IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL
LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR,
In His Official Capacity as Secretary
of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:17-cv-2645 (EGS)

PLAINTIFF'S COMBINED OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND
REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION AND SUMMARY OF ARGUMENT

The Secretary's final rule is unlawful because it rewrites the statutory definition of "applicable laboratory" to exclude virtually all hospital laboratories from the data-reporting requirements imposed by section 216 of the Protecting Access to Medicare Act ("PAMA"). Instead of determining whether a hospital laboratory receives a majority of "its" Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule, as Congress directed, *see* 42 U.S.C. § 1395m-1(a)(2), the Secretary's rule red pencils the statute to change "laboratory" to read an "entity that has at least one component that is a laboratory" and, as a result, takes into account the revenues of the hospital as a whole. Because the Medicare revenues of the hospital as a whole, attributable to services that have nothing to do with clinical laboratory services, will always dwarf the Medicare revenues of the hospital's laboratory, the result of the Secretary's rule is to eliminate the statute's majority-of-revenues requirement as applied to hospital laboratories and to categorically exempt hospital laboratories from PAMA's data-reporting requirements. Excluding that large and important segment of the laboratory market has imposed unfair burdens on non-hospital laboratories and prevented the Secretary from collecting private payor data that accurately reflects the market.

The Secretary has very little to say in defense of the merits of his final rule. He does not dispute that his final rule imposes substantial regulatory burdens on ACLA's members — costing some laboratories millions to comply — that are not imposed on competing hospital laboratories. He also does not dispute the severe consequences that his final rule will have for the nation's health care system, leading to the scaling back of services and the shuttering of laboratories that, especially in remote or rural areas, are the only source of diagnostic services for elderly and disabled Medicare beneficiaries. Nor does he offer any reasoned justification for his

statutory rewrite. He contends that the statute is ambiguous, but he never identifies any *relevant* ambiguity that would render his interpretation permissible or even reasonable. He also complains that it would be too much of a hassle to comply with Congress's directives and criticizes the alternative proposals offered by ACLA. But nothing excuses the Secretary's statutory violation and *ultra vires* conduct.

Because his merits defense is so weak, the Secretary devotes much of his brief to advancing overreaching jurisdictional arguments. He suggests, for example, that although Congress directed the Secretary to engage in notice-and-comment rulemaking to establish the parameters for imposing new data reporting requirements on regulated parties, the Court should infer that Congress intended to insulate the results of that rulemaking from judicial review, because in a separate statutory provision it barred review of any Medicare payment amounts established by the Secretary. But the Secretary's final rule does not establish payment amounts — the Secretary did that more than 17 months later in a separate agency action that is not before the Court — and the Secretary's request that the Court read the jurisdictional bar very broadly is contrary to precedent and the strong presumption in favor of judicial review. He also makes the extraordinary claim that, even though ACLA's members are directly regulated by the Secretary's final rule and must comply on threat of civil penalties, they lack standing because they have not precisely calculated the number of hospital laboratories unlawfully exempted from the statutory requirements. And he asserts that, although there is no administrative process that could resolve ACLA's objections and although those objections have been repeatedly presented to the Secretary, the Court should wait to adjudicate this case until ACLA has fully exhausted a futile administrative process that will serve no purpose.

None of the Secretary's jurisdictional objections has merit. And none should prevent this Court from vacating the Secretary's unlawful final rule. The Court should direct the Secretary to comply with the statute that Congress enacted.

ARGUMENT

I. The Court Has Jurisdiction To Review The Agency's Final Rule.

The Secretary appears to have raised every jurisdictional argument he could think up in hopes of convincing this Court not to consider his statutory violation. But he has not carried the heavy burden that precedent requires to shield his rule from review. His jurisdictional arguments are meritless.

A. This Action Is Not Precluded By Any Jurisdictional Bar.

The Secretary concedes that the Court has jurisdiction to review his final rule if it is *ultra vires*. *See* HHS Br. 18. He nonetheless tries to narrow the scope of review, claiming that his final rule imposing data-reporting obligations on certain laboratories, while excluding thousands of others, is exempt from judicial scrutiny because Congress barred review of the "establishment of payment amounts." *Id*. at 14–18. That argument cannot be reconciled with PAMA's text and structure, or the fact that the Secretary's final rule does not establish payment amounts.

As ACLA's opening brief explains, there is a "strong presumption" that Congress intends judicial review of administrative action, which can be overcome only with a showing of "clear and convincing" evidence that Congress wanted the agency to police its own conduct. *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015). That presumption is especially strong when an agency "is charged with acting beyond its authority" or has taken action that disregards a statutory directive. *See Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1172–73 (D.C. Cir. 2003); *Dart v. United States*, 848 F2d 217, 220 (D.C. Cir. 1988). In seeking to insulate its actions from review, an agency "bears a heavy burden" to show "that Congress

prohibited all judicial review of the agency's compliance with a legislative mandate." *Mach Mining*, 135 S. Ct. at 1651 (alternations accepted and internal quotation marks omitted); *see also Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir. 1979)).

The Secretary has not satisfied this heavy burden. He cannot dispute that ACLA seeks review of a final regulation, which is a quintessential form of agency action subject to review under the Administrative Procedure Act. *See* 5 U.S.C. § 553 (rulemaking); *see also id.* § 702 ("[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review"). Nor can he deny that his final rule does not purport to establish payment amounts, but instead "establish[es] . . . parameters for data collection," as Congress instructed. 42 U.S.C. § 1395m-1(a)(12). The statute specifically distinguishes between the final agency action required to impose data-collection requirements (rulemaking following notice and comment) and the separate agency action required to establish payment amounts (notice with public explanation). *Compare id. with id.* § 1395m-1(c)(4). The notice published by the Secretary establishing payments amounts — which he issued more than 17 months after he promulgated his final rule — is not before this Court.

With no argument that this action falls within the express terms of the statutory bar, the Secretary argues that review of his final regulation should be prohibited by inference. According to the Secretary, the provision precluding review of "the establishment of payment amounts," *id.* § 1395m1-(h)(11), should be construed broadly to sweep in the Secretary's final rule "establish[ing] . . . the parameters for data collection." *Id.* § 1395m-1(a)(12). But that is wrong on its own terms. It is well settled that statutory provisions precluding judicial review must be read "narrowly." *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 518 (D.C. Cir. 2016). If a statute is subject to different interpretations, courts must "adopt the

reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review." *Kucana v. Holder*, 558 U.S. 233, 251 (2010). The fact that a statute bars judicial review of a particular agency decision does not mean that parties are precluded from challenging "the general rules" leading to that decision. *Parkview Medical Assocs. v. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998); *see also Fla. Health*, 830 F.3d at 522 (recognizing this distinction and noting that plaintiff had "not brought a challenge to any general rules leading to the Secretary's estimate").

