BANNER HEALTH et al v. SEBELIUS Doc. 83

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BANNER HEALTH f/b/o **BANNER GOOD SAMARITAN MEDICAL CENTER**, *et al.*,

Plaintiffs,

v.

KATHLEEN SEBELIUS, Secretary of the U.S. Department of Health and Human Services,

Defendant.

Civil Action No. 10-01638 (CKK)

MEMORANDUM OPINION
(May 16, 2013)

Plaintiffs are twenty-nine organizations that own or operate hospitals participating in the Medicare program. They have sued the Secretary of the Department of Health and Human Services (the "Secretary"), challenging certain regulatory actions taken by her in the course of administering Medicare's reimbursement scheme. Plaintiffs allege that as a result of the Secretary's flawed promulgation and implementation of various payment regulations, they were deprived of more than $350 million dollars in Medicare "outlier"[1] payments for services provided during fiscal years ending 1998 through 2006. Presently before the Court is Plaintiffs' [60] motion to compel the Secretary to file the complete administrative record and to certify the same. The motion has been fully briefed and ripe for adjudication. Upon a searching review of the parties' submissions, the applicable authorities, and the record as a whole, the Court shall **GRANT-IN-PART** and **DENY-IN-PART** Plaintiffs' motion to compel.

[1] As explained in greater detail *infra* Part I.A., an outlier payment is a supplemental payment granted to a hospital when it treats an extreme case in which its costs, as estimated based upon the hospital's billed charges, exceed the standard Medicare payment by more than a certain dollar amount set by the Secretary, known as the "fixed loss threshold."

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I. BACKGROUND

Although the merits of Plaintiffs' challenge to the Secretary's actions are not currently before the Court, a discussion of the relevant statutory and regulatory background underlying Plaintiffs' claims in this case will help to place the parties' arguments with respect to the pending motion to compel in the proper context. Accordingly, the Court shall recount its explanation of the regulatory scheme and the factual and procedural background, to the extent here relevant, as set out in its prior memorandum opinions. *See Banner Health v. Sebelius*, 797 F. Supp. 2d 97 (D.D.C. 2011); — F. Supp. 2d —, Civ. A. No. 10-01638, 2012 WL 5901034 (D.D.C. Nov. 26, 2012).

A. Statutory and Regulatory Framework

Medicare "provides federally funded health insurance for the elderly and disabled," *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1226-27 (D.C. Cir. 1994), through a "complex statutory and regulatory regime," *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402 (1993). The program is administered by the Secretary through the Centers for Medicare and Medicaid Services ("CMS"). *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011).

From its inception in 1965 until 1983, Medicare reimbursed hospitals based on "the 'reasonable costs' of the inpatient services that they furnished." *Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999) (quoting 42 U.S.C. § 1395f(b)), *cert. denied*, 530 U.S. 1204 (2000). However, "[e]xperience proved . . . that this system bred 'little incentive for hospitals to keep costs down' because '[t]he more they spent, the more they were reimbursed.'" *Id.* (quoting *Tucson Med. Ctr. v. Sullivan*, 947 F.2d 971, 974 (D.C. Cir. 1991)).

In 1983, with the aim of "stem[ming] the program's escalating costs and perceived inefficiency, Congress fundamentally overhauled the Medicare reimbursement methodology."

Cnty. of Los Angeles, 192 F.3d at 1008 (citing Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149). Since then, the Prospective Payment System, as the overhauled regime is known, has reimbursed qualifying hospitals at prospectively fixed rates. *Id.* By enacting this overhaul, Congress sought to "reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost[-]effective hospital practices." H.R. Rep. No. 98-25, at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351.

In calculating prospective payment rates, the Secretary begins with the "standardized amount," a figure that approximates the average cost incurred by hospitals nationwide for each treated patient. *See* 42 U.S.C. § 1395ww(d)(2).[2] To account for regional variations in labor costs, the Secretary then "determines the proportion of the standardized amount attributable to wages and wage-related costs and then multiples that labor-related proportion by a wage index that reflects the relation between the local average of hospital wages and the national average of hospital wages."[3] *Cape Cod*, 630 F.3d at 205 (internal quotation marks omitted; citing, *inter alia*, 42 U.S.C. § 1395ww(d)(2)(H), (d)(3)(E)). Finally, the standardized amount is weighted to "reflect[] the disparate hospital resources required to treat major and minor illnesses." *Cnty. of Los Angeles*, 192 F.3d at 1008 (citing 42 U.S.C. § 1395ww(d)(4)). Specifically, "Medicare patients are classified into different groups based on their diagnoses, and each of these 'diagnosis-related groups' ["DRGs"] is assigned a particular 'weight' representing the relationship between the cost of treating patients within that group and the average cost of

[2] Following Congress's directive, the Secretary "does not calculate the standardized amount from scratch each year," but "[i]nstead . . . calculated the standardized amount for a base year and . . . carrie[s] that figure forward, updating it annually for inflation." *Cape Cod*, 630 F.3d at 205 (citing, *inter alia*, 42 U.S.C. § 1395ww(b)(3)(B)(I), (d)(2), (d)(3)(A)(iv)(II); 42 C.F.R. § 412.64(c)-(d)).

[3] "Unlike the standardized amount, wage indexes are calculated anew each year." *Cape Cod*, 630 F.3d at 205 (citing, *inter alia*, 42 U.S.C. § 1395ww(d)(2)(H), (d)(3)(E)).

treating all Medicare patients." *Cape Cod*, 630 F.3d at 205-06 (citing 42 U.S.C. § 1395ww(d)(4)). Therefore, to calculate how much a hospital should be paid for treating a particular case, the Secretary "takes the [standardized amount], adjusts it according to the wage index, and then multiplies it by the weight assigned to the patient's [DRG]." *Cnty. of Los Angeles*, 192 F.3d at 1009. The result is commonly referred to as the "DRG prospective payment rate." *Id.*

"Congress recognized that health-care providers would inevitably care for some patients whose hospitalization would be extraordinarily costly or lengthy" and devised a means to "insulate hospitals from bearing a disproportionate share of these atypical costs." *Cnty. of Los Angeles*, 192 F.3d at 1009. Specifically, Congress authorized the Secretary to make supplemental "outlier" payments to eligible providers. *Id.* Outlier payments are governed by 42 U.S.C. § 1395ww(d)(5)(A), which provides, in relevant part, as follows:

> (ii) . . . [A] hospital [paid under the Prospective Payment System] may request additional payments in any case where charges, adjusted to cost, . . . exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F)[4] plus a fixed dollar amount determined by the Secretary.
>
> (iii) The amount of such additional payment . . . shall be determined by the Secretary and shall . . . approximate the marginal cost of care beyond the cutoff point applicable under clause . . . (ii).

42 U.S.C. § 1395ww(d)(5)(A); *see also* 42 C.F.R. §§ 412.80-412.86 (implementing regulations).

Each fiscal year, the Secretary determines a fixed dollar amount that, when added to the DRG prospective payment, serves as the cutoff point triggering eligibility for outlier payments.

