UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASCENSION BORGESS HOSPITAL, *et al.*, Plaintiffs, v. XAVIER BECERRA, Secretary of Health and Human Services, Defendant.	Civil Action No. 20-139 (BAH) Chief Judge Beryl A. Howell

MEMORANDUM OPINION

Pending before the Court are cross-motions for summary judgment regarding the dismissal of claims asserted by forty-eight plaintiff hospitals before the U.S. Department of Health and Human Services' ("HHS") Provider Reimbursement Review Board ("PRRB") for lack of jurisdiction. Plaintiffs challenged their reimbursement from HHS for serving a disproportionate share of low-income patients, arguing before the PRRB that the use of an undisclosed audit protocol to estimate the relevant factors and determine the amounts of reimbursements was improper because the protocol is a substantive rule that HHS failed to properly promulgate through notice-and-comment rulemaking. The PRRB dismissed for lack of jurisdiction, on the ground that, pursuant to a statutory bar on administrative and judicial review codified at 42 U.S.C. § 1395ww(r)(3), challenges to the methodology used in calculating the disproportionate share payments are precluded regardless of whether the challenge is characterized as procedural or substantive.

In this appeal of the PRRB rulings, plaintiffs contend that notice-and-comment challenges fall outside the scope of the statutory preclusion provision and that the relevant audit protocols are *ultra vires*. Plaintiffs' attempts to evade the statutory bar on administrative or

judicial review are foreclosed, however, by binding precent. For the reasons set forth below, HHS's motion for summary judgment is granted, and plaintiffs' motion for summary judgment is denied.

I. BACKGROUND

Resolving the instant motions requires navigating the "labyrinthine world" of Medicare reimbursements. *See Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 694 (D.C. Cir. 2014). The background of this case is described below, including a description of the relevant portions of the Medicare Act, the key regulations and rulemakings, and the factual and procedural background underlying the challenged agency action.

A. Statutory Background

The Medicare program was established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., to pay for health-care services furnished to eligible beneficiaries, who are generally individuals over the age of sixty-five or individuals with disabilities. *See id.* § 1395c. A sub-agency of HHS, the Centers for Medicare and Medicaid Services ("CMS") administers Medicare, *id.* § 1395kk, and, among other responsibilities, pays hospitals for providing inpatient hospital services, *id.* § 1395ww(d).

The dispute between the parties here is narrow, but requires some background on the key statutory provision, 42 U.S.C. § 1395ww(r). Section 1395ww governs payments to hospitals for inpatient hospital services, and § 1395ww(d)(5)(F) directs HHS to make supplementary payments to certain hospitals that serve a disproportionate number of low-income patients (known as Disproportionate Share Hospitals or "DSHs"). *Id.* § 1395ww(d)(5)(F); *see also Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.* ("*Florida Health II*"), 830 F.3d 515, 517 (D.C. Cir. 2016). Historically, DSH payments were calculated "based on the number of days per year that the hospital served Medicaid and low-income Medicare patients," *Florida*

Health II, 830 F.3d at 517. The Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111–148, enacted in 2010, revised the DSH payment criteria and limited administrative and judicial review of the Secretary of Health and Human Services' ("Secretary") application of those criteria. ACA § 3133, codified at 42 U.S.C. § 1395ww(r); *see also Florida Health II*, 830 F.3d at 517.

The amended DSH criteria, which became effective in fiscal year ("FY") 2014, create two payments: An "empirically justified" payment equal to twenty-five percent of the amount due to a hospital based on the pre-ACA formula, 42 U.S.C. § 1395ww(r)(1), and an "additional payment" for uncompensated care based on a hospital's estimated proportional share of the uncompensated care of all DSHs, *id.* § 1395ww(r)(2). This additional payment is calculated by multiplying three factors: (a) seventy-five percent of the Secretary's estimate of the upcoming fiscal year's DSH payments nationwide based on the pre-ACA formula; (b) an estimate of the decline in the national uninsured rate for the fiscal year as compared to 2013; and (c) an estimate of each qualifying hospital's proportional share of the total nationwide amount of uncompensated care. *Id.* § 1395ww(r)(2)(A)–(C). Paragraph 3 of § 1395ww(r)—the Preclusion Provision—limits review as follows:

> There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:
>
> (A) Any estimate of the Secretary for purposes of determining the factors described in paragraph (2);
>
> (B) Any period selected by the Secretary for such purposes.

42 U.S.C. § 1395ww(r)(3).

Paragraphs (2)(c) and (3) of § 1395ww(r) are implicated in this suit. Plaintiffs challenge the auditing procedure used by the Secretary in calculating Factor Three of their uncompensated

care payments, *see* 42 U.S.C. § 1395ww(r)(2)(C), and HHS argues that such a challenge is foreclosed by the Preclusion Provision.

