# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF COLORADO HEALTH,

AT MEMORIAL HOSPITAL, et al., : Civil Action No.: 14-1220 (RC)

.

Plaintiffs. : Re Document Nos.: 139, 141

:

v.

.

ALEX M. AZAR II, Secretary of Health

and Human Services,

:

Defendant. :

# **MEMORANDUM OPINION**

GRANTING IN PART AND DENYING IN PART DEFENDANT'S PARTIAL MOTION TO DISMISS;
GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO SUPPLEMENT THE
ADMINISTRATIVE RECORDS

#### I. INTRODUCTION

Plaintiffs in these consolidated cases are a group of fifty-one hospitals. They are challenging the implementation of the Medicare outlier-payment program by the Secretary of Health and Human Services ("HHS" or "the Secretary").

The Secretary now moves to dismiss some of the hospitals' claims, arguing that they are precluded based on prior litigation or are otherwise deficient. Separately, the hospitals move to supplement the administrative records. For the reasons discussed below, the Court will grant both motions in part and deny them in part.

#### II. FACTUAL BACKGROUND

# A. Statutory Framework

This Court assumes familiarity with its prior opinions in this case, which provide detailed background on the Medicare outlier-payments program. *See* Mem. Op. Granting Def.'s Mot.

Leave to Suppl. Answer ("Mem. Op. Suppl."), ECF No. 89; Mem. Op. Granting Def.'s Mot. for Clarification ("Clarification Op."), ECF No. 57; Mem. Op. Granting in Part and Denying in Part Pls.' Mot. to Compel Produc. of Complete Admin. R. ("Suppl. Rec. Op."), ECF No. 47. A simplified summary is provided here for orientation; additional detail will be provided as needed.

## 1. The Outlier-Payments Program

Under Medicare, the federal government reimburses hospitals for supplying medical services to the elderly and disabled. *See* Social Security Amendments of 1965 ("Medicare Act"), Pub. L. No. 89–97, tit. XVIII, 79 Stat. 286, 291.<sup>1</sup> Providers are not reimbursed for the full costs that they incur; instead, they are paid at fixed rates for different categories of services and treatments, known as "diagnosis-related groups" ("DRGs"). *See Billings Clinic v. Azar*, 901 F.3d 301, 303 (D.C. Cir. 2018) (citation omitted). However, hospitals are also eligible for certain outlier payments as a form of protection against unusually complicated and costly cases. *Id.* at 303–04 (citing 42 U.S.C. § 1395ww(d)(5)(A)(ii)). These payments become available when the provider's (1) "cost-adjusted charges" for a case exceed (2) the sum of (2a) the default reimbursement payment and (2b) a fixed dollar amount (known as the "outlier threshold" or the "fixed loss threshold" (FLT) and determined by the Secretary through an annual rulemaking process). *Id.* at 304 (citation omitted).

That first figure—the provider's "cost-adjusted charges"—is intended to estimate the provider's real cost of care, without any markups, and is calculated by multiplying a provider's actual charges by a historical "cost-to-charge ratio." *Id.* at 304–05 (citation omitted). The second figure—the sum of the base reimbursement plus the fixed loss threshold—is known as the "fixed-loss cost threshold." *Id.* at 304 (citation omitted). Cost-adjusted charges above the

<sup>&</sup>lt;sup>1</sup> Codified as amended in 42 U.S.C. § 1395 et seq.

fixed-loss cost threshold are reimbursed at a rate intended to approximate the marginal cost of care, currently set at 80 percent in most cases. *Id.* at 305 (citation omitted).

As an example: imagine a hospital charges \$100,000 for an unusually complicated procedure.<sup>2</sup> The \$100,000 will be multiplied by a cost-to-charge ratio (imagine it's 72:100 or 72 percent, which HHS will have calculated based on historical data), leaving \$72,000 of cost-adjusted charges. Imagine too that the standard DRG reimbursement rate for this kind of procedure is \$8,000, and the fixed loss threshold set by the Secretary that year is \$11,000. The hospital will automatically receive the base reimbursement of \$8,000. And because the cost-adjusted charges (\$72,000) are greater than the fixed-loss cost threshold (\$19,000), the hospital is also eligible for an outlier payment. That payment will be 80 percent of the difference between the cost-adjusted charges (\$72,000) and the fixed-loss cost threshold (\$19,000), or \$42,400.

That leaves an important question: how does the Secretary determine each fiscal year's fixed loss threshold? Well, Congress has limited the aggregate amount of Medicare outlier payments to a narrow range: it "may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year." 42 U.S.C. § 1395ww(d)(5)(A)(iv). To satisfy this directive, HHS conducts an annual rulemaking to set the fixed loss threshold at a level that it estimates will result in total payments within the statutorily-determined range. *See Billings Clinic*, 901 F.3d at 306–07 (citation omitted). (Specifically, since 1989, HHS has attempted to set an annual threshold that will result in total outlier payments being 5.1 percent of all Medicare payments.

<sup>&</sup>lt;sup>2</sup> This is based on example offered in the Secretary's opening brief, *see* Def.'s Mem. Supp. Mot. Dismiss at 6, ECF No. 139-1, which is in turn drawn from an August 29, 1997, Federal Register notice: *Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates*, 62 Fed. Reg. 45,966, 46,011 (Aug. 29, 1997).

*Id.* at 307.) Crucial to the Secretary's projections are the providers' estimated future cost-to-charge ratios. *Id.* For instance, if HHS overestimates a future year's cost-to-charge ratios (expecting, say, 90 percent when it turns out to be 72 percent), then reimbursable, cost-adjusted charges will be lower than expected—meaning that HHS may have set the fixed loss threshold too high and therefore be at risk of undershooting its 5.1 percent payment target.

This is all the more important because, in order to fund outlier payments, the Secretary withholds the predicted 5.1 percent from all other standard reimbursements. *See* 42 U.S.C. § 1395ww(d)(3)(B). And the Secretary need not take corrective action when the actual outlier payments differ from the 5.1 percent target. *See Dist. Hosp. Partners L.P. v. Burwell*, 786 F.3d 46, 51 (D.C. Cir. 2015) (citing *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1020 (D.C. Cir. 1999)). As a result, undershooting the 5.1 percent target results in a net loss of payments to providers as a whole.

### 2. Judicial Review

Procedurally, healthcare providers are reimbursed on a rolling basis, but at the end of their fiscal years, they submit annual cost reports to so-called "medicare administrative contractors" or "fiscal intermediaries." *See* 42 U.S.C. § 1395h(a); 42 U.S.C. § 1395kk-1; 42 C.F.R. § 413.20. Fiscal intermediaries then issue a total reimbursement determination for the entire year<sup>4</sup> through a Notice of Program Reimbursement ("NPR"). 42 C.F.R. § 405.1803. Hospitals are permitted to challenge an NPR by appealing to the Provider Reimbursement

<sup>&</sup>lt;sup>3</sup> "Medicare administrative contractor" is the current statutory terminology. *See* 42 U.S.C. § 1395h(a). Fiscal intermediary is an older term, *see Palisades General Hospital Inc. v. Leavitt*, 426 F.3d 400, 401 (D.C. Cir. 2005), but it remains in usage, *see*, *e.g.*, 42 U.S.C. § 1395*oo*(a). The Court will use both terms interchangeably to refer to the kind of entities described in 42 U.S.C. § 1395h(a).

<sup>&</sup>lt;sup>4</sup> Note that a hospital's fiscal year may not align with the federal fiscal year, meaning that a single NPR may be governed by two different fiscal year thresholds.

Review Board ("PRRB"), a specialized administrative body. 42 U.S.C. § 139500(a). Hospitals can in turn seek judicial review of a PRRB's final decision. § 139500(f)(1). Providers also "have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the [PRRB] determines . . . that it is without authority to decide the question"; such determinations for expedited review can be made *sua sponte* by the PRRB or at the request of a provider. *Id.* In either case, a district court reviews the challenged action "pursuant to the applicable provisions" of the Administrative Procedure Act ("APA"). *Id.* 

## **B.** Procedural History

Many of the plaintiff hospitals here were plaintiffs in two other related cases. *Banner Health v. Azar*, No. 10-cv-1638 (D.D.C.) was filed in 2010. In addition to advancing some other claims, the *Banner Health* plaintiffs challenged the fixed loss threshold determinations for federal fiscal years 1997 through 2007. *Banner Health v. Burwell*, 126 F. Supp. 3d 28, 43 (D.D.C. 2015). The district court disposed of the plaintiffs' claims through various motions to dismiss and for summary judgment. *See Banner Health v. Burwell*, 174 F. Supp. 3d 206, 207 (D.D.C. 2016). The Circuit largely affirmed, though it reversed the district court's grant of summary judgment as to fiscal years 2004 through 2006 on the grounds that HHS inadequately explained certain aspects of those threshold calculations. *See Banner Health v. Price*, 867 F.3d 1323, 1337–39 (D.C. Cir. 2017). The case remains pending in the district court.

Another group of cases were filed in 2013 and 2014 and were consolidated in *Lee Memorial Hospital v. Burwell*, No. 13-cv-643 (D.D.C.). The *Lee Memorial* plaintiffs challenged certain rulemaking actions taken in 2003 and the fixed loss threshold determinations for federal fiscal years 2008 through 2011. The court granted summary judgment for the Secretary on all

the plaintiffs' claims. *Lee Mem'l Health Sys. v. Burwell*, 206 F. Supp. 3d 307, 336 (D.D.C. 2016). On appeal of those cases (under the caption *Billings Clinic v. Azar*), the Circuit affirmed, finding that that the calculations were reasonable and that the challenge to the 2003 rulemaking actions was precluded by *Banner Health*. *See Billings Clinic v. Azar*, 901 F.3d 301, 302–03 (D.C. Cir. 2018).

