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

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| UNIVERSITY OF COLORADO HEALTH AT MEMORIAL HOSPITAL, *et al.*, | : | | |
| Plaintiffs, | : | Civil Action No.: | 14-1220 (RC) |
| v. | : | Re Document No.: | 29 |
| SYLVIA M. BURWELL, Secretary, United States Department of Health and Human Services, | : | | |
| Defendant. | : | | |

# MEMORANDUM OPINION

**GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF THE COMPLETE ADMINISTRATIVE RECORD**

## I. INTRODUCTION

This case is one in a series of cases in which various hospitals have challenged regulations promulgated by the Department of Health and Human Services ("HHS") to implement the Outlier Payment System, which provides for supplemental Medicare payments to hospitals when a particular patient's hospitalization and care is unusually costly. Plaintiffs here, a group of thirty-five acute care hospitals, seek review of the Medicare reimbursements awarded to them under that system. Before the Court is Plaintiffs' motion to compel production of the complete administrative record (ECF No. 29). This issue is well-traveled ground. In several other cases challenging HHS's outlier payment regulations, courts in this district have similarly considered motions to supplement the administrative record that sought many of the same materials Plaintiffs seek here. *See generally Lee Mem'l Hosp. v. Burwell*, No. 13-643, 2015 WL 3631811 (D.D.C. June 11, 2015); *Dist. Hosp. Partners v. Sebelius*, 971 F. Supp. 2d 15 (D.D.C.

2013), *aff'd*, 786 F.3d 46 (D.C. Cir. 2015); *Banner Health v. Sebelius*, 945 F. Supp. 2d 1 (D.D.C. 2013). Upon consideration of the parties' filings, and for the reasons stated below, the Court will grant in part and deny in part Plaintiffs' motion to compel production.

## II. FACTUAL BACKGROUND

### A. The Outlier Payment System

To comprehend the parties' dispute about the administrative record's contents, one must have a keen understanding of the complex, and at times technical, Medicare Outlier Payment System. Hospitals were originally reimbursed under Medicare for the "reasonable costs" that they incurred when treating patients. *See Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015). Under that model, "[t]he more [hospitals] spent, the more they were reimbursed." *Id.* (first alteration in original) (quoting *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999)). By 1983, however, Congress had determined that a reasonable cost system failed to provide adequate incentives for hospitals to operate efficiently. *Id.* To remedy the potential for over-spending and to reward cost-effective hospital practices Congress passed as section 1886(d) of the Social Security Act ("Section 1886(d)") what is called the Inpatient Prospective Payment System ("IPPS"), administered by the Centers for Medicaid and Medicare Services ("CMS"). *See Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011); *see also* 42 U.S.C. § 1395ww(d). Instead of reimbursing a hospital simply for its reasonable costs, Congress directed CMS to calculate a "standardized amount" representing the average operating cost for inpatient hospital services. *Cape Cod Hosp.*, 630 F.3d at 205. Section 1886(d) then provides that Medicare reimbursements made to hospitals are to be based on that standardized amount, regardless of the particular costs a hospital incurs in an individual case. *See id.*

Congress did recognize that different illnesses may necessarily involve more or less costly care, however. To account for those variations, Congress also directed the Secretary of Health and Human Services (the "Secretary") to modify the standardized amount based on a number of diagnosis-related groups ("DRGs"). DRGs are "group[s] of related illnesses to which the Secretary assigns a weight representing 'the relationship between the costs of treating patients within that group and the average cost of treating all Medicare patients.'" *Dist. Hosp. Partners*, 786 F.3d at 49 (quoting *Cape Cod Hosp.*, 630 F.3d at 205–06).

Congress further recognized that, notwithstanding the standardized reimbursement system, "health-care providers would inevitably care for some patients whose hospitalization would be extraordinarily costly or lengthy." *Cnty. of L.A.*, 192 F.3d at 1009. To account for those situations, Congress created the Outlier Payment Program, which permits a hospital to recoup an additional payment, referred to as an "outlier payment," if the costs incurred during the care of a particular patient exceed a certain dollar amount. *Id.* As relevant here, section 1886(d) provides that a hospital "may request additional payments in any case where charges, adjusted to cost, . . . exceed the sum of the applicable DRG prospective payment rate . . . plus a fixed dollar amount determined by the Secretary." 42 U.S.C. § 1395ww(d)(5)(A)(ii). That fixed dollar amount—referred to as the "fixed loss threshold"—"serves as the cutoff point triggering eligibility for outlier payments." *Banner Health*, 945 F. Supp. 2d at 8.

Section 1886(d) further mandates that the aggregate amount of outlier payments made in any one fiscal year "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). During each fiscal year at issue in this case, the

Secretary has endeavored to establish payment rates and policies that will produce outlier payments equaling 5.1% of total projected IPPS payments.[1]

Hence, it is somewhat of an understatement to say that "calculating outlier payments is an elaborate process." *Dist. Hosp. Partners*, 786 F.3d at 49. For simplicity's sake "three particular numbers are important: (1) the cost-to-charge ratio, (2) the fixed loss threshold, and (3) the outlier threshold." *Id.* The cost-to-charge ratio, or "CCR," is calculated on an individual hospital level and represents the average differential between the charges that a particular hospital lists on a patient's invoice and the actual costs that hospital incurs in treating a patient. In essence, the figure represents the hospital's "average markup" on its services. *Id.* at 50. To calculate a hospital's CCR, the Secretary considers the hospital's "most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period." *See* 42 C.F.R. § 412.84(i)(2).

As indicated above, the fixed loss threshold is the "fixed dollar amount" above the DGR prospective payment rate that the cost of a patient's care must exceed before a hospital becomes eligible for an outlier payment. 42 U.S.C. § 1395ww(d)(5)(A)(ii). The fixed loss threshold "'acts like an insurance deductible because the hospital is responsible for that portion of the treatment's excessive cost' above the applicable DRG rate." *Dist. Hosp. Partners*, 786 F.3d at

[1] *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 71 Fed. Reg. 47,870, 48,149 (Aug. 18, 2006) [hereinafter "FY 2007 Final Rule"]; Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130, 47,419 (Aug. 22, 2007) [hereinafter "FY 2008 Final Rule"]; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Changes and FY 2011 Rates, 75 Fed. Reg. 50,042, 50,430 (Aug. 16, 2010) [hereinafter "FY 2011 Final Rule"]; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates, 76 Fed. Reg. 51,476, 51,795 (Aug. 18, 2011) [hereinafter "FY 2012 Final Rule"].

50 (quoting *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1229 (11th Cir. 2009)). A hospital is simply expected to absorb the additional costs that fall above the DGR but below the fixed loss threshold. The fixed loss threshold is calculated annually and a new threshold is set for each fiscal year. *Id.* at 50.

The third number, the "outlier threshold," is calculated by adding the DRG rate for a particular illness to the fixed loss threshold. *Id.* Any costs a hospital incurs above the outlier threshold may be reimbursed through an outlier payment, although CMS only reimburses a hospital for a fixed percentage of the hospital's costs above that outlier threshold. Since at least 2003, CMS has reimbursed hospitals for 80% of their adjusted costs above the outlier threshold. *Id.* (citing Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2004 Rates, 68 Fed. Reg. 45,346, 45,476 (Aug. 1, 2003); 42 C.F.R. § 412.84(k)).

It is important to note that outlier payments do not provide hospitals with additional funding that is not already allocated to the Medicare program. Instead, outlier payments simply redistribute a portion of IPPS payments that would normally flow to hospitals as reimbursement for typical DRG patients to those hospitals that treat outlier patients. *See* 42 U.S.C. § 1395ww(d)(3)(B). To compensate for the anticipated percentage of outlier payments to be made during the fiscal year, the reimbursements that hospitals receive for ordinary cases under the IPPS program are therefore subject to a percentage reduction "by a factor equal to the proportion of [outlier] payments." *Id.*

**B. The Challenged Regulations**

Plaintiffs' claims implicate two types of regulations that HHS has promulgated to implement the outlier payment system. The first is the 2003 Outlier Payment Regulations (the

"Payment Regulations"),[2] which establish the general model for calculating whether a hospital's treatment of a particular patient qualifies for an outlier payment. *See* Medicare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment Systems, 68 Fed. Reg. 34,494 (June 9, 2003) [hereinafter "2003 Payment Regulations"].