B. Regulatory Background

To implement the mandates of § 1395ww(r), HHS employs a data collection tool known as "Worksheet S-10," which is a component of the Medicare cost report submitted annually to HHS by hospitals. FY 2020 Final Rule, 84 Fed. Reg. 42,044, 42,359, 42,364–68 (Aug. 16, 2019). In Worksheet S-10, hospitals provide data on the volume and value of uncompensated care provided to low-income patients, and Worksheet S-10 is "the only national data source that includes data for all Medicare hospitals." FY 2014 Final Rule, 78 Fed. Reg. 50,496, 50,635 (Aug. 19, 2013). Until recently, "most of the data elements reported on Worksheet S-10" were "unused for payment purposes." *Id.* Medicare Administrative Contractors ("MACs") are hired by HHS to carry out "certain auditing and payment functions for" the agency, including managing payments for inpatient services and, relevant here, auditing hospitals' Worksheet S-10 submissions. Def.'s Mem. Supp. Mot. Dismiss & Mot. Summ. J. ("Def.'s Mem.") at 3, ECF No. 24-2 (citing 42 U.S.C. §§ 1395h, 1395x(u), 1395kk-1).

Each year since 2013, HHS has proposed and adopted the methodology for calculating the estimates underlying the following year's uncompensated care through rulemaking. *See generally, e.g.*, 84 Fed. Reg. 42,044; 78 Fed. Reg. 50,496. Although HHS has long used Worksheet S-10 to collect uncompensated care data from hospitals, the agency used other proxy data to calculate Factor 3 in the DSH rulemaking process through FY 2017 because of concerns "that hospitals [had] not had enough time to learn how to submit accurate and consistent data through this reporting mechanism." 78 Fed. Reg. at 50,635; *see also* Def.'s Mem. at 7 ("HHS ultimately decided . . . not to [base payments on Worksheet S-10 data] in connection with the FYs 2014, 2015, 2016, and 2017 because of concerns about: the accuracy, consistency, and

completeness of the data reported in Worksheet S-10."). Throughout this period, however, HHS indicated that it intended use Worksheet S-10 data to calculate uncompensated care payments in the future. *See, e.g.,* 78 Fed. Reg. at 50,635 ("[W]e stated in the proposed rule that we may proceed with a proposal to use data on the Worksheet S-10 to determine uncompensated care costs in the future, once hospitals are submitting accurate and consistent data through this reporting mechanism."); FY 2017 Final Rule, 81 Fed. Reg. 56,762, 56,773 (Aug. 22, 2016) ("In light of public comments, we believe it would be appropriate to institute certain additional quality control and data improvement measures to the Worksheet S-10 instructions and data prior to moving forward with incorporation of Worksheet S-10 data into the calculation of Factor 3. . . . We expect data from the revised Worksheet S-10 to be available to use in the calculation of Factor 3 in the near future, and no later than FY 2021.").

After years of proposing to use Worksheet S-10 data, and "[l]ong after the S-10 audits were completed," Pls.' Mem. Supp. Cross-Mot. Summ. J. & Opp'n Def.'s Mot. Dismiss & Mot. Summ. J. ("Pls.' Opp'n") at 6, ECF No. 30, HHS announced via notice-and-comment rulemaking that its FY 2020 estimates of Factor 3—the proportions of hospitals' uncompensated care—would be based on the data provided in Worksheet S-10 for FY 2015. 84 Fed. Reg. at 42,048. HHS justified its decision to use FY 2015 data from Worksheet S-10, in part, because "this was the most recent year of data that [it] had broadly allowed to be resubmitted by hospitals." *Id.* at 42,364. Since "it was not feasible to audit all hospitals," *id.* at 42,365, the decision of which hospitals to audit was "based on a risk-based assessment process," *id.*, resulting in a selection of hospitals for audit whose combined uncompensated care payments "represented approximately half of the proposed total uncompensated care payments for FY 2020," *id.* at 42,364.

C. Factual & Procedural Background

Plaintiffs are forty-eight hospitals eligible to receive uncompensated care payments under 42 U.S.C. § 1395ww(r). Consolidated Compl. ("Compl.") ¶ 14, ECF No. 21.[1] Each hospital had its Worksheet S-10 for FY 2015 audited by MACs, and, per the FY 2020 final rule, those audits resulted in "changes to the Worksheets S-10 [that] reduced or otherwise altered the amounts of payments made by CMS," *id.* ¶ 51, for FY 2020, *id.* ¶ 60. Plaintiffs timely administratively appealed these reimbursement decisions to the PRRB, arguing that HHS's use of unpublished audit protocols to establish uncompensated care payments violated the notice-and-comment rulemaking requirements of the Medicare Act and Administrative Procedure Act.[2] Compl. ¶¶ 59–60, 64–65. The PRRB determined that administrative review of the uncompensated care payments was barred by § 1395ww(r)'s preclusion provision and, consequently, that it did not have jurisdiction over the issues in the appeals. AR (*Ascension Borgess*) 4–5, ECF No. 37-1; AR (*Atrium*) 5–6, ECF No. 37-2.[3]

Plaintiffs subsequently appealed the PRRB's final decisions to this Court, challenging the PRRB's dismissal of their reimbursement appeals for lack of jurisdiction. Compl. ¶¶ 2, 80, 88; *see also* 42 U.S.C. § 1395oo(f)(1) ("Providers shall have the right to obtain judicial review of