The Secretary cannot show that his broad interpretation is the only permissible reading of the statute. Nonetheless, the Secretary argues that his final rule should be immune from judicial scrutiny because it is a step in a larger process that ultimately leads to the establishment of payment amounts. HHS Br. 15. But that position is untenable. If it were correct, the bar on judicial review would preclude any review of the Secretary's final rule, even preventing a laboratory from challenging the regulations in response to an enforcement action by the Secretary imposing civil penalties on the laboratory for alleged noncompliance. *See* 42 U.S.C. § 1395m-1(a)(9). There is no evidence that Congress took such a drastic step. Under the statute's plain terms, Congress did not bar review of the regulations it required the Secretary to promulgate establishing the parameters for collecting information, *see id*. § 1395m-1(a)(2); it barred review only of the Secretary's "establishment of payment amounts," *id.* § 1395m-1(h)(11); *see also Chevron U.S.A. Inc. v. Echazabal*, 536 U.S. 73, 80 (2002) ("expressing one item of [an] associated group or series" — here, the establishment of payment amounts but not the establishment of data collection parameters — "excludes another left unmentioned"). In short, Congress required the Secretary to complete two different types of regulatory actions and intended to subject each action to different levels of judicial scrutiny.

Congress undoubtedly recognized that by directing the Secretary to promulgate regulations governing the reporting and collection of market data, it was authorizing the Secretary to regulate primary conduct by imposing new substantive obligations on applicable laboratories, including authorizing the Secretary to apply substantial penalties for non-compliance. *See* 42 U.S.C. § 1395m-1(a)(9) (imposing civil penalties). Congress thus directed the Secretary to comply with the Administrative Procedure Act's notice-and-comment requirements and its attendant provisions for judicial review. *See* 5 U.S.C. § 702. It would raise constitutional concerns of the highest order if Congress were to require the Secretary to promulgate substantive legislative regulations that directly regulate primary conduct on threat of civil penalties but then attempt to insulate those regulations, as well as the Secretary's enforcement of them, from any form of judicial review. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 681 n.12 (1986). In contrast, it is unsurprising that Congress precluded review of the Secretary's establishment of payment amounts. Under the statute, the task of establishing payment amounts is a ministerial, administrative function. The Secretary is not directly regulating laboratories' primary conduct or promulgating substantive legislative regulations. And it is nonsensical to think in terms of the Secretary taking action against regulated parties to enforce his "establishment of payment amounts." Instead, when establishing payment amounts, the Secretary is merely applying a formula prescribed by Congress and exercising administrative discretion informed by advice from a panel of experts. *See, e.g.*, 42 U.S.C. § 1395m-1(f)(1).

The Secretary relies heavily on *Florida Health*, but that case is readily distinguished. In *Florida Health*, the D.C. Circuit held that a statutory provision precluding review of the Secretary's "estimate" of a hospital's amount of uncompensated care also precluded review of

the Secretary's choice as to what "underlying data" it would use to make that estimate. *Id*. at 518–19. Notably, Congress did not require the Secretary to select the data through a separate public notice-and-comment rulemaking process. Instead, Congress left the choice of data to the Secretary's unfettered discretion in estimating the amount of uncompensated care. And both the estimate and his underlying choice of data were part of the same agency action that petitioners challenged. *See* 78 Fed. Reg. 50,496 (Aug. 19, 2013). Nonetheless, petitioners argued that because the data was only an input into the Secretary's estimate, Congress did not bar judicial review of the Secretary's choice of data. The D.C. Circuit rejected this "categorical distinction between inputs and outputs" and instead analyzed "the relationship between the challenged decision and the agency action shielded from review." *Fla. Health*, 830 F.3d at 518. Noting that "[n]o other data factored into the Secretary's estimate," the Court concluded that permitting a challenge to the Secretary's discretionary choice of data would "eviscerate the bar on judicial review." *Id*. (citations omitted). The Secretary's decision on what data to use could not be separated from the Secretary's estimate because the data were "the entire basis for the estimate" and the two were "inextricably intertwined" as part of the same final agency action. *Id*.

In this case, the Secretary is advancing the same sort of "categorical" approach that *Florida Health* rejected. In the Secretary's view, because the data collected by the Secretary can be characterized as an "input" that the Secretary later used to establish payment amounts, the bar on review must apply. But that misunderstands *Florida Health*'s central teaching. As the D.C. Circuit explained, the key focus should be on the nature of the "agency action shielded from review." *Id.* at 519. That focus is essential, because the question is not whether the agency relies on one decision in the context of making another, but 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. In *Florida Health*, because the agency's discretionary decision about what data to use was "the entire basis for [its] estimate," there was no way to disentangle the agency's choice of data from its estimate— the choice of data and the estimate were in fact the same decision. That is because the "data" were cost information reported on a specific line in hospital cost reports, and the Secretary established his "estimate" by selecting a cost report that was superseded by an updated cost report to determine payment. The D.C. Circuit thus concluded that the government had satisfied its burden to show with clear and convincing evidence that Congress intended to bar judicial review. 830 F.3d at 519.

Under PAMA, the action that Congress shielded from review was not the Secretary's final regulation imposing new data collection and reporting obligations on laboratories. Nor would permitting a challenge to the regulation "eviscerate the bar on judicial review" that Congress imposed. *Id.* Unlike in *Florida Health*, where the Secretary's discretionary choice of data was "inextricably intertwined" with his estimate — both were made together as part of the same agency action — Congress in PAMA imposed a non-discretionary obligation on the Secretary to promulgate a regulation imposing data-reporting requirements, and expressed its intent that the regulation would be subject to the Administrative Procedure Act's notice-and-comment requirements. That final agency action, which directly regulates certain laboratories' primary conduct and has its own administrative record, is separate from the Secretary's later establishment of payment amounts. While Congress undoubtedly required the Secretary to take into account the collected market information when establishing payment amounts, there is no way to conclude that the two separate actions are so closely intertwined that Congress clearly expressed an intent to shield both from judicial review. *Cf. Universal Health Servs. of McAllen v. Sullivan*, 770 F. Supp. 704, 710 (D.D.C. 1991) (statutory provision precluding judicial review

of Board reclassification decisions did not bar review of underlying guidelines used by Board to decide reclassification requests). Indeed, as noted above, the Secretary promulgated his final rule more than 17 months before he separately established payment amounts. Moreover, ACLA has a strong interest in overturning the Secretary's final regulation — which subverts Congress's reforms and imposes substantial burdens on many of ACLA's members while exempting similarly situated hospital laboratories — that goes beyond and exists in addition to its concerns that the Secretary's statutory violation will lead to dramatic reductions in Medicare rates. *See* HHS Br. 35 (acknowledging that hospital associations urged the Commission to make the statutory obligations optional so they could avoid "an unreasonable reporting burden"); *cf. Fla. Health*, 830 F.3d at 521 (noting that challenge to general rule is barred when it is "*solely* in order to reverse an individual . . . decision" shielded from review) (emphasis added; citation omitted).

