**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| AMERICAN CLINICAL LABORATORY ASSOCIATION,<br><br>Plaintiff,<br>v.<br><br>ALEX M. AZAR II,<br><br>Defendant. | Civil Action No. 1:17-cv-2645 (ABJ) |

**RESPONSE TO THE SECRETARY'S**
**NOTICE OF SUPPLEMENTAL AUTHORITY**

The Secretary of Health and Human Services has brought to the Court's attention *Mercy Hospital, Inc. v. Azar*, No. 16-5267, 2018 WL 2749727 (D.C. Cir. Jan. 8, 2018). As the Secretary notes, that decision is "relevant" to his argument that this lawsuit is precluded by the statutory bar on any challenge to the "establishment of payment amounts." 42 U.S.C. § 1395m-1(h)(1). But instead of supporting the Secretary's position, the decision further undermines it.

In *Mercy Hospital*, the D.C. Circuit considered whether a statutory provision directing that there "shall be no administrative or judicial review . . . of the establishment of . . . prospective payment rates," 42 U.S.C. § 1395ww(j)(8), precluded review of a decision by the Centers for Medicare and Medicaid Services ("CMS") setting a prospective payment rate for a particular hospital. The Court noted that the statute instructed CMS to establish rates through a two-step process: (1) establishing standardized reimbursement rates, and (2) adjusting those standardized rates to reflect the particular circumstances of each hospital. 2018 WL 2749727, at *1. Mercy Hospital argued that the statutory bar applied only to the unadjusted rate set at step

one. The Court disagreed. Quoting specific statutory language, the Court concluded that the statutory text showed that Congress intended the "bar on reviewing the prospective payment rate" to "protect[] the rate determined at step two," as well as "the adjustments used to calculate that rate." *Id*. at *3 (quoting 42 U.S.C. § 1395ww(j)(3)(A)).

The same type of careful statutory analysis, when applied here, confirms that this lawsuit does not fall within any statutory bar.

*First*, in the Protecting Access to Medicare Act ("PAMA"), unlike the statute addressed in *Mercy Hospital*, Congress distinguished between (1) the Secretary's obligation to promulgate a final regulation "establish[ing] . . . the parameters for data collection," 42 U.S.C. § 1395m-1(a)(12), and (2) the Secretary's separate obligation to establish payment amounts, *id.* § 1395m-1(b)–(d). The statute expressly precludes judicial review of the establishment of payment amounts, but says nothing to indicate that Congress intended to bar review of the Secretary's final regulation requiring parties to report private sector market information. *See id.* § 1395m-1(h)(1). The Secretary's final regulation does not itself establish any payment amounts. And the Court can review the legality of the Secretary's final regulation without reviewing or expressing an opinion on any payment rates.

*Second*, Congress's decision to distinguish between the Secretary's final regulation and the Secretary's payment rates makes sense and was constitutionally appropriate. The Secretary's notice establishing payment amounts is the type of ministerial action that Congress sometimes chooses to shield from judicial review. The rates are a take-it-or-leave it proposition. They represent the amounts the government is willing to pay for services provided; they do not directly regulate primary conduct; nor do they impose affirmative obligations on regulated parties.

In sharp contrast, the Secretary's final rule establishing the parameters for reporting and collecting private market data is a substantive regulation that directly regulates primary conduct by imposing new (and burdensome) affirmative obligations on parties to report confidential business information. *See id.* § 1395m-1(a)(10). Parties are required to certify the accuracy and completeness of the information reported. *See id.* § 1395m-1(a)(7). And failure to comply with the regulation can result in substantial civil monetary penalties. *See id*. § 1395m-1(a)(9). That is why Congress required the Secretary to engage in notice-and-comment rulemaking — a procedure that would be unnecessary if Congress did not intend the results of the rulemaking process to be subject to judicial review.

Unlike in *Mercy Hospital*, the Secretary here has not demonstrated with "clear and convincing evidence" that Congress intended to bar judicial review of the Secretary's final regulation. *Mercy Hosp*., 2018 WL 2749727, at *2. The presumption in favor of judicial review therefore applies and the Court should consider on the merits whether the Secretary has violated the statutory requirements.

Respectfully submitted,

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Dated: June 13, 2018

**CERTIFICATE OF SERVICE**

I hereby certify that on June 13, 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
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