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[1] This is a consolidated action combining the complaints of two groups of plaintiff-hospitals. Compl. ¶ 15; *see also* Min. Order (Aug. 18, 2020) (consolidating *Atrium Medical Center. v. Azar*, Case No. 20-cv-1957, with *Ascension Borgess Hospital v. Azar*, Case No. 20-cv-193). The only difference between the groups of plaintiffs is that one group initially appealed HHS's decision based on Notices of Program Reimbursement, while the other appealed from payment adjustments published in the Federal Register. Compl. ¶¶ 16–17. The distinction has since blurred since, by the time plaintiffs filed a consolidated complaint, nine of the plaintiffs in the first group alleged that they were adversely affected by the Federal Register publication as well, *id.* ¶ 18, and plaintiffs represented in subsequent briefing "that by the time of the Government's reply deadline, [plaintiffs] anticipate this issue will be moot and that all of the Hospitals will then be pursuing only Federal Register appeal denials from the PRRB," Pls.' Opp'n at 30.

[2] The PRRB is charged with reviewing challenges to DSH payments. 42 U.S.C. § 1395oo(a).

[3] HHS submitted a certified list of the contents of the administrative record, in accordance with Local Civil Rule 7(n)(1). *See* Index of Admin. Record, ECF No. 25. Consistent with Local Civil Rule 7(n)(1), the portions of the administrative record cited or otherwise relied upon in the parties' briefing have been separately docketed. *See* J.A., ECF No. 37. For clarity, "AR" citations are to the full administrative records, rather than to the joint appendix. The administrative records for the two consolidated cases are separately designated.

any final decision of the [PRRB.]"). Count I of the complaint alleges violations of the Medicare Act predicated on the alleged failure of the Secretary to implement the Worksheet S-10 audit protocol without promulgating the protocol through notice-and-comment rulemaking. Compl. ¶¶ 75–80. Count II of the complaint alleges that, for various reasons, the Worksheet S-10 audit protocol was contrary to law and arbitrary and capricious under the APA. *Id.* ¶¶ 81–88.

Plaintiffs' complaint seeks an order declaring the Worksheet S-10 audit protocol unlawful, vacating the payments based on the Worksheet S-10 audit, requiring the Secretary to recalculate those payments, and setting aside the PRRB decisions refusing to exercise jurisdiction over their appeals. *Id.* at 17 ("Request for Relief").[4] Defendant filed a motion for summary judgment, *see* Def.'s Mot., and plaintiffs responded with a cross-motion for summary judgment, both of which motions have been fully briefed and are ripe for resolution. *See* Pls.' Cross-Mot. Summ. J., ECF No. 28; Def.'s Opp'n; Pls.' Reply.

II. LEGAL STANDARD

Summary judgment will be granted when the court finds, based upon the pleadings and other factual materials in the record, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). When a party challenges a final decision of the PRRB, *see* 42 U.S.C. § 1395oo(f)(1), the Medicare Act incorporates the standard of review of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*. *See New LifeCare Hosps. of*

[4] In requesting relief beyond review of the PRRB decision, plaintiffs prematurely raised merits challenges under the Administrative Procedure Act and Medicare Act, Compl. ¶¶ 75–79, 82–87, prompting HHS to move for dismissal under Federal Rule of Civil Procedure 12(b)(1), Def.'s Mot. Dismiss & Mot. Summ. J, ECF No. 24. The parties now agree, however, that the only issue properly before the Court is whether the PRRB erred in dismissing plaintiffs' complaint for lack of jurisdiction. Pls.' Opp'n. at 13; Pls.' Reply Supp. Cross-Mot. Summ. J. ("Pls.' Reply") at 2, ECF No. 36; Def.'s Reply Supp. Mot. Dismiss & Mot. Summ. J. & Opp'n Pls.' Cross-Mot. Summ. J. ("Def.'s Opp'n") at 16, ECF 33.

N. Carolina, LLC v. Becerra, --- F.4th ---, 2021 WL 3502068, at *4 n.1 (D.C. Cir. Aug. 10, 2021) (citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)).

A district court considering a challenge to agency action under the APA treats the "entire case on review [as] a question of law," *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009), because the "complaint, properly read, actually presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Id.* (quoting *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993)); *see also Am. Wild Horse Campaign v. Bernhardt*, 442 F. Supp. 3d 127, 143 (D.D.C. 2020) (emphasizing the role of the district court in APA cases is to resolve legal questions, "not resolve factual issues" (quoting *James Madison Ltd v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996))).

Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A); in excess of statutory authority, *id.* § 706(2)(C); or "without observance of procedure required by law," *id.* § 706(2)(D). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).[5]

III. DISCUSSION

The parties' cross-motions for summary judgment present a single issue within the jurisdiction of this Court: whether 42 U.S.C. § 1395ww(r)(3) precludes administrative and

[5] Although HHS also filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), Def.'s Mot., plaintiffs have conceded that the only issue currently before the Court is the jurisdictional decision of the PRRB, Pls.' Opp'n at 22 n.7 (noting that "the Hospitals believe it more appropriate for the Court to rule on the cross-motions for summary judgment"); Pls.' Reply at 2 (requesting remand to the PRRB for further proceedings), making HHS's Rule 12(b)(1) motion moot.

judicial review of the Secretary's decision to use the audited Worksheet S-10 data in his calculation of plaintiffs' uncompensated care factor. *See* Pls.' Opp'n at 29 (conceding that "the scope of this Court's jurisdiction is currently limited to only review of the PRRB's dismissal of the Hospitals' appeals under the Preclusion [Provision]"). For the reasons explained below, plaintiffs' challenge to the audit protocol is precluded, and HHS's motion for summary judgment is granted.