This reading of *Florida Health* is confirmed by the functional analysis that courts have applied in other contexts when a statute does not expressly preclude review, but an agency claims that final action should escape review by inference. The Court considers three factors: "the need for judicial supervision to safeguard the interests of the plaintiffs; the impact of review on the effectiveness of the agency in carrying out its congressionally assigned role; and the appropriateness of the issues raised for judicial review." *Nat. Res. Def. Council,*, 606 F.2d at 1044. These considerations all favor review in this case. Again, Congress treated differently the task of promulgating a legislative rule imposing new data-collection obligations on private parties (and the civil penalties that apply) from the separate administrative task of establishing payment amounts. Because the Secretary's final rule directly regulates primary conduct — as opposed to merely exercising executive discretion to set payment amounts — judicial review is needed to protect laboratories' rights, including their right not to be burdened with regulations

imposed by an agency that has exceeded its delegated authority. Moreover, there is no impediment to judicial review. The Court is being asked only to determine whether the Secretary's final rule defining "applicable laboratory" complies with Congress's mandate and whether the Secretary has justified his final rule consistent with the requirements of reasoned decision-making. There is no need for the Court to make any inquiry into payment amounts or how the Secretary established them.

The Secretary asserts that granting relief would "undo years of painstaking effort" by the agency. HHS Br. 17. But that disruption is only a consequence of the agency's refusal to comply with the statute and respond seriously to the hundreds of comments it received during the notice-and-comment process. ACLA has been engaged in years of "painstaking effort" urging the Secretary to comply with its congressionally assigned role under the law. *See* Doc 1-4, Khani Decl. At this point, the agency has no one to blame but itself. Its patent violation of the statutory requirements should not be shielded from review.

B. ACLA Has Associational Standing.

The Secretary next argues that ACLA does not have standing to pursue its claims. That argument is also meritless. ACLA's associational standing is self-evident and well supported.

Associations have representational standing on behalf of their members if: "(1) at least one of their members has standing to sue in her or his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit." *Am. Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C. Cir. 2005). The Secretary argues that the first of these three requirements is lacking. HHS Br. 20. For an individual member to have standing to sue in its own right, it must satisfy the familiar three-part inquiry: (1) an "actual or imminent," "concrete and particularized" injury-in-fact, (2) a "causal connection between the injury" and the

challenged action, and (3) a likelihood that the "injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992).

These requirements are satisfied. Where, as here, an association's member is "'an object of the action (or forgone action) at issue' — as is the case usually in review of a rulemaking . . . — there should be 'little question that the action or inaction has caused [the plaintiff] injury, and that a judgment preventing or requiring the action will redress it." *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002) (quoting *Lujan* 504 U.S. at 561–62 (1992)); *see also Otay Mesa Prop., LP v. United States Dep't of the Interior*, 144 F. Supp. 3d 35, 57 (D.D.C. 2015) (plaintiff had a "personal stake in this matter and, thus, ha[d] constitutional standing" where it had "participated in the underlying rule-making proceedings"). Because there is no doubt that ACLA's members are the direct objects of the Secretary's final rule, and because ACLA's members directly participated in the rulemaking process, *see, e.g.*, A.R. 1949–52, 3861–93, they have standing to challenge the "allegedly illegal . . . rule under which [they are] regulated" and no additional evidence of standing is required. *State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015); *see also Sierra Club*, 292 F.3d at 900 (when party's standing is self-evident, "no evidence outside the administrative record is necessary"); *N. Carolina Fisheries Ass'n, Inc. v. Gutierrez*, 518 F. Supp. 2d 62, 81 (D.D.C. 2007) (noting that because agency action regulated plaintiffs' "primary conduct," there was no need for them to "supplement the record . . . to explain and substantiate [their] entitlement to judicial review") (citation omitted).

ACLA's complaint and other submissions confirm that ACLA's members are the direct objects of the Secretary's regulation, for they are the laboratories that have been required to report information and are subject to civil penalties if they do not comply. *See* Doc. 1, Compl. ¶¶ 71–72; *see also* Doc. 1-3, Shorten Decl. ¶¶ 20–30. ACLA and many of its members were

active participants in the notice-and-comment process that resulted in the Secretary's final rule. Doc. 1, Compl. ¶¶ 14, 46–48; *see also* Doc. 1-4, Khani Decl. ¶ 12. They have a right to have the statute properly implemented and have standing to complain that the Secretary exceeded his statutory authority, unlawfully imposing greater burdens on ACLA's members than other types of laboratories. *See Zivotofsky v. Secretary of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) (finding that party has standing to challenge agency failure to comply with statutory obligations imposed by Congress for party's benefit); *Electric Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1262 (D.C. Cir. 2004) (association has standing to enforce its members' statutory right to "fair decisionmaking" by the Commission, even without making any particularized showing of financial harm). There is also no doubt that these injuries are directly traceable to the Secretary's final rule. As the D.C. Circuit has held, a party has standing to challenge agency action that authorizes third parties to engage in conduct — in this case permitting hospital laboratories to escape the data-reporting requirements — that otherwise "would allegedly be illegal[.]" *Animal Legal Defense Fund, Inc. v. Glickman*, 154 F.3d 426, 440 (D.C. Cir. 1998).

In these circumstances, it is "inconceivable" that the Secretary's final regulation imposing new data-reporting obligations on ACLA's members but not on hospital laboratories "would fail to affect" even one of ACLA's members. *S. Coast Air Quality Mgmt. Dist. v. Envtl. Prot. Agency*, 472 F.3d 882, 895–96 (D.C. Cir. 2006) (concluding that the plaintiff had demonstrated a substantial probability of injury because it was "inconceivable" that EPA's action "would fail to affect the requirements of even a single [association] member"), *modified on other grounds*, 489 F.3d 1245 (D.C. Cir. 2007). The Secretary cites no case that has ever concluded that an association lacks standing to challenge a regulation that directly regulates the conduct of

its members, subjecting them to substantial civil penalties for non-compliance. The Secretary's attempt to rewrite the law of standing, like his attempt to rewrite PAMA, should be rejected.

