IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, *In His Official Capacity as Secretary of Health and Human Services*, Defendant.	Civil Action No. 1:17-cv-2645 (ABJ)

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

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INTRODUCTION

In passing the Protecting Access to Medicare Act of 2014 ("PAMA"), Congress sought to "align Medicare reimbursement rates for laboratory tests with rates paid for such tests in the private market." *Am. Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1198 (D.C. Cir. 2019). The Secretary of Health and Human Services has thwarted Congress's goal by failing to reasonably implement the statute's data-collection provisions. Instead of determining whether a hospital laboratory receives a majority of "its [Medicare] revenues" from the relevant fee schedules, as Congress directed, *see* 42 U.S.C. § 1395m-1(a)(2), the Secretary's final rule unreasonably sweeps in the revenues of any "entity that has at least one component that is a laboratory," thereby taking into account massive amounts of revenue received by the hospital as a whole (and not just the laboratory). Because the Medicare revenues of an entire hospital, attributable to services that have nothing to do with clinical laboratory services, will always dwarf the Medicare revenues of the laboratory itself, the Secretary's final rule unreasonably eliminates the statute's majority-of-revenues requirement as applied to hospital laboratories and exempts them from PAMA's data-collection requirements. Moreover, by categorically excluding hospital laboratories from the statutory requirements, the Secretary's final rule fails to capture a complete and accurate view of the laboratory market and, as a result, guarantees that payment amounts will not be set at the levels that Congress intended. When ACLA and other parties raised these serious concerns during the rulemaking proceedings, the Secretary declined to justify the rule's deviation from the statute's text and clear purpose. The Secretary's rule thus fails on both substantive and procedural grounds.

The Secretary's brief only confirms these conclusions. In response to ACLA's motion, the Secretary barely defends his rule on its merits. He asserts that the statute is ambiguous, but he never identifies any *relevant* ambiguity that would render his interpretation reasonable. He tries

to explain why he rejected a variety of approaches suggested by commenters, but he offers no basis for concluding that the statute's majority-of-revenues requirement is reasonably interpreted to sweep in non-laboratory revenues of larger entities with which laboratories are affiliated. He also advances a host of policy arguments about administrative convenience, but none of these arguments justify his unreasonable departure from the statutory requirements or his failure to provide a reasoned explanation for his rule.

With no meaningful defense on the merits, the Secretary focuses most of his brief on relitigating the D.C. Circuit's jurisdictional analysis, raising another round of unsound barriers to judicial review. But these efforts to escape review misconstrue the law and the record before this Court. Because ACLA's members are directly regulated by the Secretary's final rule — which is causing them injury-in-fact by inappropriately reducing the payments they receive and harming them competitively — ACLA has standing to bring suit and to require that the Secretary implement the statute as Congress intended. The Court can redress ACLA's injuries by vacating the Secretary's rule and requiring the Secretary to remedy his errors, which will necessitate that the Secretary collect data consistent with the statutory requirements and reimburse laboratories at the levels that Congress intended. That live controversy is ripe for this Court's decision. Moreover, because the agency has already twice concluded that the administrative process does not provide a vehicle for resolving the claims that ACLA's members have presented, any further administrative proceedings would be a waste of time. There is no reason to delay judgment.

This Court should grant ACLA's motion, set aside the Secretary's rule, and direct the Secretary to comply with the statute that Congress enacted.

REPLY IN SUPPORT OF ACLA'S MOTION FOR SUMMARY JUDGMENT

The Secretary's final rule impermissibly and unreasonably redefines "applicable laboratory" in contradiction of PAMA, exempting almost all hospital laboratories from the statute's data-collection requirements. To make matters worse, the Secretary failed to justify or even acknowledge his departure from the statutory text. Accordingly, the rule fails as both an unreasonable interpretation of the statute and an arbitrary and capricious exercise of administrative authority.

I. The Secretary's Final Rule Is Arbitrary and Capricious, an Abuse of Discretion, and Contrary to Law Because it is Substantively Invalid.

The text, structure, and purpose of PAMA foreclose the Secretary's interpretation of "applicable laboratory." *See* ECF No. 53-1 at 17–24. "Even under *Chevron*'s deferential framework, agencies must operate 'within the bounds of reasonable interpretation.'" *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 321 (2014) (quoting *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013)). The Secretary has failed to do so here.