A. Preclusion

Although "plaintiffs bear the burden of establishing jurisdiction," courts must "presume the Congress intends that agency action be judicially reviewable." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017). Nonetheless, Congress may preclude judicial review of an administrative action by statute. *See Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (citing *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984)). The presumption of reviewability "may be overcome by 'clear and convincing' indications, drawn from 'specific language,' 'specific legislative history,' and 'inferences of intent drawn from the statutory scheme as a whole,' that Congress intended to bar review." *Cuozzo Speed Techs. v. Lee*, 136 S. Ct. 2131, 2140 (2016) (quoting *Cmty. Nutrition Inst.*, 467 U.S. at 349–50); *see also Am. Clinical Lab. Ass'n v. Azar ("American Clinical")*, 931 F.3d 1195, 1204 (D.C. Cir. 2019) ("Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." (quoting *Cmty. Nutrition Inst.*, 467 U.S. at 345)). In interpreting a provision precluding judicial review, the court "'must determine whether the challenged agency action is of the sort shielded from review' and 'may not inquire whether a challenged agency decision is arbitrary, capricious, or

procedurally defective' unless [sure of its] subject matter jurisdiction." *Knapp Med. Ctr.*, 875 F.3d at 1128 (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004)).

The subsection of the Medicare statute at issue here, governing calculation of uncompensated care payments to Disproportionate Share Hospitals, has been the subject of much litigation. As described above, *see supra* Part I.A, 42 U.S.C. § 1395ww(r) contains three paragraphs. Paragraph 1 establishes the "[e]mpirically justified DSH payments," paragraph 2 establishes the "[a]dditional payment" for uncompensated care, and paragraph 3 limits administrative and judicial review of specific aspects of the Secretary's calculation of the uncompensated care payments. 42 U.S.C. § 1395ww(r)(1)–(3).

Before the PRRB, plaintiffs challenged an audit procedure for the Worksheet S-10 used to estimate each hospital's share of uncompensated care and, ultimately, determine their DSH payments under 42 U.S.C. § 1395ww(r)(2). *See* Compl. ¶ 84 ("The Secretary's inclusion of the S-10 Audits in the adjustments that reduced the Hospitals' [uncompensated care] DSH payments is thus contrary to the law."); *see also* Pls.' Opp'n at 1. Aware that "the Preclusion Provision applies to substantive challenges to the Secretary's [uncompensated care] DSH estimates and time periods," Pls.' Opp'n at 15, plaintiffs frame their challenge as a procedural one, asserting that "procedural challenges to the Secretary's improper establishment of reimbursement policy" fall outside the scope of the Preclusion Provision, *id.* at 16. HHS argues that, regardless of whether the plaintiffs' challenge is characterized as procedural, their claims are precluded because plaintiffs' ultimate aim is to force HHS to re-calculate one of the factors articulated in § 1395ww(r)(2). *See* Def.'s Mem. at 27.

B. Scope of the Preclusion Provision

The D.C. Circuit has instructed that, when determining whether review is barred by § 1395ww(r)(3), "[t]he dispositive issue is whether the challenged [action is] inextricably

intertwined with an action that all agree is shielded from review, regardless of where that action lies in the agency's decision tree." *Florida Health II,* 830 F.3d at 521 (emphasis omitted). In *Florida Health II*, the D.C. Circuit held that the Preclusion Provision bars judicial review of the choice of data used to estimate a hospital's amount of uncompensated care. Selecting the underlying data is "indispensable," "integral to," and "inextricably intertwined" with the estimate of uncompensated care and review is therefore precluded. *Id.* at 519 (internal quotation marks omitted); *see also Knapp Med. Ctr.*, 875 F.3d at 1131 (characterizing *Florida Health II* as "us[ing] a functional analysis to determine whether we could entertain the plaintiffs' claims without frustrating the Congress's desire to place certain administrative actions beyond review"). A challenge to this underlying "data would 'eviscerate the bar on judicial review' . . . [because] the data are the entire basis for the estimate." *Florida Health II,* 830 F.3d at 519 (quoting *El Paso Natural Gas Co. v. United States*, 632 F.3d 1272, 1278 (D.C. Cir. 2011)). The Circuit therefore concluded that the Preclusion Provision "expressly precludes" administrative and judicial review of the data choices underlying the DSH estimates. *Id.*