Even if the law were not clear on this point, ACLA's complaint and its exhibits are more than sufficient to demonstrate that ACLA's members have suffered cognizable injury as a result of the Secretary's final rule. *See Hardaway v. Dist. of Columbia Housing Auth.*, 843 F.3d 973, 978 (D.C. Cir. 2016) (when party was the object of government action, it was "obvious" the party had demonstrated "injury in fact"). One obvious concrete injury, which the Secretary ignores, is the fact that the Secretary's final rule saddles many of ACLA's members with regulatory compliance obligations and the threat of civil penalties while unlawfully exempting their direct competitors from the statutory reporting requirements. *See* Doc. 1-3, Shorten Decl. ¶¶ 24–30. As the D.C. Circuit has recognized, "economic actors 'suffer [an] injury in fact when agencies lift regulatory restrictions on their competitors . . . ." *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010) (quoting *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998)); *see also Mendoza v. Perez*, 754 F.3d 1002, 1011 (D.C. Cir. 2014) (recognizing competitor standing). This type of "traditional economic interest" is more than sufficient to support a claim of standing. *Gutierrez*, 518 F. Supp. 2d at 82 (citation omitted). By being required to report information, ACLA's members have been "significantly disadvantaged as compared to other laboratories that, while required to report under PAMA, were excused from that obligation by the Secretary." Doc. 1-3, Shorten Decl. ¶ 20; *see also* HHS Br. 35 (acknowledging comments by hospital associations urging the Secretary to exempt hospital laboratories from the "unreasonable reporting burden"). Indeed, satisfying the reporting requirements cost one of ACLA's members almost $2 million and took approximately 240

people 8 weeks to complete — expenses and labor that competitors affiliated with hospital laboratories did not share. Doc. 1-3, Shorten Decl. ¶¶ 21, 29.

The Secretary also cannot dispute that, if ACLA's allegations are correct, the Secretary's final rule violates the statute by exempting virtually all hospital laboratories from the data-reporting requirements that Congress imposed. While there are an estimated 7,000 hospital laboratories that bill the Medicare program for diagnostic services under the Clinical Laboratory Fee Schedule, only 21 hospitals were required to report information under the Secretary's final rule. *See* Doc. 1-2, Kolozsvary Decl. ¶ 23. Nor can he reasonably dispute that ACLA's declarations, based on personal information, attest to the fact that "hospital laboratories typically receive higher commercial rates than other types of laboratories." *Id*. ¶ 24; *see also* Doc. 1-3, Shorten Decl. ¶ 14 ("private payors typically pay hospitals as much as 1.5 to 4 times higher than the rates they pay large independent laboratories for the same laboratory tests"). The Secretary's failure to collect data from hospital laboratories, as PAMA requires, means that he has subverted Congress's purpose and has not collected information from the laboratory market as a whole.

The Secretary also cannot deny that ACLA's declarations establish that "[a]s a direct result of the Secretary's decision to exclude hospital laboratories from the reporting requirement," some of ACLA's members "will be forced to discontinue" offering their services, which will deprive patients of essential laboratory services, especially in rural markets. Doc. 1-2, Kolozsvary Decl. ¶ 27; *see also* Doc. 1-3, Shorten Decl. ¶ 16 (explaining that "the Secretary's failure to collect the market data that Congress required and the resulting reductions in the Clinical Laboratory Fee Schedule rates will negatively affect" one of ACLA's members' businesses). As one of ACLA's declarations explains, "[e]xcluding important sectors of the clinical diagnostic laboratory market from PAMA's reporting requirement means Armageddon

for laboratories serving elderly patients in skilled nursing facilities, nursing homes, and other long-term care facilities." Doc. 1-1, Gudaitis Decl. ¶ 23. If the Secretary's failure to require data reporting for all applicable laboratories is not corrected, one of ACLA's member companies will be out of business within "one or two years" — after having been in operation for more than 45 years as a family-owned business. *Id.*; *see also* Doc. 1-2, Kolozsvary Decl. ¶ 27. The declarations are consistent with the amicus briefs, explaining that the Secretary's failure to collect accurate payment data will ultimately cause substantial harm to laboratories and patients. *See* Doc. 21, Amicus Br. of the Nat'l Ass'n for the Support of Long Term Care, at 6; Doc. 22, Amicus Br. of the Advanced Med. Tech. Ass'n, at 7; Doc. 23, Amicus Br. of the Am. Ass'n of Bioanalysts, at 15–17; Doc. 25, Amicus Br. of the Coll. Of Am. Pathologists, at 13.

This evidence is more than sufficient to establish a "substantial probability" that the "challenged regulation" will injure ACLA's members and that those injuries are "fairly traceable" to the Secretary's final rule. *See Sierra Club*, 292 F.3d at 899 (at summary judgment stage, burden is on party to show a "substantial probability" that it has been injured). Ignoring the applicable standard, the Secretary complains that ACLA has not calculated a precise amount of economic harm or come forward with precise data showing how many hospital laboratories would have reported if the Secretary had complied with his statutory obligations. *See* HHS Br. 20–21. According to the Secretary, ACLA cannot demonstrate that the Secretary's statutory violation exempting hospital laboratories from the statutory data-reporting obligations will necessarily result in the injuries that ACLA alleges. *See id*. But that sort of precision has never been required. *See Russell-Murray Hospice, Inc. v. Sebelius*, 724 F. Supp. 2d 43, 53–54 (D.D.C. 2010) (citing cases) (holding that economic harm is not required when plaintiff subject to agency action shows that the agency failed to comply with Congress's directions); *see also*

Compassionate Care Hospice v. Sebelius, No. CIV-09-28-C, 2009 WL 2163503, at *2 (W.D. Okla. Jul. 10, 2009) (observing that "the injury is [the] application of the allegedly invalid regulation").

The standing inquiry requires only that the party's injury be "fairly traceable to the defendants' allegedly unlawful conduct." *Gutierrez*, 518 F. Supp. 2d at 83 (quoting *DaimlerChrysler v. Cuno*, 547 U.S. 332, 342 (2006)). All ACLA must show is that the Secretary's final rule "increase[s] the probability" that by exempting hospital laboratories from the reporting requirements, fewer hospitals will be required to report data and ACLA's members will suffer competitive and other injuries. *Id*. (rejecting the view, advanced by the Secretary here, that a party must show proximate or but-for causation to establish standing). That burden has been satisfied. The Secretary cannot violate a statute and then escape review on the theory that, although regulated parties are injured, they have no ability to calculate precisely the magnitude of harm caused by the violation.

