Medicare payments, dated March 1, 2018. Even if this letter could constitute a satisfactory claim for benefits, it was submitted over two months after the Complaint in this case was filed on December 11, 2017. "It has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" *Grupo Dataflux v. Atlas Glob. Grp., L.P.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 9 Wheat. 537, 539 (1824)). "Whether a plaintiff has cured her failure to exhaust administrative remedies prior to bringing a civil action by exhausting those remedies after filing her complaint depends on whether the exhaustion requirement at issue imposes a jurisdictional or non-jurisdictional barrier." *Holmes v. PHI Serv. Co.*, 437 F. Supp. 2d 110, 118-19 (D.D.C. 2006). "If a particular exhaustion requirement constitutes a jurisdictional prerequisite to suit, the Court may not excuse its failure." *Id.* at 119; *see Avocados Plus Inc. v. Veneman*, 370 F.3d 1243, 1247 (D.C. Cir. 2004).

Plaintiff does not dispute that 42 U.S.C. § 405(h), as incorporated into the Medicare statute, constitutes a jurisdictional barrier, requiring presentment of an administrative claim

before suit can be filed. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 24 (2000) ("At a minimum . . . the matter must be presented to the agency *prior* to review in a federal court.") (emphasis added); *Action All. of Senior Citizens*, 483 F.3d at 857. Accordingly, the failure to present an administrative claim prior to the filing of the Complaint cannot be excused by the Court here. *See, e.g.*, *Avacados Plus Inc.*, 370 F.3d at 1247 ("If the statute does mandate exhaustion, a court cannot excuse it."). To hold otherwise would permit a plaintiff to rush to federal court upon finding any grievance with Medicare, as the Plaintiff has done here, and only "present" its claims to the agency once summary judgment briefing was already underway. Such a rule would eviscerate the Congressional design which "demands the 'channeling' of virtually all legal attacks through the agency . . . ." *Ill. Council*, 529 U.S. at 13.

Nor can Plaintiff establish that exhausting administrative remedies would be futile. Plaintiff avers that the instant challenge presents a "pure legal issue" which the agency does not have the authority to decide. Pl. Opp'n. at 18. This argument ignores the fact that the challenge now submitted to the agency involves discrete payment amounts for specific Medicare claims, such that fact issues may well be present. And even if all claims involved were "purely legal[,]" Plaintiff concedes that "[t]he Secretary has adopted regulations that grant reviewers the authority to acknowledge purely legal challenges and to certify those claims to federal court." *Id*. (citing 42 C.F.R. § 405.990). In making such a determination, the agency "has a role in shaping the controversy that is subject to judicial review . . . ." *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 406-07 (1988). Because the administrative process explicitly accounts for claims that may receive expedited judicial review, and because the agency can and should properly determine in the first instance the issues that will be certified for review in court, Plaintiff cannot show that exhaustion here would be futile.

More fundamentally, "it is clear beyond cavil that the mere fact that a plaintiff cannot receive under the administrative review process the particular type of relief sought in court is not material to the applicability of the channeling requirement." *Cal. Clinical Lab. Ass'n v. Sec'y of Health & Human Servs.*, 104 F. Supp. 3d 66, 81-82 (D.D.C. 2015); *see also Ill. Council*, 529 U.S. at 23 ("The fact that the agency might not provide a hearing for [a] particular contention, or may lack the power to provide one . . . is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency."). Plaintiff's desire to avoid the administrative process because it may not immediately provide the adjudication and relief sought does not constitute a "most exceptional circumstance[]" such that exhaustion could be excused here. *See Am. Orthotic & Prosthetic*, 62 F. Supp. 3d at 123 (citation omitted).

IV. The Final Rule is Reasonable

A. *Chevron* Step One - Plaintiff Cannot Show that the Secretary Contravened an Unambiguous Statutory Command

Even if this Court reaches the merits, judgment should still be entered for Defendant. Under *Chevron* Step One, the Court should determine first whether "Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). Plaintiff concedes that "the statute does not speak to the precise issue of how to define a 'laboratory' that receives Medicare 'revenues.'" Pl. Opp'n. at 19-20 (citation omitted). It is therefore a matter of common ground that Congress did not speak to the "precise question at issue," and as a result, Plaintiff cannot show that the "challenged term is susceptible of only one possible interpretation." *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012). Plaintiff's claim that the Secretary somehow disregarded unambiguous statutory language accordingly fails.

