IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR II, Defendant.	Civil Action No. 17-2645 (ABJ)

RESPONSE TO NOTICE OF SUPPLEMENTAL AUTHORITY

The Secretary respectfully responds to Plaintiff's notice of supplemental authority, ECF No. 39, which addressed the Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). In that case, the Court addressed the scope of a statutory provision precluding appellate review of certain determinations of the Patent Trial and Appeal Board, concluding that it did not bar challenges that the Patent Office had "engaged in 'shenanigans,' by exceeding its statutory bounds." *Id.* at 1359.

That case has no bearing on this suit, as it simply applies the same principles of judicial review that have already been discussed in the parties' briefing. Moreover, *SAS Institute* did not involve the Medicare statute; the scope of review-preclusion provisions under that statute have been addressed by the D.C. Circuit on multiple occasions. *See Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1131 (D.C. Cir. 2017); *Fla. Health Sciences Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 519 (D.C. Cir. 2016); *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012).

Plaintiff invokes *SAS Institute* for the proposition that a statutory preclusion of review would not foreclose a challenge to *ultra vires* action. But that proposition has never been in

doubt in this case; the Secretary does not dispute that agency action may be reviewed for *ultra vires* conduct "when an agency 'patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute.'" *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 23 (D.D.C. 2014). But that narrow exception to the preclusion of review is of no help to Plaintiff here. Far from engaging in any "shenanigans," the Secretary has reasonably interpreted the statutory phrase "applicable laboratory" to mean an entity that bills Medicare Part B under its own National Provider Identifier, for the reasons that the Secretary has explained in his briefing. *See* Def. Cross-Mot. at 18-19, 29-45.

If anything, *SAS Institute* supports the common-sense proposition that Plaintiff may not circumvent the bar on review of the "establishment of payment amounts," 42 U.S.C. § 1395m-1(h)(1), simply by giving its challenge another name. Indeed, the *SAS Institute* Court relied upon its prior decision in *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), which held that the statute there barred review of any suit involving "questions that are *closely tied* to the application and interpretation of statutes related" to the shielded agency decision. *Cuozzo*, 136 S. Ct. at 2141 (emphasis added). Here, there can be no plausible dispute that the decision as to which payment data to collect, and from which laboratories, is closely tied to the "establishment of payment amounts" that is shielded from review under 42 U.S.C. § 1395m-1(h)(1). *See id.*; *see also Tex. All.*, 681 F.3d at 409, 411 (holding that suit was barred where the challenged agency action was "indispensable" or "integral" or "inextricably intertwined with" the decision shielded from review).

Dated: May 9, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2018 I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notice of such filing to all parties.

/s/ Michael L. Drezner
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