The Secretary also contends that any injury is not redressable. HHS Br. 23. But that is also wrong. All that is needed to redress the ACLA members' injuries is for the Court to order the Secretary to implement the statute that Congress enacted and to strike down the Secretary's *ultra vires* attempt to rewrite the statute to his own liking. That would not require the Secretary to devise an "appropriate" definition, for the statutory definition already exists. ACLA's members have a right to have the statute applied as written and not to be singled out for regulatory burdens that Congress intended to be applied to all applicable laboratories.

C. ACLA Has Satisfied the Presentment Requirement.

The purpose of the jurisdictional presentment requirement, found in section 405(g), is to channel claims through the agency's administrative process to ensure that the agency has an opportunity to "correct is own errors" and "compile a record which is adequate for judicial

review." *Weinberger v. Salfi*¸ 422 U.S. 749, 765 (1975); *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). There can be no dispute that the purpose of this requirement has been satisfied. ACLA and its members have repeatedly presented their objections to the Secretary, the Secretary has had every opportunity to correct his errors, and the Secretary has compiled an administrative record that is adequate for judicial review. *See* Doc. 1-4, Khani Decl. ¶ 12; *see also* Op. Br. 22. The Secretary cites cases where comments and letters have not been deemed sufficient under section 405(g), but he cannot deny that ACLA has given the Secretary every opportunity to revise his regulations to comply with the law. He also cannot deny that in it least one case the D.C. Circuit has suggested that submitting a letter to the agency is sufficient to satisfy the jurisdictional presentment requirement. *See Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010).

The Secretary has not meaningfully responded to ACLA's assertion that the presentment and channeling requirements of section 405(g) do not apply because the nature of ACLA's claim cannot be reviewed administratively. In any event, out of an abundance of caution, one of ACLA's members has already submitted its objections to the Secretary's administrative contractor in the context of specific claims for payment. *See* Exhibit A (seeking redetermination of an initial determination) That member has thus complied with the Secretary's narrow view of what the law requires, filing an administrative appeal challenging the Secretary's regulation that conflicts with the statutory definition of "applicable laboratory." Even though the contractor has no authority to adjudicate the member's legal claim, the presentment requirement is therefore satisfied and there is no bar to judicial review.

Because an administrative appeal has been filed by one of ACLA's members, if section 405(g) applies, the only question that remains is whether this Court should excuse further

exhaustion. As ACLA's opening brief explains, excusing exhaustion is appropriate when further exhaustion would be futile. *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 other factors"). As courts have recognized, "exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law." *Hall v. Sebelius*, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) (quoting *DL v. Dist. of Columbia*, 450 F. Supp. 2d 11, 17 (D.D.C. 2006)).

The Secretary cannot dispute that ACLA's challenge to the regulations presents a pure legal issue. Nor can he dispute that the agency's adjudicators are required to follow the Secretary's data-reporting regulation. *See* 42 C.F.R. § 405.1063(a). This is not a challenge to an individual decision, where agency expertise could be important; instead, it is a challenge to the Secretary's regulation as a whole, reflecting the Secretary's failure to comply with the statutory requirements in promulgating a system-wide rule of general applicability. *See DL*, 450 F. Supp. 2d at17. Where the final administrative adjudicator does not have authority to decide the question of law, Congress has recognized that there is no need for administrative review and has authorized the Secretary to grant expedited access to judicial review. 42 U.S.C. § 1395ff(b)(2). The Secretary has adopted regulations that grant reviewers the authority to acknowledge purely legal challenges and to certify those claims to federal court. *See* 42 C.F.R. § 405.990. There is no reason that should not occur here, for further exhaustion through the administrative process would be clearly useless. The Secretary offers no plausible reason to delay this Court's consideration of the issues set forth in ACLA's complaint.

II. The Secretary's Final Rule Exceeds His Authority.

The Secretary's final rule is unlawful and *ultra vires* because it rewrites the statute to exempt hospital laboratories from the data-reporting requirements that Congress imposed. It does that by changing the definition of "applicable laboratory" and effectively eliminating the statute's "majority of revenue requirement" as applied to hospital laboratories. Instead of looking at the Medicare revenues of the laboratory itself as Congress directed — comparing the *laboratory*'s total Medicare revenues with the *laboratory*'s revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule — the Secretary's final rule considers the Medicare revenues of the hospital as a whole, thereby taking into account massive amounts of revenues that have nothing do with the services that the laboratory provides. Because a hospital's total Medicare revenues will always dwarf the revenues of the laboratory itself, the final rule exempts hospital laboratories from the data reporting requirements, even if a majority of the laboratory's revenues are from the relevant fee schedules. *See* Op. Br. 27, 29 (showing how Secretary has rewritten the statute and changed the equation required by PAMA).

The Secretary offers no serious defense of this clear statutory violation. He asserts that the statute is ambiguous, but he identifies no *relevant* ambiguity that could justify reading "laboratory" to mean "hospital as a whole." He cannot show that his interpretation is either a reasonable or permissible interpretation of what the statute requires. Instead, he suggests that it is too difficult to comply and he is dissatisfied with the alternatives proposed by ACLA. None of his arguments justify his patent violation of the statutory requirements.

A. The Secretary's Final Rule Violates the Statute.

The Secretary contends that the definition of "applicable laboratory" is ambiguous and, therefore, he is entitled to do as he pleases. But the Secretary does not identify any *relevant* ambiguity. Although the statute "does not speak to the precise issue of how to define a

'laboratory' that receives Medicare 'revenues,'" as the Secretary contends, HHS Br. 29, that does not mean that the statute is ambiguous for *Chevron* purposes. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837, 843 (1984) (statute must be "silent or ambiguous *with respect to the specific issue*" to defer to the agency's reasonable construction) (emphasis added). "[C]lever lawyers with strong motivation can always imagine multiple meanings for any word in any context." *Athridge v. Aetna Cas. & Sur. Co.*, 351 F.3d 1166, 1172 (D.C. Cir. 2003). Accordingly, for an agency's interpretation to be entitled to deference, the statute must be ambiguous in some "relevant sense." *Cf. NetCoalition v. SEC,* 715 F.3d 342, 352 (D.C. Cir. 2013) (because statutory language was "not ambiguous in any sense relevant here," the court could not "displace, or [] improve upon, the jurisdictional choices of Congress") (citation omitted). As Justice Scalia explained, "[d]eference is appropriate" only "where the relevant language, carefully considered, can yield more than one reasonable interpretation, not where discerning the only possible interpretation requires a taxing inquiry." *Pauley v. BethEnergy Mines, Inc*., 501 U.S. 680, 707 (1991) (Scalia, dissenting).