Despite Plaintiff's apparent acknowledgement that "applicable laboratory" is ambiguous on its face, Plaintiff maintains that this is not "*relevant* ambiguity" for purposes of interpreting the statute. Pl. Opp'n. at 19. But it is unclear why Plaintiff believes that the ambiguity of the exact term that it challenges would be irrelevant to determining whether Congress spoke to the "precise question at issue." *See Chevron*, 467 U.S. at 842.

Plaintiff again argues that the statute directed the agency to consider "whether a majority of each laboratory's revenues are from the relevant Medicare fee schedules," but again offers no explanation as to how "laboratory" or "revenues" must be defined pursuant to some unambiguous statutory language. Pl. Opp'n. at 20. Nor does Plaintiff advance any "ordinary" definition of a laboratory that receives Medicare revenues, which the Secretary should have adopted. *Id*. at 22. Without setting forth the definition that it believes was clearly required by the statute, Plaintiff appears to suggest that the definition in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), alone, could have been used to define "applicable laboratory" here. *Id*. Although the CLIA language was adopted as part of the overall definition in the Final Rule, as Defendant previously pointed out: "the CLIA certificate in no way defines a laboratory that can be said to receive Medicare revenues. . . . The CLIA certificate has no intrinsic relationship to the business-level entity that bills Medicare, nor does the agency provide Medicare payments to the building or other area recognized in a CLIA certificate." Def. Cross-Mot. at 31. Plaintiff fails to dispute or otherwise respond to this point, and therefore cannot show that the CLIA definition, standing alone, could somehow define an "applicable laboratory," namely a "laboratory" that receives certain Medicare "revenues."[4]

[4] Plaintiff previously argued that, in another part of the statute, the narrower term "single laboratory" should be defined not only as a "laboratory," but also as its "parent corporation," any

Plaintiff admits that "it might not always be a simple task to determine the revenues attributable to a hospital laboratory." Pl. Opp'n. at 23. In other words, Plaintiff recognizes that there is no unambiguous statutory language that instructed the Secretary as to how to define an "applicable laboratory," especially in the context of hospital laboratories. The conceded difficulty in determining such a definition in the first place, at the very least, defeats Plaintiff's claim that there exists some clear statutory command that was somehow disregarded by the Secretary.

B. *Chevron* Step Two - The Final Rule Reasonably Defined "Applicable Laboratory"

Plaintiff similarly fails to establish that the Final Rule issued by the Secretary was unreasonable. The Final Rule easily passes muster under *Chevron* Step Two, as it is "rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute." *See Agape Church, Inc. v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013) (citation omitted).

In order to determine the Medicare "revenues" received by a given laboratory, the agency defined an "applicable laboratory," in part, as one which bills Medicare pursuant to its own NPI. This definition was certainly reasonable, since "in order to bill Medicare for services, and thereby receive Medicare revenues, a provider must do so pursuant to its individual NPI number." *See* Def. Cross-Mot. at 36.

The Secretary's definition appropriately recognizes that a hospital laboratory, or indeed any laboratory, lacking an NPI, "does not itself receive revenues." *Id*. at 38. Plaintiff again does

"wholly owned subsidiaries," and "other entities under common ownership." Administrative Record at 03413-16; ECF No. 1-4 at 174. If nothing else, such comments refute Plaintiff's argument that the Secretary disregarded some obvious, more narrow definition of the term "applicable laboratory." Pl. Opp'n. at 20.

not dispute this key point. Thus, in arguing that more hospital laboratories should have reported data, Plaintiff demands reporting from laboratories that do not themselves receive Medicare revenues. Yet, as Plaintiff previously explained, the statute directs the Secretary to "consider[] the Medicare revenues received by the laboratory *itself* . . . ." Pl. Mot. at 27 (emphasis added); *see also id.* at 25 ("No one disputes that the statute directs the Secretary to collect data from all laboratories that receive a majority of their Medicare revenues from either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule."). Even according to Plaintiff, the statute required reporting from only those laboratories that receive Medicare revenues. The Secretary's use of the NPI to identify those laboratories that receive Medicare revenues was thus a reasonable interpretation of the statute.