As noted above, IPPS payments are based on the costs a hospital incurs in treating a patient, not the charges as actually listed on a patient's invoice. *Dist. Hosp. Partners*, 786 F.3d at 49–50. CMS adjusts a hospital's charges to reflect actual costs using a hospital's cost reports. *Id.* at 49–50, 51. But there is an inevitable time delay between the charges a hospital incurs today and the point at which those charges, as adjusted to cost, will be reflected in a cost report. *See* 2003 Payment Regulations, 68 Fed. Reg. at 34,496. By 2003, it became clear that several hospitals had learned how to exploit this time lag. *Id.* Specifically, if a hospital "dramatically increased charges between past cost reports and the patient costs for which reimbursement is sought, [that hospital's] cost-to-charge ratio would be too high and would overestimate the hospital's costs." *Dist. Hosp. Partners*, 786 F.3d at 51 (internal quotation marks omitted). Such overestimation "may result in some cases receiving outlier payments when th[ose] cases, in actuality, are not high-cost cases." 2003 Payment Regulations, 68 Fed. Reg. at 34,497. This practice is referred to as turbo-charging. *Dist. Hosp. Partners*, 786 F.3d at 51.

In an effort to remedy this problem and to prevent turbo-charging in the future, HHS modified its payment methodology in 2003 to, among other things, provide for the use of "the

[2] Plaintiffs refer to these regulations interchangeably as the "Payment Regulations" and the "Outlier Payment Regulation." *Compare,* Pls.' Mem. Supp. Mot. to Compel Produc. at 5, ECF No. 29, *with* Fourth Am. Compl. ¶ 77. The Court will refer to the 2003 regulations as the "Payment Regulations."

most recent tentative settled cost report," in lieu of a settled cost report, when calculating a hospital's CCR. *See* 2003 Payment Regulations, 68 Fed. Reg. at 34,497. HHS projected that the use of tentative reports would "reduce[] the time lag for updating cost-to-charge ratios by a year or more." *Id.* The Payment Regulations also provided that "outlier payments would become subject to reconciliation when hospitals' cost reports are settled." *Id.* at 34,501. HHS did not propose to retroactively adjust the fixed loss threshold for prior fiscal years in light of the reconciled cost reports, however. *Id.* Instead, HHS explained that it continued to believe that the threshold "should be based on projected payments using the latest available data without retroactive adjustment." *Id.*

Using this updated methodology, HHS calculates a new fixed loss threshold each fiscal year to govern hospitals' eligibility for outlier payments during that fiscal year (collectively, the "Threshold Regulations"). The Threshold Regulations for certain fiscal years (2007, 2008, 2011, and 2012) are the second type of regulations challenged in this case. Using the fiscal year 2008 as an illustration, HHS typically arrives at the upcoming fiscal year's fixed loss threshold through the following process:[3]

First, the agency "simulate[s] payments" that will be made under the IPPS program during the upcoming fiscal year. FY 2008 Final Rule, 72 Fed. Reg. at 47,267. In 2008, the agency simulated payments with reference to the actual cases and discharges made two years earlier (during fiscal year 2006); that data is set forth in what is called the "MedPAR file," which contains "fully coded diagnostic and procedure data for all Medicare inpatient hospital bills." *Id.* Before simulating the projected payments for the fiscal year, however, the agency omits

[3] In their respective memoranda the parties often use the 2008 rulemaking as an illustration. The Court follows suit, reserving additional detail with respect to certain aspects of HHS's methodology for the analysis, below.

inaccurate data from the file—a process that is referred to as "trimming" the data.[4] *Id.* The trimmed data forms the universe of cases upon which the next fiscal year's projected payments will be based. The agency then adjusts those charges for anticipated inflation. For 2008, HHS "inflated the charges on the MedPAR claims by 2 years, from FY 2006 to FY 2008." *Id.* at 47,417. The agency calculates "the 1 year average annualized rate-of-change in charges-per-case" by comparing the charges over the first two quarters of the relevant fiscal year (e.g., 2006) to charges over first two quarters of the following fiscal year (e.g., 2007). *Id.* at 47,418. That average annual rate of change is referred to as the "charge inflation factor," and that factor is applied to the 2006 cases to determine the anticipated charges in 2008. *Id.* at 47,417.

Because charges submitted for reimbursement will ultimately be adjusted to costs, however, the agency also projects hospitals' CCRs for the upcoming fiscal year. The agency starts with the "most recent available data at the time of the [proposed or final] rule," as contained in a particular update to what is called the "Provider Specific File (PSF)." *Id.* at 47,417, 47,418. For the 2008 final rulemaking, the agency used the data contained in the "March 2007 update to the PSF." *Id.* at 47,418. That PSF data for all Medicaid providers is compiled into a single, aggregated electronic file referred to as an "Impact File." The Impact File provides "a static snapshot of the actual variables that CMS used in the rate-setting and payment modeling work for the rule with which the impact file is associated." *See* Cheng. Decl. ¶ 10, ECF No. 32–1. Those CCRs are then adjusted for anticipated inflation by applying what is called a "CCR adjustment factor." FY 2008 Final Rule, 72 Fed. Reg. at 47,418.

[4] For example, among other alterations, HHS subtracts "organ acquisition costs" from the charges for certain types of organ transplants, deletes claims with total charges or total lengths of stay less than or equal to zero, and removes statistical outliers from the data sets. *See* FY 2008 Final Rule, 72 Fed Reg. at 47,268.

In 2008, using the 2006 MedPAR charges and the March 2007 CCRs, both as adjusted for inflation, HHS simulated payments for the upcoming fiscal year and determined that a fixed loss threshold of $22,635 would ensure outlier payments equaling "5.1% of total IPPS payments" during the fiscal year. *Id.* at 47,419. Of course, the agency's projections are dependent on tentative cost reports from prior fiscal years, which may be subject to reconciliation once a final cost report is finalized. *See* 2003 Payment Regulations, 68 Fed. Reg. at 34,501. Despite this possibility, HHS has repeatedly elected not to adjust its annual projections to account for the possibility that a hospital's CCR and outlier payments might be reconciled once the final cost reports are settled.[5]

### C. Procedural History

In this action, Plaintiffs have challenged both the 2003 Payment Regulations and the Threshold Regulations for the 2007, 2008, 2011, and 2012 fiscal years. *See* Fourth Am. Compl. ¶¶ 4–5, ECF No. 41[6]; *see also* Pls.' Mem. Supp. Mot. to Compel Produc. at 15, ECF No. 29 [hereinafter "Pls.' Mem. Supp."]. Plaintiffs claim that the Threshold Regulations violate Section 1886(d) of the Social Security Act because they fail to comply with the statutory mandate that outlier payments fall between five and six percent of all DRG-related payments, and that the

[5] *See, e.g.*, FY 2007 Final Rule, 71 Fed. Reg. at 48,149; FY 2008 Final Rule, 72 Fed. Reg. at 47,419; FY 2011 Final Rule, 75 Fed. Reg. at 50,428–29; FY 2012 Final Rule, 76 Fed. Reg. at 51,793.

[6] On June 16, 2015, and in the midst of briefing with respect to this motion to compel, Plaintiffs were granted leave to file a Fourth Amended Complaint. The amended complaint added additional claims by certain hospitals, which were already Plaintiffs in this case, based on recent activity of the Provider Reimbursement Review Board. Because the amended complaint did not "implicate any new rulemaking records," the Plaintiffs represented that the "existing briefs associated with Plaintiffs' Motion to Compel with respect to the completeness of the administrative record will not be impacted by [the] proposed Fourth Amended complaint." Pls.' Unopposed Mot. for Leave to File Fourth Am. Compl. ¶ 12, ECF No. 40. Throughout this memorandum opinion the Court will cite to the Fourth Amended Complaint, as the governing complaint.

regulations are arbitrary and capricious in violation of the Administrative Procedure Act ("APA"). *See* Fourth Am. Compl. ¶¶ 72–73, 75. Plaintiffs also contend that the 2003 Payment Regulations are procedurally invalid and that, because the later fiscal year regulations are implemented using the 2003 methodology, those regulations are also invalid. *See id.* ¶ 77. Plaintiffs seek an order vacating the Payment Regulations, remanding these appeals to the Secretary so that she can "recalibrate and reset" the fixed loss threshold for each fiscal year at issue, and allowing the Plaintiffs to submit amended claims for outlier payments under the recalibrated threshold levels. *See* Fourth Am. Compl. at 38.