[4] The referenced subparagraphs contemplate certain add-on payments to offset the costs of graduate medical education and care of low-income patients. *See* 42 U.S.C. § 1395ww(d)(5)(B), (F). These and other intricacies of the outlier payment system are not at issue in this action.

See 42 U.S.C. § 1395ww(d)(5)(A)(ii), (iv); 42 C.F.R. § 412.80(a)(2)-(3). This fixed dollar amount is known as the "fixed loss threshold." If a hospital's approximate costs actually incurred in treating a patient exceed the sum of the DRG prospective payment rate and the fixed loss threshold, then the hospital is eligible for an outlier payment in that case. *See* 42 U.S.C. § 1395ww(d)(5)(A)(ii)-(iii); 42 C.F.R. § 412.80(a)(2)-(3). In this way, the fixed loss threshold represents the dollar amount of loss that a hospital must absorb in any case in which the hospital incurs estimated actual costs in treating a patient above and beyond the DRG prospective payment rate. An increase in the fixed loss threshold reduces the number of cases that will qualify for outlier payments as well as the amount of payments for qualifying cases.

In designing the Prospective Payment System, Congress provided that "[t]he total amount of the additional [outlier] payments . . . for discharges in a 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)(iv). Under the Secretary's interpretation of the statute, which has been upheld by the United States Court of Appeals for the District of Columbia Circuit, "she must establish the fixed [loss] thresholds beyond which hospitals will qualify for outlier payments" at the start of each fiscal year. *Cnty. of Los Angeles*, 192 F.3d at 1009. To do so, the Secretary first makes a predictive judgment about the total amount of payments that can be expected to be paid based on DRG prospective payment rates. *Cnty. of Los Angeles*, 192 F.3d at 1009. She then examines historical data to determine the threshold that "would probably yield total outlier payments falling within the five-to-six-percent range." *Id.* For obvious reasons, "[w]hether the Secretary's projections prove to be correct will depend, in large part, on the predictive value of the historical data on which she bases her calculations." *Id.* In each of the fiscal years at issue in this action, the

Secretary set fixed loss thresholds at a level so that the anticipated total of outlier payments would equal 5.1% of the anticipated total of payments based on DRG prospective payment rates.

As aforementioned, if a hospital's approximate costs actually incurred in treating a patient exceed the sum of the DRG prospective payment rate and the fixed loss threshold, then the hospital is eligible for an outlier payment in that case. *See* 42 U.S.C. § 1395ww(d)(5)(A)(ii)-(iii); 42 C.F.R. § 412.80(a)(2)-(3). The amount of the outlier payment is "determined by the Secretary" and must "approximate the marginal cost of care" beyond the fixed loss threshold. 42 U.S.C. § 1395ww(d)(5)(A)(iii). During the time period relevant to this action, the implementing regulations generally provided for outlier payments equal to eighty percent of the difference between the hospital's estimated operating and capital costs and the fixed loss threshold. *See* 42 C.F.R. § 412.84(k). In this way, "[t]he amount of the outlier payment is proportional to the amount by which the hospital's loss exceeds the [fixed loss] threshold." *Dist. Hosp. Partners*, 2011 WL 2621000, at *2 (citing 42 C.F.R. § 412.84(k)).

B. Procedural Background

Plaintiffs are twenty-nine organizations that own or operate hospitals participating in the Medicare program. Am. Compl., ECF No. [16], ¶ 22. Plaintiffs contend that during fiscal years 1998 through 2006, they were deprived of more than $350 million in outlier payments. *Id.* ¶ 17. Plaintiffs filed appeals with the Provider Reimbursement Review Board ("PRRB"), each challenging the Secretary's final outlier payment determinations for the fiscal years in question. *Id.* ¶¶ 191-92. Because Plaintiffs' administrative appeals called into question the underlying validity of regulations promulgated by the Secretary, the PRRB determined that it was without authority to resolve the matters raised and, upon Plaintiffs' petition, authorized expedited judicial review pursuant to 42 U.S.C. § 1395oo(f)(1). *Id.* ¶¶ 193-95 & Exs. A-B.

Plaintiffs commenced the instant civil action on September 27, 2010, claiming that this Court has jurisdiction under the Medicare Act, 42 U.S.C. § 1395oo(f)(1), and the Mandamus Act, 28 U.S.C. § 1361. *See* Compl., ECF No. [1]. On December 23, 2010, Plaintiffs filed an Amended Complaint as a matter of right, which remains the operative iteration of the Complaint in this action. *See* Am. Compl., ECF No. [16].

As this Court has previously observed, Plaintiffs' Amended Complaint is "sprawling"; it contains over two hundred paragraphs, spans fifty-nine pages, and appends two lengthy exhibits. In the opening paragraph, Plaintiffs claim to seek "judicial review of the final administrative decisions of the Secretary . . . as to the amount of Medicare 'outlier' payments due Plaintiffs for services provided under the Medicare program for fiscal years 1998 - 2006," Am. Compl. ¶ 1, but in fact, the allegations in the Amended Complaint sweep much more broadly. *See Banner Health*, 797 F. Supp. 2d at 104. Plaintiffs do not claim that the Secretary made a clerical error resulting in a miscalculation of their outlier payments; rather, Plaintiffs contend that the agency regulations underlying those calculations were inherently flawed. Specifically, Plaintiffs challenge the validity of a series of regulations establishing the methodology for calculating outlier payments (the "Outlier Payment Regulations"), 42 C.F.R. §§ 412.80-412.86, as well as the Secretary's annual promulgation of the regulations through which she set the fixed loss threshold for the upcoming fiscal year, for fiscal years 1998 through 2006 (the "Fixed Loss Threshold Regulations").[5]

[5] *See* MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1998 RATES, 62 Fed. Reg. 45,966 (Aug. 29, 1997); MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1999 RATES, 63 Fed. Reg. 40,954 (July 31, 1998); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2000 RATES, 64 Fed. Reg. 41,490 (July 30, 1999); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2001 RATES, 65 Fed. Reg. 47,054 (Aug. 1, 2000); CHANGES TO THE HOSPITAL INPATIENT

Regarding the Outlier Payment Regulations, Plaintiffs allege that these regulations contained "vulnerabilities" that made them "uniquely susceptible to manipulation" by unscrupulous hospitals. Am. Compl. ¶¶ 52-98, 138. Specifically, they claim that the Outlier Payment Regulations, in the form they existed prior to 2003,[6] required calculation of a hospital's estimated costs based upon "inherently inaccurate and unaudited data," including uninterrogated data gleaned from non-concurrent cost reports, Am. Compl. ¶¶ 56-84; contemplated that a hospital's cost-to-charge ratio would default to a statewide average whenever that ratio fell more than three standard deviations above or below the nationwide mean, Am. Compl. ¶¶ 85-92; and failed to provide a mechanism that would allow for outlier payments to be audited and adjusted by fiscal intermediaries[7] as a check against aggressive charge inflation, Am. Compl. ¶¶ 93-98. According to Plaintiffs, the confluence of these three "vulnerabilities" in the Outlier Payment

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PROSPECTIVE PAYMENT SYSTEMS AND RATES AND COSTS OF GRADUATE MEDICAL EDUCATION: FISCAL YEAR 2002 RATES, 66 Fed. Reg. 39,828 (Aug. 1, 2001); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2003 RATES, 67 Fed. Reg. 49,982 (Aug. 1, 2002); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2004 RATES, 68 Fed. Reg. 45,346 (Aug. 1, 2003); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2005 RATES, 69 Fed. Reg. 48,916 (Aug. 11, 2004); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2006 RATES, 70 Fed. Reg. 47,278 (Aug. 12, 2005).

