UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LEE MEMORIAL HOSPITAL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 13-643 (RMC)**
	)	
SYLVIA M. BURWELL, Secretary, U.S. Department of Health and Human Services,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiffs, a group of non-profit organizations that own and operate acute care hospitals participating in the Medicare program,[1] contend that the Department of Health and Human Services has underpaid them for Medicare services provided during the fiscal years ending in 2008-2010. The dispute requires a huge leap into Medicare and its regulations, but, in essence, Plaintiffs allege that the Secretary *knew* that her basic approach and formulas produced the wrong results but continued to underpay them for years, notwithstanding.

At issue here is Plaintiffs' Motion to Compel: the Secretary has produced an Administrative Record, which Plaintiffs complain is incomplete. The Secretary of Health and Human Services repeatedly insists the record is more than sufficient for judicial review. For the reasons set forth below, Plaintiffs' motion will be granted in part and denied in part.

[1] While Plaintiffs' Memorandum in Support of its Motion to Compel the Administrative Record [Dkt. 51] states that Plaintiffs "are thirty-four acute care hospitals participating in the Medicare program," *id.* at 1, the Third Amended Complaint [Dkt. 58] states that Plaintiffs are a group of non-profit organizations that own and operate thirty-three acute care hospitals, *id.* ¶ 1.

I. BACKGROUND

It is not necessary to take a reader through the underlying dispute in this case. There are, however, a few fundamental points. Under Medicare, certain hospitals may be reimbursed in part for their operating costs per patient. "Because different illnesses entail varying costs of treatment, the Secretary uses diagnosis-related groups (DRGs) to 'modif[y]' the average rate.'" *Dist. Hosp. Partners, L.P. v. Burwell*, No. 14-5061, 2015 WL 2365718, at *1 (D.C. Cir. May 19, 2015) (quoting *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205-06 (D.C. Cir. 2011)). Hospitals are paid at fixed rates determined by the Secretary based on DRG prospective payment rates, which are intended to reflect the estimated average cost of treating a patient whose condition falls within that DRG. *See* 42 U.S.C. § 1395ww(d). When patient costs become extraordinarily high, hospitals may request an "outlier payment" 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).

"[T]hree particular numbers are important" in calculating outlier payments: "(1) the cost-to-charge ratio, (2) the fixed loss threshold, and (3) the outlier threshold." *Dist. Hosp. Partners*, 2015 WL 2365718, at *2. First, a hospital's cost-to-charge ratio "represents a hospital's average markup" and "is calculated from data in its most recent cost report." *Id.* (internal quotations and citations omitted); *see also* Def. Mem. in Opp. to Pl. Mot. to Compel (Def. Opp.) [Dkt. 53] at 4 ("The Secretary estimates a hospital's costs for a case by multiplying the hospital's charges by a cost-to-charge ratio, which is a fraction that represents the estimated amount that the hospital incurs in costs for every dollar that the hospital bills in charges."). A hospital's cost-to-charge ratio is generally calculated specifically for that hospital based on data contained in its prior cost reports. Def. Opp. at 4 (citing 42 C.F.R. § 412.84(i)).

Second, as noted above, a hospital can request an outlier payment if its charges exceed the sum of the DRG payment rate and a "fixed dollar amount." 42 U.S.C. § 1395ww(d)(5)(A)(ii). The "fixed dollar amount" is otherwise known as the "fixed loss threshold." 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,* 2015 WL 2365718, at *2 (quoting *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1229 (11th Cir. 2009)); *see also* Def. Opp. at 5 ("The fixed loss threshold essentially represents the loss that a hospital must absorb before it is eligible to receive an outlier payment."). The fixed loss threshold is set annually in advance of each fiscal year based on projections about aggregate payments to hospitals and a consideration of past charges. Def. Opp. at 5. The Secretary determines the figure in part by looking at historical data on charges actually submitted by hospitals and then applies an inflation adjustment factor to the data to produce an approximation of what hospital charges might look like in the future. *Id*. The Department of Health and Human Services (HHS) attempts to set the fixed loss threshold at a level such that total outlier payments for the upcoming year will represent 5.1% of projected total DRG payments. Pl. Mem. in Support of Mot. to Compel Complete Admin. Record (Pl. Mem.) [Dkt. 51] at 2 (citing 72 Fed. Reg. 47,130 at 47,419).

The third relevant number—the outlier threshold—is the sum of the fixed loss threshold and the DRG rate. *Dist. Hosp. Partners,* 2015 WL 2365718, at *2. "Any cost-adjusted charges imposed above the outlier threshold are eligible for reimbursement under the outlier payment provision." *Id.* (citing 42 U.S.C. § 1395ww(d)(5)(A)(ii)).[2]

[2] An example is instructive: "Assume that the Secretary sets the fixed loss threshold at $10,000. Assume also that a hospital treats a Medicare patient for a broken bone and that the DRG rate for the treatment is $3,000. The Medicare patient required unusually extensive treatment which

These figures are set by HHS each fiscal year. In this case, Plaintiffs challenge HHS administrative regulations governing outlier payments and the fixed loss thresholds, asserting that those regulations led to an incorrect determination of their outlier payment amounts for 2008-2011. Specifically, they allege that HHS improperly applied two sets of regulations: (1) "Payment Regulations," which establish a model for determining whether individual hospital cases qualify for outlier payments; and (2) "Threshold Regulations," which set the annual fixed loss threshold. Pl. Mem. at 5. They also take issue with HHS amendments to the rules governing outlier payments made in 2003, maintaining that those amendments form the basis for how the fixed loss thresholds were set in 2008-2011. *Id.*