The point should go without saying: "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Bennett v. Islamic Republic of Iran*, 618 F.3d 19, 22 (D.C. Cir. 2010) (quoting *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist*, 541 U.S. 246, 252 (2004)). In ordinary usage, the statute's reference to a laboratory's revenues ("its revenues"), 42 U.S.C. § 1395m-1(a)(2), means the revenues of a *laboratory*. It is not reasonable — as a matter of basic English — for the Secretary's rule to rewrite the statute in a way that inescapably sweeps in the *non-laboratory* revenues of each hospital laboratory's broader host hospital. *See* 42 C.F.R. § 414.502. Congress instructed the Secretary to look at the revenues received by each laboratory

("*its* revenues"); those revenues do not include the revenues of other entities with which the laboratory may be affiliated.

Even if that were not so obvious, the statute's structure and its clear, uncontroverted purpose would preclude the Secretary's rule. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132–33 (2000) ("the words of a statute must be read in their context and with a view to their place in the overall statutory scheme") (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989)). The statute's data-reporting provisions exist to give the Secretary an accurate picture of the private market for laboratory testing. *See* 42 U.S.C. § 1395m-1(a)(1). The statute then directs the Secretary to use that data to calculate market-approximating Medicare reimbursement rates. *Id.* § 1395m-1(b)(2). The end goal is to "ensure that Medicare rates reflect true market rates for laboratory services." 160 Cong. Rec. S2860 (May 8, 2014) (statement of Sen. Richard Burr, affirmed by Sen. Orrin Hatch); *see also Am. Clinical Lab. Ass'n*, 931 F.3d at 1199 ("A central goal of the Act is to set Medicare reimbursement rates for laboratory tests at approximately the price private insurers pay for the same tests."). The data cannot serve that purpose if it systematically excludes an entire subset of "applicable laboratories" that tend to receive higher payments for the relevant services they provide. *See* Kolozsvary Decl. ¶ 16; Shorten Decl. ¶ 14; *see also* ECF No. 53-1 at 18–20 (explaining the statutory scheme and the Secretary's rule in detail).

Yet that is exactly what the Secretary's final rule does. By looking at revenues on the NPI level, the Secretary all but guaranteed that a hospital's non-laboratory total Medicare revenue would overwhelm the relevant fee schedule revenue of the hospital laboratory itself. *See* ECF No. 53-1 at 19. The rule thus excludes virtually all hospital outreach laboratories from the reporting requirements — an abridgment of the data set that frustrates the statute's end goal. *See id.* And

although the Secretary may exempt certain laboratories from reporting through volume or expenditure thresholds, *see* 42 U.S.C. § 1395m-1(a)(2), that provision cuts against the Secretary's claim to broader exemption authority. *See Sierra Club v. EPA*, 551 F.3d 1019, 1028 (D.C. Cir. 2008) (explaining that statutory grants of certain exception powers indicate an intent to withhold others). Context thus confirms what the plain text indicates: The Secretary's rule is unreasonable because it defies congressional intent.

The Secretary's brief fails to show otherwise. The Secretary claims that ambiguity in the meaning of "laboratory" left room for the Secretary's interpretation. *See* ECF No. 54-1 at 25–27. But no one disputes that a "laboratory" is correctly defined in the final rule to mean "a facility for the … examination of [bodily] materials" in furtherance of medical treatment. *See* 42 C.F.R. § 414.502(1) (incorporating 42 C.F.R. § 493.2 by reference). The disagreement is over what revenues should be attributed to each laboratory and, whatever ambiguity might exist, the statute cannot reasonably be interpreted to include revenues attributable to entities that have nothing to do with the provision of clinical laboratory services. Under no reasonable interpretation can non-laboratory revenues received by a larger entity be reasonably ascribed to the laboratory itself ("its revenues," 42 U.S.C. § 1395m-1(a)(2)). *Cf. Loan Syndications & Trading Ass'n v. SEC*, 882 F.3d 220, 224 (D.C. Cir. 2018) ("Even under *Chevron*, after all, agencies only 'possess whatever degree of discretion [an] ambiguity allows.'") (quoting *City of Arlington,* 569 U.S. at 296); *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 592 (D.C. Cir. 2004) ("[T]he ambiguity regarding the permissibility of service-by-service impairment determinations" does not reasonably "extend[] to whether long distance services … are 'services' within the meaning of [the statute] in the first place."). In short, no reasonable interpretation of laboratory revenues could include revenues for services provided by other parts of the hospital, such as revenues received for surgeries.