This case, *University of Colorado Health at Memorial Hospital v. Azar*, No. 14-cv-1220, was consolidated for all purposes with seven later-filed cases. *See* Dec. 19, 2018 Order, ECF No. 108; Feb. 15, 2019 Order, ECF No. 112; April 1, 2019 Order, ECF No. 131. There are therefore eight currently operative complaints, each containing similar allegations:

- Am. Compl., Bayshore Community Hospital v. Azar, ECF No. 114
- Second Am. Compl., Riverview Medical Center v. Azar, ECF No. 115
- Second Am. Compl., West Virginia University Hospital v. Azar, ECF No. 116-5<sup>5</sup>
- Second Am. Compl., Charleston Area Medical Center v. Azar, ECF No. 126
- Fifth Am. Compl., *University of Colorado Health at Memorial Hospital v. Azar*, ECF No. 127
- Second Am. Compl., Grady Memorial Hospital v. Azar, ECF No. 128<sup>6</sup>
- Compl., Cabell Huntington Hosp. v. Azar, No. 19-cv-722, ECF No. 1
- Compl., Sarasota Mem'l Hosp. v. Azar, No. 19-cv-860, ECF No. 1

Together, they challenge various aspects of the fixed loss threshold rulemakings for fiscal years 2007 to 2016. Because the claims are complex and at times overlapping, they are worth spelling out in more detail.

<sup>&</sup>lt;sup>5</sup> This Complaint was never posted separately on the docket, but was accepted by the Court during the March 22, 2019 status conference. *See* Tr. of Status Conference at 5:7–8, ECF No. 130.

<sup>&</sup>lt;sup>6</sup> Plaintiffs at some points refer to ECF No. 113, which is the Amended Complaint in *Grady Memorial Hospital v. Azar. See, e.g.*, Pls.' Opp'n to Def.'s Mot. Dismiss ("Pls.' Opp'n MTD") at 6, ECF 143. It appears to have been superseded by the Second Amended Complaint in *Grady*, ECF No. 128, so the Court refers to that as the operative complaint.

First, Plaintiffs challenge (at least) the threshold rulemakings for fiscal years 2012–2016. See Pls.' Opp'n to Def.'s Mot. Dismiss at 7 ("Pls.' Opp'n MTD"), ECF 143 ("The Hospitals will show that HHS's rulemakings setting the fixed loss thresholds during FYs 2012 through 2016, which governed the Hospitals' outlier payments for their cost reporting years at issue, were performed in a manner that is contrary to the Medicare Act and the intent of Congress and [the APA].") (footnote omitted). Again, these rulemakings (FYs 2012–2016) postdate the ones at issue in Banner Health and Billings Clinic. At other points, however, Plaintiffs more broadly characterize their complaints as challenging threshold rulemakings dating back to 2006. See Mot. to Suppl. Administrative Records ("Pls.' MTS"), ECF No. 141 ("The Hospitals contend that HHS's rulemakings setting the fixed loss thresholds during FYs 2006 through 2016, which governed the Hospitals' outlier payments for their cost reporting years at issue, were performed [contrary to law]." (emphasis added)). These rulemakings overlap with the ones upheld in Banner Health and Billings Clinic, but Plaintiffs clarify that, in challenging them, they "do not intend to present arguments that are foreclosed by the law of the circuit established in [Banner *Health*], or [*Billings Clinic*]." *Id.* at 3 n.3.<sup>7</sup>

Second, Plaintiffs allege "[t]he fixed loss thresholds for FYs 2007 through 2013 were also unlawful because HHS promulgated them 'without observance of procedure required by law." Pls.' Opp'n MTD at 7 (quoting 5 U.S.C. § 706)(2)(D) (citing Am. Compl., ECF No. 113, ¶ 95–103); see also Am. Compl. ¶¶ 94–104 ("Count Two"), ECF No. 114. The claim here is that

<sup>&</sup>lt;sup>7</sup> See also Am. Compl. ¶ 93 n.7, ECF No. 114 ("In alleging that the FYs 2008-2011 FLTs are arbitrary and capricious, the Hospitals do not intend to present arguments that are foreclosed by the law of the circuit established in [Banner Health], or [Billings Clinic]."); Second Am. Compl. ¶ 93 n.7, ECF No. 115 ("In alleging that the FYs 2007 and 2008 FLTs are arbitrary and capricious, the Hospitals do not intend to present arguments that are foreclosed by the law of the circuit established in [Banner Health], or [Billings Clinic].")

the particular methods used to project cost-to-charge ratios were independent "rules" or "statements of policy" requiring their own notice and comment procedures, which they were not accorded. *See*, *e.g.*, Am. Compl. ¶ 98, ECF No. 114 ("[B]efore using the method used to project CCR decreases when setting the FLT, HHS was required to follow the notice and comment procedures of the Medicare Act and/or the Administrative Procedure Act.") (citing 42 U.S.C. § 1395hh, 5 U.S.C. § 553).

Third, Plaintiffs claim that "the Hospitals will also show that HHS's rulemakings in FYs 2012 and 2013 were arbitrary and capricious because HHS ignored six years of data, described by commenters, showing the adjustment factor for cost-to-charge ratios was a poor and unreliable model." Pls.' Opp'n MTD at 7. These are essentially an extension of claims discussed in *Billings Clinic* (which, again, only considered the FY 2008–2011 thresholds). *Billings Clinic* rejected the claim that HHS acted arbitrarily in using a particular model for forecasting cost-to-charge ratios during those three years, but noted that "a methodology used for prediction 'can look more arbitrary the longer it is applied." 901 F.3d at 314 (quoting *American Petroleum Inst. v. EPA*, 706 F.3d 474, 477 (D.C. Cir. 2013)). Because HHS switched to a new methodology starting with the FY 2014 rulemaking, this challenge applies only to FYs 2012 and 2013. *See* FY 2014 Final Rule, 78 Fed. Reg. 50,496, 50,978 (Aug. 19, 2013).

Most of the consolidated cases here were stayed pending the issuance of the D.C. Circuit's mandates in *Banner Heath* and *Billings Clinic*. *See*, *e.g.*, Min. Order (Oct. 4, 2018). After those rulings, the Plaintiffs in the as-then consolidated cases filed a notice identifying matters that they no longer intended to pursue in light of the D.C. Circuit's decisions in those cases. *See* Notice of Matters No Longer to Be Pursued Post Consolidation ("Notice"), ECF No.

107. Plaintiffs provided further clarity in a March 22, 2019 status conference. *See* Min. Entry (Mar. 22, 2019); Tr. of Status Conference, ECF No. 130.

Two motions are now ripe for disposition. The Secretary is moving to dismiss the consolidated action in part, *see* Def.'s Mem. Support Mot. Dismiss ("Def.'s MTD"), ECF 139-1, and the plaintiffs oppose, Pls.' Opp'n MTD.<sup>8</sup> Plaintiffs are moving to supplement the administrative records, Mot. Suppl. Administrative Records ("Pls.' MTS"), ECF No. 141, and the Secretary opposes, Secretary's Mem. Opp'n Pls.' Mot. Suppl. Administrative Records ("Def.'s Opp'n MTS"), ECF No. 142. After reviewing the general legal standards applicable to each, the Court will discuss each motion in turn.

#### III. LEGAL STANDARDS

#### A. Motion to Dismiss

When a defendant moves to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), a court must accept all of the complaint's factual allegations as true and must draw all reasonable inferences in the plaintiff's favor. *Momenian v. Davidson*, 878 F.3d 381, 387 (D.C. Cir. 2017) (citation omitted). If the allegations plausibly demonstrate that the plaintiff may be entitled to relief, dismissal is inappropriate. *Id.* at 390; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.") (internal quotation marks and citation omitted). In determining whether a complaint fails to state a claim, a court may consider "the facts alleged in the complaint, any documents either attached to or incorporated in the

<sup>&</sup>lt;sup>8</sup> After the motion to dismiss was fully briefed, Plaintiffs also objected to certain evidence cited in the Secretary's reply. *See* Pls.' Objs. to Evidence in Def.'s Reply in Supp. Mot. Dismiss, ECF No. 148. The Court notes the objection, but does not resolve it, as it relates to the question of issue preclusion, which the Court does not reach.

complaint and matters of which [the court] may take judicial notice." *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997) (citation omitted).

In considering a Rule 12(b)(1) motion to dismiss for a lack of subject-matter jurisdiction, a court must similarly accept all of the factual allegations in the complaint as true. *See Jerome Stevens Pharm., Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (citation omitted). The court is, however, also permitted to consider materials outside the pleadings to determine whether it has jurisdiction. *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000) (citations omitted). Additionally, "[b]ecause Rule 12(b)(1) concerns a court's ability to hear a particular claim, the court must scrutinize the plaintiff's allegations more closely when considering a motion to dismiss pursuant to Rule 12(b)(1) than it would under a motion to dismiss pursuant to Rule 12(b)(6)." *Schmidt v. U.S. Capitol Police Bd.*, 826 F. Supp. 2d 59, 65 (D.D.C. 2011) (citations omitted).

# **B.** Motion to Supplement the Records

When a court reviews an agency's action under the APA, it must "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706; see also Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971) ("[R]eview is to be based on the full administrative record that was before the Secretary at the time he made his decision."). Agencies bear the responsibility of compiling the administrative record, which must include all of the information that the agency considered "either directly or indirectly." Marcum v. Salazar, 751 F. Supp. 2d 74, 78 (D.D.C. 2010). Once produced by the agency, the record "is entitled to a strong presumption of regularity." Id. (citations omitted).

A party may seek to supplement the record produced by the agency, however, in "one of two ways." *WildEarth Guardians v. Salazar*, 670 F. Supp. 2d 1, 5 n.4 (D.D.C. 2009). First, a

party may seek to include "evidence that should have been properly a part of the administrative record but was excluded by the agency." Id. Where a plaintiff follows this first route, supplementation is appropriate if the agency "did not include materials that were part of its record, whether by design or accident." Marcum, 751 F. Supp. 2d at 78. But to overcome the presumption of regularity, "a plaintiff must put forth concrete evidence that the documents it seeks to 'add' to the record were actually before the decisionmakers." *Id.* (citation omitted). To make that showing, a plaintiff must do more than simply assert "that materials were relevant or were before an agency when it made its decision." Id. (citations omitted). "Instead, the plaintiff 'must identify reasonable, non-speculative grounds for its belief that the documents were considered by the agency and not included in the record." Id. (emphasis in original) (quoting Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng'rs, 448 F. Supp. 2d 1, 6 (D.D.C. 2006)). The plaintiff must also "identify the materials allegedly omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are 'likely' to exist as a result of other documents that are included in the administrative record." Banner Health, 945 F. Supp. 2d at 17 (citation omitted).