HHS initially produced to the Plaintiffs what HHS purported to be the administrative record for the 2003 Payment Regulations and the Threshold Regulations for fiscal years 2007, 2008, 2011, and 2012. *See* Certified List of Contents of the Rulemaking Record, ECF No. 25. With respect to the Threshold Regulations, the initial record included: the Impact Files and MedPAR data files for each fiscal year rulemaking, public comments related to those fiscal years' proposed rules, the proposed and final rulemaking notices, and, for some fiscal years, certain documents specifically referenced in each rulemaking. *Id.* For the 2003 Payment Regulations, the administrative record included the MedPAR data file, the public comments related to the proposed rule, and the proposed and final rulemaking notices. *Id.*

Plaintiffs claim that these documents do not reflect the complete administrative record that was before the agency when it considered these regulations. Specifically, Plaintiffs have moved to compel the production of nine documents or categories of documents including: (1) an Interim Final Rule considered at the time HHS promulgated the 2003 Payment Regulations; (2) the Impact File for the 2003 Payment Regulations; (3) the formulas used to calculate the fixed loss threshold for each fiscal year at issue in this case; (4) the formulas and data used to calculate

estimated outlier payments, made during the previous FYs; (5) the actuarial analysis and data upon which HHS relied to calculate the CCR adjustment factors; (6) purportedly missing data HHS used to calculate the inflation factors; (7) purportedly missing and incomplete Impact Files and related data; (8) materials supporting HHS's regulatory impact analysis considered when promulgating each Threshold Regulation; and (9) materials supporting HHS's conclusion that it need not consider reconciliation of outlier payments when setting the fixed loss thresholds. *See generally* Pls.' Mem. Supp. at 21–44.[7]

## III. LEGAL STANDARD

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."). A reviewing court "should have before it neither more nor less information than did the agency when it made its decision." *IMS, P.C. v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997). Reviewing "less than the full administrative record," might "allow a party to withhold evidence unfavorable to its case," while reviewing "more than the information before the agency at the time of its decision," risks "requiring administrators to be prescient or allowing them to take

[7] For ease of reference, the Court refers to the specific documents discussed in the argument section of Plaintiffs' memorandum. Although Plaintiffs provide a bullet point list in their memorandum listing the documents they seek, *see* Pls.' Mem. Supp. at 17–18, that list differs in some respects from the description in the subsequent analysis section. For example, the Court understands Plaintiffs' general reference to "supporting data which HHS actually used to determine certain key assumptions for projected outlier payment calculations as set forth in HHS's Impact Files for each FY at issue," Pls.' Mem. Supp. at 17, to encompass *both* Plaintiffs' request for missing data used to calculate inflation factors and their request for the data missing from the purportedly incomplete impact files, *see id.* at 34, 36.

advantage of post hoc rationalizations." *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984). 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). The record that an agency produces "is entitled to a strong presumption of regularity." *Id.*

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, as Plaintiffs do here, 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*. 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.* "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.

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). Those 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. F.A.A.*, 628 F.3d 581, 590 (D.C. Cir. 2010) (quoting *Am. Wildlands*, 530 F.3d at 1002).

The Court agrees with another judge in this district in noting that the dual use of the term "supplement" has caused "some confusion" about the proper test to apply when a party seeks to supplement the administrative record. *See The Cape Hatteras Access Pres. Alliance v. U.S. Dep't of Interior*, 667 F. Supp. 2d 111, 113 (D.D.C. 2009). "Supplement" has been used synonymously to refer to both a circumstance in which a party argues that the administrative record does not actually reflect the materials that the agency had before it when it made its decision, and a circumstance in which a party seeks to add extra-record or extra-judicial information to the record that was concededly *not* before the agency. *Id*. Perhaps because of that dual use, courts in this district have regularly invoked the language from *Dania Beach* and *American Wildlands*—and have asked whether a party has shown the existence of one of the

"unusual circumstances"—even when considering claims that an agency had not produced materials that it *actually had* before it. Both parties similarly invoke the *Dania Beach* and *American Wildlands* language in this case. But this Court reads those cases to set forth the test for supplementation only with respect to *extra-record* information. *Accord Cape Hatteras*, 667 F. Supp. 2d at 114–15. For one thing, both cases—and the D.C. Circuit precedent they rely on—involved a party's effort to introduce information that had not been before the agency when it considered the challenged rule. *See, e.g.*, *Dania Beach*, 628 F.3d at 590 (seeking to introduce documents from *prior* environmental impact statement processes); *Am. Wildlands*, 530 F.3d at 1002 (seeking to introduce letters that "were written after the [Fish and Wildlife] Service issued its Reconsidered Finding" and thus were "not part of the administrative record"); *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996) (seeking to introduce bank files that the party conceded "were not part of the administrative record compiled by the agency when the Senior Deputy Comptroller declared the banks insolvent"). For another, the Court presumes that, for judicial review to be effective, materials that *were* before the agency should be included in the administrative record irrespective of whether those materials are "adverse to [the agency's] decision" or otherwise satisfy any of the three unusual circumstances identified in *American Wildlands* and *Dania Beach*. Similarly, the test's references to "background information" or an agency's failure to adequately explain its action both imply that the information a court is considering adding to the administrative record in those circumstances is information that was not before the agency in the first instance. If a party provides concrete, non-speculative evidence that material an agency did actually consider "either directly or indirectly" is absent from the record, *Marcum*, 751 F. Supp. 2d at 78, however, that should be the end of the matter. In those

circumstances a court need not go on to ask whether one of the three "unusual circumstances" has been shown.

The Court acknowledges that in *District Hospital Partners* the D.C. Circuit recently applied the *American Wildlands* test when considering a party's effort to supplement the administrative record with materials similar to those the Plaintiffs seek to add to the record in this case. *See* 786 F.3d at 55–56. Yet, in that case the Circuit does not seem to have been confronted with materials that the parties claimed had been before the agency in the first instance. The Circuit's recitation of the test suggests as much. After reiterating that APA review must "be based on the *full administrative record* that was before the Secretary," the court explained that, to "ensure that [courts] review *only those documents that were before the agency*," a party may supplement the record only if "they can demonstrate unusual circumstances justifying *a departure from this general rule*." *Id.* at 55 (emphasis added). Thus, the Circuit appears to have been dealing with a situation in which the parties sought to add extra-record information to the administrative record.[8] As a result, the Court does not read the opinion to

[8] This was undoubtedly the case with two of the three types of material at issue in *District Hospital Partners*. First, the plaintiffs there sought to supplement the record with the "congressional testimony of a former HHS official," *Dist. Hosp. Partners*, 786 F.3d at 56, which, quite obviously, was not part of the agency's rulemaking record. Second, plaintiffs also argued that the "'trimmed' version of hospital charge data" should have been added to the record. *Id.* at 55. But the Circuit noted that there is no stand-alone version of the trimmed data that differs from the data files already in the record. *Id.* at 55; *see also infra* note 17 (explaining that the Federal Register identifies the trims applied to the existing MedPAR files). As for the third category of material, the Circuit generally explained that plaintiffs had sought to supplement the record with "source data used to approximate cost-to-charge ratios for 2004." *Id.* It is not immediately clear from the Circuit's description, however, whether the Circuit was referring to data that it understood the agency to have considered directly. As this Court explains below, although an agency must include in the administrative record all materials it directly or indirectly considered, an "agency is not normally obligated to make available the raw data upon which [reports or documents] considered by the agency were based *if the agency itself did not rely on the raw data* when it reached its decision." *Common Sense Salmon Recovery v. Evans*, 217 F. Supp. 2d 17, 22 (D.D.C. 2002) (emphasis added). And with respect to these rulemaking records,

hold that, had the plaintiffs requested to supplement the record with materials that had been before the agency, the Circuit would nevertheless have required the plaintiffs to show an "unusual circumstance" warranting supplementation.