The Secretary's position relies on a gross overreading of the D.C. Circuit's conclusion that the Secretary's final rule is not *ultra vires*. *Ultra vires* review extends only to "patent violation[s] of agency authority" amounting to "rogue action." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1208 (quoting *Indep. Cosmetic Mfrs. & Distribs., Inc v. U.S. Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978)). It follows that even an otherwise-negligible degree of ambiguity can defeat an *ultra vires* claim. *Cf. Trudeau v. FTC*, 456 F.3d 178, 190 (D.C. Cir. 2006) (explaining that a claim of *ultra vires* action must go beyond a showing of unlawfulness). Accordingly, despite noting some uncertainty in Congress's use of the term "laboratory," the D.C. Circuit held only that the Secretary's rule was "not clearly … so far outside the scope of the task" at hand as to render it *ultra vires*. *Am. Clinical Lab. Ass'n*, 931 F.3d at 1208.

The D.C. Circuit did not purport to be prejudging the merits or the result of proceedings on remand. Whether *ultra vires* or not, it is still far from *reasonable* to think that Congress intended to permit the Secretary to exempt virtually all hospital outreach laboratories from the statute's reporting regime by rewriting the statute's mandate that the Secretary collect data from all "applicable laboratories." *See supra* at 3–5; ECF No. 53-1 at 17–24. Even under the "deferential *Chevron* standard of review, an agency cannot, absent strong structural or contextual evidence, exclude from coverage certain items that clearly fall within the plain meaning of a statutory term." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 592 (D.C. Cir. 2004). The Secretary's attempt to do so here must therefore fail.

The Secretary all but confirms that his statutory argument is deficient by attempting to justify his rule on policy grounds alone. *See* ECF No. 54-1 at 27–33. According to the Secretary, the rule should survive *not* because it actually requires reporting from all "applicable laboratories"

as the statute demands, but because it offers an easily administrable way of approximating the data Congress intended the statute to reach. *See id.*

Even if the Secretary were right, that would not bring his rule in line with the statute. "Policy concerns cannot … turn a textually unreasonable interpretation into a reasonable one." *Loan Syndications*, 882 F.3d at 226. And the fact that an unlawful rule might approximate Congress's end goal is no defense under the APA. *See, e.g.*, *Waterkeeper All. v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017) ("[A]s we've long made clear, '[a]gencies are ... "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."'") (quoting *Colo. River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139–40 (D.C. Cir. 2006)).

The Secretary's failure to grasp this point illustrates the fundamental problem with his position. Contrary to the Secretary's repeated assertions, ACLA does not in the abstract fault the rule for collecting "data from *too few* hospital laboratories." ECF No. 54-1 at 30–31 (emphasis added); *see also id.* at 1, 14, 15 (repeating similar claims). The statute provides the Secretary several lawful ways to limit the quantity of reports. *See* 42 U.S.C. § 1395m-1(a)(2). But that is not what happened here. ACLA takes issue with the *manner and means* by which hospital laboratories were excluded. *See, e.g.*, ECF No. 53-1 at 1–2. Put differently, this lawsuit is about whether the data set the Secretary collected was *qualitatively* different from the set that Congress envisioned. By attempting to minimize the importance of Congress's mandate, the Secretary all but concedes that his final rule does not fall within the bounds of interpretive reasonableness. This Court should thus set the Secretary's rule aside as arbitrary, capricious, an abuse of discretion, and contrary to law.

II. The Secretary's Final Rule Is Arbitrary, Capricious, an Abuse of Discretion, and Contrary to Law Because it is Procedurally Invalid.

The Secretary's rule also fails because it is procedurally infirm. When an administrative agency engages in rulemaking, it must "articulate a satisfactory explanation for its action." *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005). If interested parties raise reasonable objections, the agency must provide reasonable responses. *Id.* (citing *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2011)). The Secretary's failure to do so here provides an independent basis for invalidating the final rule.

