UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

FIRSTHEALTH MOORE REGIONAL HOSPITAL,

Plaintiff,

Civil Action No. 20-1007 (BAH)

v.

Chief Judge Beryl A. Howell

XAVIER BECERRA, Secretary of Health and Human Services,

Defendant.

MEMORANDUM OPINION

Plaintiff FirstHealth Moore Regional Hospital made a deliberate and strategic decision to pursue review of a calculation for reimbursement of Medicare uncollectible patient debts by asking the U.S. Department of Health and Human Services ("HHS") contractor administering the calculation process to revisit certain issues that plaintiff believed involved errors. This choice of review process avoided the higher-overhead and potentially more time-consuming process of formal agency review authorized by statute. Ultimately, however, when the contractor reviewed plaintiff's objections, made adjustments to certain calculations, and declined to make adjustments to others, this choice of review pathway, effectuated by withdrawal of the initial appeal, foreclosed continuing with the formal appeals process before HHS's Provider Reimbursement Review Board ("PRRB") for the items the contractor reviewed but did not adjust.

Plaintiff now seeks to force HHS to reinstate its formal appeal filed before the PRRB, arguing that the PRRB's rules unlawfully deprived plaintiff of statutory appeal rights, first, by forcing withdrawal of its formal appeal to pursue the more informal review process with the

contractor and then, second, by refusing to allow reinstatement of plaintiff's formal appeal after the informal contractor review failed to produce an entirely satisfactory modification of the reimbursement amount that plaintiff claims was erroneously calculated. HHS disputes plaintiff's first assertion and denies that agency rules forced plaintiff's initial withdrawal of its formal appeal, and also defends the agency's denial of plaintiff's right to reinstatement of the formal appeal after the informal contractor review process was completed. Thus, at issue is not only what the agency's review rules actually provide but also whether those rules are lawful. In the agency's view, plaintiff took two voluntary steps by seeking informal contractor review and withdrawing its formal agency appeal, the combination of which extinguished its formal appeal rights.

This case offers a cautionary tale to any provider navigating "the labyrinthine world of Medicare," *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 694 (D.C. Cir. 2014), and HHS's complex system of reimbursements. Plaintiff withdrew its formal agency appeal based on an understanding of a rule making the healthcare provider "responsible" for doing so, combined with the further understanding that reinstatement of that formal appeal would be possible if sought. Plaintiff apparently also believed that the relevant regulations provided a right to maintain or revive its appeal as to any issue that the contractor reviewed, regardless of whether the contractor modified the outcome as to that issue. Indeed, the governing regulations and PRRB rules may allow for misinterpretation. Improving the clarity of the Medicare rules, however, is not a task for this Court.

As explained more fully below, (a) the agency's interpretation of its rules is reasonable and entitled to deference; (b) the rules, as so interpreted, are lawful; and (c) the agency correctly applied the rules under its interpretation. Presented with two routes by which it could obtain

review of Medicare reimbursement calculations with which it disagreed, plaintiff chose one route over the other, and must now bear the consequences of that choice. Accordingly, summary judgment is granted to defendant HHS and denied to plaintiff.

I. BACKGROUND

The statutory and regulatory scheme underlying the parties' dispute is described below, followed by the factual and procedural history in this case.

A. Statutory and Regulatory Background

"Medicare is a federally funded program that reimburses healthcare providers for delivering medical care to qualifying elderly and disabled individuals." *New LifeCare Hosps. of N.C., LLC v. Becerra*, 7 F.4th 1215, 1219 (D.C. Cir. 2021) (citing 42 U.S.C. § 1395 *et seq.*). Participating healthcare providers, such as plaintiff, receive reimbursement from the HHS Secretary for health care services provided to enrollees. 42 U.S.C. § 1395g. Much of the administration of these payments is performed by private Medicare Administrative Contractors ("MACs") acting on behalf of the Secretary. *Id.* §§ 1395h(a), 1395kk-1(a)(4); 42 C.F.R. §§ 421.100, 421.400.

Each fiscal year, a participating hospital files a "cost report" with its MAC to provide the basis for calculating reimbursements due the hospital for services provided to beneficiaries over the course of the year. 42 C.F.R. §§ 413.20, 413.24(f); *see also New LifeCare Hosps.*, 7 F.4th at 1220 ("Healthcare providers file annual cost reports with these contractors, 42 C.F.R. § 413.20(b), and the contractors issue notices indicating which payments Medicare will cover, *id.* § 405.1803(a)."). The MAC reviews and audits the cost report and thereafter issues a Notice of

Program Reimbursement ("NPR") indicating the MAC's determination of amounts to be paid to, or recouped from, the hospital. 42 C.F.R. §§ 405.1803, 413.60, 413.64(f).

"Providers can then appeal reimbursement decisions from the contractors to the Provider Reimbursement Review Board (["PRRB"]), an administrative tribunal within HHS." *New LifeCare Hosps.*, 7 F.4th at 1220 (citing 42 U.S.C. § 139500(a)). The provider's appeal of an NPR issued by the MAC must be within 180 days of its issuance if the provider is "dissatisfied . . . as to the amount of total program reimbursement due the provider" and "the amount in controversy is \$10,000 or more." 42 U.S.C. § 139500(a); 42 C.F.R. § 405.1835. The statute vests in the PRRB "full power and authority to make rules and establish procedures" to govern the appeals and review process. 42 U.S.C. § 139500(e). The PRRB has periodically issued such rules, which are not promulgated through a notice-and-comment process. As relevant here, one set of rules (the "2015 PRRB Rules") was effective starting July 1, 2015, and another set (the "2018 PRRB Rules") has been in effect since August 29, 2018. This action spans both versions of the PRRB Rules, but they are materially interchangeable in relevant respects other than numbering. A provider may seek judicial review, including in this Court, of any final PRRB decision within 60 days of its issuance. 42 U.S.C. § 139500(f)(1).²

A provider may receive an "interim" reimbursement in advance based on historical and/or estimated use of services. The NPR and subsequent payment (or recoupment, if Medicare had overpaid for the year in question) serves to "true-up" reimbursements to actual eligible costs incurred during the fiscal year. *See* 42 C.F.R. §§ 413.60, 413.64.