In their Motion to Compel, Plaintiffs argue that HHS failed to produce information used by the agency in determining the fixed loss threshold. They seek the following materials: (1) the draft Interim Final Rule from the 2003 amendments to the payment regulations; (2) the formulas used to calculate the fixed loss thresholds; (3) data used to calculate a cost-to-charge adjustment factor and an inflation factor, which were then used to calculate the fixed loss thresholds; (4) the formulas and data that HHS used to calculate estimated outlier payments, made during previous fiscal years, which HHS considered in determining the fixed loss thresholds for the relevant years; (5) the supporting data which HHS used to determine certain key assumptions for projected outlier payment calculations as set forth in HHS's Impact Files; (6) materials supporting HHS's regulatory impact analysis considered in each of the fixed loss threshold regulations; and (7) materials supporting HHS's statements in the fixed loss threshold

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caused the hospital to impose $23,000 in cost-adjusted charges. If no other statutory factor is triggered . . . the hospital is eligible for an outlier payment of $8,000, which is 80% of the difference between its cost-adjusted charges ($23,000) and the outlier threshold ($13,000)." *Dist. Hosp. Partners,* 2015 WL 2365718, at *3.

regulations that it would not consider the mandatory reconciliation of outlier payments in setting the fixed loss thresholds.[3] Pl. Mem. at 3. The parties conferred extensively but were unable to resolve this dispute. HHS contends that the materials sought were properly excluded from the Administrative Record and avers that "HHS has provided certified administrative records of the rulemaking proceedings for regulations concerning the establishment of fixed loss thresholds for 2008 through 2011 which contain: the agency's proposed rule and final rule; the comments received; and the data that the agency considered in developing the outlier payment amount and rule and the fixed-loss threshold." Def. Opp. at 8 (citing Ex. A, Decl. of Ing-Jye Cheng, Director, Division of Acute Care, Hospital and Ambulatory Care Group, Centers for Medicare and Medicaid Services (CMS), HHS [Dkt. 53-1] (Cheng Decl.) ¶¶ 2–3).

II. LEGAL STANDARDS

A. Jurisdiction and Venue

This Court has jurisdiction to review Plaintiffs' challenge to the agency regulations under the Medicare Act, which incorporates the Administrative Procedure Act (APA). *See* 42 U.S.C. § 1395oo(f)(1); 5 U.S.C. § 706. Venue is proper under 42 U.S.C. § 1395oo(f) and 28 U.S.C. § 1391(c).

[3] Plaintiffs originally also sought the administrative record for the 2003 amendments to the payment regulations as well as the Medicare Claims Processing Manual in effect for FYs 2008-2011. The Secretary has now agreed to supplement the record with those materials, with the exception of the Interim Rule and the Impact File for the 2003 rulemaking. *See* Def. Opp. at 9, 11. Defendants also note that they have supplemented the record with MedPAR data for FYs 2006 and 2007, which had been inadvertently omitted from the rulemaking records for FYs 2008 and 2009, respectively. *Id.* Plaintiffs also requested a comment to the FY 2009 fixed loss threshold regulations, but subsequently withdrew their request upon receipt of HHS's representation that it did not consider the comment for outlier policy purposes. *See* Pl. Reply in Support of Motion to Compel Administrative Record (Pl. Reply) at 21.

B. Standard of Review for Supplementation of Administrative Record

The Administrative Procedure Act requires reviewing courts to "set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. In reviewing agency rulemakings, the APA requires courts to "review the whole record or those parts of it cited by a party." *Id.* "If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision." *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977) (APA requires courts to review "the full administrative record that was before the Secretary at the time he made his decision").

"The 'whole' administrative record . . . consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Stainback v. Sec'y of Navy*, 520 F. Supp. 2d 181, 185 (D.D.C. 2007) (internal quotation omitted); *see also Banner Health v. Sebelius*, 945 F. Supp. 2d 1, 15 (D.D.C. 2013) ("Courts in this Circuit have interpreted the whole record to include all documents and materials that the agency directly or indirectly considered . . . [and nothing] more nor less.") (internal quotations omitted). The record must include "all materials that might have influenced the agency's decision, [ ] not merely those on which the agency relied in its final decision." *Stainback*, 520 F. Supp. 2d at 186 (internal quotation omitted). An "agency may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made." *Blue Ocean Inst. v. Gutierrez*, 503 F. Supp. 2d 366, 369 (D.D.C. 2007). "[A]n agency may exclude arguably relevant information that is not

contained in the agency's files but that may be available from third parties" and "generally may exclude material that reflects internal deliberations." *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 197 (D.D.C. 2005).

"Although an agency may not unilaterally determine what constitutes the administrative record, the agency enjoys a presumption that it properly designated the administrative record absent clear evidence to the contrary." *Id.*; *Pac. Shores Subdivision, Cal. Water Dist. v. U.S. Army Corps of Eng'rs*, 448 F. Supp. 2d 1, 5 (D.D.C. 2006) ("[A]n agency is entitled to a strong presumption of regularity that it properly designated the administrative record."). Accordingly, "[s]upplementation of the administrative record is the exception, not the rule." *Pac. Shores*, 448 F. Supp. 2d at 5.