Under the Secretary's initial rulemaking proposal, the regulatory definition of "applicable laboratory" would have required facilities to report at the TIN level. *See* HHS, *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System*, 80 Fed. Reg. 59,386, 59,392 (Oct. 1, 2015). But the Secretary also discussed the possibility of "defining an applicable laboratory at the NPI level instead," and solicited comments on that proposal. *Id.* Neither definition squares with the statute as discussed in ACLA's opening brief. *See* ECF No. 53-1 at 17–24. But after receiving a host of comments and other communications raising this concern and proposing alternatives, *see* ECF No. 53-1 at 25, the Secretary finalized the NPI-level definition nonetheless. *See* HHS, *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System*, 81 Fed. Reg. 41,036, 41,098 (June 23, 2016).

The Secretary gave short shrift to the serious objections raised by ACLA and other stakeholders. Most notably, although the comments repeatedly stressed that the rule would radically change the statute's data-reporting requirements — and distort the resulting rates — by cutting out hospital outreach laboratories, *see* ECF No. 53-1 at 25, *see also* 81 Fed. Reg. at 41,046 (noting commenters' concerns that the "proposed definition of applicable laboratory would

exclude hospital outreach services"), the Secretary offered no rational response. Instead, the Secretary stated only that defining "applicable laboratory" on the NPI level cured his rewrite of the statutory requirements because "[h]ospital outreach laboratories *will be able* to be included as applicable laboratories under the final policy." *id* (emphasis added).

That is not reasoned decisionmaking. Obviously outreach laboratories *could* be included in the data set — if and only if they have their own NPI number. But the overwhelming majority of hospital laboratories *do not* have their own NPI number, Khani Decl. ¶¶ 10, 32, and the Secretary's rule reduced their incentive to get one, *see* Shorten Decl. ¶ 21 ("[R]eporting was a difficult, resource-intensive, and burdensome task …."); *id.* ¶¶ 25–30 (describing the reporting process); *see also* 42 U.S.C. § 1395m-1(a)(9) (providing substantial civil penalties for errors in reporting). Indeed, the Secretary has recognized this very issue in amending the rule for subsequent reporting periods. *See* ECF No. 53-1 at 13–14. More importantly, and in any event, the statute does not permit laboratories to decide for themselves whether they will report. The Secretary's failure to address this criticism in any meaningful way dooms the rule.

The Secretary's only response is to claim that his policy-based justifications for the under-inclusive rule somehow addressed ACLA's more fundamental statutory concerns. *See* ECF No. 54-1 at 34–36. But again, it is not enough to say that the rule might *approximate* the reporting scheme that Congress provided by law. *See, e.g.*, *Waterkeeper*, 853 F.3d at 535. The Secretary had an obligation under the APA to explain why his rule is reasonable and within the statute's parameters. *See Chief Couns. Office v. Labor Relations Auth.*, 739 F.3d 13, 20 (D.C. Cir. 2014) ("[W]hatever the validity of the Authority's policy rationale, it has failed to justify its atextual construction of [the law]."). He did not — indeed, *could not* — do so.

* * *

Congress directed the Secretary to collect data from all laboratories that receive a majority of their revenues from certain fee schedules. It did that to ensure that the data collected by the Secretary would be representative of the market and that the rates calculated based on the data would better approximate market rates. The Secretary's attempt to rewrite the statute to categorically exclude a major group of market participants is unreasonable and contrary to the statute's requirements. Moreover, because the Secretary did not respond meaningfully to comments, the rule is also procedurally invalid. For these reasons, the Court should set aside the Secretary's final rule and direct the Secretary to remedy his statutory violation. *See Philbrick v. Azar,* 397 F. Supp. 3d 11, 32 (D.D.C. 2019) (noting that vacatur and remand is the "presumptively appropriate remedy for a violation of the APA") (quoting *Ill. Pub. Telecomms. Ass'n v. FCC*, 123 F.3d 693, 693 (D.C. Cir. 1997)).

RESPONSE IN OPPOSITION TO THE SECRETARY'S CROSS MOTION FOR SUMMARY JUDGMENT

With no meaningful defense on the merits, the Secretary moves for summary judgment on the theory that this Court lacks authority to resolve this case. ECF No. 54-1 at 13–24. That too is wrong. As indicated on appeal and confirmed by the record on remand, ACLA has both standing to sue and a live controversy with the Secretary. Moreover, and contrary to the Secretary's assertions, the Medicare channeling provisions do not preclude judgment in this case.