There is nothing taxing about the interpretive inquiry required in this case. The statutory definition of "applicable laboratory" and the statutory command that the Secretary collect data from all applicable laboratories unambiguously precludes the Secretary's approach. *See Rapanos v. United States*, 547 U.S. 715, 752 (2006) (plurality opinion) (finding that the statutory text was "in *some* respects ambiguous," but that "[t]he scope of that ambiguity [did] not conceivably extend" to the interpretation advocated by the agency) (emphasis original). Instead of considering whether a majority of each laboratory's revenues are from the relevant Medicare fee schedules, the Secretary's final rule looks at the revenues of the larger hospital as a whole. But there is no way to construe "laboratory" to mean "hospital as a whole." The Secretary's

position simply cannot be reconciled with the statutory text and structure. *Brown v. Gardner*, 513 U.S. 115, 118 (1994) ("[a]mbiguity is a creature not of definitional possibilities but of statutory context"). As ACLA's opening brief explains, the Secretary's position not only rewrites the statutory term "applicable laboratory," it also effectively drains any meaning or purpose from the majority of revenues requirement as applied to hospital laboratories. *See Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018) ("the Court rejects an interpretation of the statute that would render an entire subparagraph meaningless").

The Secretary does not dispute that his final rule on its face changes the calculation called for under the statute. *See* Op. Br. 27, 29 (describing how the Secretary's rule changes PAMA's equation); *see also* 81 Fed. Reg. 41,036, 41,043 (June 23, 2016) (explaining that for purposes of applying the majority of revenues requirement, the Secretary would consider not only whether the entity is a laboratory but whether it "is a larger entity that has at least one component that is a laboratory"); *id.* at 41,046 (rejecting proposal where "the majority of Medicare revenues threshold would be applied to the hospital's laboratory rather than to the entire hospital"). Nor does he point to any evidence that Congress intended to exempt virtually all hospital laboratories from the data-reporting requirements. To the contrary, during the rulemaking proceedings the Secretary highlighted the importance of "defin[ing] laboratory broadly enough to encompass every laboratory type that is subject to the" Clinical Laboratory Fee Schedule. 81 Fed. Reg. at 41,042. The Secretary also recognized that "hospital outreach laboratories should be accounted for in the new [Clinical Laboratory Fee Schedule] payment rates" and that "it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting [Clinical Laboratory Fee Schedule] payment amounts." *Id.* at 41,045.

With no answer, the Secretary tries to distract from the inconsistencies between his final rule and the statute by focusing on ACLA's comments. But to prevail in this case, it is enough for ACLA to show the Secretary has not complied with the statute. The Secretary cannot violate the statute by pointing to supposed inadequacies in the comments he received. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1199 (D.C. Cir. 2005) ("[I]t was not [the plaintiff's] burden to present alternatives; it was the Commission's burden to prove the reasonableness of its" action.).

In any event, the Secretary does not fairly describe ACLA's position. For example, the Secretary notes that, in comments, ACLA acknowledged that the terms "laboratory" and "revenues" are not defined in the statute. HHS Br. 30; *but see Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1373 (D.C. Cir. 2007) ("the absence of a statutory definition does not render a word ambiguous," it merely requires that the term be given its ordinary meaning). But as ACLA's opening brief explains, the Secretary defined "laboratory" by appropriately looking to the Clinical Laboratory Improvement Amendments of 1988, which define "laboratory" to include any "facility for the biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings." 81 Fed. Reg. at 41,042 (citing 42 C.F.R. § 493.2). No one challenges this definition, which certainly covers laboratories *in* hospitals. The definition is broad, but it is not so broad to include all of the component parts of entities (like hospitals) that are not themselves laboratories and do not provide laboratory services. For example, the definition cannot possibly

describe a hospital radiology department, yet the Secretary includes revenue from that department in his new regulatory test.

Moreover, the Secretary's new definition does not in fact resolve any purported ambiguity. Instead of clarifying the term "laboratory," he has effectively replaced it with "any entity with an NPI that has at least one component that is a laboratory." 81 Fed. Reg. at 41,043. On its face, that rewrite is inconsistent with the statute Congress enacted. There is no textual basis for taking into account Medicare revenues generated by parts of an entity that are not laboratories and have nothing to do with providing clinical laboratory services.

The Secretary also notes that ACLA acknowledged that it might not always be a simple task to determine the revenues attributable to a hospital laboratory. *See* HHS Br. 30. But that does not mean that the Secretary was free to just "throw up [his] hands" and rewrite the statutory requirements. *Cobell v. Salazar*, 573 F.3d 808, 813 (D.C. Cir. 2009). ACLA repeatedly told the Secretary that the statutory definition of "applicable laboratory" must include hospital laboratories that perform outreach testing services and must take into account the revenue of the laboratory itself, and not of the hospital as a whole. *See, e.g.*, Doc. 1-4, Khani Decl. at 26, 39, 99, 157 and 265. By stating that the Secretary "first must determine whether an 'applicable laboratory' includes a hospital laboratory, where a majority of the *laboratory's* Medicare revenue comes from" the Clinical Laboratory Fee Schedule or Physician Fee Schedule, *id*. at 39, 71 (emphasis added), ACLA did not mean that the statute authorized the Secretary to exempt hospital laboratories from the statutory requirements. The context of ACLA's comments makes this clear. *See, e.g.*, *id.* at 39 ("[t]he law is clear that the appropriate inquiry is from what sources a *laboratory's* Medicare revenues are derived [and t]o answer that, it is appropriate to look at the laboratory within the hospital . . . .").

In short, the Secretary has no authority to rewrite the definition of "applicable laboratory" to change the words "a laboratory" to read a "hospital as a whole." ACLA's point is and has always been that a laboratory means a laboratory, and the Secretary has no authority to change the statute. The Secretary's contrary interpretation is impermissible and, because it violates the statute's plain text, should not be allowed to stand.

B. The Secretary's Final Rule Is Unreasonable and Arbitrary and Capricious.

Even if this Court were to identify some relevant ambiguity in the statute, the Secretary's attempt to rewrite "laboratory" to mean the "hospital as a whole" is unreasonable. No one could reasonably conclude that Congress intended the revenues from a hospital's surgery department, for example, to be relevant in determining whether a majority of the laboratory's revenues are from certain laboratory fee schedules such that the laboratory operates predominantly as an outreach laboratory. Moreover, because the Secretary has never responded reasonably to ACLA's objections, his final rule is also arbitrary and capricious.