The D.C. Circuit expanded upon the reasoning of *Florida Health II* in *DCH Regional Medical Center v. Azar* ("*DCH II*"), 925 F.3d 503 (D.C. Cir. 2019). In the latter case, the plaintiff argued that the Preclusion Provision did not bar review of the methodology used to make the estimates under § 1395ww(r)(2). *Id.* at 505. The D.C. Circuit held that "[i]n this statutory scheme, a challenge to the methodology for estimating uncompensated care is unavoidably a challenge to the estimates themselves" and that review of the methodology was barred by the Preclusion Provision. *Id.* at 506. In so holding, the D.C. Circuit highlighted the relief the plaintiff hospital sought—recalculation of the additional DSH payment predicated on recalculation of one of the § 1395ww(r)(2) factors—and noted that any "distinction between

methodology and estimates would eviscerate the statutory bar, for almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.*[6]

Here, plaintiffs' challenge to the Worksheet S-10 audit protocol is inextricably intertwined with the Secretary's Factor 3 estimates used to calculate the plaintiffs' uncompensated care payments, and therefore is precluded from administrative and judicial review by § 1395ww(r)(3). Plaintiffs acknowledge that their claims "focus" on Factor 3 of § 1395ww(r)(2) because "if a hospital's uncompensated care is understated by an audit, it will receive a reduced percentage of the 'total uncompensated care.'" Compl. ¶ 34; *see also* Pls.' Opp'n at 6 ("Using the 2015 audited and unaudited S-10 data reported by MACs in the February 2019 Healthcare Cost Report Information System (HCRIS) data files, CMS proposed calculating each DSH hospital's Factor 3, which is their *pro rata* share of the [uncompensated care] pool, in their usual manner for Factor 3.") As HHS correctly argues, *see* Def.'s Opp'n at 2, the audit protocols at issue are part of the methodology used by the Secretary to determine "the amount of uncompensated care for [each] hospital." 42 U.S.C. § 1395ww(r)(2)(C)(i). These protocols are therefore "inextricably intertwined" with the resulting uncompensated care estimates. *Florida Health II*, 830 F.3d at 519. This fact is evident from plaintiffs' request for relief, in which they seek an order "[r]equiring the Secretary to recalculate the Hospitals' [uncompensated care] DSH payments without reliance on any changes made as a result of the unlawful audit protocol." Pls.' Request for Relief.

[6] Another Judge on this Court recently applied *Florida Health II* and *DCH II* to a challenge to "the manner in which [the Secretary] calculated [plaintiffs'] uncompensated care adjustment," *Scranton Quincy Hospital Co. v. Azar*, 514 F. Supp. 3d 249, 253 (D.D.C. 2021), and concluded that "the plain language of section 1395ww(r)(3) precludes administrative and judicial review" of "the method . . . used, and the particular data the Secretary chose to rely upon, when estimating the amount of uncompensated care," *id.* at 262–63.

The structure of the statute lends further support to HHS's reading of the Preclusion Provision. An individual hospital's reimbursement under § 1395ww(r)(2) is dependent on the fraction of the amount of that hospital's uncompensated care over "the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection." *Id.* § 1395ww(r)(2)(C). As HHS correctly observes, this payment structure means that a change to any of the § 1395ww(r)(2) factors would require "changes to every single provider's DSH payment." Def.'s Mem. at 26. The D.C. Circuit noted in interpreting a different Medicare subsection precluding review that "piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system . . . [and] review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Amgen*, 357 F.3d at 112. Just so here. In light of "the structure of the statutory scheme," *American Clinical*, 931 F.3d at 1204 (quoting *Cmty. Nutrition Inst.*, 467 U.S. at 345), permitting review of agency action aimed at recalculating DSH payments would undoubtedly "frustrat[e] the Congress's desire to place certain administrative actions beyond review," *Knapp*, 875 F.3d at 1131.

Where the ultimate relief sought is recalculation of the estimates used to determine DSH payments—which are themselves precluded from review—the statute precludes review regardless of whether the challenge is characterized as substantive or procedural, or whether the estimates themselves are directly challenged. *See DCH II*, 925 F.3d at 506; *Florida Health II*, 830 F.3d at 519. To hold otherwise would allow hospitals to challenge the estimates themselves through procedural attacks on the data and methodologies used to establish the estimates, eviscerating the statutory bar and undercutting Congress's express language insulating the estimates from review.

Plaintiffs' arguments to the contrary are unpersuasive. In an attempt to distinguish *Florida Health II* and *DCH II*, plaintiffs argue that their claims are distinct by alleging a *procedural* failure by the Secretary to abide by "the Medicare Act's express notice-and-comment obligations," Pls.' Opp'n at 16, and that this kind of claim is distinct from the "substantive appeals" that were at issue in those cases, *id* at 15. In plaintiffs' reasoning, *Allina Health Services v. Price* ("*Allina I*"), 863 F.3d 937 (D.C. Cir. 2017), *aff'd sub nom. Azar v. Allina Health Services* ("*Allina II*"), 139 S. Ct. 1804 (2019)—which held that "the Medicare Act requires notice-and-comment rulemaking for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services,'" *id.* at 943 (quoting 42 U.S.C. § 1395hh(a)(2))—establishes a procedural requirement that applies here and permits them to bypass the Preclusion Provision. Pls.' Opp'n at 15–21.