I. This Case Is Justiciable.

The Secretary's brief raises standing and mootness arguments aimed at relitigating its loss on appeal. But as the D.C. Circuit's analysis confirms, ACLA has suffered financial harms traceable to the Secretary's unlawful reporting rule that are redressable by an order from this Court

setting that rule aside. The D.C. Circuit held ACLA has standing based on evidence in the record. *Id.* at 1203–04. It likewise held that the statutory bar on challenging reimbursement rates *does not prevent* review of — or relief against — the Secretary's data-reporting regulations. *Id.* at 1204–08. That such relief will implicate reimbursement rates is no barrier to judicial review. On the contrary, the fact that this case falls *outside* of PAMA's jurisdictional bar means that Congress intended the courts to grant effective relief against the Secretary's arbitrary, capricious, and unlawful conduct, regardless of that relief's potential impact on rates and the need for the Secretary to reimburse laboratories that have been short-changed by his unreasonable statutory departure. *Cf., e.g.*, *Sprint Commc'ns, Inc. v. Jacobs*, 571 U.S. 69, 77 (2013) ("Jurisdiction existing … a federal court's 'obligation' to hear and decide a case is 'virtually unflagging.'" (quoting *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976))).

A. ACLA Has Standing to Sue.

The Secretary's assertion that ACLA lacks standing has no basis in law or fact. "To establish standing under Article III, a party 'must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Twin Rivers Paper Co. LLC v. SEC*, 934 F.3d 607, 612 (D.C. Cir. 2019) (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)). ACLA has made those showings here.

ACLA's members have suffered multiple legally cognizable injuries. Their standing is self-evident because they are the direct targets of the regulation and, as parties burdened by the final rule, have the right to insist that the rule comply with the statutory mandate. Where, as here, a party "is 'an object of the action (or foregone 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 [that

party] injury, and that a judgment preventing or requiring the action will redress it." *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561–62 (1992)); *see also Bonacci v. TSA*, 909 F.3d 1155, 1160 (D.C. Cir. 2018) (holding that pilot had standing to challenge screening policies as contrary to statutory requirements even though he admitted that he was "not harmed, per se, by enhanced searching"). Precisely because the Secretary's final rule requires ACLA's members to collect and report private confidential data, while exempting hospital laboratories from the same requirements, it is unsurprising that the Secretary's departure from the statute has caused ACLA's members injury-in-fact sufficient to satisfy standing. ACLA members have suffered concrete injury in several distinct ways.

First, the Secretary's deviation from the statute resulted in lower reimbursement rates than Medicare would otherwise have paid. *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1203 ("ACLA has adequately shown that at least one of its members is reimbursed by Medicare at a rate lower than it would be" without the "limitation in the definition of 'applicable laboratory.'"). Because the final rule does not reasonably implement the statutory requirements, the Secretary's rule has unreasonably denied ACLA and its members the reimbursement that Congress intended for the clinical laboratory services they have provided. In particular, the sworn statements before this Court show that the Secretary's failure to collect data from "large sectors of the clinical laboratory market" has resulted in Medicare reimbursement rates that are "not representative" of the market as a whole. Gudaitis Decl. ¶ 21. Because the non-reporting hospital outreach laboratories "often incur higher costs to provide diagnostic services" and pass those costs on in the form of higher prices, Kolozsvary Decl. ¶ 16, *see id.* at ¶ 27; *see also* Shorten Decl. ¶ 14 (noting hospital laboratories are paid by private payors between 1.5 and 4 times more than independent laboratories), their absence from the data set has depressed the Medicare rates, Kolozsvary Decl.

¶ 32. The resulting injury is sufficient to establish standing because any financial harm, even a single dollar's worth, constitutes an injury-in-fact for standing purposes. *See, e.g.*, *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017) (noting that the amount of injury is "irrelevant").

Second, ACLA's members suffered harm from the reporting process itself. The D.C. Circuit has recognized that the onus to comply with an unlawful regulation is a legally cognizable injury. *See State Nat. Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (holding that a state bank has standing to challenge legality of Consumer Financial Bureau because the bank is regulated by the agency). And the costs of compliance work a financial harm to a regulated party as well. *See City of Waukesha v. EPA*, 320 F.3d 228, 236 (D.C. Cir. 2003) (a showing that a regulated party will face a substantial probability of higher compliance costs is enough to establish standing). In addition, regulated parties can ground standing in the conferring of a relative advantage on their competitors. *Louisiana Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) ("We repeatedly have held that parties suffer constitutional injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition.").