The PRRB's "decision is final unless the Secretary—acting through the [Centers for Medicare & Medicaid Services ("CMS")] Administrator—'reverses, affirms, or modifies' the [PRRB]." New LifeCare Hosps., 7 F.4th at 1220 (citing 42 U.S.C. § 139500(f)(1); 42 C.F.R. § 405.1875(a)). A request for review of a PRRB decision must be submitted to the CMS Administrator within 15 days of receipt of the decision. 42 C.F.R. § 405.1875(c)(1). Whether to conduct such a review is within the sole discretion of the CMS Administrator. Id. § 405.1875(c)(3). "From there, a provider may seek judicial review by filing a civil action in district court." New LifeCare Hosps., 7 F.4th at 1220–21 (citing 42 U.S.C. § 139500(f); 42 C.F.R. § 405.1877(b)). The possibility of the CMS Administrator's discretionary review, however, does not create an additional exhaustion requirement. By regulation, "[a] provider is not required to seek Administrator review . . . first in order to seek judicial review of a Board decision." 42 C.F.R. § 405.1877(a)(3)(ii).

In addition to the review mechanism available through the PRRB, the Secretary by regulation has also made available an alternative review process by which an NPR may be "reopened, with respect to specific findings on matters at issue in a determination or decision." 42 C.F.R. § 405.1885(a)(1). Such a process, the Secretary has recognized, may "hasten resolution of the case." Medicare Program; Provider Reimbursement Determinations and Appeals, 73 Fed. Reg. 30,190, 30,232 (May 23, 2008). The MAC may—but is not required to reopen a matter sua sponte or "by granting the request of the provider affected." 42 C.F.R. § 405.1885(a)(2). A provider may still appeal revisions made by the MAC in the reopening process, but only with respect to "those matters that are specifically revised in a revised determination or decision." *Id.* § 405.1889(b); see also Def.'s Mem. Supp. Opp'n Pl.'s Mot. Summ. J. & Cross-Mot. Summ. J. ("Def.'s Opp'n") at 4, ECF No. 16-1 (noting that "appeals of post-reopening revised NPRs are limited to the specific matters at issue that are adjusted by the Contractor in the revised NPR" (citing 42 C.F.R. § 405.1887(d))). A Revised NPR is "final and binding' unless it is further revised as a result of an appeal or a later reopening." Def.'s Opp'n at 4 (quoting 42 C.F.R. § 405.1807).

MAC reopening and PRRB appeals may proceed simultaneously, since a MAC "may reopen . . . [a] determination that is currently pending on appeal before the [PRRB] or Administrator." 42 C.F.R. § 405.1885(c)(3). Nevertheless, "[a]ny matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision." *Id.* § 405.1889(b)(2). The PRRB appeal route and a reopening request to the MAC are thus distinct, concurrently available methods by which a provider may seek review of an NPR, though they become mutually exclusive when the MAC declines to revise an original determination on a reopened review.

The PRRB rules allow a provider to "request to withdraw an issue(s) or case" from appeal. 2015 PRRB Rule 48; *see also* 2018 PRRB Rule 46. This particular rule further states that "[i]t is the Provider's responsibility to withdraw . . . an issue(s) for which the [MAC] has agreed to reopen the final determination for that issue(s) and attach a copy of the correspondence from the [MAC] where the [MAC] agreed to that reopening." 2015 PRRB Rule 48. A provider "may request reinstatement of an issue(s) . . . within three years" of the PRRB's receipt of the withdrawal request by filing a motion "in writing setting out the reasons for reinstatement." 2018 PRRB Rule 47.1. In the instance of issues withdrawn "because the [MAC] agreed to reopen/revise the cost report for that issue(s)," reinstatement is available if the MAC "failed to reopen the cost report and issue a new final determination (e.g., Revised NPR) for that issue(s) as agreed." *Id.* R. 47.2.2.³ In other words, if the reopened MAC review is not completed, the provider may reinstate the formal appeal to the PRRB, but that reinstatement must be sought within three years from the date of withdrawal of the issue.

Separately, the PRRB rules allow a provider to make a request for abeyance, which if granted "suspends action on an appeal until specified events occur or conditions are met." 2015 PRRB Rule 39(A); see also 2018 PRRB Rule 39. As relevant here, abeyance may be deemed appropriate "where the Provider can demonstrate that the case will be resolved without a hearing upon the occurrence of specified conditions or events." 2015 PRRB Rule 39(A). Grants of abeyance are at the discretion of the PRRB. *Id*.

The Rule further requires that for such a reinstatement request, "the provider must attach a copy of its reopening request and the correspondence from the [MAC] where the [MAC] agreed to reopen the final determination for that issue(s)." 2018 PRRB Rule 47.2.2.

B. Factual Background

Plaintiff is a Medicare-participating hospital in North Carolina that provides services to Medicare beneficiaries. Compl. ¶ 1, ECF No. 1. On June 9, 2015, Palmetto GBA, the MAC administering reimbursements for plaintiff, issued an NPR for the fiscal year ending September 30, 2011, showing Medicare's overpayment of \$1,458,636 to plaintiff, which consequently owed that amount back to Medicare. Admin. Record ("AR") at 70.4 Dissatisfied with the calculated reimbursement amounts, plaintiff filed with the PRRB an appeal, which was received on December 1, 2015, within the 180-day window provided by statute, 42 U.S.C. § 139500(a)(3). AR at 64–68. In its statement of issue attached to the appeal, plaintiff explained the dispute with the MAC's "disallowance of [certain] Medicare bad debts," such as deductible and coinsurance amounts not paid by beneficiaries when due, reimbursable by the Secretary under Medicare regulations provided that certain criteria are met. AR at 83–84; see also 42 C.F.R. § 413.89.

Plaintiff also elected to pursue relief through the reopening process. When the PRRB appeal had been pending for about eight months, plaintiff wrote to the MAC "request[ing] a reopening" of the cost report. Def.'s Opp'n, Ex. C, August 19, 2016 Request for Reopening Medicare Cost Report at 1, ECF No. 16-4. In its letter, plaintiff identified six issues related to bad debt reimbursement in dispute and indicated that it had a pending appeal before the PRRB.