Alternatively, a party may seek to supplement the record with "extra-judicial evidence that was not initially before the agency but [which] the party believes should nonetheless be included in the administrative record." *WildEarth Guardians*, 670 F. Supp. 2d at 5 n.4. In these circumstances, a more stringent standard applies. To "justify[] a departure from [the] general rule" that review "is to be based on the full administrative record that was before the Secretary at the time he made his decision," a party must demonstrate one of three "unusual circumstances." *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (internal quotation marks omitted). These circumstances include: (1) when "the agency 'deliberately or negligently

excluded documents that may have been adverse to its decision," (2) when "background information [is] needed 'to determine whether the agency considered all the relevant factors," and (3) when the "agency failed to explain administrative action so as to frustrate judicial review." *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010) (quoting *Am. Wildlands*, 530 F.3d at 1002).

#### IV. ANALYSIS

#### A. Motion to Dismiss

The Secretary raises multiple arguments, each of which only applies to a certain subset of claims.

# 1. Voluntarily-Abandoned Claims

First, the Secretary argues that Plaintiffs have "voluntarily abandoned" some of their claims in the wake of decisions in *Banner Health* and *Billings Clinic*. As mentioned, on December 10, 2018, the plaintiffs in the five as-then consolidated cases indicated that they did not intend to pursue certain claims "to the extent they depend on challenges to the identified federal fiscal year ('FY') threshold rulemakings." Notice at 2. Plaintiffs then proceeded to list various claims based on the mid-year 2003 rulemaking and the 2007–2011 annual rulemakings. *Id.* at 3–7. The apparent logic was that claims depending on challenges to these rulemakings, which had been upheld in *Banner Health* and *Billings Clinic*, would be fruitless. The Notice concluded by noting that "the Hospitals intend to submit appropriate filings to effect the respective, relevant withdrawals." *Id.* at 7. At a later status conference, Plaintiffs' counsel further clarified that the Hospitals were "not challenging the 2003 rules." Tr. of Status

<sup>&</sup>lt;sup>9</sup> Cabell Huntington Hosp., No. 19-cv-722, and Sarasota Mem'l Hosp., No. 19-cv-860, had not yet been filed. Bayshore Community Hospital, No. 18-cv-2684, was consolidated with the main group of cases on February 15, 2019. See Order (Feb. 15, 2019), ECF No. 112.

Conference, 13:14 (Mar. 22, 2019). The Secretary argues, simply enough, that "the plaintiffs should be held to their statements." Def.'s MTD at 2.

Plaintiffs respond that such a dismissal would be unduly harsh. Pls.' Opp'n MTD at 12–13. They explain that they filed the Notice based on their understanding of the legal issues at the time, and their promised later filings (namely, their amended complaints) clarified more precisely the issues they intended to press even after *Banner Health* and *Billings Clinic*. *Id*. Plaintiffs concede that they are abandoning challenges to the mid-2003 rulemaking, but acknowledge that they are "continuing to pursue certain challenges, not foreclosed by circuit precedent, that could be understood to be among those the Notice said they intended to withdraw." *Id*.

Under Rule 41(b), a district court can dismiss a case for failure to prosecute a claim. *See* Fed. R. Civ. P. 41(b). "A Rule 41(b) dismissal is proper if, in view of the entire procedural history of the case, the litigant has not manifested reasonable diligence in pursuing the cause." *Bomate v. Ford Motor Co.*, 761 F.2d 713, 714 (D.C. Cir. 1985) (citations omitted). Here, the Court finds it would inappropriate to dismiss the claims depending on challenges to the FY 2007–2011 rulemakings. The Notice was just that—a notice of future intent. Plaintiffs indicated that they would make later filings to "effect" the withdrawals, which they did with relative promptness (the amended complaints were filed in February and March of 2019). Those complaints made clear that they had reassessed the viability of certain claims based on the FY 2007–2011 rulemakings and wanted to pursue those claims. The challenges to the 2003 rulemaking, however, present different considerations. At the March 22, 2019 status conference (after amended complaints in all eight cases had been finalized), Plaintiffs' counsel indicated definitively on the record that the Hosp were not challenging the 2003 rules. Tr. of Status

Conference at 13:14. Based on that representation, the Secretary prepared and filed a motion to dismiss, reasonably assuming that the 2003 rules were not at issue. Def.'s Reply in Supp. of Mot. Dismiss ("Def.'s MTD Reply") at 3–4, ECF No. 146. And the complaints do not clearly articulate a challenge to any 2003 rulemaking procedure. As a result, it is difficult for the Plaintiffs to argue that they have manifested "reasonable diligence" in claims related to the mid-2003 rules and, in any case, they do not object to dismissal. The Court will therefore grant the Secretary's motion in this respect.

# 2. Claims Barred by Prior Litigation in Banner Health and Billings Clinic

The Secretary's main argument is that many of Plaintiffs' claims in this case are barred by the prior litigation in *Banner Health* and *Billings Clinic*. This Court had previously allowed the Secretary to amend his answer in *University of Colorado Health at Memorial Hospital v*.

Azar to assert these kinds of preclusion defenses, judging that it would not be futile to assert them. See Mem. Op. Suppl. at 1.

## a. Claim Preclusion

"Under the doctrine of claim preclusion, a final judgment forecloses 'successive litigation of the very same claim, whether or not relitigation of the claim raises the same issues as the earlier suit." *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 748 (2001)). "A subsequent lawsuit is barred by [claim preclusion] if there has been prior litigation (1) involving the same claims or cause of action, (2) between the same parties or their privies, and (3) there has been a final, valid judgment on the merits, (4) by a court of competent jurisdiction." *Alaska Forest Ass'n v. Vilsack*, 883 F. Supp. 2d 136, 141 (D.D.C. 2012) (internal quotation marks and citations omitted). The parties do not contest the final three

elements, but they do disagree about whether the current case and *Banner Health* and *Billings*Clinic involve "the same claims or causes of action."

Specifically, the Secretary argues that "plaintiffs' challenge to the fixed loss threshold rule for each year is a discrete 'claim' for purposes of claim preclusion"; as a result, he maintains, Plaintiffs here that also brought claims in *Banner Health* and *Billings Clinic* cannot challenge the validity of the rules upheld in those cases (specifically, FYs 2007–2011). <sup>10</sup> Def.'s MTD at 18–19. The contention is that the underlying challenge to each fiscal year's rule defines the claim. *Id.* at 18.

Plaintiffs disagree, arguing that this approach defines "claim" at the wrong level of generality. They maintain that each separate dispute over a particular annual cost report constitutes a separate claim. Pls.' Opp'n MTD at 14. It cannot be, they say, that "a hospital must be governed by a rule that turns out to be invalid, simply because the hospital contested the rule in a previous reimbursement appeal." *Id.* at 21. As an example, Plaintiffs invite consideration of "a hypothetical Hospital X that was a plaintiff in *Billings Clinic*, where it litigated over its 2007 cost report. Hospital X's cost reporting period aligns with the calendar year, so its 2007 reimbursement depended on the FY 2007 and 2008 thresholds. Now Hospital X is appealing its 2008 cost report—which implicates the FYs 2008 and 2009 fixed-loss thresholds." *Id.* at 14. Under these circumstances, Plaintiffs say, claim preclusion does not bar a fresh attack on the already-litigated FY 2008 threshold. *Id.*; see also id. at 32.

What constitutes a "claim" or "cause of action" for purposes of claim preclusion is, unfortunately, "rather ambiguous." 18 Wright & Miller, Federal Practice and Procedure § 4407

<sup>&</sup>lt;sup>10</sup> Of course, claims in this case based on challenges to the FY 2012–2016 threshold rulemakings, which were not at issue in either *Banner Health* or *Billings Clinic*, would not be barred.

(3d ed. 2019). Our Circuit has said that the test is "whether [the claims] share the same nucleus of facts." *NRDC v. EPA*, 513 F.3d 257, 261 (D.C. Cir. 2008) (quoting *Apotex, Inc. v. FDA*, 393 F.3d 210, 217 (D.C. Cir. 2004)). Elsewhere, applying D.C. law to determine the preclusive effect of a D.C. Court of Appeals decision, the Circuit has explained: "The District of Columbia, like the majority of jurisdictions, has adopted the Second Restatement's 'transactional' approach under which a 'cause of action, for purposes of claim preclusion, comprises all rights of the plaintiff to remedies against the defendant with respect to all or any part of the transaction, or series of connected transactions, out of which the action arose." *Stanton v. D.C. Court of Appeals*, 127 F.3d 72, 78 (D.C. Cir. 1997) (citations omitted). What facts constitute a "transaction" or "series of transactions" is to be determined "pragmatically." *Id.* (quoting Restatement (Second) of Judgments § 24(1) (1982)). Of course, "[a]dmonitions to pragmatism do not decide cases, and this standard is obviously far from self-explanatory." *Id.* 

As the Court explained previously, *see* Mem. Op. Suppl. at 12–16, in *NRDC v. EPA*, the D.C. Circuit applied the "same nucleus of facts" test in analogous circumstances. In its first suit, the NRDC unsuccessfully challenged EPA's 2005 final rule on use of methyl bromide, which was based on a 2004 "Framework Rule." *Id.* at 258–59. EPA subsequently relied on the same Framework Rule to issue final rules on methyl bromide in 2006 and 2007. *Id.* at 259. Then, in a second case, NRDC challenged the 2007 rule, presenting somewhat different arguments against the 2004 Framework Rule. *Id.* at 259–61. The D.C. Circuit held that this second suit was barred

<sup>&</sup>lt;sup>11</sup> Although *Stanton* was discussing claim preclusion as a matter of D.C. law, it noted that "[t]he D.C. law of claim preclusion does not differ significantly from the federal [version]. D.C. courts articulating the doctrine commonly cite federal cases applying federal law." 127 F.3d at 78 n.4 (citations omitted); *see also U.S. Industries, Inc. v. Blake Construction Co.*, 765 F.2d 195, 204 n.20 (D.C. Cir. 1985) ("[W]e can discern no material differences in the District of Columbia's law of res judicata and the federal common law of res judicata.").

by claim preclusion because "NRDC's claim has not changed: in the first case it argued that the 2004 framework was invalid as adopted and applied to determine the 2005 exemption, and now it challenges the 2004 framework—which EPA left unchanged—as applied to determine the 2007 exemption." *Id.* at 258. The D.C. Circuit characterized the two cases as "simply offer[ing] different legal theories to support the same claim: that . . . the Framework Rule [was] unlawful. NRDC doesn't get a second bite at that same apple." *Id.* at 261 (citations omitted). The court held that the "nucleus of facts" was the same, because both claims were based on problems with the 2004 Framework Rule. *See id.* ("None of the underlying facts has changed; in defining the 2007 critical use exemption, EPA applied the same principles that it had established—unlawfully, according to NRDC—in its Framework Rule.").