All of these considerations apply here. One of ACLA's members spent nearly $2,000,000 meeting the reporting obligations, Shorten Decl. ¶ 21, while at the same time risking thousands more in potential penalties attached to reporting errors, 42 U.S.C. § 1395m-1(a)(9). Meanwhile, the hospital outreach laboratories that would otherwise have reported under the statute's mandates escaped these same burdens, reducing their operational costs and improving their ability to compete with ACLA's members. ACLA's members have standing to object that they should not

have to comply with a rule that does not faithfully implement the statutory requirements and is causing competitive injury.

Each of the harms identified trace to a common source: the Secretary's disregard for the statute's proper reporting parameters in the reporting rule. The compliance costs and competitive disadvantages obviously derive from the Secretary's unlawful rule. *Cf. Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 636 (D.C. Cir. 2000) (finding traceability and redressability based on averred compliance costs); *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 11 (D.C. Cir. 1998) ("MD's competitive injury is fairly traceable to DEA's decision to issue a certificate of registration to Mallinckrodt."). And ACLA has likewise shown that the reduced rates stem from "the *regulatory definition* of 'applicable laboratory[.]'" ECF No. 54-1 at 14. As ACLA has explained, *see* ECF No. 53-1 at 20, it is only through the Secretary's final rule that the hospital outreach laboratories have been exempted from reporting. *Compare* 42 U.S.C. § 1395m-1(a)(2) (mandating reporting based on *laboratory* revenues), *with* 42 C.F.R. § 414.502 (systematically sweeping in non-laboratory revenues).

Moreover, and contrary to the Secretary's assertions, this Court's invalidation of the Secretary's unlawful rule will redress the injuries suffered by ACLA's members. *See Nat'l Parks Conservation Ass'n v. Manson*, 414 F.3d 1, 7 (D.C. Cir. 2005) (concluding that the redressability requirement was satisfied because a court order setting aside an agency letter would "significantly affect" ongoing proceedings before the agency, even if it would not itself result in a favorable permitting decision). As the D.C. Circuit observed on appeal, "[r]equiring the Secretary to collect more fully representative market data and use it to calculate a new weighted median appears sufficiently likely to increase Medicare reimbursement rates." *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1204. And requiring the nonreporting laboratories to report will also equalize the

regulatory burden. *See Louisiana Energy*, 141 F.3d at 367 (holding that an injury "fairly traceable to FERC's decision freeing [a company] to price at market-based rates … would be redressed by a favorable decision of this court vacating FERC's order" at a competitor's request). A ruling in ACLA's favor — vacating the Secretary's final rule and requiring the Secretary to implement the statute as Congress intended — would require the Secretary to promulgate a new rule, correct his errors, and reimburse the laboratories for services provided at appropriate rates calculated as Congress intended. Accordingly, so long as the unlawful reporting regime is set aside and replaced with a lawful one (as it must be), ACLA's financial injuries will be redressed.

Attempting to avoid this reality, the Secretary contends that ACLA has not provided the *evidence* necessary to support standing at the summary judgment stage. *See* ECF No. 54-1 at 13–14; *but cf. Sierra Club*, 292 F.3d at 900 (D.C. Cir. 2002) (noting that ordinarily "no evidence outside of the administrative record is necessary" to establish standing when a party is a direct object of regulation). But that simply is not true. The analysis above rests on sworn statements — not mere allegations. *See supra* at 12–13 (referencing Gudaitis Decl. ¶ 21, Kolozsvary Decl. ¶¶ 16, 27; 32, Shorten Decl. at ¶ 14). And despite limiting its holding to the standing question at issue, the D.C. Circuit relied on this same evidence in its earlier standing analysis. *See Am. Clinical Lab. Ass'n,* 931 F.3d at 1203–04.

Contrary to the Secretary's suggestion, *see* ECF No. 54-1 at 14–15, ACLA's standing does not turn on its ability to specify precisely how many laboratories should have reported or exactly how much the rates would increase under a proper rule. ACLA cannot be expected to access or analyze confidential, private data the Secretary has refused to collect. Nor can the Secretary bootstrap his statutory violation into an impediment to standing. When a party has suffered financial loss, "the amount" of that loss "is irrelevant." *Carpenters Indus. Council*, 854 F.3d at 5.