The D.C. Circuit has held that supplementation of the record is only permitted in one of three "unusual circumstances": "'(1) the agency deliberately or negligently excluded documents that may have been adverse to its decision; (2) the district court needed to supplement the record with background information in order to determine whether the agency considered all of the relevant factors; or (3) the agency failed to explain administrative action so as to frustrate judicial review.'" *Dist. Hosp. Partners*, 2015 WL 2365718, at *7 (quoting *American Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008)); *see also City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010). "To rebut the presumption of regularity, the party seeking supplementation must introduce 'concrete evidence' to 'prove' that the specific documents allegedly missing from the record were 'before the actual decisionmakers' involved in the challenged agency action." *Banner Health*, 945 F. Supp. at 16-17 (quoting *Pac. Shores*, 448 F. Supp. 2d at 6). In making this showing, the party seeking to supplement the record "must 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." *Id.* at 17. A district court's refusal to supplement the administrative record is reviewed for abuse of discretion. *Kempthorne*, 530 F.3d at 1002.

III. ANALYSIS

Plaintiffs seek to compel several types of information from HHS, arguing that the materials should be supplemented to the Administrative Record because they meet one or more of the *Kempthorne* criteria.

A. 2003 Draft Interim Rule

In 2003, HHS initiated a rulemaking for Medicare payment regulations in order to more accurately compensate hospitals for their costs exceeding the fixed loss threshold. In February 2003, then-HHS Secretary Tommy H. Thompson executed a draft Interim Rule and sent it to the Office of Management and Budget (OMB) for its review. The Interim Rule recognized that a small group of hospitals had gamed the system by rapidly inflating charges, making it appear that they had incurred greater costs, so that they would obtain greater outlier payments. As a result, HHS set falsely high fixed loss thresholds, thereby causing insufficient payments to be made to other hospitals that had not inflated their charges but that still provided care that was more expensive than the set Medicare rate.[4] According to Plaintiffs, the Interim Rule concluded that HHS should immediately lower the 2003 fixed loss threshold. However, the Interim Rule was never implemented and the Rule that was ultimately proposed did not lower the threshold or include any of the analysis or data that had underscored the Interim Rule.

[4] The higher the fixed loss threshold, the more expensive patient care must be to qualify for an outlier payment.

HHS has failed repeatedly to include the Interim Rule in the Administrative Record on challenges to outlier payments. *See Banner Health*, 945 F. Supp. 2d at 24-26. Just as in *Banner Health*, Plaintiffs here correctly argue that "this document goes to the heart of establishing the Secretary's promulgation of and continued application of invalid Fixed Loss Threshold Regulations as arbitrary and capricious, because it demonstrates that the agency knew that lowering the threshold would correct the problems engendered by its earlier regulations and believed it was obligated to do so immediately, but did not." *Id.* at 26. Moreover, Plaintiffs provide evidence that the Interim Rule was considered by the agency in the rulemaking process, as it was signed by Secretary Thompson and both the Interim Rule and the proposed rule bear the same Regulatory Identification Number and are mostly identical in content. *See* Pl. Mem. at 23-24. Accordingly, the Hospitals have met their burden of showing that agency decisionmakers considered the material at issue and that the agency failed to include in the record documents that may have been adverse to its decision. *See City of Dania Beach*, 628 F.3d at 590.

HHS argues that inter-agency documents should be granted the same "predecisional" and deliberative status as internal agency documents. Def. Opp. at 11-16. While it is settled law that "materials reflecting an agency's internal deliberations should not be part of an administrative record unless there is a strong showing of bad faith or improper behavior," *see id.* at 13 (citing *San Luis Obispo Mothers for Peace v. U.S. Nuclear Regulatory Comm'n*, 789 F.2d 26, 44 (D.C. Cir. 1986)), that argument carries no weight with respect to proposed drafts of agency rules that are submitted to OMB and then publicly posted on OMB's website. *See* Executive Order (E.O.) 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993) (requiring that after a regulation becomes final, OMB make available to the public all documents exchanged between it and agency during the inter-agency review). The deliberative process privilege is intended to

"ensure open communication between subordinates and superiors, prevent premature disclosure of policies before final adoption, and to avoid public confusion if grounds for policies that were not part of the final adopted agency policy happened to be exposed to the public." *Ctr. for Medicare Advocacy, Inc. v. Dep't of Health and Human Servs.*, 577 F. Supp. 2d 221, 234 (D.D.C. 2008) (citations omitted). A document is properly withheld if "disclosure of [the] materials would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions." *Formaldehyde Inst. v. Dep't of Health and Human Servs.*, 889 F.2d 1118, 1122 (D.C. Cir. 1989) (internal quotation omitted). "[A] document protected pursuant to the deliberative process privilege loses protection if the agency used the document in its dealing with the public." *Banner Health*, 945 F. Supp. 2d at 22 (internal quotation omitted).