In compliance with D.D.C. LOCAL CIVIL RULE 7(n)(1), defendant submitted a certified list of the contents of the 84-page administrative record, *see* Certified List of Contents of Admin. Record ("AR Contents"), ECF No. 13, and the parties separately docketed the portions of the administrative record cited or otherwise relied upon in the parties' briefing, see J.A., ECF No. 22. For clarity, "AR" citations herein are to the full administrative record, rather than to the joint appendix. The only documents in the administrative record not filed with the Court are a request by plaintiff for PRRB-assisted mediation and an acknowledgment by the PRRB of that request. *Compare* AR Contents at 1, *with* J.A. at ii; *see also* 2015 PRRB Rule 43 (setting forth procedures for a mediation process). At the time of filing the PRRB appeal, plaintiff indicated that it was requesting mediation, AR at 66, and concurrently filed a separate letter containing a mediation request, AR Contents at 1, as required by the rule, 2015 PRRB Rule 43.2. The disposition of the mediation request is not in the record, but the chronology of events in the case suggests that the request for mediation became moot upon the MAC's agreement to reopen the cost report with respect to the issues disputed by plaintiff.

Id. If the MAC agreed to reopen the cost report to examine these issues, plaintiff agreed to withdraw its appeal, but "reserve[d] the right to reinstate the appeal, if applicable, as outlined in [2015 PRRB] Rule 46.1." Id. The MAC agreed to reopen the cost report to examine the disputed issues on August 26, 2016. AR at 38–39. Plaintiff then, on August 29, 2016, wrote to the PRRB "request[ing] a withdrawal" of its appeal, "conditioned upon the [MAC's] action through reopening of the September 30, 2011 cost report," noting that it "reserve[d] the right to reinstate the appeal, if applicable." AR at 34.

The MAC performed a review and, on September 27, 2017, issued a Revised NPR that allowed reimbursement for some previously disallowed bad debts but continued to deny reimbursement for others. AR at 19 (indicating revisions to reimbursement amounts); id. at 10-12, 14–15 (explaining the MAC's determinations on reopening with respect to various of plaintiff's objections). The effect of the Revised NPR was to increase the total reimbursement plaintiff was eligible to receive for the fiscal year by \$833,242. AR at 19. Plaintiff did not appeal the Revised NPR to the PRRB, Def.'s Opp'n at 6, nor did it otherwise signal any objections within the 180-day statutory appeals window. Apparently still dissatisfied, nearly two years later, on August 13, 2019, plaintiff wrote to the PRRB "request[ing] reinstatement" of its original appeal because, plaintiff asserted, in the Revised NPR "[t]he MAC only partially accounted for the issues outlined." AR at 22. This was within the requisite three years of the date plaintiff had withdrawn its PRRB appeal, see 2018 PRRB Rule 47.1, and thus the timeliness of this reinstatement request is not at issue here. Plaintiff did not, however, enclose any documents with its request nor elaborate on how the Revised NPR "only partially accounted" for the bad debt disputes.

The MAC wrote to the PRRB, on September 12, 2019, opposing reinstatement because, in its view, (a) plaintiff did not explain the reasons reinstatement was warranted, (b) the MAC did in fact reexamine the issues for which reopening was requested, as demonstrated by workpapers documenting such reexamination, (c) the MAC issued a Revised NPR, and (d) the MAC otherwise complied with the reopening agreement. AR at 4–5. Accordingly, the MAC argued, the condition in 2018 PRRB Rule 47.2.2 for reopening, that the MAC had "failed to reopen the cost report and issue a new final determination . . . as agreed," was not met. *Id.* at 5.

On February 19, 2020, the PRRB issued a decision denying reinstatement of plaintiff's appeal. AR at 1–3. The principal reason given for the denial was that the MAC did, "in fact, issue[] a [Revised] NPR consistent with the agreed withdrawal." AR at 2–3. As such, the PRRB concluded, plaintiff's "right to reinstatement was extinguished when the [MAC] issued a new determination *on September 27, 2017* that specifically dealt with the issues for which the Provider is seeking reinstatement." *Id.* at 3 (footnote omitted) (emphasis in original).

C. Procedural Background

On April 17, 2020, plaintiff filed the instant complaint challenging the PRRB's February 19, 2020 decision to deny reinstatement of its appeal. *See* Compl. ¶ 5. In a single count, the complaint alleges that the denial of reinstatement was "contrary to the Medicare statute," *id.* ¶ 42, and violated the APA because the denial was arbitrary and capricious, was contrary to statute, lacked observance of required procedures, and was unsupported by substantial evidence, *id.* ¶ 43. The parties subsequently filed and briefed cross-motions for summary judgment and submitted, on June 17, 2021, a joint appendix containing relevant excerpts of the administrative record, J.A., ECF No. 22.⁵ The pending motions are now ripe for resolution.

In addition to the administrative record, plaintiff included, with its reply brief in support of its motion for summary judgment, Pl.'s Reply Mem. Supp. Mot. Summ. J. & Opp'n Def.'s Cross-Mot. Summ. J. ("Pl.'s Opp'n") at

II. LEGAL STANDARD

A. Administrative Procedure Act

The APA provides for judicial review of any "final agency action for which there is no other adequate remedy in a court," 5 U.S.C. § 704, and "instructs a reviewing court to set aside agency action found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 61 (D.C. Cir. 2020) (quoting 5 U.S.C. § 706(2)(A)). This standard "requires agencies to engage in reasoned decisionmaking,' and . . . to reasonably explain to reviewing courts the bases for the actions they take and the conclusions they reach." *Brotherhood of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 115 (D.C. Cir. 2020) (quoting *Dep't of Homeland Sec. v. Regents of Univ. of Cal.* ("*Regents*"), 140 S. Ct. 1891, 1905 (2020)). Judicial review of agency action is limited to "the grounds that the agency invoked when it took the action," *Regents*, 140 S. Ct. at 1907 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)), and the agency, too, "must defend its actions based on the reasons it gave when it acted," *id.* at 1909.

B. Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56, "[a] party is entitled to summary judgment only if there is no genuine issue of material fact and judgment in the movant's favor is proper as a matter of law." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018) (quoting *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 805 (D.C.