Accordingly, so long as the Secretary's rule excluded *some* of the necessary data, and that exclusion is reasonably likely to cause *some* reduction in rates or to cause competitive injury, ACLA can seek redress through an APA remedy in this Court.

B. The Case Is Not Moot.

The Secretary's repackaging of its standing theory as a mootness theory also fails. *See* ECF No. 54-1 at 22–24. "In general a case becomes moot 'when the issues presented are no longer "live" or the parties lack a legally cognizable interest in the outcome.'" *Murphy v. Hunt*, 455 U.S. 478, 481 (1982) (quoting *United States Parole Comm'n v. Geraghty*, 445 U.S. 388, 396 (1980)). "The mootness inquiry" thus "asks whether events subsequent to the filing of the complaint 'have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future.'" *Hardaway v. D.C. Hous. Auth.*, 843 F.3d 973, 978 (D.C. Cir. 2016) (quoting *Am. Bar Ass'n v. FTC*, 636 F.3d 641, 645 (D.C. Cir. 2011)). Any potential for relief, "even … a 'partial remedy,'" can "prevent [a] case from being moot." *Calderon v. Moore*, 518 U.S. 149, 150 (1996) (quoting *Church of Scientology v. United States*, 506 U.S. 9, 13 (1992)).

As already explained, the ability of this Court to set aside the Secretary's unlawful reporting rule gives ACLA a continuing stake in the outcome of this case. If the Secretary's rule is vacated, he will have to (1) replace it with a lawful rule, (2) gather the missing data, (3) recalculate the fee schedules, and (4) provide reimbursement consistent with the proper rates. *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1204. That makes it more than speculative — indeed, "sufficiently likely," *id.* — that a favorable ruling will inure to ACLA's benefit.

The Secretary nonetheless claims — as an apparent offshoot of his "redressability" theory — that this Court "cannot provide a remedy that would change the current … payment rates for

2018 through 2020." ECF No. 54-1 at 22. According to the Secretary, the statute (1) does not allow him to collect new data and (2) precludes ACLA from challenging the resulting reimbursement rates anyway. *See id.* Both points are wrong.

Nothing in the statute prohibits the Secretary from gathering the data necessary to calculate lawful rates. The statute itself directs "applicable laborator[ies]" to report "[b]eginning January 1, 2016, and every three years thereafter." 42 U.S.C. § 1395m-1(a)(1). Accordingly, if ACLA is correct regarding what facilities must qualify as "applicable laborator[ies]," then the excluded hospital outreach laboratories are in arrears with respect to the needed data and should promptly be made to comply. Moreover, given the statute's directive to the Secretary to calculate payment amounts based on "all payment rates reported," *id.* § 1395m-1(b)(2), the reporting of new data would necessarily require calculation of revised rates, *see Am. Clinical Lab. Ass'n*, 931 F.3d at 1204. Such recalculation would yield financial benefits for ACLA's members.

ACLA's inability to challenge the reimbursement rates themselves changes none of this. As the D.C. Circuit recognized, the Secretary's dogged insistence that the bar on challenging the "establishment of payment amounts" shields review of the Secretary's data collection "conflates two issues." *Id.* To be sure, the Secretary's unlawful reporting rule is "linked" to the reimbursement rates. *Id.* But those rates can change *without* any challenge to their "establishment." *See id.* And because the D.C. Circuit has already held that this lawsuit *is not* a "back-door challenge to reimbursement rates in circumvention of the statutory bar," *id.*, the fact that requiring the Secretary to comply with the statute's data-collection requirements would necessarily result in a change to the rates is no barrier to review. *See id.*

II. ACLA Has Met Its Presentment and Exhaustion Obligations.

The Secretary's reanimated claim-channeling argument is also meritless and does not foreclose review. *See* ECF No. 54-1 at 17–21. As ACLA explained in its opening brief, the Secretary passed on his opportunity to raise this issue on appeal, *see* ECF No. 53-1 at 15, even though (*if* correct) it could have resolved all other issues and made them unnecessary to address, *see, e.g.*, *Forras v. Rauf*, 812 F.3d 1102, 1105 (D.C. Cir. 2016) ("Without jurisdiction the court cannot proceed at all in any cause.") (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)). That notable failure speaks to both the merits of the argument and the fairness of allowing the Secretary to hide behind what in this context would be a meaningless exhaustion requirement that would serve no practical purpose except to cause further delay.