[6] The Outlier Payment Regulations were first enacted in 1985 and have been revisited periodically over the years, most notably in 1988 and 2003. *See* MEDICARE PROGRAM; CHANGES TO IMPLEMENT THE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1989 RATES, 53 Fed. Reg. 38,476 (Sept. 30, 1988); MEDICARE PROGRAM; CHANGE IN METHODOLOGY FOR DETERMINING PAYMENT FOR EXTRAORDINARILY HIGH-COST CASES (COST OUTLIERS), 68 Fed. Reg. 34,494 (June 9, 2003). Plaintiffs' allegations are directed principally towards the regulations in the form in which they were enacted in 1988. *See, e.g.*, Am. Compl. ¶¶ 75-85, 98, 107-10.

[7] By way of background, to obtain reimbursement under the Medicare Act, hospitals submit yearly cost reports to fiscal intermediaries – typically private insurance companies acting on behalf of the Secretary. After auditing the cost report, the intermediary issues a Notice of Program Reimbursement, in which it determines the amount owed to the hospital for the reporting year at issue. 42 CFR § 405.1803.

Regulations allowed unscrupulous hospitals to submit excessive reimbursement claims, "led to massive overpayments" to the wrong hospitals, prompted the Secretary to raise the fixed loss threshold at the beginning of each fiscal year as a misguided countermeasure, and ended with Plaintiffs being denied the outlier payments "to which they were entitled." Am. Compl. ¶ 55.

Regarding the Fixed Loss Threshold Regulations, Plaintiffs contend that the Secretary, faced with an "aberrantly high" level of projected outlier payments caused by a flood of excessive reimbursement claims, made no attempt to diagnose the actual source of the problem but instead, as a misguided countermeasure, made "enormous, unprecedented and irrational increases" in the fixed loss threshold for the fiscal years at issue in this action, and did so without providing an adequate, reasoned explanation for the increases. *See* Am. Compl. ¶¶ 14, 69, 112, 114, 119, 121, 125-26, 129-38, 147-48, 155-61. To illustrate this point, Plaintiffs allege that the fixed loss threshold increased by 246% from fiscal year 1997 to fiscal year 2003, even though there was only a modest level of cost inflation during the same period. *See* Am. Compl. ¶¶ 14, 121, 137, 147. Plaintiffs attribute the "irrational" increase in fixed loss thresholds to the following alleged flaws in the Secretary's Fixed Loss Threshold Regulations: they lacked a means for accurately distinguishing between inflation in legitimate reimbursement claims from inflation in illegitimate reimbursement claims; they made no meaningful attempt to correlate the increase in the fixed loss threshold with the rate of cost inflation; and they made no attempt to compare the rate of increase in the fixed loss threshold with the rate of inflation in commonly used inflationary indices (*e.g.*, the CPI-Medical Index). *See* Am. Compl. ¶¶ 128-133. Plaintiffs contend that the Secretary's failure to account for these flaws led to an irrational increase in the fixed loss thresholds for fiscal years 1998 through 2006, which allegedly had the ultimate effect

of reducing the number of Plaintiffs' cases that qualified for outlier payments and the amount of payments for those cases that did qualify. *Id.* ¶ 50.

On January 28, 2011, the Secretary filed a motion to dismiss Plaintiffs' Amended Complaint, which this Court granted in part and denied in part. *See Banner Health v. Sebelius*, 797 F. Supp. 2d 97 (D.D.C. 2011). Specifically, the Court dismissed Plaintiffs' claims seeking payments under the Mandamus Act, 28 U.S.C. § 1361, as well as Plaintiffs' claims under the Medicare Act to the extent that such claims relied on vague allegations challenging the Secretary's "implementation" and "enforcement" of the outlier payment system that are "unconnected to any discrete agency action." *See id*. at 118. The Court otherwise denied the Secretary's motion to dismiss. Further, the Court concluded that, in light of the extraordinary breadth of the allegations in the Amended Complaint, proceeding immediately to the filing of the administrative record and the subsequent briefing of motions for summary judgment would not be the most expeditious manner of proceeding in the action. Rather, the Court considered it appropriate to gain further clarity as to the precise contours of Plaintiffs' claims and to that end ordered Plaintiffs to file a "notice of claims," identifying, in bullet-point format, each circumscribed, discrete agency action that Plaintiffs intend to challenge. *Id*. at 117-18.

On July 27, 2011, Plaintiffs filed their Notice of Claims. For convenience of the Court and parties, and for good reason, Plaintiffs' Notice of Claims does not specify each and every outlier payment challenged by the twenty-nine individual hospital plaintiffs. Rather, the filing groups all agency actions contested in this action by hospital fiscal years ("FYs").[8] While the

[8] The Amended Complaint identifies each specific FY of Medicare reimbursement that each separate hospital plaintiff is challenging. *See* Am. Compl. ¶ 22. According to Plaintiffs, as pleaded, the individual hospitals' FYS do not cover identical periods, but instead end on a variety of dates in any given calendar year. *See* Pls.' Notice of Claims at 2. Plaintiffs further note that any one of the given hospitals' FYs typically spans two federal fiscal years (which ends

challenged outlier payment determinations span nine years, the alleged flaws in the regulatory scheme listed by Plaintiffs repeat year after year. Synthesized thematically, the discrete agency actions enumerated in Plaintiffs' Notice are limited to the following:

- "the Secretary's determination of the number and dollar amounts of outlier program payments for the Plaintiffs' respective FYs [as challenged by each Plaintiff as set forth in Paragraph 22 of the Amended Complaint]"[9];

- "the Secretary's determination, promulgation and application of invalid Fixed Loss Threshold Regulations applicable to patient discharges occurring during the [Federal Fiscal Years] ending September 30 [of 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, and 2007]"[10];

- "the Secretary's promulgation of and continued application of invalid Outlier Payment Regulations, as amended in 1988 [,] further amended in 1994 [,] and further amended in 2003"[11];

- "the Secretary's failure to grapple with and correct for CMS's acknowledged historical mistakes, which resulted in underpayments [ ], in connection with her promulgation and application, in 2003, of amended Outlier Payment Regulations and Fixed Loss Threshold Regulations"[12]; and

Pls.' Notice of Claims, ECF No. [29], at 2-11.