^{3–6,} ECF No. 18, the following two extra-record statements made in 2021 by certain HHS personnel ostensibly interpreting the PRRB's withdrawal rule at issue here: (1) an email from a "[p]aralegal [s]pecialist" at the Centers for Medicare & Medicaid Services ("CMS"), responding to an email inquiry in April 2021 by a consultant for plaintiff, advising that a provider "must withdraw an issue/case if the MAC has agreed to reopen the final determination for that issue(s)," Pl.'s Opp'n, Ex. 1, Exhibit 1 to Decl. of Josh Steedley, ECF No. 18-1; and (2) slides from a March 2021 conference presentation by three representatives of HHS, with a disclaimer that "[p]resenter comments do not reflect the views or positions of CMS or HHS," likewise suggesting that PRRB rules "require[] withdrawal of issue if . . . MAC has agreed to reopen issue," Pl.'s Opp'n, Ex. 2, Exhibit 1 to Decl. of Joseph D. Glazer, Esq., ECF No. 18-2.

Cir. 2006)); see also Fed. R. Civ. P. 56(a). In APA cases such as this one, involving cross-motions for summary judgment, "the district judge sits as an appellate tribunal. The 'entire case' on review is a question of law." Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083–84 (D.C. Cir. 2001) (footnote omitted) (collecting cases). Thus, a court need not and ought not engage in fact finding, since "[g]enerally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions." James Madison Ltd. by Hecht v. Ludwig, 82 F.3d 1085, 1096 (D.C. Cir. 1996); see also Lacson v. U.S. Dep't of Homeland Sec., 726 F.3d 170, 171 (D.C. Cir. 2013) (noting, in an APA case, that "determining the facts is generally the agency's responsibility, not [the court's]"). Judicial review, when available, is typically limited to the administrative record, since "[i]t is black-letter administrative law that in an [APA] case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." CTS Corp. v. EPA, 759 F.3d 52, 64 (D.C. Cir. 2014) (internal quotation marks and citation omitted).

III. DISCUSSION

Plaintiff argues that the PRRB's withdrawal rule is mandatory for providers seeking a MAC reopening review and, as such, is unlawful and, in any event, that the PRRB failed properly to apply its reinstatement rule here. These assertions do not withstand scrutiny. HHS's interpretation of the PRRB withdrawal rule as non-mandatory is reasonable and entitled to deference, and under this interpretation, the rule is unquestionably lawful. Furthermore, the plain text of the reinstatement rule demonstrates that plaintiff was not automatically entitled to reinstatement in this case. HHS is therefore entitled to summary judgment.

A. Plaintiff Has Not Waived Its Challenge to PRRB Appeal Rules

As an initial matter, HHS argues that plaintiff waived the argument that PRRB's "mandatory withdrawal rule," as characterized by plaintiff, is unlawful. According to HHS, plaintiff "could have argued before the [PRRB]" its grievance with the rule and, by failing to do so, is barred from raising the issue here. Def.'s Opp'n at 10. Citing "black-letter administrative law principles," HHS argues that because plaintiff withdrew its PRRB appeal without suggesting either that it was required to do so or that such requirement was unlawful, plaintiff "deprived [the PRRB] of the opportunity to consider an 'objection made at the time appropriate under its practice." *Id.* at 10–11 (quoting *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)).

The problem with this waiver argument is that plaintiff does not contend that a "mandatory withdrawal rule" is unlawful standing alone. Rather, plaintiff takes issue with "[t]he PRRB's Mandatory Withdrawal Rule and subsequent refusal to reinstate the Hospital's appeal after the MAC's reopening did not fully resolve issues." Pl.'s Mem. Supp. Mot. Summ. J. ("Pl.'s Mem.") at 12, 15, 17, ECF No. 14. This distinction is essential; if the PRRB had reinstated plaintiff's appeal, the earlier withdrawal, regardless whether deemed mandatory or not, would have worked no alleged deprivation of plaintiff's statutory appeal rights and would not have been raised as a basis for review in this Court.

Although framed as an argument that the mandatory withdrawal rule is in itself unlawful, the better description of the concern is that the unlawfulness stems from the *combination* of the purported mandatory withdrawal of issues from appeal with the denial of reinstatement of the withdrawn claim after the intermediary finishes its review without changing the calculations at issue. That result only became apparent when the PRRB issued its decision to deny reinstatement.

HHS correctly observes that its waiver argument sounds in the "issue exhaustion" doctrine. Def.'s Reply Pl.'s Opp'n Def.'s Cross-Mot. Summ. J. ("Def.'s Reply") at 10, ECF No. 20. As the Supreme Court has repeatedly noted, when, as here, the relevant statutes or regulations do not expressly impose an issue exhaustion requirement, "[t]he desirability of a court imposing a requirement of issue exhaustion depends on the degree to which the analogy to normal adversarial litigation applies in a particular administrative proceeding." Carr v. Saul, 141 S. Ct. 1352, 1358 (2021) (emphasis added) (quoting Sims v. Apfel, 530 U.S. 103, 109 (2000)). Defendant unpersuasively suggests that these authorities should be read as inquiring into whether proceedings before a particular body "are generally adversarial in nature" rather than looking at "a specific process within the administrative scheme," Def.'s Reply at 10–11, but the plain command of Carr and Sims suggests otherwise.

Applied here, formal substantive review on the particulars of a Medicare reimbursement is unquestionably adversarial. The request for reinstatement, however, is less clearly so. To be sure, a "request for reinstatement is a motion" and must "set[] out the reasons for reinstatement," 2018 PRRB Rule 47.1, and "an opposing party may send a response," *id.* R. 44.3; *see also id.* R. 10.2 (allowing a response if the MAC opposes any type of "request"). At that point, however, a challenge to the rules themselves would have been premature given plaintiff's apparent belief that it was entitled to reinstatement under those rules. The MAC's letter of opposition to reinstatement said nothing about the circumstances of withdrawal or the interaction between the two rules, *see* AR at 4–5, and in any event, the PRRB rules do not contemplate a reply to such an opposition.