Applied to this case, *NRDC v. EPA* suggests that the proper measure of Plaintiffs' claim is the challenge to each year's particular rule: that the particular threshold is unlawful. As a result, Plaintiffs' challenge to the same year's rule (based on a cost report from a different year) represents only an opportunity to present "different legal theories" in support of that claim. *See id*.

Plaintiffs, obviously, disagree with this interpretation of *NRDC v. EPA*. They argue that the relevant "nucleus of facts" is the dispute over a particular year's reimbursement, and draw analogies to other areas of law where a subsequent act of "enforcement" can animate a new claim. *See* Pls.' Opp'n MTD at 16–17, 21 (discussing, *inter alia*, *Comm'r v. Sunnen*, 333 U.S. 591 (1948) (tax enforcement), *United States v. Stone & Downer Co.*, 274 U.S. 225 (1927) (customs), and *Tesoro Alaska Petroleum Co. v. FERC*, 234 F.3d 1286 (D.C. Cir. 2000) (ratemaking), as well as *Stanton*, 127 F.3d at 78 ("[E]ach successive enforcement of a statute—such as each year a taxpayer is subjected to a tax—creates a new cause of action.") and

Burlington N. Santa Fe R.R. v. Assiniboine & Sioux Tribe, 323 F.3d 767, 770 (9th Cir. 2003) ("The core of Sunnen is the holding that tax cases by their nature raise different claims concerning different tax years, although the issues may be precisely the same."). Relying on Sunnen in particular, they point out the similarities between tax and Medicare reimbursement disputes. See Pls.' Opp'n MTD at 18–19 (noting that both are based on annual assessments and channeled through similar processes for administrative and judicial review). And continuing to echo Sunnen, they also argue on policy grounds that "[i]f a hospital loses a challenge to a rule while disputing one year's cost report, applying claim preclusion to that challenge would mean the hospital is subject to the rule forevermore, even if a court later decides the rule is invalid."

The Court is not persuaded that these examples—which are drawn from specialized areas of the law and do not purport to articulate general rules of claim preclusion—are enough to undermine the application of *NRDC v. EPA* to the circumstances here. The Circuit has explained that *Tesoro*'s ratemaking exception, for example, is justified by particular concerns specific to that context. *See Sorenson Communications, LLC v. FCC*, 897 F.3d 214, 225-227 (D.C. Cir. 2018) ("Claim preclusion has a limited application in the ratemaking context because new rates and new rate orders are almost always based on new facts and circumstances that were not present at the time of the earlier judgment[.]"). Similarly, the Circuit has cited *Stanton* for the more limited proposition that "claim preclusion [does not] bar a subsequent suit based on events and circumstances that post-date and *materially differ* from those previously at issue." *Id.* (emphasis added) (citing 127 F.3d at 79). Here, in contrast, the circumstances giving rise to the renewed challenges to the previously-challenged rulemakings are not only materially similar (claim underpayment), but also legally irrelevant: the core of Plaintiffs' dispute is with the

general rulemaking itself. Said differently, the underlying reimbursement cost reports trigger Plaintiffs' ability to seek judicial review, but have no relationship to the merits of the Plaintiffs' claims. It would likely be different if Plaintiffs were alleging something like an as-applied challenge—for example, that the Secretary had made "a unique calculational error" in applying an already-upheld rule to a new cost report. Mem. Op. Suppl. at 14. But here, in contrast, Plaintiffs are merely offering "new legal theor[ies]" against already-challenged and upheld rulemakings. They, in a meaningful sense, already had their bite at the apple. Indeed, the case resembles the "packag[ing] of successive facial attacks in successive retrospective litigations," which the Circuit has disapproved of. *Stanton*, 127 F.3d at 79. Finally, the Court is reluctant, in the absence of further authority, to extend *Sunnen* beyond its taxpaying context. This is particularly so because the practical concerns expressed in *Sunnen*—that a taxpayer could be subjected to a faulty tax decision *ad infinitum*, with competition-hindering effects—do not apply here, where a hospital is free to challenge future annual rulemakings (subject, of course, to the separate doctrine of issue preclusion).

As a result, the Court finds that Plaintiffs who have previously challenged particular year's rulemakings are barred from raising subsequent challenges to the same year's fixed loss threshold determinations. 12

#### b. Broader Preclusion

The Secretary also moves for two further, more aggressive applications of preclusion doctrines.

<sup>&</sup>lt;sup>12</sup> Because this holding resolves the Secretary's preclusion claims (with the exception of two broader arguments discussed below), the Court does not discuss whether the separate, related claim of issue preclusion would apply in these circumstances.

First, the Secretary suggests that "any hospital that was a plaintiff in *Banner Health* or *Billings Clinic* is barred from challenging any fixed loss threshold determination that was challenged and upheld in the earlier case, regardless of whether that hospital's participation in the earlier case was based on payment claims for the same federal fiscal year." Def.'s MTD at 16. Thus, under the Secretary's view, even if a party in *Billings Clinic* did not challenge the 2008 threshold in that case, it would be precluded from challenging it here because a different plaintiff did so there. Def.'s MTD at 20. For this proposition, the Secretary primarily relies on the Restatement (Second) of Judgments, *see id.*, which states that a party is generally "bound [b]y... the rules of res judicata with respect to determinations made while he was a party." 1 Restatement (Second) of Judgments § 34(2) (1982). But that simply reframes the question: what do the rules of res judicata require?

The situation is complicated by the jurisdictional requirements of 42 U.S.C. § 139500(f)(1). Before presenting a claim to a federal court, a hospital has to submit payment claims involving that fiscal year' rules. *Id.* Under the Secretary's theory, this limitation is irrelevant: even if a hospital is jurisdictionally unable to challenge a particular year's rule, it would nevertheless be bound by another hospital's challenge of that rule in the same case. In effect, then, a hospital could be precluded from contesting a threshold rule even though it previously had no power to do so. The Secretary has not cited any cases that apply preclusion in such a context, and the Court is reluctant to apply the doctrine in such circumstances. It is reasonably well settled that claim preclusion does not bar a claim which could not have been brought in the earlier action. *See* 18 Wright & Miller, Federal Practice and Procedure § 4412 (3d ed. 2019) ("Limitations on the jurisdiction or the nature of the proceedings brought in a first court may justify relaxation of the general requirement that all parts of a single claim or cause of

action be advanced. It is clear enough that a litigant should not be penalized for failing to seek unified disposition of matters that could not have been combined in a single proceeding.").

Second, the Secretary now "asserts preclusion defenses not only against hospitals that were plaintiffs in *Banner Health* or *Billings Clinic*, but also against hospitals under common control with those hospitals"—even if they were not parties in either suit. Def.'s MTD at 17. To support this theory, the Secretary relies on references in the complaints indicating that certain hospitals are subject to the "common ownership and control" of certain hospital groups that were plaintiffs in those prior cases. *See, e.g.*, Am. Compl. at ¶ 6.h, ECF No. 114 ("Plaintiff Banner Casa Grande Medical Center, is a non-profit organization . . . under the common ownership and control of Banner Health."). Because Banner Health was, obviously enough, a plaintiff in *Banner Health*, Banner Casa Grande (the Secretary maintains) should not be able to challenge the 2007 threshold. *See* Def.'s MTD at 24.

The Court is unwilling to reach such a conclusion on the basis of the pleadings alone. A boilerplate recital that a new claimant is currently subject to the "common ownership and control" of a previous claimant is insufficient basis to invoke issue preclusion against the new claimant. As the Secretary himself recognizes, our Circuit has "cautioned that common ownership 'may not always show sufficient control." *Id.* at 24 (quoting *Gulf Power Co. v.FCC*, 669 F.3d 320, 324 (D.C. Cir. 2012)). *Gulf Power* goes on to suggest that the inquiry is fact-specific and context-dependent. *See* 669 F.3d at 324 (citing evidence that the two companies under common control also operated as part of a single integrated electric system). Here, there is not comparable evidence that the parents and subsidiary were so integrated at the relevant time periods.

The Secretary suggests that "if the Court were to find that the plaintiffs' allegations are not enough to establish common control, then it should authorize discovery into who has controlled the litigation on behalf of the plaintiffs, or it should conduct its own inquiry." Def.'s MTD Reply at 16. But it is not clear to the Court how this would be possible or desirable. It would not, for instance, promote "the avoidance of unnecessary judicial waste," because the challenges to each year's threshold would continue, regardless. *Arizona v. California*, 530 U.S. 392, 412 (2000) (quoting *United States v. Sioux Nation of Indians*, 448 U.S. 371, 432 (1980) (Rehnquist, J., dissenting)).

For these reasons, the Court will only grant the Secretary's motion to dismiss as to entities that actually challenged the relevant year's rulemakings in previous cases.

3. Claims that Certain Methods Amount to a "Rule" Requiring Separate Notice and Comment

Plaintiffs' operative complaints in this case also specifically challenge the Secretary's method for computing projected cost-to-charge ratios ("CCRs") in the FY 2007–2013 rulemakings. *See, e.g.*, Am. Compl. ¶ 94–104 ("Count Two"), ECF No. 114. Specifically, the claim is that the CCR calculation methods constitute a separate "rule, requirement or other statement of policy," 42 U.S.C. § 1395hh(a), or "rule," 5 U.S.C. § 551(3), requiring independent notice and comment procedures. *See, e.g.*, Am. Compl. ¶ 102, ECF No. 114 ("HHS's failures to follow notice and comment procedures with respect to the agency's method to project CCR decreases violated the Medicare Act and the Administrative Procedure Act."). The Secretary argues that there is no jurisdiction to hear this kind of claim, that notice and comment procedures are not required for these particular methods, and that certain Plaintiffs who were plaintiffs in *Banner Health* should be judicially estopped from advancing such challenges. Def.'s MTD

Reply at 16–22. The Court agrees with the Secretary's first argument and therefore declines to address the second and third.