Plaintiffs' Notice of Claims likewise lists among the challenged agency actions "the Secretary's directions, starting in late 2002, to CMS's fiscal intermediaries to reopen hospital

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September 30) and that due to the variety of periods comprising the hospitals' FYs, up to three federal fiscal years of regulations promulgated by the Secretary may be implicated with respect to reimbursement for any given year's grouping of FY for the hospital plaintiffs. *Id*.

[9] Plaintiffs contest this agency action as applicable to outlier payments received from the Secretary for discharges occurring during Plaintiffs' FYs 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, and 2006.

[10] Plaintiffs contest this agency action as applicable to outlier payments received from the Secretary for discharges occurring during Plaintiffs' FYs 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, and 2006.

[11] Plaintiffs contest this agency action as applicable to outlier payments received from the Secretary for discharges occurring during Plaintiffs' FYs 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, and 2006.

[12] Plaintiffs contest this agency action as applicable to outlier payments received from the Secretary for discharges occurring during Plaintiffs' FYs 2003, 2004, 2005, and 2006.

cost reports only for purposes of reconciling and recovering outlier overpayments, but not for purposes of reconciling and recovering outlier underpayments, as set forth in the Secretary's issuance, through CMS, of Program Memorandum A-02-122 (December 3, 2002), Program Memorandum A-02-126 (December 20, 2002), Program Memorandum A-03-058 (July 3, 2003) [, and] Transmittal 707 (Medicare Claims Processing Manual, Chapter 3, § 20.1.2.5(A))".[13] However, on November 26, 2012, the Court granted the Secretary's motion to dismiss all claims premised on this agency action because, among other reasons, Plaintiffs failed to rebut the Secretary's well-reasoned jurisdictional arguments and in fact expressly disclaimed any intent to bring a direct challenge to reopening determinations or instructions as such. *See Banner Health v. Sebelius*, 797 F. Supp. 2d 97 (D.D.C. 2011); — F. Supp. 2d —, Civ. A. No. 10-01638, 2012 WL 5901034 (D.D.C. Nov. 26, 2012). Rather, Plaintiffs explained in their brief in opposition to the Secretary's motion to dismiss that they listed the four CMS documents in their Notice of Claims because, among other reasons, the record produced in this case would be deficient without the CMS issuances and documents related thereto, as such documents are an integral part of the Secretary's rulemakings and implementation of the outlier regulations and statute. *See id.* at 10-11. However, the Court held it would not allow Plaintiffs to achieve supplementation of the administrative record by injecting the action with ill-defined claims, but rather, whether the administrative record should be supplemented to include the CMS documents was a question

[13] As aforementioned, *see supra*, n.8, to obtain reimbursement under the Medicare Act, hospitals submit yearly cost reports to fiscal intermediaries – typically private insurance companies acting on behalf of the Secretary. After auditing the cost report, the intermediary issues a Notice of Program Reimbursement, in which it determines the amount owed to the hospital for the reporting year at issue. 42 C.F.R. § 405.1803. The Act gives a dissatisfied hospital 180 days to appeal a reimbursement determination to the PRRB, whose decision is subject to judicial review in federal district court. 42 U.S.C. § 1395oo. A regulation also gives the provider three years within which to ask the intermediary to reopen a determination.

more appropriately addressed in the context of the Court's consideration of Plaintiffs' motion to compel (for which the parties' supplemental briefing was at that time outstanding). *Id*.

Accordingly, in addition to the outlier payment determinations specific to each of the hospital plaintiffs, the remaining claims in this action may be succinctly summarized as challenging the promulgation and implementation of the following agency actions: three sets of Outlier Payment Regulations promulgated in 1988, 1994, and 2003; and eleven sets of Fixed Loss Threshold Regulations for federal fiscal years 1997 through 2007.

After Plaintiffs filed their Notice of Claims, the Court ordered the Secretary to file the complete administrative record (with the exception of the record relating to Plaintiffs' subsequently dismissed claims regarding the four directives issued by CMS) by December 14, 2011. *See* Scheduling and Procedures Order (Aug. 19, 2011), ECF No. [29]. The Secretary filed the administrative records for the fourteen challenged agency actions on November 8, 2011, November 23, 2011, December 14, 2011, and December 28, 2011. *See* Def.'s Notice of Filing of Admin. R., ECF No. [39]; Def.'s Notice of Filing of Admin. R., ECF No. [41]; Def.'s Notice of Filing of Admin. R., ECF No. [45]; Def.'s Notice of Filing Supplement to Admin. Record, ECF No. [48].[14] On January 6, 2012, the Secretary supplemented these productions with additional data in electronic form after the Court entered a protective order pertaining to such data.[15] All together, the fourteen administrative records filed by the Secretary constitute over 10,000 pages of documents, as well as tens of thousands of megabytes of electronic data that have been produced to Plaintiffs. Def.'s Opp'n at 6.

[14] In addition to these rulemaking records, the Secretary also filed records of Plaintiffs' proceedings before the Medicare Provider Reimbursement Review Board, the adequacy of which is not in dispute. *See* Def.'s Notice of Filing Admin. Rs., ECF No. [30].

[15] The Secretary requested, and was granted, leave to dispense with filing the data with the Court because the files together totaled approximately 90 gigabytes in uncompressed form. *See* Min. Order (Jan. 6, 2012).

On February 22, 2012, Plaintiffs filed a motion to compel, challenging the completeness of the administrative record, Pls.' Mot. to Compel Def. to File the Complete Administrative R. and to Certify Same, ECF No. [52], which the Court dismissed without prejudice to renew, in light of the Secretary's represented intent to file supplements to the record. *See* Min. Order (Feb. 24, 2012). The Secretary subsequently filed two additional supplements. *See* Def.'s Notice of Filing Supplements to Admin. R., ECF No. [57]; Def.'s Notice of Filing Supplements to Admin. R., ECF No. [58]. *See also* Def.'s Notice of Filing Certified Copies of Previously Filed Supplements to Admin. R., ECF No. [59].

On March 23, 2012, Plaintiffs filed a renewed motion to compel, requesting that the Court order the Secretary to file the "complete administrative record," by supplementing the records she had previously filed with various documents, including certain data files, identified by Plaintiffs and all other documents that were before the agency in connection with its rulemakings, and further order the Secretary to certify to the Court and Plaintiffs that the administrative record is complete. *See* Pls.' Mem. of P. & A. in Supp. of Renewed Mot. to Compel Def. to File the Complete Admin. R. and to Certify Same ("Pls.' Mem."), ECF No. [60], at 37. The Secretary filed her opposition brief on April 6, 2012. *See* Def.'s Opp'n to Pls.' Mot. Seeking Discovery and Supplementation of Admin. Rs ("Def.'s Opp'n"), ECF No. [61]. Plaintiffs filed their reply on April 13, 2012. *See* Pls.' Reply Mem. in Supp. of Renewed Mot. to Compel Def. to File the Complete Admin. Record and to Certify Same ("Pls.' Reply"), ECF No. [62].