HHS thus fails to identify precisely when in the administrative process leading up to the PRRB decision plaintiff was required to raise its argument that the PRRB withdrawal and

reinstatement rules are collectively unlawful. Plaintiff's entitlement to judicial review, under 42 U.S.C. § 139500(f)(1), arose *at the same time* as plaintiff became aware of the PRRB's position that reinstatement was not available, the condition which in plaintiff's view rendered the mandatory withdrawal rule unlawful. Thus, to the extent HHS's administrative waiver argument is predicated on requiring plaintiff to have somehow raised this complaint before the agency earlier, this argument lacks merit.⁶ Accordingly, plaintiff has not waived this issue and may raise its challenge to the PRRB withdrawal rule here.

B. PRRB's Interpretation of Its Own Withdrawal Rule Is Entitled to Deference

Under the disputed PRRB rule, "[i]t is the provider's responsibility to withdraw . . . an issue(s) for which the [MAC] has agreed to reopen the final determination for that issue(s)."

2015 PRRB Rule 48. The parties vigorously debate whether the use of the word "responsibility" in this disputed rule means that a provider *must* withdraw its appeal as to an issue that is being reopened by agreement with the contractor. On the one hand, plaintiff describes this provision as a "Mandatory Withdrawal Rule" whereby "[t]he hospital has no choice regarding that withdrawal." Pl.'s Mem. at 7, 9; *see also id.* at 12–13; Pl.'s Reply Mem. Supp. Mot. Summ. J. & Opp'n Def.'s Cross-Mot. Summ. J. ("Pl.'s Opp'n") at 1–6, ECF No. 18. HHS, on the other hand, argues that the Rules elsewhere "use[] mandatory language like 'must' to establish a requirement" and "the word 'responsibility' is best read as *not* implying a command." Def.'s Opp'n at 16–17. Both readings appear reasonable and, in this legal context, that ambiguity only helps the agency.

Plaintiff conceivably could have raised the issue by seeking discretionary review by the CMS Administrator after PRRB issued its decision denying reinstatement of the appeal, *see supra* note 2, but the language of the regulation governing judicial review expressly forecloses opting-out of Administrator review as a basis for a waiver argument, *see* 42 C.F.R. § 405.1877(a)(3)(ii) ("A provider is not required to seek Administrator review under [42 C.F.R.] § 405.1875(c) first in order to seek judicial review of a [PRRB] decision that is final and subject to judicial review under [42 U.S.C. § 1395oo(f)(1)].").

When "interpreting a regulation involves a choice between (or among) more than one reasonable reading," courts "should defer to the agency's construction of its own regulation." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2411 (2019) (opinion of Kagan, J.) (recognizing the doctrine of deference set forth in *Auer v. Robbins*, 519 U.S. 452 (1997)). Such deference, however, is not unlimited. First, the doctrine only applies "if a regulation is . . . genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation." *Id.* at 2414 (majority opinion). Second, even if genuine ambiguity is established, "the agency's reading must still be 'reasonable.' In other words, it must come within the zone of ambiguity the court has identified after employing all its interpretive tools." *Id.* at 2415–16 (citation omitted) (noting that even when the "tools" fail to resolve an ambiguity, they help to "establish the outer bounds of permissible interpretation"). HHS's interpretation of the PRRB's withdrawal rule as non-mandatory survives this analysis.⁷

1. The Disputed Rule Is Ambiguous and HHS's Interpretation Is Reasonable

HHS rightly concedes that the phrase "it is the responsibility of" in the disputed rule is ambiguous. Def.'s Opp'n at 18. As plaintiff suggests, the disputed rule can reasonably be read to require that when a provider secures the contractor's agreement to reopen an issue, the provider then bears a duty to withdraw that issue from its PRRB appeal. The rule does not, however, use language, such as "shall" or "must," that makes withdrawal clearly mandatory. To be sure, the absence of such "magic words" does not foreclose the possibility that the rule nonetheless states a requirement. *Cf. In re Grand Jury Investigation*, 315 F. Supp. 3d 602, 633—

Granting deference to HHS's interpretation of 2015 PRRB Rule 48 and 2018 PRRB Rule 46—that this rule does not mandate withdrawal of an issue upon its reopening—renders moot plaintiff's argument that the PRRB rules are contrary to statute. Plaintiff does not argue any impairment of its statutory appeal rights by a voluntary withdrawal rule.

34 (D.D.C. 2018), *aff'd*, 916 F.3d 1047 (D.C. Cir. 2019) (noting, while analyzing a regulation employing the term "should" instead of "shall," that "context is the key to determining whether the term 'should' carries a mandatory or permissive meaning").

HHS contends that the rule need not be read as stating a mandatory step, citing, for example, instances elsewhere in the Rules where the term "responsibility" is used but, HHS argues, does not "imply[] a command," such as: (a) "It is the responsibility of the Provider to maintain record of delivery"; (b) "It is the Provider's responsibility to maintain evidence of timely filing" and (c) "It is the responsibility of the party calling a remote witness to ensure that the witness has available both parties' organized and labeled exhibits." Def.'s Opp'n at 17.

These examples simply beg the question, however, since each of HHS's illustrative provisions appears susceptible to the same inquiry as to whether a requirement is established as opposed to a mere exhortation. HHS also leans on the Rules' reference to "[a] provider's *request* to withdraw an issue(s)" as militating against the provider being mandated to do so. *See id.* at 16–17. This is similarly unhelpful, as the mere fact that a provider makes a "request" does not, in itself, make clear that the provider was not compelled by a rule to make said request.

Finally, HHS argues, more persuasively, that "the non-mandatory character" of the rule is both evidenced and clarified by "the fact that the [PRRB] Rules gave Plaintiff *a choice* between requesting withdrawal of its appeal under Rule 46 and requesting that the appeal be held in abeyance or suspended under Rule 39," *id.* at 18, while MAC reopening and review took place. Certainly, plaintiff's exercise of the option of requesting abeyance would have better served its interests by putting it in the position of being able to revive its PRRB appeal after the MAC reopening and review. For the purpose of interpreting the withdrawal rule, however, this

argument is circular at best: the general availability of abeyance of an appeal need not have any effect on a rule that demands withdrawal of an issue upon reopening by an intermediary.⁸

An easier path exists to conclude that the word "responsibility" admits of some ambiguity. This word can mean "[t]he quality, state, or condition of being duty-bound, answerable, or accountable," BLACK'S LAW DICTIONARY (11th ed. 2019), which indeed suggests that a provider bears a "duty" to withdraw an issue on appeal upon a MAC agreement to reopen. The word can also mean "[t]hat for which one is answerable or accountable," *id.*, suggesting perhaps that *if* withdrawal is to be done, the provider is the person "answerable or accountable" for making it happen.