As explained above, providers have the right to obtain expedited judicial review ("EJR") of "any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the [PRRB] determines . . . that it is without authority to decide the question[.]" 42 U.S.C. § 139500(a); see also 42 C.F.R. § 405.1842(g)(2) ("If the Board grants EJR, the provider may file a complaint in a Federal district court in order to obtain EJR of the legal question."). This requirement—that issues for judicial review be articulated as a particular question of law, which the PRRB approves—helps insure that the PRRB "has a role in shaping the controversy that is subject to judicial review." Bethesda Hospital Ass'n v. Bowen, 485 U.S. 399, 407 (1988). It is also consistent with ordinary exhaustion principles. See Am. Chiropractic Ass'n, Inc. v. Leavitt, 431 F.3d 812, 816 (D.C. Cir. 2005) (stating that, under the Medicare Act, "[j]udicial review may be had only after the claim has been presented to the Secretary and administrative remedies have been exhausted").

It follows that a district court lacks jurisdiction over claims outside the scope of PRRB's order authorizing a provider's request for expedited review. This jurisdictional requirement was applied in *District Hospital Partners, L.P. v. Sebelius*, 794 F. Supp. 2d 162 (D.D.C.), *mot. for reconsideration denied*, No. 11-cv-0116, 2011 WL 13248160 (D.D.C. Sept. 1, 2011). There, the plaintiffs' complaint alleged that the Secretary acted arbitrarily and capriciously by failing to

<sup>&</sup>lt;sup>13</sup> Judicial review can also be obtained through two other pathways: (1) if an EJR request is submitted to the board and the PRRB fails to render a determination within 30 days, or (2) if the PRRB determines "on its own motion" that there is a legal question that it is without authority to decide. *See* 42 U.S.C. § 1395*oo*(f)(1). In either case, the legal question is still limited to a particular universe of claims: what the provider has asked the Board to review, or what the Board itself has decided to determine.

make midyear adjustments to the outlier threshold. *Id.* at 168. The court found that this claim was "not a part of the 'action' plaintiffs ha[d] brought under the Medicare Act" because it had not been presented to the PRRB, unlike the other claims in the complaint. *Id.* As a result, the court lacked subject matter jurisdiction. *See id.* at 168–69.

Here, Plaintiffs' requests for EJR are broadly articulated, but they are nonetheless focused on a particular set of regulations. For example, an illustrative request frames the "[i]ssue [u]nder [a]ppeal" as follows:

Whether the specific regulations governing Outlier Case Payments as set forth in the two regulatory sources—the Outlier Payment Regulations and the fixed loss threshold ("FLT") Regulations (collectively, the "Medicare Outlier Regulations")—. . . are contrary to the Outlier Statute and/or are otherwise substantively or procedurally invalid?

Riverview Medical Center v. Azar, Second Am. Compl. Ex. A at 1, ECF No. 115 (footnotes omitted). Citing the providers' own definition of "outlier payment regulations," the PRRB understood this request to mean that "the Providers are challenging the validity of the outlier regulations, 42 C.F.R. §§ 412.80–412.86." Second Am. Compl. Ex. A at 4. The "fixed loss threshold" regulations appear to refer to the annual rulemaking that sets the threshold for the applicable fiscal year. Noticeably absent is any suggestion that the providers were challenging the cost-to-charge methods as a further, separate category of rule or policy. Compare Banner Health v. Burwell, 126 F. Supp. 3d 28, 67 (D.D.C. 2015) (finding jurisdiction in part because the "the legal question presented to the PRRB . . . referr[ed] to each of the revisions to the outlier payment regulations and each of the fixed loss threshold regulations at issue for the payment years in question—that is, each of the regulations challenged in th[e] action") , rev'd in part on other grounds, 867 F.3d 1323 (D.C. Cir. 2017).

The Plaintiffs here argue that, nevertheless, their requests for EJR were broad enough to encompass a challenge to the cost-to-charge ratio methodologies as a standalone action. *See* Pl.'s Opp'n MTD at 10 (arguing that the EJRs in this case "encompass[] a range of issues, [including] anything establishing whether a given fixed loss threshold is 'substantively and/or procedurally invalid.'"). But they do not point to any language indicating a specific challenge to cost-to-charge methods as a particular rule, requirement, or statement of policy. Instead, they suggest that it is permissible to "disput[e] a policy *embedded* in the [the FY 2007-2013 outlier] thresholds that the EJRs address." *Id.* at 11 (emphasis added). Or, to use a different formulation, "[t]he EJR-approved question of whether the thresholds were 'procedurally valid' easily encompasses the Hospitals' contention that notice and comment on the thresholds was deficient with respect to this policy." *Id.* at 11–12. But claims that (1) a particular regulation is invalid and (2) a particular methodology mentioned by that regulation is a policy or regulation separately subject to notice and comment are two different things. The latter question was not presented to or approved by the PRRB.

This does not mean, however, that the cost-to-charge methodologies are immune from scrutiny. As explained above, projected cost-to-charge ratios are a crucial element in the overall calculation of a given year's fixed lost threshold. *See also* Pls.' Opp'n MTD at 37 ("[T]he forecasting of cost-to-charge ratios is half the work."). And Plaintiffs are on firm ground in arguing that "[n]otice-and-comment on a proposed threshold means notice and comment on the methods and facts supporting the choice of threshold." *Id.* at 35. Indeed, "[i]ntegral" to the APA "is the agency's duty 'to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. . . . An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time

to allow for meaningful commentary." *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (quoting *Connecticut Light & Power Co. v. NRC*, 673 F.2d 525, 530–31 (D.C. Cir. 1982)). Thus, for example, at least when "the output of [a] model was central" to an agency's decision to adopt a rule, "[t]he failure to provide an opportunity for comment on the model's methodology . . . constitute[d] a violation of the APA's notice-and-comment requirements." *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007).

Importantly, though, the Secretary does not appear to take issue with this line of argumentation. See Def.'s MTD Reply at 18 ("This . . . type of argument—disputing the adequacy of the notice and comment provided for a fixed loss threshold, but not positing the existence of any 'rule' other than the dollar amount of the fixed loss threshold—is not within the scope of the Secretary's present motion to dismiss."). As a result, Plaintiffs remain free to argue, if it is otherwise appropriate and within the scope of their complaints to do so, that the challenged fixed loss thresholds regulations are deficient because the cost-to-charge methodology in particular was not adequately made available or explained.

# 4. Claims that Are Untimely

Finally, the Secretary argues that certain claims introduced in some of Plaintiffs' amended complaints (specifically, *Charleston Area Medical Center* and *West Virginia University Hospital*) should be dismissed because they were added by amendment under Rule 15(a), without this Court's approval. Def.'s MTD at 37. The Secretary suggests that, because these particular claims had been approved for expedited judicial review *after* the filing of the original complaints, they should have been added by supplementation under Rule 15(d) (which requires court approval). *Id.* (citing Fed. R. Civ. P. 15(d)). As a result, according to the Secretary, these

claims were filed "without legal effect" and are now barred, because they were not actually submitted within 60-day period for filing a district court action under § 139500(f)(1). *Id.* at 38.

The difference between supplementation and amendment is that an amendment "typically rest[s] on matters in place *prior to* the filing of the original pleading," while a supplement "sets forth 'transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." *United States v. Hicks*, 283 F.3d 380, 385 (D.C. Cir. 2002) (quoting Fed. R. Civ. P. 15(d) (amended 2007)); *see also Hall v. C.I.A.*, 437 F.3d 94, 100 (D.C. Cir. 2006) (finding that a filing, insofar as it added a claim based on a set of FOIA requests made after the filing of the original complaint, was "plainly a supplemental pleading" because it concerned post-complaint events). As a result, the filings of these claims here seem to have required leave of this Court.

In response, Plaintiffs cite a few cases that have allowed the introduction of new facts by amendment. See, e.g., Scahill v. District of Columbia, 909 F.3d 1177, 1184 (D.C. Cir. 2018) (holding "that a plaintiff may cure a standing defect under Article III through an amended pleading alleging facts that arose after filing the original complaint"); Northstar Fin. Advisors Inc. v. Schwab Investments, 779 F.3d 1036, 1044, 1048 (9th Cir. 2015), as amended on denial of reh'g and reh'g en banc (Apr. 28, 2015) (allowing plaintiff to file a supplemental pleading alleging post-complaint facts that established standing). But neither case suggests that a plaintiff can add entirely new claims without court approval—and in any case, as Plaintiffs' acknowledge, "[i]n Scahill and Northstar the amended complaints were by leave of court," which made the distinction between supplementation and amendment less meaningful. Pls.' Opp'n MTD at 44.

The only case cited by plaintiffs addressing the actual addition of claims is Feldman v. Law Enforcement Associates Corp., 752 F.3d 339 (4th Cir. 2014). There, the court mentioned that at some point, "[plaintiffs] amended the complaint, adding their respective . . . claims that had since become ripe." Id. at 343 (footnote omitted). But again, Feldman appears to have assumed that the amendments were made with permission of the district court, which made the mislabeling less significant. See id. at 347 (noting that "although [plaintiff] presented his [post-complaint] claim in the form of an amended pleading, he clearly sought and was allowed by the court—with [defendants'] consent—to add this claim"). Plaintiffs suggest this is a misinterpretation of the actual record. See Pls.' Opp'n MTD 44 n.18 (arguing that "the district court docket [in Feldman] demonstrates that the court simply extended the deadline for an amendment by right, rather than giving leave for the amendment itself"). But even granting this, it is difficult to read Feldman as meaningful authority for the affirmative position Plaintiffs are trying to establish.