On September 11, 2012, Plaintiffs moved for a status conference, for the purpose of bringing to the Court's attention developments regarding a dispute over the completeness of a substantively similar administrative record filed by the Secretary in *District Hospital Partners,*

L.P. v. Sebelius, Civ. A. No. 11-116 (D.D.C.), a case pending before District Court Judge Ellen S. Huvelle in which another group of hospitals is challenging some of the same actions being challenged in this case, and in which the plaintiff hospitals have filed motions challenging the administrative record filed by the Secretary. *See* Pls.' Mot. for Status Conf., ECF No. [69]. The Court denied Plaintiffs' motion for a status conference but granted Plaintiffs leave to file a supplemental memorandum in support of their motion to compel addressing those developments, which Plaintiffs filed on September 21, 2012. *See* Pls.' Supplemental Mem. ("Pls.' First Supp. Mem."), ECF No. [73]. The Secretary filed her response to Plaintiffs' supplemental memorandum on October 1, 2012. *See* Def.'s Resp. to Pls.' Supplemental Mem. ("Def.'s Resp. to Pls.' First Supp. Mem."), ECF No. [74]. Further, on November 19, 2012, Plaintiffs filed a motion for leave to file a further supplement in support of its renewed motion to compel to put the Court on notice of additional significant developments in the *District Hospital Partners* discovery proceedings that are also purportedly directly relevant to the instant case. The Court granted Plaintiffs leave to file a second supplemental memorandum, *see* Min. Order (Nov. 20, 2012), which Plaintiffs filed on December 13, 2012, *see* Pls.' Second Supp. Mem. in Supp. of Renewed Mot. to Compel ("Pls.' Second Supp. Mem."), ECF No. [78]. The Secretary filed her response to Plaintiffs' second supplemental memorandum on December 17, 2012, *see* Def.'s Response to Pls.' Second Supp. Mem. in Supp. of Renewed Mot. to Compel ("Def.'s Resp. to Pls.' Second Supp. Mem."), ECF [79], and Plaintiffs filed their reply in further support of its second supplemental memorandum on December 21, 2012, *see* Pls.' Reply Re: Second Supp. Mem. in Supp. of Renewed Mot. to Compel, ("Pls.' Reply in Supp. of Second Supp. Mem."), ECF No. [80]. Finally, on April 12, 2013, Plaintiffs filed a Notice, informing the Court of the conclusion of the previously reported discovery proceedings in the *District Hospital Partners*

case. *See* Pls.' Notice of the Conclusion of Previously Reported Discovery Proceedings in the *District Hospital Partners* Case ("Pls.' Notice"), ECF No. [81].

Accordingly, Plaintiffs' [60] motion to compel the Secretary to file the complete administrative record and to certify the same is now fully briefed and ripe for this Court's determination.

II. LEGAL STANDARD

Judicial review of Plaintiffs' claims under the Medicare Act rests on 42 U.S.C. § 1395oo(f)(1), which incorporates the APA. *See* 42 U.S.C. § 1395oo(f)(1) ("Such action[s] . . . shall be tried pursuant to the applicable provisions under chapter 7 of Title 5."); *see also Abington Crest Nursing & Rehab. Ctr. v. Sebelius*, 575 F.3d 717, 719 (D.C. Cir. 2009). In undertaking its review of the agency decision, the APA directs a court to "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706. This requires the Court to review "the full administrative record that was before the Secretary at the time he made his decision." *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). *See also Natural Res. Def. Council, Inc. v. Train*, 519 F.2d 287, 292 (D.C. Cir. 1975) (holding that the district court's review of a "partial and truncated record" was error and remanding the case for review on the "entire administrative record"). 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.'" *Pac. Shores Subdivision, Cal. Water Dist. v. U.S. Army Corps of Eng'rs*, 448 F. Supp. 2d 1, 4 (D.D.C. 2006) (quoting *Maritel, Inc. v. Collins*, 422 *F. Supp. 2d* 188, 196 (D.D.C. 2006)). *See also Camp v. Pitts*, 411 U.S. 138, 142, 93 S. Ct. 1241, 36 L. Ed. 2d 106 (1973) ("The focal point

for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.").

"Supplementation of the administrative record is the exception, not the rule." *Id.* at 5 (quoting *Motor & Equip. Mfrs. Assn. Inc. v. EPA*, 627 F.2d 1095, 1105 (D.C.Cir.1979)). *See also Franks v. Salazar*, 751 F. Supp. 2d 62, 67 (D.D.C. 2010) ("A court that orders an administrative agency to supplement the record of its decision is a rare bird."). This is because "an agency is entitled to a strong presumption of regularity, that it properly designated the administrative record." *Pac. Shores*, 448 F. Supp. 2d at 5. "The rationale for this rule derives from a commonsense understanding of the court's functional role in the administrative state [:] 'Were courts cavalierly to supplement the record, they would be tempted to second-guess agency decisions in the belief that they were better informed than the administrators empowered by Congress and appointed by the President.'" *Amfac Resorts, L.L.C. v. Dep't of Interior*, 143 F. Supp. 2d 7, 11 (D.D.C. 2001) (quoting *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 751 F.2d 1287, 1325-26 (D.C. Cir. 1984)). Indeed, "[c]ommon sense dictates that the agency determines what constitutes the whole administrative record, because it is the agency that did the considering, and that therefore is in a position to indicate initially which of the materials were before it – namely, were directly or indirectly considered." *Pac. Shores*, 448 F. Supp. 2d at 6 (citation and quotation marks omitted).

With that said, 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 Institute v. Guttierez*, 503 F. Supp. 2d 366, 369 (D.D.C. 2007). Further, the agency may not exclude information from the record simply because it did not "rely" on the excluded information in its final decision. *Maritel, Inc. v. Collins*, 422 F. Supp. 2d 188, 196

(D.D.C. 2006). Rather, "a complete administrative record should include all materials that might have influenced the agency's decision[.]" *Amfac Resorts*, 143 F. Supp. 2d at 12 (citations and internal quotes omitted). "[I]f the agency decisionmaker based his decision on the work and recommendations of subordinates, those materials should be included as well." *Id.*

"[A]n administrative record may be 'supplemented' in one of two ways—either by (1) including evidence that should have been properly a part of the administrative record but was excluded by the agency, or (2) adding extra-judicial evidence that was not initially before the agency but the party believes should nonetheless be included in the administrative record." *Wildearth Guardians v. Salazar*, 670 F. Supp. 2d 1, 5 n.4 (D.D.C. 2009); *accord Styrene Info. and Research Ctr., Inc. v. Sebelius*, 851 F. Supp. 2d 57, 63-64. Here, Plaintiffs have made clear that they move for supplementation only under the first approach. *See* Pls.' Reply at 7. That is, Plaintiffs argue that the myriad of documents and data they allege are missing from the administrative record should be included therein because they were considered, either directly or indirectly, by the Secretary in connection with the challenged rulemakings.[16]