Plaintiffs here seek to supplement the administrative record with materials that they claim were in fact before the agency. *See* Pls.' Mem. Supp. at 17 (claiming, before listing documents Plaintiffs seek, that "HHS has not produced significant additional documents which were before the agency during the rulemakings here at issue"). Consequently, the Court need only consider whether the Plaintiffs have provided concrete, non-speculative information that the agency directly or indirectly considered the materials Plaintiffs seek in order to resolve this motion.[9]

## IV. ANALYSIS

Plaintiffs have moved to supplement the administrative record with materials they claim are relevant to both the 2003 Payment Regulations and the annual Threshold Regulations. Generally, Plaintiffs contend that "the administrative records that HHS has produced contain only some of the data inputs and none of the formulas that the agency actually used to set the thresholds" and that "HHS had omitted a critical document from the rulemaking record for its

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some underlying source data was considered, analyzed, and manipulated by the agency, itself, while other data was not. *See infra* at 28–30 (explaining that cost report data was analyzed and manipulated by the agency), 32–33 (explaining that, with respect to provider CCRs, the agency relied on the Impact Files provided by Enterprise Data Center Group and did not review the underlying source data itself). Accordingly, given the Circuit's explanation in *District Hospital Partners* that it was considering the plaintiffs' efforts to "justify[] a departure from th[e] general rule" that the record should include "only those documents that were before the agency," this Court assumes that the underlying source data at issue there had not been considered by the agency. 786 F.3d at 55.

[9] Nonetheless, as explained below, the Court notes that in each instance in which it will order the record supplemented in this case, one of the three unusual circumstances is satisfied. *See infra* notes 14–16, 20.

2003 amendments to the outlier payment regulations." Pls.' Mem. Supp. at 2. Without these materials, Plaintiffs claim that "any explanation by HHS of the path taken in arriving at the challenged agency actions will necessarily be incomplete and will thus hinder the Court's review." *Id.* For its part, HHS responds that Plaintiffs are seeking materials "that are not properly included in the administrative records." Def.'s Mem. Opp. at 2, ECF No. 32. The Court considers each identified document or category of documents in turn.[10]

### A. Documents Relevant to the 2003 Payment Regulations

#### 1. The 2003 Interim Final Rule

Plaintiffs first seek to supplement the record with the draft of a 2003 "Interim Final Rule" that HHS developed at the same time that it proposed the Payment Regulations. The draft Interim Final Rule was signed by then-Secretary of Health and Human Services Tommy G. Thompson on February 6, 2003, the same day that the Secretary signed the proposed final rule, and submitted to the Office of Management and Budget ("OMB") on February 13, 2003 pursuant

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[10] To the extent that Plaintiffs' at times vague references to missing "data" or "documents" are intended to reference any materials not explicitly discussed in this memorandum opinion, Plaintiffs have failed to describe those materials with the necessary specificity to overcome the presumption of regularity. Similarly, Plaintiffs make passing reference to CMS's Record Schedule which defines an official rulemaking record to include:

> the published proposed rule, all public comments received in response to the proposed rule or notice that the agency considered in developing the final policy, the public comment log prepared by the recordkeeping office, any computer runs, internal/external studies, final actuarial determinations, and all data that supported the policy, data that refuted the policy and data that would support alternative options.

*See* Pls.' Mem. Supp. Ex. B (reproducing the records schedule). Despite Plaintiffs' assertion that this policy makes clear "that there are many other types (or categories) of documents that have not yet been filed with the Court," Pls.' Mem. Supp. at 26, the Court interprets this policy to merely detail what records must be retained and submitted to the National Archives and Records Administration. The policy does not indicate that every rulemaking will necessarily lead to the production or creation of each of the listed types of documents nor that every record that falls into one of these categories must necessarily become part of the administrative record under the APA.

to Executive Order 12,866.[11] *See generally* Pls.' Mem. Supp. Ex. A (reproducing the Interim Final Rule). In light of certain hospitals' turbo-charging practices, which had artificially inflated outlier payments, the Interim Final Rule would have immediately lowered the fixed loss threshold for the 2003 fiscal year from $33,560 to $20,760. *See id.* at 34–38. The Interim Final Rule also set forth a detailed analysis of why HHS believed that an immediate reduction in the fixed loss threshold was warranted. When HHS published its notice of proposed rulemaking for the new outlier payment methodology on March 5, 2003, however, the agency did not mention the Interim Final Rule and did not address any of the data or analysis that had been laid out in that interim rule. Instead, the agency proposed to make no change to the 2003 fixed loss threshold. *See* Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System, 68 Fed. Reg. 10,420, 10,427 (Mar. 5, 2003). In its subsequent final rule, and contrary to the analysis contained in the Interim Final Rule, the agency explained that, "in light of the relatively small difference between the current threshold and our revised estimate, and the limited amount of time remaining in the fiscal year, we have concluded it is more appropriate to maintain the threshold at $33,560." 2003 Payment Regulations, 68 Fed. Reg. at 34,506.

The Court agrees with three other courts in this district that this course of events provides concrete and non-speculative evidence that the substance of the Interim Final Rule—and its differing conclusion and analysis about the need to lower the fixed loss threshold—was

[11] Executive Order 12,866 requires agencies to submit "significant regulatory action[s]" to the OMB for review. *See generally* Exec. Order No. 12,866 § 6, 58 Fed. Reg. 51,735 (Sept. 30, 1993). Plaintiffs represent that they obtained the draft of the Final Interim Rule through a Freedom of Information Act Request submitted to the OMB. Pls.' Mem. Supp. at 22.

considered by the agency when settling on the final 2003 Payment Regulations.[12] *See Lee Mem'l Hosp.*, 2015 WL 3631811, at *4; *Dist. Hosp. Partners*, 971 F. Supp. 2d at 30; *Banner Health*, 945 F. Supp. 2d at 26. The Interim Final Rule, itself, makes clear that the agency at least *considered* lowering the 2003 fixed loss threshold. *Marcum*, 751 F. Supp. 2d at 78. Moreover, contemporaneous testimony before Congress by then-Administrator of the Center for Medicare and Medicaid Services, Thomas Scully, confirms that the agency contemplated lowering the fixed loss threshold but ultimately receded from that position. *See Medicare Outlier Payments to Hospitals: Hearing Before a Subcomm. of the Comm. on Appropriations*, 108th Cong. 108-268, at 12–13 (2003) (statement of Thomas Scully) ("I feel strongly that, and I have argued strongly within the administration that we should lower the threshold back to $22,000 or $23,000, but you can understand from OMB's point of view . . . so I agreed with them in the draft rule to leave it where it was."). As the court pointed out in *Banner Health*, both the Interim Final Rule and the rule the agency ultimately proposed "bear the same Regulatory Identification Number" and "the content of the documents are, in large part, identical (except that the proposed rule omits the recommended reduction of the fixed loss threshold and supporting analysis contained within the Interim Final Rule)." 945 F. Supp. 2d at 26. Therefore, "there can be little doubt that the Interim Final Rule reflects views adverse to those finally adopted by the Secretary and that the Secretary considered—and indeed proposed to OMB—the Interim Final Rule as an alternative in its path to promulgation of the 2003 amended Outlier Payment Regulations now challenged by Plaintiffs." *Id.* at 27.

[12] The D.C. Circuit recently held that one of those courts did not abuse its discretion in so deciding. *See Dist. Hosp. Partners*, 786 F.3d at 55 n.3.