Given that the claims were not properly added to the complaints, what is the result? Plaintiffs argue that, unlike some other cases where a filing was refused or disallowed, the Court here "accepted the filings as submitted" and the Secretary actually answered one of the amended complaints and "largely admitted the fresh allegations." Pls.' Opp'n at 44–45 (citing *Charleston Area Med. Ctr. v. Burwell*, Answer to the Am. Comp., No. 15-3031, ECF No. 12, at ¶ 6(x)–6(ii) (Feb. 22, 2016)). Relatedly, Plaintiffs argue that the Secretary waived any statute of limitations offense by not raising it in the first pleading or motion responding to the complaint. *Id.* at 45.

But the Clerk's "acceptance" of a filing is not equivalent to leave of Court, as the Secretary notes. Def.'s MTD Reply at 25. And the waiver argument falls short as a technical matter, because the Defendant's present motion to dismiss is the initial response to the relevant

claims. *Pinson v. U.S. Dep't of Justice*, 69 F. Supp. 3d 108, 113 (D.D.C. 2014) ("It is well established that once an amended complaint is filed, it supersedes the original complaint, thereby making the first complaint a 'dead letter' devoid of any legal effect and making the new complaint the operative document moving forward.") (citations omitted). The Secretary deserves a chance to assert new defenses, even if they were not offered before.

Despite these considerations, the Court is not inclined to dismiss these claims on these highly technical grounds. *See* 6A Wright & Miller, Federal Practice and Procedure § 1504 (3d ed. 2019) ("Parties and courts occasionally confuse supplemental pleadings with amended pleadings and mislabeling is common. . . . Indeed, the distinction between amended and supplemental pleadings is sometimes ignored completely."). Even though the difference does become salient when, as here, "a supplemental pleading is interposed by a party without leave of court in the mistaken belief it is a Rule 15(a) amendment that may be made as a matter of course," it is generally "doubtful" that any prejudice "accrue[s] to the opposing party" in such a situation. *Id.* That is "because the time during which amendments as of right may be filed is relatively short and comes early in the action," and "[a]n opposing party who does feel aggrieved may move to strike the mislabeled pleading, which would have the practical effect of bringing the question of its propriety before the court as if it had been raised on a motion under Rule 15(d)." *Id.* 

Here, instead of filing a motion to strike and bringing the labelling issue before the Court, as Wright and Miller suggest, the Secretary waited many months—until after the end of the 60-day period for filing claims in district court—before asserting this argument for the first time.

Thus, while the Secretary's argument was not technically waived, it does have a distinct "gotcha" quality. Moreover, there is no reason to think the Court would not have granted the

motion to supplement, given the interests in judicial economy. And finally, the Secretary has not pointed to any undue prejudice that has resulted from the mislabeling. For these reasons, the Court exercises its discretion to treat the mislabeled amended complaint as a supplemental complaint, *nunc pro tunc. See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1337 n.5 (Fed. Cir. 2008) (suggesting that "[u]nder Rule 15(d) the district court had discretion to decide whether or not to allow [a] supplemental complaint" that had been improperly filed as an amended complaint as a matter of right).

# B. Motion to Supplement the Records

Separately, Plaintiffs seek to add a variety of additional materials to the administrative record. Their requests encompass both (1) materials that they claim "clearly were before the agency in its decisionmaking" during the FY 2007 and FY 2014–16 rulemakings and (2) "additional materials that merit extra-record consideration." Pls.' MTS at 1. Each request is discussed in turn below.

But first, one note: not all of these requests present issues of first impression. In the lead case here (*University of Colorado Health*), this Court has already ruled on disputes regarding the scope of the administrative record. *See* Suppl. Rec. Op.; Clarification Op. And similar issues were litigated in related cases. *See* Suppl. Rec. Op. at 1 (noting that the issues raised by the plaintiffs' motion contesting the records were "well-traveled ground"); Mem. Op. at 1, *Charleston Area Med. Ctr. v. Burwell*, No. 15-cv-2031 ("*Charleston Area Med. Ctr.* Suppl. Rec. Op."), ECF No. 27 (finding that the plaintiffs' motion contesting the administrative records presented "well-worn legal disputes" that "have been rigorously and persuasively examined in numerous other opinions"). The Court will refer to related rulings as necessary, keeping in mind Plaintiffs' well-taken suggestion that the Court "consider, on their own terms, the arguments that

the parties have presented here." Pls.' Reply Supp. Mot. Suppl. ("Pls.' MTS Reply") at 2, ECF No. 147.

Materials Allegedly Before the Agency during the FY 2007 and FY 2014–16 Rulemakings
 a. FY 2007 Rulemaking

Plaintiffs first seek "a specific document for which HHS has provided only an attachment labeled 'Attachment A' and the rest of the actuarial analysis on which HHS relied to derive its pivotal CCR adjustment factor method in the FY 2007 rulemaking." Pls.' MTS at 12. As explained above, projected cost-to-charge ratios (CCRs) form an important part of the outlier threshold calculation. Beginning in 2007, HHS began using a new "adjustment factor" to help project hospitals' historical CCRs by "account[ing] for cost and charge inflation." FY 2007 Final Rule, 71 Fed. Reg. at 48,150. Broadly speaking, that methodology involves comparing two different measures of cost inflation—the average increase in hospitals' costs per discharge and a "market basket increase" determined by Global Insight, Inc., a government consultant—over a three year period and then dividing that three year average measure of cost inflation by the one year average change in charges. *Id.* HHS explained that it "worked with our actuarial office in deriving the methodology . . . to develop the CCR adjustment factor." *Id.* 

Plaintiffs' core contention is that, beyond the bare description of the methodology offered in the rulemaking notice itself, HHS "offered scant explanation for choosing its method." Pls.' MTS at 14. To substantiate this charge, they point to a document in the FY 2007 rulemaking record (a one-page printout captioned "Attachment A"), which they contend indicates the existence of additional analysis. The relevant excerpt from Attachment A is reproduced here:

Attachment A  Applying "historic" ratio of cost increase to MB increase to projected 2005 MB						
FY	Oper MB Increase	Operating Cost per Discharge Increase	Cost/MB	Mean Ratio to 2004	Num Years in Mean	2005 "projected" Cost Increase
1998	1.0260	1.0146	0.9889	1.0149	7	1.0575
1999	1.0250	1.0282	1.0031	1.0192	6	1.0620
2000	1.0320	1.0296	0.9977	1.0224	5	1.0654
2001	1.0410	1.0581	1.0164	1.0286	4	1.0718
2002	1.0370	1.0836	1.0449	1.0327	3	1.0761
2003	1.0400	1.0698	1.0287	1.0266	2	1.0697
2004	1.0390	1.0645	1.0245	1.0245	1	1.0676
2005	1.0420					
2006	1.0420					
2007	1.0340					

Proposed Charge Inflation Factor: 7.57%
Final Charge Inflation Factor: %

1.000358
0.997299
1.035
1.0792
0.997114
0.959044

Pls.' MTS Ex. A, ECF No. 141-1 (AR 14403). As Plaintiffs argue, the "Attachment" label implies the existence of a relevant main document that was not supplied as part of the administrative record. Pls.' MTS at 16. Additionally, Plaintiffs say, the content of the table is itself suggestive. The last column ("2005 'Projected' Cost Increase") shows different estimates for projected cost increases, depending, in part, on how many years of historical cost inflation are included in the calculation (ranging from one to seven, as indicated in the "Num Years in Mean" column). Pls.' MTS at 15. As mentioned, the Secretary opted to use an average based on three years' worth of data, which, in the table, corresponds to the highest projected cost increase (1.0761). This—not coincidentally, Plaintiffs suggest—is the option that is "least favorable to hospitals." Pls.' MTS at 15. Overall, considering Attachment A alongside HHS's own admission that it "worked with [its] actuarial office in deriving the methodology," 71 Fed. Reg. at 48,150, Plaintiffs suggest that HHS must have conducted but has not disclosed "some larger analysis." Pls.' MTS at 17.

In response, the Secretary first contends that this Court rejected a similar request in its earlier opinion, Suppl. Rec. Op. at 27–28, as did two other district courts in related opinions, *Banner Health*, 945 F. Supp. at 27–30, 36–38; *Charleston Area Med. Ctr.* Suppl. Rec. Op. at 14–15. But to the Court's knowledge, no decision has discussed "Attachment A" as evidence of

additional documentation or analysis. *See also* Def.'s Opp'n MTS at 10 (conceding that "[t]he Court's ruling in *Banner Health* did not specifically discuss the significance of the 'Attachment A' label'). As to the import of the label, the Secretary argues that it "at most suggests that the document was at one time attached to some other document," not that "that the other document contained material that should have been included in the fiscal year 2007 record." *Id.* at 10.

The Court finds that Plaintiffs have offered enough here to overcome the presumption of regularity accorded to the Secretary. In plain terms, a free-floating attachment strongly indicates the existence of a primary document. And, though it is not guaranteed, it is reasonable to conclude that the primary document contained relevant material considered by the agency in its deliberations. As a result, the disclosure of "Attachment A" offers a "reasonable, non-speculative ground[]" to believe that at least one other document was "considered by the agency and not included in the record." *Pac. Shores Subdivision Cal. Water Dist.*, 448 F. Supp. 2d at 6. And finally, insofar as it seeks just the "missing" main document, Plaintiffs' request "identif[ies] the materials allegedly omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are 'likely' to exist" *Banner Health*, 945 F. Supp. 2d at 17. As to other "rest of the actuarial analysis" sought by the Plaintiffs, the Court adheres to its prior conclusion that they have not "describe[d] with specificity" any other information or analysis supposedly considered or relied up by HHS. *See* Suppl. Rec. Op. at 28.

For these reasons, the Court will direct the Secretary to disclose to Plaintiffs the full document with which "Attachment A" is associated. Once such document is disclosed, Plaintiffs may, if appropriate, renew their argument that this document should be part of the administrative record.

## b. FY 2014–2016 Rulemakings

Trivial impact of reconciliation. Beginning in 2003, HHS implemented a procedure under which excess payments could be recouped through a "reconciliation" process. See 68 Fed. Reg. 34,494. Hospitals have maintained that the annual threshold rulemakings should take into account funds recovered through this process, but HHS has declined to do so. See, e.g., FY 2014 Final Rule, 78 Fed. Reg. 50,980 ("[W]e continue to believe that [due to the 2003 rules] CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement as demonstrated by the total outlier payments provided by the commenter."). Hospitals seek here some basis—calculations or other analysis—for the Secretary's conclusion that the impact of reconciliation would be trivial. See Pls.' MTS at 18.