Here, neither HHS nor Secretary Thompson would have anticipated that the Department's Interim Final Rule would remain confidential. Indeed, protecting the document as privileged would not further the purpose behind the rule because the draft would be seen by the public. This Court concurs with *Banner Health* that there is no way that "inclusion of the Interim Final Rule from the administrative record would in any way 'expose' HHS's decisionmaking process in a manner that would discourage candid discussion within the agency or otherwise contravene the purpose of the deliberative process privilege." *Health v. Sebelius*, Civil Case No. 10-1638 (CKK), 2013 U.S. Dist. LEXIS 147713 (D.D.C. July 30, 2013); *see also Dist. Hosp. Partners*, 2015 WL 2365718, at *7 n.3 (affirming district court's decision to supplement record with the OMB draft outlier correction rule). Accordingly, the draft Interim Final Rule must be produced as part of the Administrative Record.

B. Impact File for 2003 Rulemaking

Plaintiffs also argue that HHS improperly excluded the Impact File for 2003 Rulemaking. Pl. Reply at 7. Impact Files are Microsoft Excel spreadsheets that contain "'data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs,' including the outlier fixed loss thresholds." *Id.* at 16 (quoting 72 Fed. Reg. 24,680 at 24,828 (AR at 150)). HHS has included in the record the Impact Files for FY 2008-2011 and acknowledges that they, along with other data, "are the bases for HHS's determination of the fixed loss thresholds." Def. Mem. at 16 (citing Cheng Decl. ¶¶ 2–3, 18) ("These are the materials that the Secretary has determined properly comprise the administrative record for each of the fixed loss threshold rulemakings at issue, and they are sufficient for meaningful judicial review."). Indeed, Impact Files are a fundamental part of the HHS process as they contain the data used to estimate outlier payments and fixed loss thresholds. Cheng Decl. ¶¶ 2, 11. Accordingly, now that HHS has also now supplemented the record with the 2003 rulemaking, *see infra* n.3, so too should it provide the 2003 Impact File as Plaintiffs have made a non-speculative showing that the Secretary considered such information. Further, the Court finds that the material is necessary "to determine whether the agency considered all the relevant factors" in taking the challenged actions, *see City of Dania Beach*, 628 F.3d at 590, based on Plaintiffs' contention that the analysis therein "served both as justification for the wholesale revision to the Payment Regulations and for HHS's decision not to lower the turbocharged, hyper-inflated fixed loss threshold." Pl. Reply at 12 ("For example, HHS estimated that implementing the 2003 Rulemaking would 'reduce outlier payments for the remainder [2 months] of FY 2003 by $150 million.'" (quoting 68 Fed. Reg. 34,494, 34,514 (June 9, 2003) (AR 3217))). *See also Banner Health*, 945 F. Supp. 2d at 32-33 (ordering

supplementation of record with Impact File relating to 2003 amendments), *aff'd on reconsideration*, 2013 U.S. Dist. LEXIS 147713 at *28-29.

C. Raw Data, Formulas, Other Materials Underlying Fixed Loss Thresholds and Outlier Payments

1. Formulas

HHS describes its process for determining fixed loss thresholds as follows:

> HHS (i) simulate[s] payments to hospitals at different possible fixed loss threshold amounts by applying the particular fiscal year's rates and policies to actual MedPAR files from two years prior, then inflating the charges on the MedPAR claims by two years, and estimating costs based on cost-to-charge ratios, and then (ii) select[s] the fixed loss threshold at which projected total outlier payments would equal 5.1 percent of total DRG payments.

Def. Opp. at 19. MedPAR files are "data files, which contain records, by FY, relating to claims paid on each Medicare beneficiary inpatient hospital encounter; they establish the universe of hospital inpatient claims which HHS uses to model claims for the upcoming FY." Pl. Mem. at 8-9.

Plaintiffs allege that HHS failed to file the relevant formulas that it "necessarily" relied on in setting the fixed loss thresholds and outlier payments. Pl. Mem. at 26-27. They argue that HHS "superficially" described its process, *id.* at 26, and that without the formulas "neither the hospitals nor the Court can test . . . whether HHS considered all relevant factors." Pl. Reply at 14.

HHS insists that the information provided in the Administrative Record is sufficient for judicial review of its annual Fixed Loss Thresholds without supplementation of the record. It relies on the "presumption of agency regularity and the general rule against supplementation," *see Banner Health*, 945 F. Supp. 2d at 29–30, and other decisions in this Court refusing to order the production of underlying raw data and formulas. Moreover, HHS

asserts, Plaintiffs' motion should be denied in this respect because they have failed to identify the specific documents they want added to the Administrative Record.

While affording HHS the presumption of regularity, it is also true that "[o]f course the Hospitals cannot identify, by file name, the specific documents containing the formulas, because only HHS knows those file names." Pl. Reply at 13. However, Plaintiffs here have met their burden of showing an "unusual circumstance" justifying supplementation of the record. *Kempthorne*, 530 F.3d at 1002. Plaintiffs explain:

> [Data from HHS's published rulemakings] shows a consistent trend of HHS assuming positive (upward) inflation in hospital costs during all the FYs at issue, but a consistent downward trend (in all FYs but one) of deflation in the fixed loss threshold. The fact that the FLT shrunk each year means that some unknown factor was applied during HHS's described step two ("select[ing] the fixed loss threshold at which projected total outlier payments would equal 5.1 percent of total DRG payments"), to counter the effect of the charge inflation factor. Without any explanation as to how HHS projected increased estimated charges and costs but nevertheless lowered the fixed loss threshold, HHS's path in setting the threshold remains hidden.