HHS's only response is its contention that the Interim Final Rule is a "predecisional document" and that "drafts of agency decisions considered within the agency are typically not considered part of the administrative record even if they are publicly available and therefore not covered by the deliberative process privilege."[13] Def.'s Mem. Opp. at 10, 12. But the cases that the agency cites are not truly comparable. In each of those cases, a court declined to supplement the administrative record with materials that reproduced the internal deliberation among or reflected the thought process of administrative decisionmakers. *See, e.g., PLMRS Narrowband Corp. v. F.C.C.*, 182 F.3d 995, 1001 (D.C. Cir. 1999) (refusing to supplement the record with a videotape of a meeting among the FCC Commissioners because agency opinions "speak for themselves" and "[w]here an agency has issued a formal opinion or a written statement of its reasons for acting, transcripts of agency deliberations . . . should not routinely be used to impeach that written opinion" (internal quotation marks and citations omitted)); *Checkosky v. S.E.C.*, 23 F.3d 452, 489 (D.C. Cir. 1994) (noting that agency opinions "speak for themselves" and that requiring an agency to produce "transcripts of closed agency meetings or intra-agency memoranda and documents recording the deliberative process leading to the agency's decision" is "warranted only in the rarest of cases"); *San Luis Obispo Mothers for Peace v. U.S. Nuclear Regulatory Comm'n*, 789 F.2d 26, 44 (D.C. Cir. 1986) (en banc) (refusing to supplement the record with transcripts of a closed meeting that "record[ed] the frank deliberations of Commission members engaged in the collective mental processes of the agency"); *cf. Citizens to Preserve Overton Park*, 401 U.S. at 420 (stating that "inquiry into the mental processes of administrative decisionmakers is usually to be avoided").

[13] HHS concedes that "the draft is publically available and not covered by the deliberative process privilege." Def.'s Mem. Opp. at 13; *see also Dist. Hosp. Partners*, 971 F. Supp. 2d at 30 (explaining why the Interim Final Rule is not protected by the deliberative process privilege).

In this case, Plaintiffs *do not* seek to supplement the record with an informal discussion among regulators, an intra-agency memorandum, or the mental processes of administrative decisionmakers. Instead, although the interim rule was in draft form when submitted to the OMB for review, it constitutes a "formal opinion or written statement of [the agency's] reasons." *See PLMRS Narrowband Corp.*, 182 F.3d at 1001, Moreover, that draft rule came to a differing conclusion about the wisdom of decreasing the fixed loss threshold—although it was ostensibly based on the same information as the final outlier correction rule. The Interim Final Rule is therefore highly probative in determining the rationality of the agency's chosen path. *Cf. Hermes Consol., LLC v. E.P.A.*, 787 F.3d 568, 576 (D.C. Cir. 2015) (explaining that, while "[j]udicial review of a change in agency policy is no stricter than our review of an initial agency action," an agency "must provide reasoned explanation for its action, which normally requires that it display awareness that it is changing position" (internal quotation marks and citations omitted)). HHS has also not cited any authority to support its blanket assertion that "unlike the views of parties outside the agency" the views "developed by HHS but ultimately not adopted" are categorically shielded from inclusion in the administrative record. Def.'s Mem. Opp. at 14–15. To the extent HHS claims that the draft was properly excluded because it "never became final," *id.* at 13, the Court agrees with other courts in this district that such a "bright-line approach—in addition to lacking legal support—is untenable because it may permit the agency to hide from judicial review information regarding alternatives that the agency considered on the path to reaching its decision." *Banner Health*, 945 F. Supp. 2d at 23 (citing cases). Accordingly,

the Court grants Plaintiffs' motion to supplement the administrative record with the Interim Final Rule.[14]

**2. The 2003 Impact File**

The Court similarly grants Plaintiffs' motion with respect to the 2003 Impact File. As explained above, and as described by the government, the Impact Files contain "all of the provider-specific sourced data, including CCRs, used to determine the FLT [the fixed loss threshold] for a given fiscal year," and are derived from data in the Provider Specific Files. Cheng Decl. ¶ 12. Elsewhere in its memorandum, HHS contends that Impact Files supply one of "the bases for HHS's determination of the fixed loss thresholds." Def.'s Mem. Opp. at 16. Although HHS has included in the administrative record the Impact Files for the fiscal year 2007, 2008, 2011, and 2012 rulemaking, the agency has not supplied the 2003 Impact File.

HHS's statements demonstrate that the Impact File is important to the rulemaking process and by themselves provide more than speculative evidence that Impact Files were considered in the 2003 rulemaking. HHS's sole response is that the passage of time has left the agency unable to definitively say whether or not Impact Files were considered during the 2003 rulemaking. Def.'s Mem. Opp. at 15; Cheng Decl. ¶ 15. But both the proposed Interim Final Rule and the promulgated Payment Regulations state that the agency reestimated the 2003 threshold when considering whether to alter it. *See* Fourth Am. Compl. Ex. A at 34–35 (stating that the agency calculated the revised outlier threshold by simulating payments using "the same data" as the existing 2003 threshold, which "included the March 2002 update of the Provider-Specific File");

[14] And to the extent Plaintiffs must show an "usual circumstance" to justify supplementation of the record, the agency's about-face certainly suggests that the agency has "deliberately or negligently excluded documents that may have been adverse to its decision." *Am. Wildlands*, 530 F.3d at 1002.

2003 Payment Regulations, 68 Fed. Reg. at 34,505 (stating that the agency "reestimated the fixed-loss threshold reflecting the changes implemented in this final rule"). And the data necessary to make that estimation—including the data from the Provider Specific File—is contained in the relevant Impact File. *See* Cheng Decl. ¶ 12. The agency has not explained how it could have simulated these payments without the crucial data contained in the Impact File. Accordingly, the record should be supplemented to include the 2003 Impact file.[15] *Accord Lee Mem'l Hosp.*, 2015 WL 3631811, at *5; *Banner Health*, 945 F. Supp. 2d at 32–33.

### B. Documents Relevant to the Annual Fiscal Year Threshold Regulations

#### 1. Formulas Used to Calculate the Fixed Loss Thresholds and Actual Outlier Payments

With respect to the annual Threshold Regulations, Plaintiffs have moved for supplementation of the record on various grounds. First, Plaintiffs seek formulas that they claim were necessarily used each fiscal year to calculate the fixed loss threshold. A critical part of HHS's efforts to set outlier payment rates and policies each fiscal year is the estimation of anticipated total IPPS payments that hospitals will incur during the upcoming fiscal year. Only by projecting payments is HHS able to determine a threshold level which, it predicts, will result

[15] The Court also takes judicial notice of the fact that HHS recently confirmed, following the district court's decision in a similar case, that it had supplemented the record with the Impact File for the 2003 Rulemaking. *See* Def.'s Mot. for Clarification at 1, *Lee Mem'l Hosp. v. Burwell*, No. 1:13-cv-0643-RMC (D.D.C. July 2, 2015), ECF No. 68; *see also Lewis v. Drug Enforcement Admin.*, 777 F. Supp. 2d 151, 159 (D.D.C. 2011) ("The court may take judicial notice of public records from other court proceedings."). HHS's filing provides non-speculative evidence that a 2003 Impact File does exist. Because the file exists, the Court finds it difficult to understand how the fixed loss threshold could have been calculated without the use of that file for the reasons stated above. For the same reasons, the 2003 Impact File plainly constitutes "background information . . . needed 'to determine whether the agency considered all the relevant factors,'" to the extent an "unusual circumstance" is necessary to supplement the record. *City of Dania Beach*, 628 F.3d at 590 (quoting *Am. Wildlands*, 530 F.3d at 1002).

in outlier payments between five and six percent of total IPPS payments. But Plaintiffs contend that HHS has failed to describe the formulas that it used to determine those fixed loss thresholds.

As already noted, the rulemaking notices explain in general terms how HHS models anticipated IPPS payments for the upcoming fiscal year. For example, in its fiscal year 2008 rulemaking, HHS explains that it "simulated payments by applying FY 2008 rates and policies using cases from the FY 2006 MedPAR files." FY 2008 Final Rule, 72 Fed. Reg. at 47,417. To account for inflation, the charges from those cases were inflated by two years using an inflation factor. HHS then uses the universe of cases from 2006, as inflated, to serve as a proxy for the cases it expects to reimburse during the upcoming fiscal year. To adjust those charges for cost, HHS also uses "the most recent available data at the time of the" proposed or final rule to model anticipated CCRs. *Id.* Those CCRs are also adjusted to take into account both cost and charge inflation. *See id.* Together, these general descriptions make clear how HHS arrives at the two crucial variables necessary to its calculation of anticipated IPPS payments: the agency uses MedPAR files from two years prior, as inflated, to approximate the charges that providers will incur and the agency then uses adjusted CCRs to convert those charges to anticipated costs.