Supplementation of the record is appropriate only under three "unusual circumstances": "(1) if the agency deliberately or negligently excluded documents that may have been adverse to its decision, (2) if background information was needed to determine whether the agency considered all the relevant factors, or (3) if the agency failed to explain administrative action so

[16] This is an important distinction, as the two approaches are governed by different standards. *See Styrene*, 851 F. Supp. 2d at 63-64. For a court to review extra-record evidence, the moving party must prove applicable one of several recognized exceptions to the general prohibition against extra-record review, including, *inter alia*, that the agency acted in bad faith. *See id.* (citations omitted). Because these exceptions govern only the introduction of extra-record evidence, and because here, Plaintiffs have made clear that they seek only to supplement the record with materials that they contend were actually before the decisionmakers, the Secretary's argument that Plaintiffs' motion should be denied because Plaintiffs failed to make a showing of bad faith is misplaced. *See* Def's Opp'n at 14-16.

as to frustrate judicial review." *City of Dania Beach v. F.A.A.*, 628 F.3d 581, 590 (D.C. Cir. 2010) (internal quotes and citation omitted). Further, 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. *Pac. Shores*, 448 F. Supp. 2d at 6 (quoting *Sara Lee Corp. v. Am. Bakers Ass'n*, 252 F.R.D. 31, 34 (D.D.C. 2008)). *Cf. County of San Miguel v. Kempthorne*, 587 F. Supp. 2d 64, 72 (D.D.C. 2008) (explaining that "a party seeking to supplement the record must establish that the additional information was known to the agency when it made its decision, the information directly relates to the decision, and it contains information adverse to the agency's decision.").

In this regard, Plaintiffs 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. *See Blue Ocean*, 503 F. Supp. 2d at 369 (finding that the plaintiff failed to overcome the presumption that the administrative record was complete where the plaintiff offered no more than conclusory allegations that the administrative record lacked unspecified reports, notes of discussions, and other documents that "must have" existed in connection with the robust debate concerning the assumptions and analyses underlying the agency action); *see also Franks*, 751 F. Supp. 2d at 73-74 (finding that the plaintiffs failed to overcome the strong presumption of regularity to which the agency was entitled in compiling its record where the plaintiffs had "not offered nonspeculative grounds for their belief that the requested documents exist, much less that the [agency] considered them").

Further, Plaintiffs cannot meet their burden by merely asserting that such documents and data are relevant, were possessed by the entire agency at or before the time the agency action was taken, and were inadequately considered. *See Pac. Shores*, 448 F. Supp. 2d at 7; *accord Franks*, 751 F. Supp. 2d at 67. Rather, for the Court to entertain a request for supplementation, "beyond [a] description and the date of the proffered exhibits," Plaintiffs must describe "when the documents were presented to the agency, to whom, and under what context." *Pac Shores*, 448 F. Supp. 2d at 7 ("Although Plaintiffs imply that the Corps possessed some of the documents because Plaintiffs obtained them through a Freedom of Information Act request, there is no evidence that the Corps' decisionmaker(s) were actually aware of the fourteen documents Plaintiffs seek to include."). Further, Plaintiffs must offer "reasonable, non-speculative" grounds for their belief that the documents were directly or indirectly *considered* by the Secretary. *See id.* If Plaintiffs "can present such proof showing that [the Secretary] 'did not include materials that were part of its record, whether by design or accident, then supplementation is appropriate.'" *Nat'l Min. Ass'n v. Jackson*, 856 F. Supp. 2d 150, 156 (D.D.C. 2012) (citing *Marcum v. Salazar*, 751 F. Supp. 2d 74, 78 (D.D.C. 2010)).

III. DISCUSSION

Plaintiffs' motion asserts what this Court views as three separate but related requests for relief. First, Plaintiffs request that the Court issue an order compelling the Secretary to file the "complete administrative record" by supplementing the record with all documents that were before the agency in connection with its rulemaking. Second, Plaintiffs request that the Court issue an order compelling the Secretary to supplement the record with thirty-six specific categories of missing documents and data files identified by Plaintiffs in the Revised Exhibit A to their motion, *see* Pls.' Second Supp. Mem., Revised Ex. A (hereinafter "Revised Exhibit A"),

ECF No. [78-1]. Third, Plaintiffs request that the Court compel the Secretary to file with the Court appropriate certification that the administrative record is complete. The Court shall address each request in turn, beginning with the last.

A. Motion to Compel the Secretary to Certify that the Administrative Record is Complete

Plaintiffs contend that the certifications accompanying the administrative record are inadequate because they indicate only that the records "constitute a true and correct copy of materials relating to the captioned case," or, for certain supplements to the record, only that those records were "used" in connection with the rulemakings. *See* Pls.' Mem. at 31-32 (citing Exs. E & F (A.R. Certifications)). Plaintiffs argue that the wording of these certifications provides no assurance to the Court or to Plaintiffs that the Secretary has filed the "complete" administrative record. For this reason, Plaintiffs request that the Court compel the Secretary to certify to the Court and to Plaintiffs that the administrative record is complete.

This request is meritless. Although the Department of Health and Human Services ("HHS"), like many other federal agencies, files certifications with administrative records as a matter of practice, certifications are not required by the APA or any other law. Plaintiffs have cited no authority suggesting otherwise and in fact expressly acknowledge in their briefing that courts in this district have held that "there is no legal authority compelling the defendants to certify an administrative record in the first instance." *See* Pls.' Mem. at 31 n.22 (citing *County of San Miguel*, 587 F. Supp. at 77). Nor have Plaintiffs cited any authority for the proposition that a purportedly inadequately worded certification – or even the complete absence of a certification – defeats the presumption of regularity to which the administrative record is entitled, and this Court has found none. *Cf. Ravulapalli v. Napolitano*, Civ. A. No. 10-447, 2012 WL 35564 at *5

(D.D.C. Jan. 9, 2012) ("The lack of certification, without more, certainly does not rise to the level of "clear evidence" necessary to overcome the presumption of regularity.").

For the foregoing reasons, the Court shall deny Plaintiffs' request to compel the Secretary to certify that the administrative record is complete.

B. Motion to "Complete" the Administrative Record

Plaintiffs also request that the Court issue an order compelling the Secretary file the "complete" administrative record. While Plaintiffs do identify several specific documents or categories of documents which they contend belong in the record, *see infra*, Part III.C, they also assert a much more sweeping request that the Secretary "complete" the record by adding all other documents which, although not specifically identified by Plaintiffs, were before the agency in connection with the various rulemakings at issue in this case. This broader request – that the Secretary "complete" the record – need not detain the Court long, as Plaintiffs have failed to rebut the presumption of regularity with regard to the record as a whole.