Pl. Reply at 14 (quoting Def. Opp. at 19). Moreover, Plaintiffs point to "concrete proof," noting that in setting the formulas and running "simulations," "HHS used computer algorithms embedded in one or more software applications." Pl. Reply at 13 (citing 72 Fed. Reg. 47,417 (AR 1145) (FY 2008)).

Because Plaintiffs contest the annual fixed loss thresholds as arbitrary and capricious, the Court agrees that the Administrative Record must include formulas used to derive those numbers, if such formulas exist. As indicated above, the basic contention here is that HHS knew or had reason to know that its annual fixed loss threshold calculations were inaccurate, thereby depriving Plaintiffs (and other hospitals) of legitimate outlier payments, but HHS repeatedly failed to make necessary adjustments. Without these calculations, this dispute cannot

be decided. Plaintiffs have provided a reasonably specific showing that the Agency relied on such formulas in making decisions about the fixed loss thresholds and outlier payments which are directly challenged in this case and have thus met their burden to support supplementation of the record because review of the formulas is necessary for the Court "to determine whether the agency considered all the relevant factors" in taking the challenged actions. *City of Dania Beach*, 628 F.3d at 590.

2. Data Trims

In setting fixed loss thresholds, HHS engages in a process known as "trimming," which "'refers to the practice of disregarding data records that are invalid or otherwise may unduly distort the analysis.'" Def. Opp. at 19 (quoting Cheng Decl. ¶ 19). HHS argues that Plaintiffs are not entitled to supplementation of such materials because "[d]ata trims do not modify data files or produce new data, and instead exclude certain data points from analysis, e.g., Medicare Advantage managed care enrollee data and critical access hospital ('CAH') data, without expunging them from the data set." *Id.* at 19-20.

Plaintiffs recognize that the data trims do not modify or produce new data. They argue that HHS "misapprehended" their supplementation request because they do not seek "new data," but instead seek "the systematic instructions which HHS applied to 'exclude certain data points from analysis.'" Pl. Reply at 13 (quoting Def. Opp. at 19). While HHS provided two examples of certain excluded data—"Medicare Advantage managed care enrollee data and critical access hospital data," Def. Opp. at 19—Plaintiffs request "a complete list of such exclusionary principles" that HHS used in setting fixed loss thresholds. Pl. Reply at 13. Plaintiffs also point out that HHS, in responding to a commenter who discovered a discrepancy

when attempting to simulate outlier payments for FY 2008, stated that the discrepancy could be because the commenter used different data trims than those used by HHS. Pl. Mem. at 27.

Plaintiffs have thus pointed to "concrete evidence" that HHS relied upon various "exclusionary principles" in determining fixed loss thresholds. *Id.* Understanding how HHS applied its methodology is necessary for the Court to weigh the merits of Plaintiffs' case and to understand whether HHS considered all the relevant factors in making its decisions.[5] Accordingly, HHS will be required to supplement the record with all instructions applied by HHS to exclude data from its analysis in conducting data trims.

3. Formulas and Data used to Calculate Estimated Outlier Payments

Plaintiffs further argue that HHS failed to include formulas and data used to calculate the estimated outlier payments made during previous fiscal years. Pl. Mem. at 28. Specifically, Plaintiffs quote an HHS statement explaining that, in estimating FY 2006 outlier payments, the Agency originally relied on "simulations using the FY 2005 MedPAR file," that is, the Agency applied FY 2006 rates and policies to available FY 2005 bills. *Id.* (quoting 72 Fed. Reg. at 47,420 (AR at 1148)). However, HHS subsequently updated its estimate using FY

[5] The Circuit's decision in *District Hospitals Partners*, 2015 WL 2365718, is not to the contrary. There, plaintiff hospitals sought inclusion of "trimmed" versions of MedPAR data files that were already included in the administrative record. *Dist. Hosp. Partners, L. P. v. Sebelius*, 971 F. Supp. 2d 15, 25 (D.D.C. 2013). Plaintiffs argued that the produced "untrimmed" files *included* data that the Secretary drew from to calculate the thresholds at issue, but were not the *actual* data subsets that the Secretary used in her calculations. *Id.* The district court found that plaintiffs "fail[ed] to provide any non-speculative basis for a finding that distinct, smaller 'trimmed' versions of MedPAR files in fact exist." *Id.* at 26. The Circuit affirmed, holding that "the process of 'trimming' involved neither the modification of the [data] files currently in the administrative record, nor the creation of new [data] files not in the record." *Dist. Hosp. Partners*, 2015 WL 2365718, at *8 (internal quotations omitted). The Circuit also held that the trimmed files were "neither background information nor material that is needed because the agency failed to explain itself" and there was "no showing that the exclusion of the trimmed files was done in bad faith." *Id.* Here, however, as set forth above, Plaintiffs do not seek actual data, but rather request a full list of what data points were excluded from the analysis.

2006 bills. *Id.* Plaintiffs contend that "[d]espite the fact that HHS expressly relied on data and formulas ('simulations') to estimate past payments, the agency has refused to provide any of these data and formulas with the administrative records." *Id.* Plaintiffs also maintain that HHS relies on estimated prior overpayments when calculating the annual fixed loss threshold. *Id.* at 29.