What is not fully explained, however, is the mechanism by which HHS uses those two variables to simulate payments and produce a particular fixed loss threshold. Presumably, HHS uses the cost-adjusted and inflated charges in some type of calculation to model actual payments. Indeed, HHS seems to describe this step as involving the application of a formula. As HHS states in its opposition, after inflating the claims data and adjusting CCRs, the Secretary "feeds the inflation-adjusted approximated charges data *into the payment calculation mechanism* that will be in effect in the coming year . . . and tallies the simulated payments that result when the fixed loss threshold is set at different levels." Def.'s Mem. Opp. at 5 (emphasis added). But that

payment calculation mechanism's absence from the administrative record—or any detail about it—presents a patent obstacle to effective judicial review.

HHS responds that Plaintiffs have relied only on an assumption that formulas beyond the analysis described in the Federal Register exists. *Id.* at 18. But the Court shares that assumption; indeed, the rulemaking notices' vague references to "simulat[ing] payments," *see, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 47,417, and HHS's own reference before this Court to a "payment calculation mechanism," Def.'s Mem. Opp. at 5, all but confirm it. The Court therefore will grant Plaintiffs' motion and orders HHS to supplement the record with the formula or algorithm through which the agency simulates payments.

The Court recognizes that other courts in this district have come to differing conclusions about the need for supplementing the administrative record with the formula or algorithm HHS has used. *Compare Lee Mem'l Hosp.*, 2015 WL 3631811, at *6 (ordering supplementation), *with Banner Health*, 945 F. Supp. 2d at 29 (concluding that Plaintiffs failed to identify specific documents "that might reveal the various formulas, algorithms, and other analysis"). Yet, this Court believes that the information is essential to delineate the path HHS has taken to arrive at the chosen fixed loss thresholds.[16]

The Court also acknowledges that HHS recently represented in a motion for clarification in *Lee Memorial*—where the court had ordered supplementation—that "HHS does not possess materials that are responsive" to that order "that have not already been included in the administrative record." *See* Def.'s Mot. for Clarification of June 11, 2015 Order and Mem. in Supp. at 2, *Lee Mem'l Hosp.*, No. 1:13-cv-0643 (D.D.C. July 2, 2015), ECF No. 68. This vague

[16] And therefore also constitutes "background information . . . needed 'to determine whether the agency considered all the relevant factors.'" *City of Dania Beach*, 628 F.3d at 590 (quoting *Am. Wildlands*, 530 F.3d at 1002).

assertion provides little explanation and the Court finds it unsatisfying. At present, and for the reasons stated above, the Court fails to understand how that can be so.

It may be that more specificity is provided in the 2003 Payment Regulations, to which CMS's Director of the Division of Acute Care, Hospital and Ambulatory Policy Group makes passing reference in her declaration. *See* Cheng Decl. ¶ 22. HHS did point to that regulation in its motion for clarification in *Lee Memorial* and that regulation does describe an elaborate formula that "simulates the IPPS outlier payment for a case at a generic hospital." 2003 Payment Regulations, 68 Fed. Reg. at 34,495. But HHS's briefing here does not mention the 2003 regulation in connection with the alleged formulas that Plaintiffs seek. Moreover, although it is perhaps conceivable that HHS employs this hospital-specific mechanism on a macro level to simulate anticipated payments across all providers (using the inflated charges and adjusted CCRs), the agency's description in the Federal Register does not make any connection immediately clear. The current briefing fails to sufficiently explain how the existing administrative record sets forth all of the formulas necessary to fully delineate the agency's path. Accordingly, HHS shall supplement the administrative record with the formulas it used to calculate the fixed loss threshold.[17]

**2. Formulas and Data Used to Calculate Estimated Outlier Payments for Prior Fiscal Years**

During each of its annual rulemakings, HHS also uses more recent data to update its estimate of the outlier payments made during the prior two fiscal years. *See, e.g.*, FY 2008 Final

[17] Plaintiffs also moved to compel HHS to disclose the data trims that the agency applied to the MedPAR files before it simulated payments. HHS pointed out in its opposition that all of those data trims are explicitly identified in the notices of final rulemaking, *see* Def.'s Mem. Opp. at 19, and Plaintiffs no longer seek to supplement the administrative record with the data trims, *see* Pls.' Reply at 14 n.7.

Rule, 72 Fed. Reg. at 47,420 (detailing the agency's "current estimate" of 2006 actual outlier payments using available 2006 bills and the agency's estimate for actual 2007 payments using 2006 bills applied to 2007 rates and policies). Plaintiffs similarly seek the formula used to update those estimates. The rulemakings yet again reference "simulations" that HHS used to compute the estimated outlier payments for previous fiscal years, *see, e.g.*, *id.*, and the Court assumes that these calculations are similar, if not identical, to those used to simulate payments prospectively when setting the fixed loss threshold. Therefore, the Court similarly concludes that the administrative record fails to fully delineate the formula used to conduct those acknowledged simulations. Accordingly, the Court grants Plaintiffs' motion with respect to the formulas used to calculate estimated outlier payments for prior fiscal years.

As for the "data" underlying those estimates, supplementation is unnecessary. The rulemaking notices explicitly list which MedPAR files were used to run the simulations. *See, e.g.*, *id.* The administrative record already contains the relevant MedPAR files for each rulemaking. *See* Def.'s Mem. Opp. at 21.

**3. Actuarial Analysis and Data Used to Calculate the CCR Adjustment Factor**

Since 2007, HHS has applied what it refers to as an "adjustment factor" to hospitals' most recent CCRs when estimating outlier payments for the upcoming fiscal year. The adjustment factor is intended "to account for cost and charge inflation." FY 2007 Final Rule, 71 Fed. Reg. at 48,150. As explained in the rulemaking notices, HHS works with "the Office of Actuary to derive the methodology . . . to develop the CCR adjustment factor." FY 2008 Final Rule, 72 Fed. Reg. at 47,417. 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.* Plaintiffs' motion to compel seeks production of the "input from [HHS's] 'actuarial office,'" the memo from that office that HHS used to develop the adjustment factor formula, and "several years of cost report data" used to calculate the average increase in cost per discharge. Pls.' Mem. Supp. at 33; Pls.' Reply at 21.

As HHS rightly points out, however, the final rulemaking notices already describe the full methodology that HHS employs. The Declaration of CMS's Director of the Division of Acute Care, Hospital and Ambulatory Policy Group explains that the memo from the Office of the Actuary simply contains the "market basket update factors." Cheng Decl. ¶ 24. Those figures are publicly reproduced in the rulemaking notices. *See, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 47,417–18 (noting that the 2006 market basket percentage increase was 1.0420 and listing the final market basket increases used in prior fiscal years [1.043 for 2005, 1.04 for 2004, and 1.041 for 2003]). Plaintiffs have not attempted to describe with specificity any other information either purportedly contained in those memos or in fact considered by the agency.[18]

The Court comes to a different conclusion respecting the cost report data. The rulemaking notices do set forth the annual "percentage increase of operating costs per discharge" figures that the agency used to calculate a particular adjustment factor for each relevant fiscal year. *See id.* at 47,418 (listing a percentage increase of 1.0564 from 2004-2005, 1.0617 from 2003-2004, and 1.0715 for 2002-2003). Yet, to the extent the administrative record does not

[18] In their initial motion, Plaintiffs also requested that HHS produce the data that Global Insight, Inc. used to calculate the market basket rate of increase. *See* Pls.' Mem. Supp. at 33. HHS has clarified that it does not consider any of the underlying data used to generate the market basket figure, Cheng Decl. ¶ 24, and Plaintiffs no longer seek to have the record supplemented with that data, *see* Pls.' Mem. Supp. at 21 n.12.

already include the cost report data used to calculate and arrive at those percentage increases, that data should be included in the administrative record.