This Court should reject the claim-channeling argument because Medicare's claim-channeling provisions do not apply to this case, ACLA has satisfied the presentment requirement, and further exhaustion of administrative remedies would be futile. *See* ECF No. 53-1 at 15. The Secretary's arguments to the contrary are wrong.

First, the Secretary asserts that ACLA members' ongoing efforts to challenge the rule via administrative channels undercut the assertion that those channels offer no hope for relief. ECF No. 54-1 at 19. But the mere engagement of an administrative process says nothing about whether that process is in fact a viable avenue for relief. The Secretary's reviewing bodies have all confirmed — at both the first and second levels of administrative review — their inability to address the legal issues at the heart of this case. *See* ECF No. 53, Ex. B at 6–7; *id*, Ex. C at 8–14. And there is no dispute that the Secretary understands ACLA's objections and has refused to correct the errors that infect its final rule. *See* Khani Decl. ¶ 12. The point of the presentment requirement is to give the agency an opportunity to "correct its own errors" and to "compile a

record which is adequate for judicial review." *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975). The purpose of this requirement has been satisfied in this case. The Court should therefore reject the Secretary's attempt to whipsaw ACLA by forcing it to continue with an administrative process that the agency's own officials have concluded offers no possibility of relief.

Second, the Secretary argues that ACLA flunks the presentment requirement because the administrative claims ACLA relies on were filed after this lawsuit began. ECF No. 54-1 at 20. Even assuming the claims had to be presented, the Supreme Court has long recognized a plaintiff's right to cure this type of alleged jurisdictional defect "while [his] case [is] pending in the District Court." *Mathews v. Diaz*, 426 U.S. 67, 75 (1975). That makes good sense, as indulging the Secretary's argument here would only cause unnecessary additional filings in service of "needless formality." *See Scahill v. Dist. of Columbia*, 909 F.3d 1177, 1184 (D.C. Cir. 2018) (holding that parties may cure jurisdictional defects through amended pleadings). In particular, if the Court were to dismiss on this ground, ACLA would be entitled to immediately re-file this litigation based on the claims that were presented in March 2018 and have since been pending for nearly twenty-two months. And the Court and parties would find themselves in the same position they are today. The Secretary's request for needless formality would thus serve no purpose except to cause more delay and unnecessarily burden both the Court and ACLA.

Third, the Secretary urges that the administrative claims are not yet exhausted because the administrative proceedings have not concluded. ECF No. 54-1 at 21. But the Secretary gives this Court no reason to believe that further administrative proceedings would be anything but "worthless." *UDC Chairs Chapter v. Bd. of Trustees*, 56 F.3d 1469, 1475 (D.C. Cir. 1995). Indeed, despite all of his attempts at nit-picking, the Secretary fails to offer any substantive rationale for further administrative review — because there is none. The Medicare channeling

provisions exist to give the Secretary an opportunity to "correct…errors," *Weinberger*, 422 U.S. at 765, and "compile a record…adequate for judicial review," *Shalala v Illinois Counsel on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Yet despite acknowledging his errors, *see* ECF No. 53-1 at 24, and having numerous opportunities to rectify them, the Secretary has declined to do so. Nor has he identified any gaps in the administrative record hindering this Court's review. *See* ECF No. 54-1 at 17–21. This case boils down to tidy questions of law, fully aired and capable of resolution in this action. The Court should reach those questions and grant summary judgment in ACLA's favor.

* * *

The Secretary has tried to defeat jurisdiction because he knows that his final rule does not comply with the statute that Congress enacted. But the D.C. Circuit disagreed with his jurisdictional arguments and, in reaching its decision, recognized that ACLA has stated facts sufficient to establish standing — facts that are supported by declarations and other record evidence. Moreover, ACLA has presented its claims to the agency, and agency officials have repeatedly concluded that the questions of law they raise cannot be resolved through the administrative process. In this context, the Secretary's overplayed jurisdictional objections should be seen for what they are — a last-ditch effort to circumvent the D.C. Circuit's decision and to avoid having the Secretary's rule reviewed on its merits. This Court should reject that gambit. It is time to require the Secretary to comply with the statute that Congress enacted.

CONCLUSION

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

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Respectfully submitted.

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CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2019, 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.

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