Plaintiffs argue that the presumption of regularity has been rebutted for three reasons. First, Plaintiffs argue that the Secretary should not be permitted to invoke the presumption of regularity because the certifications accompanying the administrative records filed in this action provide no assurance that the Secretary has filed the "complete" administrative record. However, for reasons already explained and because there exists no authority compelling an agency to certify an administrative record in the first instance, the Court declines to hold that a purportedly inadequate certification defeats the presumption of regularity to which the Secretary's administrative record is entitled. *See supra*, Part III.A.

Second, Plaintiffs argue that the administrative record filed by the Secretary deserves no presumption of regularity because the agency has lost several documents – including three to five

boxes of rulemaking records for the FY 2004 fixed loss threshold, a major public comment for the FY 2005 rulemaking record, and a report by the RAND Corporation for the record pertaining to the 1988 amendments to Outlier Payment Regulations. Pls.' Mem. at 4. Although the Secretary has supplemented the record with a small number of the missing public comments – some of which were discovered in connection with separate litigation – Plaintiffs contend that many others remain missing. *Id*. Plaintiffs argue that the fact that the agency lost these documents and has provided no log, rulemaking index, or other record establishing what documents were before the agency during its rulemakings demonstrates a lack of diligence in creating and maintaining the rulemaking record. *Id*.

Before filing any records in this matter, the Secretary acknowledged that she was unable to locate some public comments received during the annual Inpatient Prospective Payment System rulemaking for FY 2004. *See* Def.'s Notice Regarding Filing of Administrative Rs. 1-2, ECF No. [37]; Def.'s Notice of Filing of Adminsitrative Rs. 1, ECF No. [39]; Def.'s Notice of Filing Supplement to Administrative R., ECF No. [48]. *See also* Decl. of Jim Wickliffe, Deputy Director of Regulations Development Group, Office of Strategic Operations and Regulatory Affairs, ECF No. [39-1]. The Secretary further represents, through counsel and in connection with her briefing regarding the instant motion, that she has conducted a thorough search and has exhausted all reasonable avenues for attempting to locate the lost public comments submitted in connection with the FY 2004 rulemaking. *See* Def.'s Opp'n at 7 n.6. The Secretary has also represented, through counsel, that she has produced all of the comment logs that the agency was able to locate. *See* Pls.' First Supp. Mem. at 5 & Ex. B (Aug. 21, 2012 Hr'g Tr. at 26:17-19). Regarding the RAND Corporation report, the Secretary concedes that the Federal Register notice regarding the 1988 amendments to the Outlier Payment Regulations suggests that the Secretary

considered research materials created by the RAND Corporation (as well as by the Congressional Research Service and the Urban Institute). *See* Def.'s Notice of Filing Supplements to Administrative Rs. 2, ECF No. [58]; *see also* Def.'s Opp'n at 7. However, the Secretary represents that she has been unable to locate and identify any such research materials, despite having made all reasonable efforts to search for them. *See* Def.'s Opp'n at 7; *see also* Def.'s Notice of Filing Supplements to Administrative Rs. 2, ECF No. [58].[17]

In summary, the Secretary has openly acknowledged, from the outset, the inadvertent loss of certain documents from the record for the 1988 amendments to the Outlier Payment Regulations and the administrative record for the fiscal year 2004 Fixed Loss Threshold Regulations. The Secretary has also represented, through counsel, that the Secretary has conducted a thorough search and has exhausted all reasonable avenues for attempting to locate the lost documents or copies thereof. *See* Def.'s Opp'n at 7 & n.6. Plaintiffs have offered no reason to doubt these representations or to believe that the agency is deliberately withholding documents that belong in the record. Nor have Plaintiffs provided sufficient grounds, based on the present record, for the Court to conclude the loss of the documents at issue renders the record so bare as to make effective judicial review impossible, in which case the proper course would be to remand to the agency for additional investigation or explanation. *See Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 338-39 (D.C. Cir. 1989). More to the point, Plaintiffs

[17] The record on this is not entirely clear, as Plaintiffs indicate in a footnote that the Secretary produced (but did not file in the administrative record) two studies – one by the RAND Corporation and the second by the Congressional Research Service. The Secretary apparently asserted that she was not filing these reports, as they were not found in files connected with the 1988 rulemaking or otherwise in the Secretary's possession. *See* Pls.' Mem. at 29 n.21. As discussed *infra*, Part III.C.5, because Plaintiffs have failed to offer any evidence or argument to support their apparent belief that the documents produced by the Secretary are in fact the research materials referenced in the Federal Register and were considered by the Secretary in connection with the challenged rulemaking(s), supplementation of the record with these two studies is not appropriate.

have failed to direct the Court to any authority suggesting that the acknowledged loss of some documents from one of many extensive administrative records constitutes grounds to supplement the administrative record with other material that was not considered by the agency. Accordingly, the Court declines to find that the loss of these documents, or the Secretary's filing of supplements adding documents to some of the administrative records, defeats the presumption of regularity to which the Secretary is entitled. *See, e.g.*, *Tomac v. Norton*, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) ("The fact that the defendants have supplemented the record with approximately 70 pages of additional information does not raise significant questions as to the completeness of the record, particularly when the supplementary material is accompanied by affidavits stating that searches were completed to ensure that no additional documents were omitted.").

Finally, Plaintiffs point the Court to the record in *District Hospital Partners v. Sebelius*, Civ. A. No. 11-116 (D.D.C.), a case pending before District Court Judge Ellen S. Huvelle in which another group of hospitals is challenging some of the same actions being challenged in this case. Through various supplemental pleadings, Plaintiffs have informed the Court of discovery proceedings that have taken place over the past year in *District Hospital Partners* regarding the parties' disputes over the completeness of the administrative record. In brief, Magistrate Judge Robinson, to whom the case was referred pursuant to Local Civil Rule 72.2(a), ordered limited discovery on the issue of whether or not the administrative records are complete. *See* Order (Apr. 23, 2012), ECF No. [52], Civ. A. No. 11-116 (D.D.C.). All in all, Magistrate Judge Robinson ordered three phases of discovery, consisting of the service of interrogatories and depositions of James Wickliffe, who signed the certifications in both *District Hospital Partners* and the present action in his capacity as Deputy Director of CMS's Regulations

Development Group, and two witnesses designated by the Secretary pursuant to Federal Rule of Civil Procedure 30(b)(6) – Michelle Shortt and Tzvi Hefter. *See* Pls.' Second Supp. Mem. at 1-2.