The Secretary offers no meaningful defense of his statutory interpretation. He asserts that Congress intended to exclude hospital laboratories, because "most hospital laboratories would not meet the majority of revenues threshold." HHS Br. 34. But the whole point of PAMA was to avoid that sort of generalization in order to obtain accurate data from the laboratory market as a whole. Hospital laboratories qualify as "applicable laboratories" if a majority of their revenues are the result of providing outreach services to non-hospital patients. Congress could have easily worded the statute differently if it had intended to grant hospital laboratories a blanket exclusion from the data-reporting requirements. Instead, using plain language, it expressed its intent that all laboratories — including hospital laboratories — would be subject to the same statutory test for determining which laboratories would be required to report data. As the Secretary acknowledges, he conceded when promulgating his rule that "hospital outreach laboratories

should be accounted for" and required to report data. HHS Br. 34–35 (quoting 81 Fed. Reg. at 41,045). That concession was necessary because hospital laboratories providing outreach services are a major segment of the market — accounting for approximately 26 percent of the payments made under Medicare's Clinical Laboratory Fee Schedule in 2016. *See* Office of Inspector General, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data,* OEI-09-16-00140 (Sept. 2017), at 2, *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf.

Having conceded this point, however, the Secretary's final rule does not come close to accomplishing his stated objective. The Secretary implies that by requiring entities to report based on their National Provider Identifier ("NPI"), the Secretary's rule reasonably distinguishes between hospital laboratories that meet the statutory majority of revenues requirement and those that do not. Stated another way, the Secretary's rule assumes that hospital laboratories that operate significant outreach programs are likely to have a separate NPI. But there is no record support for that unreasonable assumption. Nothing in statute or regulation requires a hospital to obtain a separate NPI for its laboratory and most do not. *See, e.g.*, Doc. 1-4, Khani Decl. ¶ 32. The fact that a hospital laboratory happens to bill under a separate NPI says nothing about the amount of outreach services provided by the laboratory compared to services provide to hospital patients. Accordingly, whether a hospital laboratory has a separate NPI is not an accurate indicator as to whether the hospital laboratory meets PAMA's majority-of-revenues requirement.

A hospital laboratory that uses a separate NPI to bill Medicare by definition collects 100 percent of its Medicare revenues from the Clinical Laboratory and Physician Fee Schedules. Accordingly, because obtaining a separate NPI is voluntary, there is no incentive for hospitals that might otherwise meet the majority revenue requirement to obtain a separate NPI for their

laboratories and be subject to burdensome reporting requirements. The NPI is an unreasonable and arbitrary proxy because it does not (and cannot) reliably identify which hospital laboratories provide most of their services on an outreach basis and, therefore, satisfy the statute's majority of revenues requirement. Moreover, because obtaining a separate NPI is entirely voluntary, the Secretary has effectively made PAMA's reporting obligations optional for hospital laboratories, but not for independent laboratories or physician office laboratories that meet the statutory requirements. The Secretary touts the fact that certain hospital associations "supported the use of an NPI to permit outreach laboratories to report private payor data." HHS Br. 35. But it is hardly surprising that hospital laboratories would be enthusiastic about escaping the burdens of the mandatory reporting obligations that Congress imposed. *See* Doc. 1-3, Shorten Decl. ¶¶ 21, 25, 29–30 (describing the substantial burdens and multi-million dollar costs associated with reporting). No reader of PAMA and its mandatory reporting penalties, however, could reasonably conclude that Congress intended PAMA's reporting obligations to be voluntary.

The Secretary cites no evidence or findings in its final rule adequate to show that the NPI requirement reliably identifies hospital laboratories that meet the statutory revenue requirements. Instead, he suggests that the NPI requirement is appropriate because otherwise it would be too difficult to determine what portion of a hospital laboratory's revenues were attributable to services provided to hospital patients (which would be reimbursed in a bundled payment under the Inpatient Prospective Payment System or the Outpatient Prospective Payment System) and what portion were attributable to services provided to non-hospital patients (which would be reimbursed on a fee-for-service basis under the Clinical Laboratory or Physician Fee Schedules). But as ACLA's opening brief explains, that "self-serving" claim of "impracticability" is not entitled to deference. *Nat'l Treasury Employees Union v. Horner*, 654 F. Supp. 1159, 1164

(D.D.C. 1987). It is also implausible. Hospitals are required to "maintain sufficient financial records and statistical data for proper determination of costs payable under the [Medicare] program . . . [using] [s]tandardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields[.]" 42 C.F.R. § 413.20(a). There is no reason hospitals cannot be required to use these accounting systems to ensure that they identify what revenues are attributable to the services their laboratories provide, even when those services are reimbursed through a bundled payment. *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 91 (2002) ("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'").

With no answer to this point, the Secretary blames ACLA for not proposing alternatives that he views as adequate. HHS Br. 31. But it is not ACLA's burden to identify appropriate alternatives; it is the Secretary's burden to comply with the statute. The Secretary is not free to violate the statute just because he is not satisfied with the alternatives that commenters propose. *See PPL Wallingford Energy*, 419 F.3d at 1199.

The Secretary is also far too dismissive of ACLA's proposals. ACLA repeatedly attempted to engage the Secretary with proposals that would allow him to comply with the statutory requirements. *See, e.g.*, Doc. 1-4, Khani Decl. at 263 (urging the Secretary to take into account laboratories that bill on certain types of claims forms associated with the Clinical Laboratory Fee Schedule and Physician Fee Schedule); *id.* at 159 (suggesting "an alternative approach" to determine whether a hospital laboratory's Medicare revenues are from the Clinical Laboratory Fee Schedule and/or Physician Fee Schedule by using hospital payment-to-charges ratios); *id.* ("defining 'applicable laboratory' as a facility that is identified by a CLIA number

would be the most accurate reflection of Congress' intent: to receive information about private payor rates for those laboratories that derive a majority of their Medicare revenues from the [Clinical Laboratory Fee Schedule] and/or [Physician Fee Schedule]"). The point of these suggestions is that the Secretary had a wide range of options available to comply with Congress's directives. The Secretary's decision to reject all of them, and not to develop any reasonable alternative of his own, only confirms that the Secretary has not taken seriously his statutory obligations.

The Secretary distorts ACLA's comments and reads them out of context, but the underlying point remains the same: The Secretary cannot comply with the statute by taking into account revenues *related to the broader hospital entity*. ACLA has never wavered on that basic objection. And the Secretary has never reasonably responded.

CONCLUSION

The Court should grant summary judgment to ACLA and set aside the Secretary's final rule rewriting the statutory definition of "applicable laboratory."