As HHS points out, however, both *Florida Health II* and *DCH II* involved procedural rulemaking requirements. *See* Def.'s Opp'n at 8. In *Florida Health Sciences Center, Inc. v. Secretary of U.S. Department of Health and Human Services*. ("*Florida Health I*"), 89 F. Supp. 3d 121 (D.D.C. 2015), *aff'd*, 830 F.3d 515, another Judge on this Court held that procedural challenges involving the data underlying the DSH payments, including a challenge based on the APA's notice-and-comment requirements, were precluded under 42 U.S.C. § 1395ww(r)(3). *Id.* at 132 n.3. On appeal, the D.C. Circuit affirmed, stating "that judicial review is not permitted 'when a procedure is challenged solely in order to reverse an individual . . . decision' that we otherwise cannot review." *Florida Health II*, 830 F.3d at 521–22 (quoting *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 405 (D.C. Cir. 2005)). Similarly, in *DCH Regional Medical Center v. Price* ("*DCH I*"), 257 F. Supp. 3d 91 (D.D.C. 2017), *aff'd*, 925 F.3d

503, another Judge on this Court held that claims predicated on the rulemaking process were precluded where "the indisputable gravamen of [plaintiff's] complaint is that the Secretary improperly calculated the amount of uncompensated care for [plaintiff.]" *Id.* at 94. There, as here, the plaintiff sought a court order requiring recalculation of the uncompensated care estimate and DSH payment, *id.*, emphasizing that the nominally procedural claim was, in essence, a precluded challenge to the uncompensated care estimate. In both cases, the district court rejected the plaintiff hospitals' claims, and the D.C. Circuit affirmed.

Plaintiffs observe that both *Florida Health II* and *DCH II* were decided before the Supreme Court's decision in *Allina II*, *see* Pls.' Opp'n at 15–16, but overlook the fact that *Allina II* affirms the D.C. Circuit's opinion in *Allina I*, and that *DCH II* was decided after *Allina I* was binding law in this Circuit. Moreover, despite the amount of ink spilled by plaintiffs discussing *Allina I* and *Allina II*, *see* Pls.' Opp'n at 3, 20–21; Pls.' Reply at 12–13, 16–17, these cases address the generally applicable Medicare notice-and-comment requirement set out in 42 U.S.C. § 1395hh(a)(2), and have limited relevance here. The scope of the Medicare Act's notice-and-comment requirement would be relevant in evaluating the merits of plaintiffs' claims—i.e., that the Worksheet S-10 audit protocol establishes or changes a substantive legal standard within the meaning of § 1395hh(a)(2)—but has no bearing on whether these claims are barred by the Preclusion Provision.

Plaintiffs also attempt to distinguish these cases by noting that, purportedly in contrast to plaintiffs' claims here, "[t]he notice-and-comment claims brought in *Florida Health* and *DCH* were still claims seeking review of the Secretary's estimates, underlying data, or methodology." Pls.' Reply at 9. The premise that plaintiffs' claims do not challenge estimates, underlying data, or methodology is simply wrong. The challenged audit procedures are part of the methodology

behind the Factor 3 estimate because the data being audited are used to calculate the hospitals' uncompensated care amounts under § 1395ww(r)(2)(C). The statute vests the Secretary with broad discretion in determining hospitals' uncompensated care, allowing the agency to estimate such care based on "appropriate data" and to use "alternative data" determined to be a better proxy in making the estimate. *Scranton Quincy Hosp. Co.*, 514 F. Supp. 3d at 267 (quoting 42 U.S.C. § 1395ww(r)(2)(C)(i)); *see also DCH II*, 925 F.3d at 510 (stating that the provision describing HHS's choice of "appropriate data" in calculating the uncompensated care payment as an "open-ended provision"). Indeed, the Worksheet S-10 audits were implemented to make sure that appropriate data could be used to estimate Factor 3 for future DSH payments. *See, e.g.*, FY 2017 Final Rule, 81 Fed. Reg. 56,762, 56,965 (Aug. 22, 2016) ("We expect to begin to incorporate Worksheet S-10 data into the computation of Factor 3 by FY 2021 once we have taken certain quality control and data improvement measures and also implemented an audit process."); *see also supra* Part I.B.

Plaintiffs' reliance on *American Clinical* and three out-of-circuit cases is similarly misplaced. In *American Clinical*, the D.C. Circuit addressed a provision of the Protecting Access to Medicare Act, Pub. L. No. 113-93, 128 Stat. 1040 (2014), that sets Medicare reimbursement rates for laboratory tests and requires certain laboratories to report private payor data to HHS. 931 F.3d at 1199; *see also* 42 U.S.C. § 1395m-1(b)(1) (setting the payment amount for "clinical diagnostic laboratory test[s]"); *id.* § 1395m-1(a) (establishing reporting requirements for applicable laboratories). The D.C. Circuit held a separate bar on judicial review applying to "the establishment of payment amounts under this section," 42 U.S.C.§ 1395m-1(h)(1), did not bar review of rules regarding data collection practices. *American Clinical*, 931 F.3d at 1205.