HHS argues that its notices of final rulemaking adequately explain that in calculating outlier payments, it applied the past fiscal year rates and policies to the bill information in that year's MedPAR files. Def. Opp. at 21. With respect to the formulas used to calculate estimated outlier payments, the Court cannot adequately determine if HHS applied the relevant factors in determining past outlier payments without knowing how it came up with those calculations. Plaintiffs point to the fact that HHS relied on specific documents to make such estimates. Pl. Reply at 16 ("HHS stated that its estimates were based on 'simulations' (i.e., formulas) using the FYs 2005-2006 MedPAR files and FYs 2006-07 'rates and policies.' In the same rulemaking, HHS also described using 'the [Provider Specific File] for this final rule' in combination with the FY 2006 MedPAR file to estimate FY 2007 outlier payments.") (internal citations omitted). This concrete data demonstrates HHS's consideration of such formulas and such information is needed to determine whether HHS considered relevant factors in taking the challenged actions. Therefore, just as the formulas underlying the calculation of fixed loss thresholds, HHS must supplement the record with formulas or documentation of HHS's calculations of estimated outlier payments in previous fiscal years.

However, as for the data underlying those calculations, "requiring an agency to produce source data upon source data so that its analysis can be replicated in minute detail would appear, in most instances, to exceed the bounds of arbitrary and capricious review." *Banner*

Health, 945 F. Supp. 2d at 28. Indeed "[P]laintiffs' bare desire to replicate each calculation contained within the Secretary's analysis – without more – will not suffice to justify supplementation, as [t]here is no general requirement that the [Secretary] include in the record the data underlying each factor considered in its decision." *Dist. Hosp. Partners, L.P. v. Sebelius*, 971 F. Supp. 2d 15, 24 (D.D.C. 2013) (internal quotation omitted). Plaintiffs here have not shown that raw data underlying the calculations and formulas are necessary for judicial review. Thus, the request for data used in calculated estimated outlier payments will be denied.

D. Data Used to Calculate Annual Cost-to-Charge Adjustment Factors

Plaintiffs also seek data used to calculate a cost-to-charge adjustment factor (used to determine the fixed loss threshold) that was implemented in FY 2007 to account for a consistent decline in cost-to-charge ratios that happened after each projection of the threshold and payment during upcoming fiscal years. Pl. Mem. at 30. Plaintiffs contend that the adjustment factor is small as compared to the actual rate of decline in ratios and that they need the underlying data to understand HHS's methodology. *Id.* at 30-31. Plaintiffs quote HHS explaining how it calculated the FY 2008 cost-to-charge adjustment factor:

> For FY 2008, we calculated the [cost-to-charge] adjustment [factor] by using the operating cost per discharge increase in combination with the final market basket increase determined by Global Insight, Inc., as well as the charge inflation factor described above to estimate the adjustment to the [cost-to-charge ratios]. We determined the operating [cost-to-charge] adjustment by taking the percentage increase in the operating costs per discharge from FY 2004 to FY 2005 (1.0564) from the cost report and dividing it by the final market basket increase from FY 2005 (1.043). We repeated this calculation for 2 prior years to determine the 3 year average of the rate of adjusted change in costs between the market basket rate of increase and the increase in cost per case from the cost report (FY 2002 to FY 2003 percentage increase of operating costs per discharge of 1.0715 divided by FY 2003 final market basket increase of 1.041, FY 2003 to FY 2004 percentage increase of operating costs per discharge of 1.0617 divided by FY 2004 final

> market basket increase of 1.04). For FY 2008, we averaged the differentials calculated for FY 2003, FY 2004, and FY 2005 which resulted in a mean ratio of 1.0210. We multiplied the 3 year average of 1.0210 by the 2006 market basket percentage increase of 1.0430, which resulted in an operating cost inflation factor of 6.49 percent or 1.0649. We then divided the operating cost inflation factor by the 1 year average change in charges (1.062) and applied an adjustment factor of 1.0027 to the operating CCRs from the PSF.

Pl. Mem. at 31 (quoting 72 Fed. Reg. at 47,418 (AR at 1146)). Plaintiffs argue they are entitled to the data from contractor Global Insight, Inc., as well as several years of market basket and cost report data.

HHS argues that the quoted explanation above clearly delineates how it determines the cost-to-charge adjustment factor. The rulemaking records for the fiscal loss thresholds include the final market basket increase and the costs per discharge based on cost reports, which were used to adjust the cost-to-charge ratios. Def. Opp. at 23 (citing Cheng Decl. ¶ 20). What Plaintiffs seek, HHS asserts, is underlying source data that is unnecessary for judicial review. Further, HHS argues, there is no evidence that unspecified data were before HHS decisionmakers: the Federal Register indicates only that HHS considered the final market basket increase and cost reports in setting the fixed loss thresholds.

HHS is correct. While Plaintiffs argue that HHS considered Global Insight data, HHS's explanation clearly states that it only relied upon the "final market basket increase" and relevant cost reports; those have already been provided to Plaintiffs in the Administrative Record. Def. Opp. at 23. Ms. Cheng further confirms that "[f]or purposes of outlier policy, [HHS] does not review raw data used in setting market baskets" but instead "applies the final adjustment factors to adjust the CCRs"—"the raw data used in deriving the market basket inflation factor is not considered in setting the outlier threshold." Cheng Decl. ¶ 20. Thus, Plaintiffs fail to overcome the presumption of regularity afforded to HHS in this respect.