To be sure, "[t]here is no general requirement that the agency include in the record the data underlying each factor," and, in some instances, a court "does not need to examine the raw data in order to determine whether or not the [agency's] decision was arbitrary and capricious or otherwise not in accordance with law." *Todd v. Campbell*, 446 F. Supp. 149, 152 (D.D.C. 1978). But a court must be precise. If the raw or underlying source data that the parties seek to add was not actually reviewed by the agency, then that data need not be included in the administrative record. *Id.* (explaining that because the Civil Service Commission's staff recommendations were "replete with detail to alert the Commission to the self-evident underlying factual data," there "was no need for the Commission to have seen the data itself" nor for the court "to examine the raw data"). "[A]n agency is not normally obligated to make available the raw data upon which" the documents, reports, or analyses "considered by the agency were based *if the agency itself did not rely* on the raw data when it reached its decision."[19] *Common Sense Salmon Recovery v. Evans*, 217 F. Supp. 2d 17, 22 (D.D.C. 2002) (declining to supplement the record with "the raw genetic data used in some of the studies" the Department of Commerce relied upon when listing a particular species as threatened).

Where, however, the raw data itself is at issue and was directly considered, analyzed, or manipulated by the agency in the course of reaching its decision, that raw or underlying data is "properly considered part of the administrative record." *Ctr. for Biological Diversity v. U.S.*

[19] At least so long as there are no "unique circumstances" suggesting that "the agency had reason to doubt the validity of a study on which it had relied." *Common Sense Salmon Recovery*, 217 F. Supp. 2d at 22 (citing *Endangered Species Comm. v. Babbitt*, 852 F. Supp. 32, 36–37 (D.D.C. 1994)).

*Bureau of Land Mgmt.*, 2007 WL 3049869, at *4 (N.D. Cal. Oct. 18, 2007) (distinguishing *Common Sense Salmon Recovery* where certain tables of raw data contained in Excel Spreadsheets and a series of maps had been directly considered by the agency in the course of designating an off-road vehicle route in the California Desert Conservation Area). This conclusion aligns with the requirement that all materials an agency considered "either directly or indirectly" must be included in the administrative record. *Marcum*, 751 F. Supp. 2d at 78. And, here, the Federal Register notices themselves make plain that HHS specifically used and analyzed the cost report data that the Plaintiffs seek in order to calculate the annual "percentage increase of operating costs per discharge" for prior fiscal years. *See, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 47,418. Thus, Plaintiffs have provided concrete and non-speculative evidence that the underlying cost report data was directly considered by the agency. The Court will grant the Plaintiffs' motion with respect to the cost report data used to calculate the pertinent annual percentage increases of operating costs listed in each of the Threshold Regulations challenged in this case.[20]

**4. Data Used to Calculate Inflation Factors**

As explained above, when HHS uses prior years' payments to simulate IPPS payments for the upcoming fiscal year, the agency accounts for inflation by applying an "inflation factor." The inflation factor is derived from a comparison of the charges submitted during the first two quarters of the fiscal year two years prior (*e.g.*, 2006 for the 2008 rulemaking) with the charges submitted during the first two quarters fiscal year one year prior (*e.g.*, 2007). *See* FY 2008 Final

[20] In addition, since the cost report data is necessary for one to understand how the agency calculated those annual percentage increases, this data constitutes "background information . . . needed 'to determine whether the agency considered all the relevant factors.'" *City of Dania Beach*, 628 F.3d at 590 (quoting *Am. Wildlands*, 530 F.3d at 1002).

Rule, 72 Fed. Reg. at 47,418. The administrative record here already contains the MedPAR data for each fiscal year between 2006 and 2011. *See* Def.'s Mem. Opp. at 24. Yet, the government admits that those MedPAR files differ in certain respects from the MedPAR data that the agency actually used to calculate the charge inflation factor. *See id.* The agency explains that the data it used to calculate the charge inflation factor set forth in the rulemaking notices "is from an early update of MedPAR that is highly sensitive and not publicly available because it contains HIPPA-protected personally-identifiable information." *Id.*; *see also* Cheng Decl. ¶ 25. The agency explains that one can pull the applicable quarters of data from the publicly available MedPAR files contained in the final rulemaking records in order to "closely approximate the inflation factor that CMS calculated." *Id.* at 24–25; Cheng Decl. ¶ 25.

Although Plaintiffs seek to compel the agency to supplement the record with the actual MedPAR files used to calculate the inflation factor, the Court agrees with HHS that supplementation with the early update of the MedPAR files is not warranted. Despite Plaintiffs' claim that the withheld files will leave the record without "the exact data before the agency," Pls.' Reply at 20, it is not clear to the Court that the withheld files differ from the produced files in any way other than form. The agency notes that the MedPAR files already produced include all of the "actual data used by the agency" and that the pertinent quarter's data can be culled from those files to approximate the charge inflation factor. Cheng Decl. ¶ 25. Other than the sensitive HIPPA-protected information, the Court does not understand the actual charge data contained in the MedPAR files to differ. Thus, the record already contains the data that the agency actually considered, and Plaintiffs' motion is denied with respect to the early update of the MedPAR files.

### 5. Missing or Incomplete Impact Files

Plaintiffs also seek to supplement the administrative record with the source data underlying the Impact Files for each rulemaking challenged in this action. The administrative record here already includes the relevant Impact Files. *See* Certified List of Contents of the Rulemaking Record, ECF No. 25. But Plaintiffs seek the underlying source data for two reasons. First, they contend that "the administrative record does not contain HHS's underlying assumptions and associated data used to compute the conclusory data contained in the Impact Files." Pls.' Mem. Supp. at 36. Second, they claim that there "are material differences between the CCRs set forth in the Impact Files and those set forth in the March updates of the Provider Specific File" ("PSF"). *Id.* at 37.

As an initial matter, the Court again notes that where an agency "itself did not rely on . . . raw data when it reached its decision," that agency is "not normally obligated to make available the raw data" in the administrative record. *Common Sense Salmon Recovery*, 217 F. Supp. 2d at 22. Here, Plaintiffs have not even alleged, never mind demonstrated, that when HHS promulgated each year's rule the agency considered any of the underlying PSF data other than the CCRs that were specifically reproduced in the Impact Files.

Indeed, as Plaintiffs correctly point out, the Impact Files contain data that is "derivative"—that is, the data has been abstracted from other files and merged to form a single Impact File. *See* Pls.' Mem. Supp. at 36. HHS has provided a robust explanation of how the Impact Files are created. Specifically, hospitals submit a Medicare cost report each fiscal period (or more frequently) to a government contractor referred to as a Medicare Administrative Contractor ("MAC"). *See* Cheng Decl. at ¶ 6. The MAC then manually calculates CCRs using that hospital's most recent settled cost report and enters that CCR into the hospital's PSF which

lists both the current and past CCRs, identified by effective date. *Id.* at ¶ 9. As HHS explains, because "cost report settlement . . . can take several years to finalize, the CCRs in the file may repeat across several records for any given provider." *Id.* Every quarter each MAC combines all of the data for the providers that the MAC services into a single "PSF Quarterly Update File" and transmits that file to a second contractor called Enterprise Data Center Group ("EDC"). *Id.* at ¶ 10. EDC then sends those Quarterly Update Files to CMS, and CMS compiles them into a single combined file which lists all of the PSF data for every Medicare provider. Occasionally, there may be problems with the transmission of the data from EDC to CMS or other errors may occur. *Id.* If CMS and EDC are unable to remedy the error in a timely manner, CMS may simply use that provider's prior CCR figure in place of the updated figure—a practice CMS refers to as "backfilling." *Id.* For purposes of the annual rulemaking, CMS then creates a smaller file—the Impact File—which lists only the PSF data, including the CCR, from the most recent update the agency has received. *Id.*

This description persuasively rebuts the Plaintiffs' contention that the underlying source data should be included in the administrative record. Instead, the record makes clear that the agency *only considered* the more recent data that was contained in the Impact File, even if, as the agency readily admits, some of that data was backfilled or substituted with the statewide average CCR. *See* Cheng Decl. ¶ 12; *see also Common Sense Salmon Recovery*, 217 F. Supp. 2d at 22. As a result, Plaintiffs have failed to satisfy their burden of providing concrete evidence that HHS either had the underlying derivative data before it or considered that data when promulgating its final rules. *See Marcum*, 751 F. Supp. 2d at 78.