Plaintiffs point to the D.C. Circuit's reliance on statutory language "that the parameters for that data collection be established through notice and comment rulemaking," *American Clinical*, 931 F.3d at 1206 (citing 42 U.S.C. § 1395m-1(a)(12)), as evidence "that rulemaking requirements signal Congress's intent to provide judicial review." Pls.' Reply at 12. This analysis, however, was grounded in the unique structure of the particular statute at issue in *American Clinical*. That statute contained its own notice-and-comment provision specifically for data collection, *see* 42 U.S.C. § 1395m-1(a)(12) (providing that "the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection"), whereas the notice-and-comment requirements plaintiffs rely upon in this case are the generally applicable rules that apply to the administration of the entire Medicare program, *see* 42 U.S.C. § 1395hh(a)(2). The inference from *American Clinical*—that Congress intended certain agency action to be reviewable because statutory text expressly required promulgation through notice-and-comment rulemaking—does not apply here. The fact that Medicare regulations are *generally* subject to notice-and-comment requirement indicates nothing about whether a specific preclusion provision bars claims alleging a failure to adhere to that notice-and-comment requirement.

Moreover, the reasoning of *American Clinical* relied heavily on the bifurcated structure of the relevant statute, which contained *separate* provisions addressing payment rates and addressing data collection parameters. 931 F.3d at 1205 (noting that the "reference to reporting private sector data for the establishment of payment amounts suggests that the two are not one and the same, but rather that collecting data from the private sector is a separate statutory duty preceding the establishment of Medicare payment rates"). By contrast, here, the audit process is not a statutory requirement, nor is it even mentioned in § 1395ww(r), so the analysis of the

distinct statutory scheme at issue in *American Clinical* is not relevant to the preclusive scope of § 1395ww(r)(3).

Plaintiffs also cite out-of-circuit cases holding—in line with plaintiffs' position in this case—that the Preclusion Provision does not reach procedural challenges to policies that affect DSH payments. *See* Pls.' Opp'n at 16–20. Specifically, plaintiffs rely primarily on *Yale New Haven Hospital v. Azar*, 409 F. Supp. 3d 3 (D. Conn. 2019), in which the district court held that a procedural challenge to promulgation of a regulation—HHS's FY 2014 Merged Hospital Policy—was not precluded even though it might itself "result[] in the 'estimate,'" *id.* at 15. The court drew a distinction between the review of the "*promulgation* of the Secretary's rules and policies," in that case grounded in the notice-and-comment requirement of 42 U.S.C. § 1395hh(a)(2), and challenges to the "*substance* of any such rules or policies or the determination of its estimates based on the substance of those rules or policies." *Id.* (emphasis in original). The district court noted that "Congress has demonstrated it knows how to encompass the process of establishing rules within the ambit of preclusion provisions," *id.*, pointing to another Medicare statutory preclusion provision that applies to "the process under this paragraph (*including the establishment of such process*)," 42 U.S.C. § 1395nn(i)(3)(I) (emphasis added).

That district court did not, however, apply the D.C. Circuit's functional analysis that looks to whether the challenged agency action is "inextricably intertwined" with the estimates the review of which is expressly precluded, *see Florida Health II*, 830 F.3d at 519, nor did the court consider the broader structure of § 1395ww(r) and the highly disruptive effect that any challenge aimed at changing the Secretary's estimates of the DSH factors would have on the statutory system. *Yale New Haven Hospital* further inferred from language in another Medicare preclusion provision barring "review of Secretary's established process and 'the establishment of

such process,'" that such language is *necessary* for a provision's preclusive scope to extend to procedural claims. 409 F. Supp. 3d at 14 (quoting 42 U.S.C § 1395nn(i)(3)(I)); *see also* Pls.' Reply at 16 (making this point with respect to § 1395nn(i)(3)(I)). This reasoning is at odds with binding precedent from the D.C. Circuit, which has repeatedly applied a "functional approach" focused on whether the challenged action was "'inextricably intertwined' with the unreviewable estimate itself" and eschewing "categorical distinction between inputs and outputs." *Knapp*, 875 F.3d at 1131 (quoting *Florida Health II*, 830 F.3d at 518). Moreover, that cited decision is at odds with the opinions issued in this Court that were affirmed in *DCH II* and *Florida Health II*.

Plaintiffs also cite *North Oaks Medical Center v. Azar*, Case No. 18-cv-9088, 2020 WL 1502185 (E.D. La. Mar. 25, 2020), and *Regeneron Pharmaceuticals, Inc. v. U.S. Department of Health and Human Services*, 510 F. Supp. 3d 29 (S.D.N.Y. 2020), both of which adopt the reasoning of *Yale New Haven Hospital*. *See N. Oaks Med. Ctr.*, 2020 WL 1502185, at * 9 (relying on *Yale New Haven Hospital* and holding that "it is possible to allege a challenge to notice and comment requirements distinct from a precluded challenge to the Secretary's estimates"); *Regeneron Pharms.*, 510 F. Supp. 3d at 45 (relying on *Yale New Haven Hospital* in holding that notice-and-comment claims are were not barred by another Medicare preclusion provision that "bars judicial review of particular facets of [certain] models" but does not "does not bar review of the propriety of the procedures used for establishing such models"). Neither of these cases contains any analysis beyond that of *Yale New Haven Hospital*, which is unpersuasive and at odds with D.C. Circuit precedent for the reasons already stated.[7]

[7] To the extent that plaintiffs independently seek relief under the Mandamus Act, 28 U.S.C. § 1361, *see* Pls.' Opp'n at 16–17, that relief is also barred by the Preclusion Provision which categorically bars review under the Medicare Act "or otherwise," 42 U.S.C. § 139ww(r)(3).