Plaintiffs do not present evidence sufficient to show that such documents "were 'before the actual decisionmakers' involved in the challenged agency action." *Banner Health*, 945 F. Supp. 2d at 17 (quoting *Pac. Shores*, 448 F. Supp. 2d at 6). Moreover, courts generally do "not need to examine the raw data in order to determine whether or not the [Secretary's] decision was arbitrary and capricious or otherwise not in accordance with law." *Dist. Hosp. Partners*, 971 F. Supp. 2d at 24 (internal quotation omitted). HHS cogently explained how it calculates cost-to-charge adjustment factors and raw underlying source data are not needed to determine whether the agency considered the relevant factors. *See Kempthorne*, 550 F.3d at 1002; *see also Dist. Hosp. Partners*, 2015 WL 2365718, at *7 (affirming district court's refusal to supplement record with source data used to approximate cost-to-charge ratios because Secretary explained how ratios were calculated, data were not "critical background information," and there was no evidence that data were deliberately or negligently excluded from record). Therefore, the Court will deny Plaintiffs' request to supplement the Administrative Record with underlying data ssed to calculate cost-to-charge adjustment factors.

E. Data Used to Calculate Inflation Factors

Plaintiffs also seek to supplement the Administrative Record with all MedPAR data relied upon by HHS in calculating annual inflation factors used for setting the fixed loss thresholds. According to HHS, in calculating the proposed FY 2008 outlier threshold, it "simulated payments by applying FY 2008 rates and policies using cases from the FY 2006 MedPAR files" thereby "inflat[ing] the charges on the MedPAR claims by 2 years, from FY 2006 to FY 2008." Pl. Mem. at 32 (quoting 72 Fed. Reg. at 47,417 (AR at 1145)). HHS described its process of inflating the charges in the final FY 2008 stating that "[u]sing the most recent data available, [HHS] calculated the 1 year average annualized rate of change in charges

per case from the first quarter of FY 2006 in combination with the second quarter of FY 2006 (October 1, 2005 through March 31, 2006) to the first quarter of FY 2007 in combination with the second quarter of FY 2007 (October 1, 2006 through March 31, 2007)." *Id.* (quoting 72 Fed. Reg. at 47,418 (AR at 1146)).

Plaintiffs contend that HHS has refused to produce MedPAR data that was used to calculate "the 1 year average annualized rate of change in charges per case," as described above, and that HHS should be required to supplement the record with such data as it was used to calculate annual inflation factors. *Id.* HHS responds that it has included in rulemaking records for the fixed loss thresholds the MedPAR data for each of the fiscal years between FY 2006 and FY 2011, which is the data used by the agency. Pl. Opp. at 24 (citing Cheng Decl. ¶ 21). HHS further explains "the MedPAR data that [HHS] used for the charge inflation calculation is from an early update of MedPAR that is not publicly available, and that the MedPAR data that is used in the final rules (which is the MedPAR data that can be made available publicly for limited uses and is included in the rulemaking records produced to Plaintiffs) could be used to closely approximate the inflation factor that [HHS] calculated." *Id.* Plaintiffs counter that they are entitled to the data that was before the agency.

Again, this Court agrees with *District Hospitals*, 971 F. Supp. 2d at 25, and *Banner Health*, 945 F. Supp. 2d at 29, and concludes that Plaintiffs are not entitled to raw data underlying HHS's calculations, despite the fact that HHS may have used that data as part of its rulemaking process. Plaintiffs broadly claim that the "data established a key variable (the inflation factor) that was used twice in the setting the fixed loss thresholds," Pl. Reply at 20, but they provide no further explanation as to why the raw data is necessary for this Court's review of the outlier threshold determination. *See Dist. Hosp. Partners*, 971 F. Supp. 2d at 25. Because

"there is no general requirement that the agency include in the record the data underlying each factor considered in its decision," *id.* (internal quotation omitted), the Court will deny Plaintiffs' request to supplement the record with data used to calculate inflation factors.

F. Data Underlying Cost-to-Charge Ratios in Impact Files

While the Administrative Record contains the Impact Files for the fiscal years at issue here, it does not include the "underlying assumptions and associated data used to compute the conclusory data contained in the Impact Files." Pl. Mem. at 34. According to Plaintiffs, the cost-to-charge ratios in the Impact Files were drawn from data in the "Provider Specific Files," which are available to the public on the Centers for Medicare and Medicaid Services (CMS) website, but there are material discrepancies between the cost-to-charge ratios set forth in the Impact Files and those in the Provider Specific Files. *Id.*

HHS argues that there is no evidence that the Provider Specific Files requested by Plaintiffs, or any other data from which the impact files were derived, were relied on by HHS decisionmakers. To the contrary, Ms. Cheng's Declaration states that the Provider Specific Files were used to derive cost-to-charge ratios contained in the impact files. Cheng Decl. ¶¶ 12-13. However, Plaintiffs fail to establish how such underlying source data is necessary to assist the Court in determining whether the Agency considered all the relevant factors. Plaintiffs contend that the material discrepancies between the cost-to-charge ratios in the Impact Files and the Provider Specific Files constitute "unusual circumstances" warranting supplementation of the record. The Court disagrees. Ms. Cheng explains that Provider Specific Files are updated quarterly and may also be subject to data trims. Cheng Decl. ¶¶ 10, 15, 19. As the Court in *Banner Health* explained on reconsideration, in denying Plaintiffs' request to supplement the record with source data underlying the Impact Files:

> 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 data that was used to generate the Impact Files. Accordingly, because any alleged inconsistences between the Provider Specific File data on the CMS website and the Impact Files do not undermine the Secretary's account, as stated in the Federal Register, of how the Impact Files were created, the ostensibly "unusual circumstances" on which the Court relied are non-existent.