The Secretary further noted that this definition was reasonable because "most hospital laboratories would not meet the majority of revenues threshold," under any type of calculation. Def. Cross-Mot. at 34. Plaintiff notably does not contest this finding, but rather deems it a "generalization." Pl. Opp'n. at 24. Yet, the agency determined that because it is likely that most hospital laboratories primarily serve hospital patients, under any formulation of "revenues" they would not "receive" a majority of such revenues from the non-patient CLFS and PFS schedules. Plaintiff offers no facts as to why this common-sense conclusion could be incorrect, and thereby fails to undermine the agency's finding. *Cf. Cmty. Care Found. v. Thompson*, 318 F.3d 219, 225 (D.C. Cir. 2003) (noting the "enhance[d]" deference accorded to the Secretary in light of the "'tremendous complexity' of the Medicare program").

Defendant also pointed out how the Secretary's definition avoids significant problems posed by any alternative definition that Plaintiff might favor. That is, if a hospital laboratory, lacking an NPI, were forced to determine its "revenues," the hospital would be required to

determine "whether [Inpatient Prospective Payment System] IPPS and [Outpatient Prospective Payment System] OPPS bundled payments constituted Medicare revenues received by the hospital laboratory." Def. Cross-Mot. at 39. The Secretary agreed with Plaintiff's original position that those portions of bundled payments attributable to various hospital services, "are not broken out or identified, nor is there any way to determine what portion constitutes revenues of the laboratory." ECF No. 1-4 at 99. Accordingly, the Secretary could not determine how a hospital laboratory would properly calculate its "revenues," when it did not bill Medicare under its own NPI.

Plaintiff now avers that its earlier position was wrong, citing a single regulation that requires hospitals to maintain certain "records and statistical data for proper determination of costs payable" under the Medicare program. Pl. Opp'n. at 27. Plaintiff argues that hospitals can "use" this data to identify "what revenues are attributable to the services their laboratories provide," but left unspecified is how exactly hospitals could use this data concerning discrete costs, to identify a relevant portion of prospectively determined revenue payments. *Id.*; *see Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1053 (D.C. Cir. 1997) (explaining that "a PPS payment is calculated without regard to a hospital's actual cost").

Indeed, Plaintiff again sets forth no clear alternative definition that the agency should or even could have incorporated. Plaintiff mentions in passing three proposals that it made at various points throughout the rulemaking process. Pl. Opp'n. at 27-28. Yet Plaintiff neglects to explain which of these proposals it currently supports and why. More importantly, Plaintiff does not dispute that their most recent proposal is contrary to the statute, as it would have hospital laboratories entirely ignore IPPS and OPPS revenues, and render the majority of revenues criterion a nullity. *See* Def. Cross-Mot. at 40. Nor does Plaintiff contest the fact that their other

cited proposals, appearing to require some method of calculating a portion of IPPS and OPPS revenues, contradicts both Plaintiff's earlier position and the D.C. Circuit, both of which explained that there is no workable method to determine what portion of a bundled prospective payment is somehow attributable to actual costs of a laboratory. *Id.* at 41; *see Appalachian Reg'l Healthcare*, 131 F.3d at 1053; ECF No. 1-4 at 99.

Plaintiff's argument therefore reduces to the contention that the agency should have done *something* different. But without any specification of what that something might be, and why it would be superior to the agency's rational choices here, Plaintiff cannot show the Secretary's actions to be unreasonable or arbitrary. *See Theodore Roosevelt Conservation P'ship v. Salazar*, 661 F.3d 66, 78-79 (D.C. Cir. 2011) (rejecting a challenge to agency action in light of the plaintiffs' failure to identify feasible alternatives that the agency should have adopted instead); *Competitive Telecomms. Ass'n v. FCC*, 309 F.3d 8, 17 (D.C. Cir. 2002) (same).

At bottom, the agency reasonably required that an applicable laboratory be defined, in part, as one which bills Medicare pursuant to its own NPI. This definition gives force to the statute's requirement that an applicable laboratory must itself receive Medicare revenues, and enables both the agency and regulated laboratories to readily calculate whether they meet the majority-of-Medicare revenues test for reporting purposes. Plaintiff's failure to clearly support even a single alternative definition stems from the simple fact that, absent an NPI, a laboratory cannot receive Medicare revenues. These requirements, that an applicable laboratory must have distinct Medicare revenues, and need not report payment data if it primarily serves hospital patients, were clear choices made by Congress, and the agency was not unreasonable by giving effect to the statute as written.

CONCLUSION

For the reasons set forth above, judgment should be entered for Defendant.

Dated: April 20, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2018 I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notice of such filing to all parties.

/s/ Michael L. Drezner
MICHAEL L. DREZNER
Trial Attorney