Here, the relevant event triggering the "responsibility" in question is the "agree[ment]" between a provider and the MAC "to reopen the final determination for that issue(s)." 2015 PRRB Rule 48. Such an agreement could plausibly yield withdrawal of the issue in the PRRB appeal in one of various ways: by the provider itself withdrawing the issue, by the MAC initiating the withdrawal, or by some automatic operation of law on account of the agreement. By stating that it "is the Provider's responsibility to withdraw" the issue, *id.*, the Rule can be read as stating that *if* the issue is to be withdrawn, the *provider* must be the one to do so, as opposed to the MAC, the PRRB, or some automatic process. Put another way, the Rule indicates *who* must effectuate the withdrawal if such withdrawal is desired, not *whether* withdrawal is a step

While not helpful in resolving the ambiguity in the rule, the existence of the abeyance option is nonetheless useful in demonstrating how the PRRB rules do not categorically abrogate providers' statutory review rights. The parties agree that, absent a mandatory withdrawal rule, plaintiff had the option to request that its appeal be held in abeyance under PRRB Rule 39 while the MAC carried out its review after reopening. Pl.'s Mem. at 17; Def.'s Opp'n at 16. The parties appear to agree that the abeyance option, if exercised, would preserve a provider's right to continue its appeal before the PRRB should it be dissatisfied with the Revised NPR—at least with respect to issues adjusted in the Revised NPR. Furthermore, it prevents the need for the provider to pursue the issues before the PRRB and the MAC simultaneously, thereby not frustrating any efficiency benefits achieved by attempting resolution through the reopening route.

that must be performed at all. In the absence of language clarifying the matter, the plain text of the Rule does not convincingly settle it one way or the other.

The normal canons of interpretation provide little interpretive guidance here. In the context of the full Rule, other types of issues or cases are also "the Provider's responsibility to withdraw": (a) "an issue(s) or case that the Provider no longer intends to pursue," (b) "an issue(s) or case in which an administrative resolution has been executed," and (c) "a case in which all issues have been handled, whether by resolution, transfer, dismissal, or withdrawal." 2005 PRRB Rule 48. Under the canon of *noscitur a sociis*, whereby a word or phrase "is generally known by the company it keeps," *Agnew v. Gov't of D.C.*, 920 F.3d 49, 56 (D.C. Cir. 2019), the character of these *other* types of issues for which a provider bears "responsibility" to withdraw may inform the character of the withdrawal "responsibility" for a MAC-reopened issue. Signs point in both directions, however. Withdrawal of an issue "that the Provider no longer intends to pursue" describes a clearly voluntary activity, while, by contrast, withdrawal of a case "in which an administrative resolution has been executed" or "in which all issues have been handled" could reasonably be read as a required withdrawal as a matter of docket management.

Given that statutory interpretation "tools" fall short of definitively resolving any ambiguity in the construction of the withdrawal rule, the decisive question is whether HHS's interpretation—that withdrawal is voluntary—is reasonable. For an agency's interpretation of a regulation to receive deference, "it must come within the zone of ambiguity the court has identified after employing all its interpretive tools." *Kisor*, 139 S. Ct. at 2415–16. The above analysis identifying the existence of ambiguity has already answered this question: "responsibility" need not mean that the provider *must* withdraw an issue upon reopening.

2. Plaintiff Cites No Authoritative Agency Sources for Its Preferred Interpretation

In response to HHS's assertion that the PRRB rules do not in fact require a provider to withdraw an issue or appeal when a MAC agrees to reopen a cost report, plaintiff offers two items of extra-record evidence, detailed *supra* note 5, that certain HHS staff members furnished information indicating that withdrawal is mandatory upon a MAC's agreement to reopen an issue. Pl.'s Opp'n at 3–6. Specifically, plaintiff cites: (a) a PRRB staff email stating that a provider "must withdraw an issue/case if the MAC agreed to reopen the final determination," in response to an April 2021 query to PRRB made by plaintiff's consultant, *id.* at 4; and (b) a slide from a presentation by three "senior staff members at the Centers for Medicare and Medicaid Services" at an industry conference noting that "Board Rule 46 requires withdrawal of issue if ... MAC has agreed to reopen issue," *id.* at 4–6.9

Assuming that these statements were in fact made by HHS staff reinforces the conclusion that the withdrawal rule is ambiguous, a point already conceded by HHS. Surely, the fact that various staff at, or associated with, PRRB represented in 2021 that the rule mandated withdrawal upon MAC reopening helps confirm that such an interpretation was a reasonable one for plaintiff to reach. The probative value of these statements, however, stops there. Not only do the statements postdate the February 2020 PRRB decision under review in this case and therefore were not before the agency at the time, *see* Def.'s Reply at 5, but also for the same timing reason, plaintiff does not—and cannot—argue that these statements were relied on by plaintiff in

HHS points out that plaintiff does not address why this extra-record evidence should be considered nor the legal standards applicable to such consideration. Def.'s Reply at 3–5. The use of such extra-record evidence in an APA case is "limited" and generally "to challenge gross procedural deficiencies—such as where the administrative record itself is so deficient as to preclude effective review." *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) (per curiam). Notwithstanding any shortcomings in plaintiff's legal support for consideration of this evidence, the staff statements highlighted by plaintiff do not affect the analysis of what the PRRB rules mean and whether HHS's interpretation is entitled to deference.

determining how to pursue review of the disputed cost report, if such reliance matters at all.

Finally, as HHS points out, plaintiff offers no evidence showing that any of the staff members making these statements was in a position to offer an authoritative, much less binding, interpretation of the withdrawal rule. *Id.* at 6–7; *cf. Kisor*, 139 S. Ct. at 2416 (noting that *Auer* deference is only afforded to regulatory interpretations that "emanate from those actors . . . understood to make authoritative policy in the relevant context"). ¹⁰ In short, the two extra-record statements are not helpful to plaintiff's position.