Health v. Sebelius, Civil Case No. 10-1638 (CKK) 2013 U.S. Dist. LEXIS 147713, at *35 (D.D.C. July 30, 2013) (emphasis added). Here too, the Court will deny Plaintiffs' motion to compel with respect to this data.

G. Regulatory Impact Analyses

Plaintiffs also request that the record be supplemented with the regulatory impact analyses for each of the rulemakings at issue here, as well as all underlying data. For every major rule, agencies must assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity), after which they must prepare a regulatory impact analysis (RIA) detailing their findings. Pl. Mem. at 38. Plaintiffs cite to a statement in the RIA section of the FY 2008 Threshold Regulation stating that FY 2007 outlier payments were lower than projected, which they argue shows that HHS directly considered the RIA in implementing outlier payment regulations. *Id.* at 39.

HHS explains that it already "included with each fixed loss threshold notice of final rule a robust RIA as an appendix to the notice" and argues that what Plaintiffs really seek is underlying source data that is "beyond the scope of what the Court needs for meaningful judicial review." Def. Opp. at 29-30. The Court agrees. There is no suggestion that data underlying each

RIA would help the Court determine whether HHS acted arbitrarily and capriciously, and thus Plaintiffs' motion to compel with respect to such data will be denied.

H. Documents Relating to Reconciliation

When HHS implemented the 2003 amendment to the outlier payment regulations, it also required the reconciliation of outlier payments made to providers upon the settlement of cost reports. This process was intended to have the excess outlier payments of those hospitals that had engaged in "turbocharging" reconciled and recouped, with interest, by HHS. Pl. Mem. at 12. HHS ultimately stated that it would not be "'making any adjustments [to its fixed loss threshold] for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.'" *Id.* at 40 (quoting 72 Fed. Reg. at 24,837 (AR at 159)). HHS explained that it believed that

> due to the policy implemented in the outlier final rule (68 FR 34494, June 9, 2003), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also noted that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are not making any assumptions about the effects of reconciliation on the outlier threshold calculation.

Id. at 13 (quoting 72 Fed. Reg. at 47,419 (AR at 1147)).

Plaintiffs maintain that HHS has failed to file any documents underlying its assertion that few hospitals had their CCR ratios reconciled after cost settlement. This position, Plaintiffs contend, is contradicted by a report from the HHS Office of Inspector General (OIG) identifying $664 million in outlier payments made in FYs 2004-2009 which were not reconciled

in accordance with HHS regulations. Pl. Mem. at 41. Plaintiffs seek either documents adverse to HHS's original statement or documents showing why it refused to account for the impact of reconciliation when setting the fixed loss thresholds at issue here.

HHS argues that the above-quoted language explains why HHS did not factor the effects of cost-to-charge reconciliation into its calculation of the fixed loss thresholds:

> as a result of the policy implemented through the outlier payment regulation [in 2003], (i) HHS expected that "cost-to-charge ratios [would] no longer fluctuate significantly," (ii) consequently it expected that "few hospitals [would] actually have these ratios reconciled upon cost report settlement," (iii) predicting the specific hospitals that would undergo reconciliation in any given year would be difficult, and (iv) the rationale for reconciliation (which is based on the time interval between interim cost-to-charge ratios and actual cost-to-charge ratios) did not apply to the fixed loss thresholds because HHS's simulations assumed accurate measures of hospital costs.

Def. Opp. at 31 (quoting 72 Fed. Reg. at 47,419 (Admin. R. 1147)).

Plaintiffs have not met their burden of demonstrating why supplementation is warranted with respect to their vague request for missing documents regarding reconciliation—they have pointed to no specific documents and fail to "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. HHS has explained that its expectation that "few hospitals" would have their CCR ratios reconciled upon cost report settlement is based on the implementation and effect of its amended policy for outlier payments. Def. Opp. at 31 (quoting 72 Fed. Reg. at 47,419). 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.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' Motion to Compel [Dkt. 51] will be granted in part and denied in part. No later than July 2, 2015, HHS will be required to supplement the record with the following materials: (1) the draft Interim Final Rule from the 2003 amendments to the payment regulations; (2) the Impact File for the 2003 Rulemaking; (3) the formulas used to calculate the fixed loss thresholds; (4) all instructions applied by HHS to exclude data from its analysis in conducting data trims; and (5) the formulas used to calculate estimated outlier payments, made during previous FYs, which HHS considered in determining the fixed loss thresholds for the relevant years.

A memorializing Order accompanies this Memorandum Opinion.

Date: June 11, 2015

/s/
ROSEMARY M. COLLYER
United States District Judge