Nor do the discrepancies Plaintiffs allege that they have identified provide grounds for supplementing the record. Plaintiffs claim that "material discrepancies" exist between the CCRs

listed in the Impact Files and the CCRs reproduced in the publicly available versions of the March update to the relevant Provider Specific File. They further claim that the March update to the files therefore "could not have been the source of all the CCRs set forth in the Impact Files."[21] Pls.' Mem. Supp. at 37. As HHS explains, however, the publicly available version of the Provider Specific File may differ from the static Impact File if a MAC later received a more recent cost report and updated the PSF to reflect that information. For that reason, HHS points out that one must consider the *effective date* listed in the PSF; only the data with an effective date in the early months of each year would have been available to HHS as part of the March update to the PSF and have been included in the Impact File. Cheng Decl. ¶¶ 16–18. HHS represents that when effective dates are considered, the number of discrepancies falls dramatically. *Id.* ¶ 19. And HHS further argues that the use of statewide averages or backfilling with earlier data in the place of data that was corrupted during transmission from EDC likely explains the remaining discrepancies. *Id.*

These explanations accord with HHS's description of the general process by which the Impact Files are compiled and seem to explain why discrepancies may exist between the public file and the Impact File for each fiscal year. *See Lee Mem'l Hosp.*, 2015 WL 3631811, at *10 (noting that "the Provider Specific File data on the CMS website is updated (and may be retroactively corrected) by fiscal intermediaries and therefore cannot be relied upon to mirror the

[21] Plaintiffs claim that 385 CCRs in the 2008 Impact File do not match the CCRs listed in the publicly-available Provider Specific File, and they argue that similar discrepancies exist for each of the fiscal years they have challenged here. *See* Pls.' Mem. Supp. at 37 & n.27. Yet, Plaintiffs have not identified the effective dates of the data that they reviewed, nor do they detail exactly how their comparative analysis was conducted. Such generalized assertions are insufficient to overcome the presumption of regularity. In any event, even assuming that Plaintiffs' contentions are accurate, as just explained it is clear that the agency only considered the data memorialized in the relevant Impact File when it promulgated each Threshold Regulation.

data that was used to generate the Impact Files" (emphasis omitted) (quoting Memorandum Order at 19, *Banner Health*, No. 10-1638, (D.D.C. July 30, 2013), ECF No. 96)). Because the agency considered only the Impact Files that have already been produced when setting the threshold level for each fiscal year, any subsequent updates that were made to the CCRs are immaterial for purposes of assessing the validity of the agency's rules.[22] At bottom, Plaintiffs' contention that the agency considered CCRs other than those memorialized in the Impact Files is speculative. Accordingly, the Court denies the motion to supplement with respect to the Impact Files.

**6. Documents Pertaining to the Regulatory Impact Analyses**

Executive Order 12,866 requires federal agencies to prepare a Regulatory Impact Analysis ("RIA") for major rules, and HHS prepared an RIA for the annual Threshold Regulations and the Payment Regulations at issue in this case. The RIAs are set forth in the rulemaking notices. Plaintiffs have moved to supplement the record with the "data, equations, assumptions, and analyses foundational to" those analyses. Pls.' Mem. Supp. at 39.

[22] Plaintiffs argue that two declarations of CMS's director of the Division of Acute Care, Hospital and Ambulatory Policy Group—one filed in this case and a second in another case in this district—confirm that the agency actually used more recent data than the March updates to create the Impact Files. *See* Pls.' Mem. Supp. at 37–38 (discussing, for March 2007 Impact file, June 2007 effective dates); Pls.' Reply at 18 (referring to effective dates extending until September 2007, the end of the fiscal year). Plaintiffs appear to take the Director's references out of context, however. In both declarations Ms. Cheng consistently maintains that CCRs were calculated with reference to, and that the Impact File only contained, the data CMS had as of the March update to the Impact Files. *See* Cheng Decl. at ¶ 19; Decl. of Ing-Jye Cheng ¶ 15, *Lee Mem'l Hosp. v. Burwell*, No. 1:13-cv-0643-RMC (D.D.C. Jan 23, 2015), ECF No. 53–1. As best the Court can discern, Ms. Cheng's references to "effective dates prior to" June 2007 and "effective dates prior to" October 2007 seem to refer to the dates by which CMS would have received a new quarterly update from EDC that would have displaced the previous March 2007 update. The Court does not read either declaration to suggest that CCRs were sourced from data received after the March 2007 updates. For this same reason, the Court disagrees with Plaintiffs' claim that Ms. Cheng's declaration in this case contradicts her prior declaration in *Lee Memorial*. *See* Pls.' Reply at 18.

Specifically, Plaintiffs point to a single paragraph in each rulemaking's lengthy RIA that references the agency's calculation and consideration of the prior year's *actual* anticipated outlier payments when determining the new regulation's costs and benefits. *See id.* at 40; *see also, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 48,160.

The Plaintiffs appear to be laboring under the mistaken impression that the RIA, itself, is missing from the administrative record. HHS points out, however, that the analysis is reproduced in its entirety as Appendix A to the pertinent year's final rulemaking notice. *See* Def.'s Mem. Opp. at 28; see *also, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 48,157–48,173. The Court does not understand Appendix A to provide merely a summary of the pertinent RIA. To the extent that Plaintiffs seek the "data, equations, assumptions, and analyses" underlying the RIAs, Plaintiffs have not detailed with specificity any particular document they believe was before the agency but has not been produced. The motion to supplement is denied with respect to the RIAs and data underlying those analyses.

**7. Documents Pertaining to Reconciliation of Outlier Payments**

Finally, HHS has explained in each Threshold Regulation rulemaking challenged here that it had chosen not to adjust its projection of anticipated outlier payments during the upcoming fiscal year for "the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement" because it believed that its 2003 correction rules would prevent CCRs from fluctuating significantly. *See, e.g.*, FY 2008 Final Rule, 72 Fed. Reg. at 47,419. As a result, HHS explained that it expects that "few hospitals will actually have these ratios reconciled upon cost report settlement." *See, e.g., id.* Contrary to this assertion, Plaintiffs claim that "HHS has failed to file any of the documents underlying and substantiating its assertion that few hospitals will actually have these ratios reconciled upon cost report settlement," and have moved

to supplement the record with any such documents that exist. Pls.' Mem. Supp. at 42 (internal quotation marks omitted).

In reality, Plaintiffs' argument is geared toward disputing the *adequacy* of the agency's proffered rationale. True, Plaintiffs do contend that two reports issued by the HHS Office of the Inspector General ("OIG") indicate that HHS has consistently failed to reconcile past outlier payments in contravention of the 2003 Payment Regulations. *See* Pls.' Mem. Supp. at 42–43. They further contend that those OIG reports make "clear that either HHS has failed to produce documents that are adverse to its assertion that few hospitals will actually have these ratios reconciled upon cost report settlement," or that "HHS has failed to provide the true rationale as to why it refused to account for the impact of reconciliation when setting the fixed loss thresholds." *Id.* at 43. But Plaintiffs merely speculate that such alternative rationales—or documents memorializing them—exist. Therefore, they have failed to carry their burden of identifying any such documents with specificity. To the extent that Plaintiffs argue that HHS's stated rational 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. *Accord Lee Mem'l Hosp.*, 2015 WL 3631811, at *12 ("Whether HHS's decision may be deemed unreasonable in light of the OIG report is a question to be addressed upon the Court's review of the merits.").

## V. CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part the Plaintiffs' motion to compel production of the complete administrative record. To summarize, Defendant shall supplement the administrative record with the following materials:

(1) The 2003 draft Interim Final Rule;

(2) The 2003 rulemaking Impact File;

(3) The formula(s) the agency used to calculate the fixed loss threshold for the Threshold Regulations;

(4) The formula(s) used to calculate estimated outlier payments for prior fiscal years; and

(5) The cost report data used to calculate each of the annual percentage increases of operating costs per discharge identified in each of the Threshold Regulations.

Defendant shall produce these materials to Plaintiffs and file a certified list of contents with the Court pursuant to the local civil rules. *See* Local Civil Rule 7(n)(1). The parties are to meet and confer and submit on or before November 23, 2015 a proposed timeframe within which to comply with this directive. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: November 9, 2015

RUDOLPH CONTRERAS
United States District Judge