3. HHS Has Special Expertise Interpreting Medicare Rules

For *Kisor/Auer* deference to be warranted, the interpretation of the regulation at issue must "in some way implicate [the agency's] substantive expertise." *Kisor*, 139 S. Ct. at 2417. Medicare, a statutory and regulatory scheme that the D.C. Circuit has described as a "labyrinthine world," *Adirondack Med. Ctr.*, 740 F.3d at 694, is prototypical subject matter for which specialized expertise is especially valuable. *See Via Christi Hosps. Wichita, Inc. v. Burwell*, 820 F.3d 451, 456 (D.C. Cir. 2016) ("We owe heightened deference to the Secretary's interpretation of a complex and highly technical regulatory program such as Medicare." (quotation marks and citation omitted)).

Plaintiff further draws upon its anecdotes of PRRB staff statements in 2021 by suggesting that should HHS's interpretation of the withdrawal rule as non-mandatory be credited, additional discovery should be permitted as to "whether that is in fact how the agency read and applied the rule to Plaintiff (and other hospitals)." Pl.'s Opp'n at 7–8. This request faces the high hurdle of well-established law that "[d]iscovery typically is not available in APA cases." *Air Transp. Ass'n of Am. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011) (citation omitted). Rare exceptions may be granted when "a party makes a significant showing... that it will find material in the agency's possession indicative of bad faith or an incomplete record," *id.* at 487–88, but plaintiff makes no such showing. Furthermore, plaintiff fails to identify how new evidence about PRRB's understanding of its withdrawal rule would affect this case. While plaintiff queries whether the agency "read and applied the rule to Plaintiff' as non-mandatory, Pl.'s Opp'n at 7, it does not acknowledge that the agency at no point had to "appl[y]" the rule at all. Plaintiff withdrew its appeal without prompting by PRRB, leaving no reason for PRRB to contemplate whether such withdrawal was mandatory.

To be sure, the narrow question of regulatory interpretation posed here—whether a provider must withdraw from its appeal an issue that its MAC has agreed to reopen—does not seem enormously "complex" or "technical" in nature. Indeed, a court is eminently capable of construing the term "responsibility" when called upon to do so. In the context of a carefully calibrated scheme for determining Medicare reimbursements owed providers, however, the implications of one construction over another may be wide ranging. Would a mandatory withdrawal rule disincentivize providers from using the reopening process and thereby increase the overall burden on the PRRB? Would MACs alter their decisions as to whether to reopen issues if doing so affected appealability before the PRRB? Would the Secretary have established a reopening process if use of that process extinguished statutory appeal rights? These are policy judgments best assessed by the agency with the expertise and task of administering a complex government program, and in this instance the agency offers a reasonable construction of its own rule, rendering further inquiry unnecessary.

C. PRRB's Reinstatement Rule Is Unambiguous and Was Correctly Applied

While the parties focus primarily on the proper interpretation of the withdrawal rule, the PRRB's decision not to reinstate plaintiff's appeal requires some examination of the reinstatement rule as well. The operative 2018 version of Rule 47.2.2 reads: "Upon written motion, [PRRB] will also grant reinstatement of an issue(s)/case if a provider requested to withdraw an issue(s) from its case because the [MAC] agreed to reopen/revise the cost report for that issue(s) but failed to reopen the cost report and issue a new final determination (e.g., Revised NPR) for that issue(s) as agreed."

Plaintiff argues that "[r]einstatement is nondiscretionary when the MAC fails to fully resolve the disputed issues that were originally appealed by the hospital" and since the MAC allegedly did not do so here, "[t]he PRRB's refusal to reinstate the appeal thus violated the

PRRB's own rules." Pl.'s Mem. at 21–22. To the contrary, PRRB's decision to deny reinstatement of the issue fits squarely within the parameters of the rule. *See* AR at 2–3 ("[S]ince it is clear that the Medicare Contractor, in fact, issued a [Revised NPR] consistent with the agreed withdrawal, the Provider's right to reinstatement was extinguished when the Medicare Contractor issued a new determination . . . that specifically dealt with the issues for which the Provider is seeking reinstatement.").

Plaintiff indisputably "requested to withdraw" its appeal, *see* AR at 35, and did so on account of the MAC's declaration that same day about "hereby reopening [plaintiff's] cost report" to examine issues including all those cited in the withdrawal letter, AR at 36. The MAC thereafter issued an "Amended Notice of Amount of Medicare Program Reimbursement" (the "Revised NPR"), AR at 19, which the PRRB found to be based on a review of all of the specific issues for which plaintiff had sought reopening, AR at 2–3. Plaintiff asserted that the Revised NPR "only partially accounted for the issues," AR at 6, but dissatisfaction with the result of a review is not the same as having no review at all.

Plaintiff is thus simply incorrect to assert that the MAC's "cost report reopening and review process did not resolve fully the previously appealed issues that were the subject of the cost report reopening," Pl.'s Opp'n at 1. On the contrary, the MAC resolved the issues "fully" and, indeed, in plaintiff's favor—to the tune of \$833,242—just not to plaintiff's liking on each and every one of the six issues raised. Nowhere in the record or the briefing does plaintiff claim that the MAC, in preparing its Revised NPR, failed to examine any of the six issues prompting the reopening, nor that the Revised NPR failed to cover all those issues.

Furthermore, even if the MAC failed to examine any reopened issue—despite its workpapers suggesting otherwise, AR at 2—plaintiff did not include in its reinstatement request,

which is the sole record evidence available to the agency reflecting plaintiff's position, any information whatsoever about the nature of the purported deficiencies in the Revised NPR, nor did it identify what "part[]" of the issues the Revised NPR failed to resolve. AR at 6. On this meager record, plaintiff has fallen far short of demonstrating that the PRRB's decision was in any way arbitrary or capricious. "[A] court is not to substitute its judgment for that of the agency" when reviewing agency decisions under this standard, *Ascension Borgess Hosp. v. Becerra*, No. 20-cv-139 (BAH), 2021 WL 3856621, at *4 (D.D.C. Aug. 30, 2021) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)), and here the "judgment" at issue is merely PRRB's refusal to act on plaintiff's conclusory assertion that the Revised NPR included some unspecified shortcomings.