Respectfully submitted,

/s/ Ashley C. Parrish
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Dated: April 6, 2018

CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2018, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notice of electronic filing to all counsel of record who have consented to electronic notification.

/s/ Ashley C. Parrish
D.C. Bar No. 464683
KING & SPALDING LLP

Exhibit A

BioReference
LABORATORIES
an OPKO Health Company

March 1, 2018

VIA U.S. EXPRESS MAIL TRACKING NO. EL 839482985 US AND FAX

Medicare Appeals
Novitas Solutions
Medicare Part B – New Jersey Part B
P.O. Box 3031
Mechanicsburg, PA 17055-1803

Re: **REQUEST FOR REDETERMINATION**

Appellant/Supplier: **BIOREFERENCE LABORATORIES, INC.**
Tax I.D. (last 5 digits): 05059
Medicare PTAN: 301910
NPI: 1134277494
Beneficiaries: Multiple (Attachment 1)

To Whom It May Concern:

In accordance with 42 C.F.R. §§ 405.940-405.946, this letter constitutes a request by BioReference Laboratories, Inc. ("BioReference") for a redetermination relating to the claims listed in **Attachment 1** ("Request"). BioReference furnished certain clinical laboratory services to the beneficiaries identified at Attachment 1, and Attachment 1 lists the name, Medicare health insurance claim number, services or items, claim number and dates of service for each Medicare beneficiary whose claims are the subject of this appeal. The claims set forth at Attachment 1 are aggregated for purposes of this Request as they all share the same issue as set forth below.

Under Section 216(a) of the Protecting Access to Medicare Act ("PAMA"), the Secretary of HHS is required to collect information regarding commercial payment rates for clinical diagnostic laboratory services from "applicable laboratories." *See* 42 U.S.C. § 1395m-1(a). PAMA defines an "applicable laboratory" as any laboratory that receives a majority of its Medicare revenue from the Clinical Lab Fee Schedule or the Physician Fee Schedule. *Id.* § 1395b-1(a)(2). Section 216(b) of PAMA requires the Secretary to use the information collected from "applicable laboratories" to determine future payment rates for clinical diagnostic services. *Id.* § 1395m-1(b). These rates apply to clinical diagnostic services provided on or after January 1, 2018.

The Secretary has adopted a regulatory definition that conflicts with PAMA 216(a) by limiting "applicable laboratories" to those that separately bill the Medicare program using their own National Provider Identifier ("NPI"). 42 C.F.R. § 414.502(b). The purpose and effect of this definition is to exclude numerous applicable laboratories from PAMA 216's reporting requirement. BioReference challenges the Secretary's regulation on the basis that it is arbitrary

and capricious, violates the Medicare statute, and exceeds the authority granted to the Secretary by Congress.

There are no material facts in dispute in this appeal. The only factor precluding a decision favorable to BioReference is a determination of the invalidity of 42 C.F.R. § 414.502(b). Medicare Administrative Contractors, Qualified Independent Contractors and Administrative Law Judges are bound by the Secretary's regulation and cannot provide that relief. BioReference respectfully requests prompt action on this appeal so that it may file a request for Expedited Access to Judicial Review pursuant to 42 C.F.R. § 405.990 at the earliest juncture.

For the foregoing reasons, BioReference respectfully requests redetermination of the claims set forth at Attachment 1.

Very truly yours,

Jane Pine Wood, Esq.
Chief Legal Officer
BioReference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NJ 07407
Email: jwood@bioreference.com
Office: 800-229-5227 ext.7800

29313

MEDICARE PART B REDETERMINATION AND CLERICAL ERROR REOPENING REQUEST FORM

FAX to: 1-888-541-3829

***EACH FIELD OF THE FORM MUST BE FILLED OUT TO AVOID HAVING YOUR REQUEST DISMISSED**

Do not complete this form for the following situations: Shade Circles like this ● Not like this ⊗ ✓

1. If you received a Medicare Redetermination Notice (MRN) on this claim DO NOT use this form to request further appeal. Your next level of appeal is a Reconsideration by a Qualified Independent Contractor (QIC) (https://www.novitas-solutions.com/partb/forms/pdf/rrf/pdf).
2. If you received a message MA-130 on the Medicare Remittance Notice for this claim, no appeal or reopening rights are available. Please submit a NEW claim with the appropriate corrections.

If this request is due to a Prior-Authorization denial select from the drop down:

***Please select one of the following jurisdictions and select YES or NO to the questions below:**

○ AR ○ CO ○ DCMA ○ DE ○ LA ○ MD

○ MS ● NJ ○ NM ○ OK ○ PA ○ TX/IHS/ Veterans

1. Does your appeal involve the Recovery Auditor (RA) decision? ○ Yes ● No
2. Does your appeal involve a 935 overpayment decision? ○ Yes ● No
3. Does the claim you are appealing involve Medicare Secondary Payer (MSP)? ○ Yes ● No

***Please select one of the choices below to identify the category which the request pertains to:**

○ Procedure Codes 00100-69999 ● Procedure Codes 70000-89999 ○ Chiropractic Services

○ Procedure code beginning with "J" or "G" or 90000-99999 or Ambulance Services ○ Other

***Please fill in the information below in all UPPERCASE letters:**

Provider Transaction Access No (PTAN):	NPI *(10 digits):*	Tax Identification Number *(last 5 digits):*
301910	1134277494	05059

Provider Name: BIOREFERENCE LABORATORIES, INC.

Beneficiary First Name:	Beneficiary Last Name:
SEE ATTACHMENT 1	SEE ATTACHMENT 1

Beneficiary Medicare Number *(11 digits):*	Claim Number *(13 digits):*
SEE ATT. 1	SEE ATT. 1

Date(s) of Service	Procedure Code(s) in Question
SEE ATTACHMENT 1	SEE ATTACHMENT 1
Requestor's Name *(Printed)* JANE PINE WOOD	Requestor's Relationship to Provider VP, Legal
Requestor's Signature [signature]	Telephone Number and Extension 800-229-5227 ext.7800

***Reason for Redetermination or Clerical Error Reopening Request:**

BioReference challenges the validity of 42 C.F.R. Section 414.502(b) for the reasons explained in detail in the attached letter and seeks redetermination of the claims set forth in Attachment 1.

Attachment 1

Attachment 1 is an excel spreadsheet that identifies 712 Medicare claims for clinical laboratory services. Plaintiff American Clinical Laboratory Association has redacted this information in full because it consists almost entirely of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review the information, however, ACLA will file it under seal upon the Court's request.