C. *Ultra Vires* Action

Finally, plaintiffs argue that HHS's application of the audited 2015 Worksheet S-10 data in implementing the FY 2020 Final Rule was *ultra vires*, and that the Court has jurisdiction to review this agency action regardless of statutory bar on judicial review. Compl. ¶¶ 88; Pls.' Opp'n at 28–29. Claims of *ultra vires* acts may be subject to judicial review in "narrow" circumstances "where Congress is understood generally to have precluded review." *Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 492 (D.C. Cir. 1988) (citing *Leedom v. Kyne*, 358 U.S. 184 (1958)). The scope of the *Kyne* exception is "very limited." *U.S. Dep't of Justice v. Fed. Lab. Rels. Auth.*, 981 F.2d 1339, 1342 (D.C. Cir. 1993); *see also Griffith*, 842 F.2d at 493 (observing that the *Kyne* exception has an "extremely limited scope"). As the D.C. Circuit recently noted, "there is not much room to contend that courts may disregard statutory bars on judicial review just because the underlying merits seem obvious," *DCH II*, 925 F.3d at 509, and such an argument "is essentially a Hail Mary pass—and in court as in football, the attempt rarely succeeds," *id.* (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)). The exception applies only when three requirements are met: "(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH II*, 925 F.3d at 509 (citing *Nyunt*, 589 F.3d at 449). "This third requirement covers only 'extreme' agency error, not merely '[g]arden-variety errors of law or fact.'" *Id.* at 509 (alteration in original) (quoting *Griffith*, 842 F.2d at 493).

HHS argues that plaintiffs fail to meet either the first or the third requirements for application of the *Kyne* exception to overcome the statutory preclusion provision. *See* Def.'s Mem. at 33–35. As support, HHS points out that the Preclusion Provision is express and that the

agency did not plainly act contrary to a statutory prohibition because the *use* of the audited 2015 Worksheet S-10 was implemented through notice-and-comment rulemaking. *See id.* Plaintiffs respond that because § 1395ww(r)(3) refers to "estimates" and "periods," the statute only expressly precludes *direct* challenges to those estimates and periods. Pls.' Opp'n at 28 (citing 42 U.S.C. § 1395ww(r)(3)).

Plaintiffs' *ultra vires* argument falls short of satisfying the first and third factors. First, plaintiffs are wrong about the proper level of analysis in considering whether the statutory preclusion is "express." Under binding precedent, the Preclusion Provision is express with regard to challenges to the methodology used to the establish the § 1395ww(r)(2) estimates. *See DCH II*, 925 F.3d at 509. As described above, *see supra* Part III.B, plaintiffs challenge the methodology used to establish the disproportionate share estimate, so the D.C. Circuit's holding in *DCH II* that the Preclusion Provision is express with the regard to challenges to methodology, plainly applies. Plaintiffs' insistence that the preclusive bar must describe in detail their particular challenge in order to be considered express is incorrect. The broad, explicit provision at issue here expressly bars review. Indeed, the D.C. Circuit in *DCH II* rejected the argument that the Preclusion Provision was not express with respect to the Secretary's choice of data, stating simply that "the bar on judicial review is express." 925 F.3d at 509. The fact that plaintiffs' challenge is characterized as "procedural" is immaterial to whether the Preclusion Provision is express, so the *Kyne* exception is unavailable.

Second, plaintiffs have failed to establish that the Secretary "plainly act[ed] in excess of [his] delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH II*, 925 F.3d at 509. While, as plaintiffs correctly note, "Congress requires CMS to engage in notice-and-comment rulemaking before it makes substantive adjustments to

payment polices," Pls.' Opp'n at 28 (citing 42 U.S.C. § 1395hh(a)(2)), plaintiffs have not shown that the Secretary "plainly" acted contrary to the Medicare Act's notice-and-comment requirement in using the audited 2015 Worksheet S-10 data to determine plaintiffs' FY 2020 DSH payments. After all, the audit protocol itself had no effect on plaintiffs' right to payment until it was implemented in the 2019 rulemaking that *did* go through notice and comment process. *See* 84 Fed. Reg. at 42,048–51; *see also* Def.'s Opp'n at 22.

Accordingly, plaintiffs may not avoid the statutory bar on review by arguing that the Secretary's actions are *ultra vires*.

IV. CONCLUSION

For the foregoing reasons, the applicable Preclusion Provision of 42 U.S.C. § 1395ww(r)(3) bars administrative and judicial review of plaintiffs' claims. HHS's motion for summary judgment is therefore granted, HHS's motion to dismiss is denied as moot, and plaintiffs' motion for summary judgment is denied.

An order consistent with this Memorandum Opinion will be entered contemporaneously.

Date: August 30, 2021

BERYL A. HOWELL
Chief Judge