The lack of evidence of any shortcomings in the MAC review and ensuing Revised NPR is fatal to plaintiff's claim that it was entitled to reinstatement under PRRB rules.¹¹

* * *

The above analysis, examining the matter through the lens of the parties' arguments, is sufficient to resolve the matter. The root cause of plaintiff's predicament, however, may well be far simpler: the language of the governing *regulations* (not merely the PRRB rules) seems to foreclose a provider's ability to avail itself of both the PRRB review route and the MAC reopening route, irrespective of the procedural choices it makes before the PRRB. So long as the

The result of this necessary conclusion is that plaintiff likely finds itself without any further avenue for administrative review of the cost report and reimbursement calculations at issue. HHS points out that "the result of a reopening is typically a revised NPR, which can itself be appealed within a 180-day period." Def.'s Opp'n at 16 (citing 42 C.F.R. § 405.1889(a)). Plaintiff made no such appeal—the window to do so has long since lapsed—and would not fare much better even if it had. As HHS also observes, "appeals of post-reopening revised NPRs are limited to the specific matters at issue that are adjusted by the [MAC] in the revised NPR." *Id.* at 4 (citing 42 C.F.R. § 405.1887(d)); *see also* Pl.'s Mem. at 4. Insofar as plaintiff continued to disagree with the MAC's calculations on any item which the MAC did *not* adjust in the Revised NPR, plaintiff was foreclosed from filing a new appeal before the PRRB as to those items. *See* 42 C.F.R. § 405.1887(d).

MAC issues a Revised NPR as promised, by regulation that issuance appears to be the end of the line for those issues the MAC actually reviewed but did not revise. Per the plain text of the regulations, "[a]ny matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision." 42 C.F.R. § 405.1889(b)(2) (emphasis added). Even if plaintiff had not withdrawn its appeal and had been entitled to resume it after issuance of the Revised NPR, the ensuing review would surely constitute "any appeal" of the Revised NPR, given that the original NPR would have been superseded.

Insofar as that critical regulatory bar to further appeal controls the outcome, the distinctions raised by the parties—between withdrawal and abeyance, or between mandatory and voluntary withdrawal—matter little. HHS has set up a system where a provider can pursue an appeal before the PRRB as of right, or, with the MAC's agreement, review of disputed items through the reopening process. So long as a provider receives the promised review through one route or the other, as plaintiff did here, it is not deprived of its right to contest the NPR.

Plaintiff does not argue that 42 C.F.R. § 405.1889(b)(2) conflicts with the Medicare Act, for good reason. While plaintiff makes much of its "statutory appeal rights" of which it was

¹² When promulgating the currently effective version of 42 C.F.R. § 405.1889, HHS expressly intended to constrain the scope of a post-reopening appeal. In Edgewater Hospital, Inc. v. Bowen, 857 F.2d 1123 (7th Cir. 1988), amended by 866 F.2d 228 (7th Cir. 1989), the Seventh Circuit rejected HHS's restrictive interpretation of the then-effective regulation, holding that the PRRB could review all items in a Revised NPR, not just those items changed on reopening, even where a provider had not timely filed an appeal to the initial NPR. See id. at 1135–37 ("It simply is nonsense to argue that the only matters which the provider can appeal are those actually changed by the [MAC]."). HHS maintained that the Edgewater court's interpretation was incorrect, and in its 2008 rulemaking added the parenthetical "including any matter that was reopened but not revised," 42 C.F.R. § 405.1889(b)(2), to effectively overrule Edgewater. See Medicare Program, 73 Fed. Reg. at 30,230-31. Oddly, the preamble accompanying the revised regulation nonetheless suggests that a provider may be able to "preserve" its appeal rights, by filing an appeal to the initial NPR, as to issues within the scope of a MAC reopening for which the MAC does not ultimately make revisions. See id. at 30,230 ("[T]) the extent that the appeal period has not already run by the time that the provider receives the reopening notice, the provider should file an appeal if it wishes to preserve the right to appeal matters covered by the notice of reopening."). It is not clear, however, how such "preserv[ation]" squares with the regulation's textual exclusion of unrevised items from "any appeal."

ostensibly deprived, *see* Pl.'s Mem. at 12, the existence of such a right does not mean that plaintiff is entitled to a specific type of hearing, before a specific body, irrespective of its election to avail itself of an alternative route for resolution. The very section of the statute that creates the PRRB, 42 U.S.C. § 139500(a), also vests in the PRRB the "full power and authority to make rules and establish procedures . . . which are necessary or appropriate to carry out the provisions of this section," *id.* § 139500(e). The D.C. Circuit has long held that regulations that constrain the scope of post-reopening appeals are permissible rules and procedures of this type. *See HCA Health Servs. of Okla., Inc. v. Shalala*, 27 F.3d 614, 620–21 (D.C. Cir. 1994). As the agency points out, rules regarding the appeals process are essential to the effective docket management of the PRRB and can include "the possibility of dismissal as a sanction for noncompliance," Def.'s Opp'n at 13–14—a sanction far harsher than what plaintiff experienced here.

In this case, plaintiff chose to divert its review to the more informal MAC reopening process and bore the docket-management consequence that when the MAC's reopening completed with the issuance of a Revised NPR, by regulation "any appeal" of "a matter that was reopened but not revised" was thereby foreclosed, 42 C.F.R. § 405.1889(b)(2). Nobody disputes, however, that plaintiff had the option to pursue its appeal at the PRRB from start to finish without detouring to MAC reopening. Likewise, nobody disputes that had the MAC failed to perform the promised review and issue a Revised NPR, plaintiff could have resumed the PRRB appeal. Simply put, at no point was plaintiff forced to give up its "statutory appeal rights."

IV. CONCLUSION

For the foregoing reasons, the PRRB rules challenged by plaintiff are lawful and were correctly applied in this case. Accordingly, plaintiff's motion for summary judgment is **DENIED** and HHS's cross-motion for summary judgment is **GRANTED**.

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

Date: September 20, 2021

BERYL A. HOWELL

Bayl A. Mondel

Chief Judge