Plaintiffs note that the Court declined a similar request in its earlier opinion as to the FY 2007–2008 and 2011–2012 rulemakings. *See* Pls.' MTS at 18 (citing Suppl. Rec. Op. at 37). But now, they point to additional data offered by commenters during the FY 2014–2016 rulemakings, including evidence that \$12 to \$14 million in outlier payments were reconciled annually and a statement from the HHS Office of the Inspector General suggesting that potentially \$664 million of outlier payments were subject to reconciliation. *See id.* at 18–19. As they explain, HHS repeatedly stuck to its guns in response to these new comments, maintaining that "[w]e do not believe that this relatively small annual amount would have an impact on the outlier threshold because total outlier payments are approximately \$4.3 billion." FY 2014 Final Rule, 78 Fed. Reg. at 50,980; *see also* FY 2015 Final Rule, 79 Fed. Reg. at 50,377; FY 2016 Final Rule, 80 Fed. Reg. at 49,781. Plaintiffs infer from this that HHS had—finally—conducted some analysis to verify the impact of reconciliation. *See* Pls.' MTS at 19.

The Court does not see how HHS's statements fairly imply the existence of additional analysis, much less specific documents containing that analysis. As the Secretary points out, HHS's determination could rest on the straightforward observation that reconciliation amounts of \$12–14 million annually "would represent only a small fraction of the \$4.3 billion per year total of outlier payments." Def.'s Opp'n MTS at 14. If that conclusion is unreasonable, Plaintiffs can address it on the merits. See Suppl. Rec. Op. at 37 ("To the extent that Plaintiffs argue that HHS's stated rational[e] does not adequately support its chosen path, that claim is better left for this Court's merits consideration of whether the challenged rules are arbitrary and capricious."); Lee Mem'l Hosp. (Billings Clinic), 109 F. Supp. 3d at 57 ("Whether HHS's decision may be deemed unreasonable . . . is a question to be addressed upon the Court's review of the merits."); Charleston Area Med. Ctr. Suppl. Rec. Op. at 16–17 ("[T]he Hospitals' claim that the Secretary made a bare, unsupported assumption in its fixed-loss-threshold regulations is better left to the merits.").

Estimates of Total Outlier Payments Made During Prior Fiscal Years. In its FY 2014–2016 rulemakings, HHS reported that it estimated the total actual outlier payments for the preceding two fiscal years and compared those estimates to its original projections for each year. For example, in its FY 2014 rulemaking, HHS estimated the total outlier payments for FYs 2012 and 2013 and noted that both were lower than the projections. See, e.g., FY 2014 Final Rule, 78 Fed. Reg. at 50,983 ("We currently estimate that . . actual outlier payments for FY 2013 will be approximately 4.77 percent of actual total MS-DRG payments, approximately 0.33 percentage point lower than the 5.1 percent we projected when setting the outlier policies for FY 2013."). Plaintiffs contend that HHS did not adequately explain how it computed these estimates of outlier payments. Pls.' MTS at 20. As they point out, the rulemakings themselves only identify

data sources and refer generally to "simulations." *See, e.g.*, FY 2014 Final Rule, 78 Fed. Reg. at 50,983 ("This estimate of 4.77 percent is based on simulations using the FY 2012 MedPAR file (discharge data for FY 2012 claims)."). According to Plaintiffs, "[b]y the time of the FY 2014 rulemaking, this matter of estimating the payments made had become quite contentious, because commenters were unable to reproduce HHS's conclusion using any available data and sought clarification regarding HHS's method." Pls.' MTS at 21.

Plaintiffs have previously raised similar concerns regarding prior rulemakings. In an earlier opinion in the *University of Colorado* case, this Court agreed that, as to the "estimated outlier payments for previous fiscal years," "the administrative record fails to fully delineate the formula used to conduct those acknowledged simulations." Suppl. Rec. Op. at 27. However, upon the Secretary's motion for reconsideration (which included a statement from a declarant further explaining HHS's methodology), the Court was satisfied that HHS "did not fail to include in the administrative record all 'materials that were part of its record, whether by design or accident.'" *See* Clarification Op. at 11 (quoting *Marcum*, 751 F. Supp. 2d at 78).

To distinguish their earlier requests, Plaintiffs clarify that they are not seeking any new "formulas" or "explanations." *See* Pls.' MTS at 22 ("To be clear, the Hospitals are not asking that HHS create anything, or that it supply an explanation for the simulations if the record did not contain one."). Instead, "the Hospitals seek only the calculations themselves that produced HHS's estimates of the preceding two years' actual outlier payments for FYs 2014, 2015, and 2016." *Id.* The Hospitals suggest that, based on the declarant's earlier statement, "those calculations necessarily were actually before HHS at the time of each rulemaking." *Id.* 

The Secretary does not deny that these calculations exist. Instead, the Secretary suggests that the estimates were provided for informational purposes only: that is, "to facilitate assessment

of the Secretary's past actions, not as justification for the next year's fixed loss threshold rule." Pls.' MTS Opp'n at 16. And "[i]n any event," he continues, "the Secretary adequately explained his calculation methods." *Id.* at 17.

The Court is not persuaded by the Secretary's responses. The question is not whether the Secretary specifically "relied" on the calculated estimates as justifications for the relevant rule; rather, it is simply whether the calculations were "before the Secretary at the time he made his decision." Citizens to Preserve Overton Park, 401 U.S. at 420; see also Ad Hoc Metals Coal. v. Whitman, 227 F. Supp. 2d 134, 139 (D.D.C. 2002) (noting that a particular document "will not be excluded simply because defendants claim that they did not 'rely' upon it"). Similarly, the adequacy of the Secretary's explanation of its calculation method is not directly at issue; Plaintiffs simply seek "HHS' actual calculations of outlier payments in past years—in whatever form they were originally prepared." Pls.' MTS at 22. Assuming they exist and were part of the record considered by the Secretary, these materials are appropriately part of the administrative record.

Cost-to-charge Adjustment Factors. As mentioned above, in its FY 2014 rulemaking, HHS began using a new method to calculate projected cost-to-charge ratios. 78 Fed. Reg. at 50,978. The new method involved multiplying hospitals' recent cost-to-charge ratios by an adjustment factor computed by measuring recent changes in the national average hospital cost-to-charge ratio. 78 Fed. Reg. at 50,978; see also Def.'s Opp'n MTS at 18. Plaintiffs seek "the calculations HHS performed and used to compute its adjustment factors [that] were before HHS during the [FY 2014–2016] rulemakings." Pls.' MTS at 23.

The Secretary maintains that the Federal Register already provides sufficient explanation of how the Secretary computed the adjustment factors. *See* Def.'s Opp'n MTS at 18 (citing 78

Fed. Reg. at 50,982; 79 Fed. Reg. at 50,379–80; 80 Fed. Reg. at 49,784). And, relying on *Banner Health*, the Secretary maintains that "a proper administrative record generally does not need to include all the materials and information that the plaintiffs or the court would need to fully replicate the agency's calculations." *Id.* (citing *Banner Health*, 945 F. Supp. 2d at 28–32). Rather, the Secretary maintains that "a record is generally adequate for judicial review if it 'delineates the path by which [the agency] reached its decision." *Id.* (quoting *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 338 (D.C. Cir. 1989)).

Yet here again, the Secretary's objections appear misplaced. Plaintiffs here are not seeking all the data or materials necessary to "fully replicate" a set of calculations, nor are they suggesting that the methodology is insufficiently explained; rather, they are (1) pointing to evidence suggesting that certain calculations were made and (2) asking that those specific calculations be disclosed. In this fashion, Plaintiffs have "identiffied] alleged omissions with sufficient specificity." Banner Health, 945 F. Supp. 2d at 28. And the Court does not read Occidental Petroleum as the Secretary seems to—namely, as allowing an agency to omit records that were before it as long as it has otherwise explained its decision. The language from that opinion is, in fact, quite modest, and does not excuse the omission of material that was actually before the agency. See Occidental Petroleum Corp., 873 F.2d at 338 ("[I]n order to allow for meaningful judicial review, the agency must produce an administrative record that delineates the path by which it reached its decision."). That "path by which [HHS] reached its decision"—no more, no less—is what Plaintiffs seek here. As a result, again assuming these calculations exist and were part of the record considered by the Secretary, the administrative record must be supplemented to include these materials.

Updated Medicare Claims Processing Manual. Plaintiffs also seek the inclusion of the "then-applicable versions of Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual," which concerns the outlier reconciliation process. Pls.' MTS at 24. Plaintiffs point out that Chapter 3 of the Manual was repeatedly cited in the rulemaking records for FYs 2011–2013. Pls.' MTS Reply at 12. The Secretary responds that he "cited the Manual purely for informational purposes," not "as support for his decisions or to identify information or factors that he considered or relied on." Def.'s Opp'n MTS at 20. The Secretary also acknowledges that he had previously agreed to include material from the Manual in the administrative records in some prior cases, but, in doing so, "did not concede that the documents were properly part of the administrative records." Def.'s MTS at 21.

As the Secretary emphasizes, "mere mention of [i]tems . . . in the Federal Register" does not show the agency considered them. *Banner Health*, 945 F. Supp. 2d at 37; *see also WildEarth Guardians v. Salazar*, 670 F. Supp. 2d 1, 6 (D.D.C. 2009) ("Although citation to a document may, as Plaintiff urges, indicate consideration of the contents of the document, the fact that a document is merely mentioned does not lead to the same conclusion."). But the references here go beyond mere citations or mentions. For example, the Federal Register describes and responds to a comment mentioning Chapter 3, Section 20.1.2 of the Manual. *See* 80 Fed. Reg. at 49,781. And it directs readers to consult an updated version of the Manual. *Id.* at 49,785. The natural inference is that the Manual was before the Secretary and considered as part of the rulemaking process. Particularly in light of the principle that a document "will not be excluded simply because defendants claim that they did not 'rely' upon it," *Ad Hoc Metals Coal.*, 227 F. Supp. 2d at 139, the Court finds that the requested section of the Manual should be included in the record.

# 2. Evidence Concededly Not Before the Agency

# a. Evidence of Reconciliation Recoveries

As noted above, one particular argument pressed by Plaintiffs is that the Secretary, in setting the fixed loss thresholds, did not sufficiently take account of funds that would be recouped through the so-called reconciliation process, including through litigation. *See* Pls.' MTS at 25. To support this argument, Plaintiffs seek the inclusion of a variety of specific documents that—they claim—indicate that the amounts recovered would likely be substantial and, as a result, undermine the Secretary's decision to discount the impact of reconciliation. *Id.* at 26–29. These include three subcategories of documents: (1) certain reports from HHS's Office of the Inspector General ("OIG"), <sup>14</sup> (2) certain annual reports from the Health Care Fraud and Abuse Control Program ("HCFAC"), <sup>15</sup> and (3) "litigation documents and court decisions" in outlier fraud cases described in those HCFAC reports. *Id.* Plaintiffs do not suggest that that these documents were actually considered by the Secretary; rather, the claim is that they qualify as adverse information that was inappropriately excluded or ignored by the agency. *Id.* at 25–26.

<sup>&</sup>lt;sup>14</sup> The Secretary points out that one of the requested OIG reports, No. A-07-10-02764, is already in the rulemaking records for 2015 and 2016, as it was attached to comments. *See* Def.'s MTS Opp'n at 23. Plaintiffs have not challenged this assertion. The Court will therefore deny as moot the request to add OIG Report No. A-07-10-02764 to the administrative records of the 2015 and 2016 rulemakings.

<sup>15</sup> The Secretary makes a particular procedural objection to the requests for the HCFAC reports: he argues that Plaintiffs did not comply with the local meet-and-confer requirements as to these requests. See Def.'s Opp'n MTS at 26. But it appears that, within the deadline set by the Court, the Plaintiffs asked HHS to supplement the record with "[e]vidence of positions taken by HHS on recovering outlier overpayments in False Claims Act and similar actions" and cited a particular HCFAC report as an illustrative example. See Def.'s Opp'n MTS Ex. A at 5, ECF 142-1. More specificity would certainly have been preferable, but the Court finds that Plaintiffs satisfied their obligations by "trying in good faith to achieve [their] objectives" and taking "real steps to confer." U.S. ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 456 F. Supp. 2d 46, 52 (D.D.C. 2006), aff'd, 530 F.3d 980 (D.C. Cir. 2008).

As Plaintiffs note, extra-record evidence can be added to the administrative record only under unusual circumstances, such as when "the agency 'deliberately or negligently excluded documents that may have been adverse to its decision." *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010) (quoting *Am. Wildlands*, 530 F.3d at 1002); *see also Kent Cty., Del. Levy Court v. EPA*, 963 F.2d 391, 396 (D.C. Cir. 1992) (finding it appropriate to supplement the record with adverse evidence when it appeared the agency was "at least negligent in failing to discover" certain internal documents). Some district court cases in this district have concluded that "[a] plaintiff can make a *prima facie* showing that an agency excluded adverse information from the record by proving that the documents at issue (1) were known to the agency at the time it made its decision, (2) 'are directly related to the decision,' and (3) 'are adverse to the agency's decision." *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 198 (D.D.C. 2005) (quoting *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1237 (D.D.C. 1986)).

The Court does not find that Plaintiffs have made even the *prima facie* showing recognized in *Fund for Animals* and *Public Citizen*. As to the first two categories of documents (the OIG and HCFAC reports), it is true that they, as high-level, official agency documents, were plausibly "known to the agency." *Ctv. of San Miguel v. Kempthorne*, 587 F. Supp. 2d 64, 72

<sup>&</sup>quot;following materials are deemed part of the administrative records for judicial review, for each document in the rulemakings that postdated that document." See Pls.' Proposed Order at 2, ECF No. 141-2 (emphasis added). It then proceeds to list the various OIG reports and the annual HCFAC Reports for FYs 2007–2014. Id. at 2–4. The Secretary interprets the italicized language to mean that Plaintiffs want supplementation "only where the report postdates the issuance of the final rule." Def.'s MTS Opp'n at 21 n.6. This is likely a misunderstanding or misstatement on the Secretary's part; the Court understands Plaintiffs' request to mean, more reasonably, that only if the report existed at the time of the rulemaking should it be included in the record for that rulemaking. Otherwise, of course, it would be difficult to show that the report was "known to the agency at the time it made its decision." Fund for Animals, 391 F. Supp. 2d at 198. The rest of the Secretary's discussion makes clear that the Secretary understood the request in this more logical way. See Def's MTS Opp'n at 21 n.6. Additionally, the Secretary points out that one of

(D.D.C. 2008); see id. at 76 ("[I]t is axiomatic that documents created by an agency itself or otherwise located in its files were before it."). And at least as Plaintiffs argue, they contained data that was "adverse" to the Secretary's decision in a loose sense, insofar as they indicated that reconciliation was more significant than the Secretary maintained. But Plaintiffs have not demonstrated that the documents were "directly related to the decision"; at most, they contained data related to one aspect of the subject of the decision. Both Fund for Animals and Public Citizen illustrate the difference: in those cases, documents that were ordered to be added to the record contained internal conclusions directly contrary to the relevant agency's final decision. See Fund for Animals, 391 F. Supp. 2d at 198 (discussing documents warning about the negative environmental effects of opening refuges to hunting when final rule opened refuges to hunting); Public Citizen, 653 F. Supp. at 1237 (discussing internal document that concluded raw milk was a public health risk when the agency refused to engage in related rulemaking). The data and reports cited by Plaintiffs are not so directly relevant or conclusive. Additionally, the Circuit has generally required the documents to have been excluded either negligently or deliberately, neither of which has been shown here. See City of Dania Beach, 628 F.3d at 590; Kent Cty., Del. Levy Court, 963 F.2d at 396.

As to the third subcategory of documents—namely, the litigation documents including "pleadings and briefs in the cases described in the HCFAC reports," Pls.' MTS at 29—the Court similarly declines to order supplementation. Plaintiffs do not describe these documents with any particular specificity and the scope of the request is (potentially, at least) exceedingly broad. *See City of Dania Beach*, 628 F.3d at 590–91 (denying supplementation in part because the

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the reports requested for inclusion is dated September 28, 2015, which is after the publication of the fiscal year 2016 rule. As a result, the Secretary argues, it does not fall within any of the Plaintiffs' requests. *Id.* at 23 n.6. Plaintiffs did not challenge that argument.

plaintiffs' "vague proffer" of hundreds of pages of material was "too generalized").

Additionally, it is unclear that these individual case filings—as opposed to the OIG and HCFAC reports discussed above—would have been "known to the agency at the time it made its decision." *Fund for Animals*, 391 F. Supp. 2d at 198. As Plaintiffs note, "they are Justice Department litigation documents and court decisions," not internal HHS documents. Pls.' MTS at 29. As a result, the Court does not find it appropriate to add them to the administrative record, even as "background information." *City of Dania Beach*, 628 F.3d at 590.

While supplementation is not appropriate, Plaintiffs are, of course, free to argue on the merits that the Secretary's decision to discount the impact of reconciliation was arbitrary and capricious. *Charleston Area Med. Ctr.* Suppl. Rec. Op. at 16–17 (concluding that "the Hospitals' claim that the Secretary made a bare, unsupported assumption in its fixed-loss threshold regulations [with respect to reconciliation] is better left to the merits").

# b. Proposed FY 2020 Rule

Finally, Plaintiffs request that the Court "consider, as background material" HHS's proposed rule setting the fixed loss threshold for the 2020 fiscal year. Pls.' MTS at 30. They acknowledge that the proposal was not before the agency during the relevant time periods, but explain that it "describes plans to take account of reconciliation, as commenters asked it to do repeatedly in the years at issue here." *Id.* (citing FY 2020 Proposed Rule, 84 Fed. Reg. 19,158, 19,593 (May 3, 2019)). Accordingly, Plaintiffs suggest, consideration of the new proposal is helpful because it shows that it was "quite feasible" for HSS to do what commenters had long urged. *Id.* at 31. Plaintiffs' legal rationale for the inclusion of a later rulemaking is somewhat unclear, but Plaintiffs clarify in their reply that otherwise "the administrative record itself is so

deficient as to preclude effective review." *See* Pls.' MTS Reply at 22 (quoting *Am. Bar Ass'n v. U.S. Dep't of Educ.*, 370 F. Supp. 3d 1, 38 (D.D.C. 2019)). 17

The Court is not convinced that supplementation of the record with a future rulemaking is justified. As a basic matter, when a particular agency action is challenged as arbitrary and capricious, the focus should be on the evidence that was "before the Secretary at the time he made his decision." *Citizens to Preserve Overton Park*, 401 U.S. at 420. Limited exceptions are available, as discussed above, but generally are limited to evidence and arguments that *should* have been considered by the Secretary. *See SIH Partners LLLP v. Comm'r*, 923 F.3d 296, 302 (3d Cir. 2019) (declining to deem regulations arbitrary and capricious when the challenger had not shown that particular "insights were known or, perhaps, at least should have been known to the agency at the time of the regulations' promulgation"). While HHS's "concession" in the 2020 rulemaking is potentially helpful to Plaintiffs' case, that is not the standard for supplementation. Additionally, as the Secretary points out, the Court remains free to take judicial notice of the 2020 rules as appropriate. *See Banner Health*, 126 F. Supp. at 61 ("The Court agrees—as does Defendant—that parties may cite to publicly available documents and that the Court may take judicial notice of such documents.").

#### V. CONCLUSION

For the foregoing reasons, Defendant's partial motion to dismiss, ECF No. 139, is **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs' motion to supplement the administrative records, ECF No. 141, is likewise **GRANTED IN PART** and **DENIED IN** 

44

<sup>&</sup>lt;sup>17</sup> In their reply, Plaintiffs also note that HHS has since finalized the 2020 proposal. *See* Pls.' MTS Reply at 23 n.8 (citing 84 Fed. Reg. 42,044, 42,630 (Aug. 16, 2019)).

**PART**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: March 31, 2020 RUDOLPH CONTRERAS

United States District Judge