Plaintiffs argue that, by ordering discovery, Magistrate Judge Robinson necessarily rejected the Secretary's argument that there exists no "concrete evidence" to overcome the presumption of regularity. Pls.' First Supp. Mem. at 4. The Court finds this argument unavailing. Preliminarily, this Court is not bound by findings made by magistrate judges in connection with discovery-related motions in separate cases. More to the point, the record in *District Hospital Partners* reveals that Magistrate Judge Robinson did *not*, in fact, make any determination that the administrative record filed by the Secretary in that case is incomplete, apart from the Secretary's acknowledged loss of the same FY 2004 public comments discussed above. Nor has Magistrate Judge Robinson found that the *District Hospital Partners* plaintiffs have defeated the presumption of regularity with respect to the administrative records for any of the rulemakings at issue in that case. To the contrary, during a March 13, 2013 hearing, Magistrate Judge Robinson held that there would be no further discovery on the issue of completeness of the record and further stated, in pertinent part:

> Finally, the Court notes, and does so only because there have been references to findings that the Court has made regarding completeness of the record, perhaps it bears repeating, that the Court ordered discovery for the sole purpose of a determination of whether the administrative record is complete. There are abundant authorities in this District for the proposition that a Court may well do so in certain circumstances, one of which was presented here, however, the Court has made no finding that the record which was filed by the Defendant is incomplete, and the Court has made no finding with respect to whether or not any presumption of completeness is or is not warranted. The Court's finding concerned only the very narrow matter which this Court was asked to address, and that is whether there was a basis upon which to allow discovery as to whether or not the administrative record is complete. …
>
> The Plaintiffs now have a basis to proceed with any arguments that are warranted by the discovery, that would support an argument that the record is not complete, or that certain documents should not have been withheld from production. Those are all matters that

> will be addressed in due course, in accordance with the briefing schedule that the assigned District Judge will set[.]

Id. at 37:24-39:2.

Accordingly, while this Court shall consider certain relevant testimony elicited during the course of the *District Hospital Partners* discovery proceedings for the purpose of making its individualized determinations as to whether Plaintiffs have offered concrete, non-speculative proof that each of the documents listed in its Revised Exhibit A was considered by the Secretary in connection with the rulemakings at issue,[18] the Court declines to find that the rulings made thus far in *District Hospital Partners* necessitate a wholesale defeat of the presumption of regularity. Therefore, the Court shall deny Plaintiffs' broad request that the Court compel the Secretary "complete" the record by adding any and all documents which, although not specifically identified by Plaintiffs, were before the agency in connection with the various rulemakings at issue in this case.

C. Motion to Compel the Secretary to Supplement the Administrative Record with Documents and Categories of Documents Listed in Revised Exhibit A

Turning to Plaintiffs' third, more specific request, Plaintiffs seek to supplement the administrative record with the following categories of materials: (1) documents exchanged between the Secretary and the Office of Management and Budget ("OMB"), which Plaintiffs allege reflect the Secretary's consideration of data, analysis and conclusions contrary to its published rulemakings, *see* Revised Exhibit A, Items 1-3; (2) data and data analysis, including (a) certain data, formulas, and algorithms allegedly used by the Secretary in connection with the rulemakings, *see id*., Items 4-11; (b) certain raw electronic data generally known as "LDS

[18] The Secretary does not dispute that the Court may consider the testimony of the *District Hospital Partners* deponents for this purpose, and as Plaintiffs correctly observe, such testimony is admissible, as party admissions of HHS, to establish facts regarding the as-filed administrative record. *See* Fed. R. Evid. 801(d)(2).

MedPAR" data (the "Electronic MedPAR Data" or "MedPAR Data"), *see id*., Items 12-13; (c) certain Microsoft Excel spreadsheets and related documents containing assumptions used in determining the Inpatient Payment System outlier payment reimbursement rates (the "Impact Files"), *see id*., Items 14-15; and (d) certain data tables included in the Federal Register pertaining to the Fixed Loss Threshold Regulations and the underlying data considered to calculate the data tables, *see id*., Items 16-17; (3) a publicly available memorandum from the HHS Office of Inspector General to the CMS Administrator and certain documents referenced therein, *see id*., Items 18-20; (4) certain allegedly missing public comments and documents relating thereto, *see id*., Items 21-25; (5) certain documents referenced in the Federal Register notices pertaining to the rulemakings at issue, *see id*., Items 26-35; and (6) all internal and external studies, reports, and analysis that were before the agency in connection with the agency actions at issue in this case, *see id*., Item 36. The Court shall separately address each of these categories, but before doing so, pauses to make several overarching observations which shall guide its analysis.

The Court shall first briefly express its concerns regarding two arguments heavily relied upon by the Secretary in her briefing. First, citing to cases involving the well-established deliberative process privilege, the Secretary broadly asserts that several of the documents and data requested by Plaintiffs are not properly included in the administrative record simply because they are "internal agency materials." *See* Def.'s Opp'n at 19-23. But this is far too generous an interpretation of the deliberative process privilege. While it is true that "deliberative intra-agency memoranda and other such records are ordinarily privileged, and need not be included in the record," *Amfac Resorts*, 143 F. Supp. 2d at 13, "[t]wo requirements are essential to the deliberative process privilege: (1) the material must be predecisional and (2) it must be

deliberative." *In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997). A document is predecisional "if it was generated before the adoption of an agency policy and deliberative if it reflects the give-and-take of the consultative process." *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 151 (D.C. Cir. 2006) (quotation marks omitted). Further, a document protected pursuant to the deliberative process privilege "loses protection if the agency used the document in its dealing with the public." *County of San Miguel*, 587 F. Supp. 2d at 75 (citations and internal quotes omitted). Accordingly, the Secretary's assertion that internal agency materials fall outside the definition of an administrative record even when they are publicly available is incorrect. *See* Def.'s Opp'n at 20.

The Secretary's second sweeping argument is that many of the documents and data requested by Plaintiffs do not belong in the administrative record merely because they were created and considered in connection with the *proposed* rules, but not the *final* rules that are the subject of this case. *See* Def.s' Opp'n at 26-28. In support, the Secretary relies on *Globalstar, Inc. v. FCC* for the proposition that a rulemaking record does not begin until publication of a proposed rule. 564 F.3d 476, 485 (D.C. Cir. 2009). However, the Secretary's reliance on *Globalstar* is misplaced, as that case simply did not consider whether materials considered by the agency to formulate a proposed rule belong in the administrative record. Quite to the contrary, the *Globalstar* Court found the petitioner's view of the relevant record in that case too narrow, explaining instead that the challenged agency action was more appropriately viewed as an "outgrowth" of an "ongoing rulemaking proceeding" "dating back" to a notice of a separate but related proposed rulemaking approximately four years earlier. *See* 564 F.3d at 486.

Furthermore, the Court finds that the Secretary's 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. *See Occidental Petroleum Corp. v. Secs & Exch. Comm'n*, 873 F.2d 325, 338 (D.C. Cir. 1989) ("[I]n order to allow for meaningful judicial review, the agency must produce an administrative record that delineates the path by which it reached its decision."). Other courts in this district appear to agree that the timing of the document is not necessarily determinative in this regard. *See Earthworks v. U.S. Dep't of the Interior*, 279 F.R.D. 180, 190 (D.D.C. 2012) (rejecting the defendants' argument that a memorandum should not be made part of the administrative record because it predates the initiation of the rulemaking process, reasoning that "[t]he issue is not the date of a particular document but rather, whether, irrespective of its date, the administrative record is complete without it"). *Cf. Nat'l Ass'n of Chain Drug Stores et al. v. U.S. Dep't of Health & Human Servs. et al.*, 631 F. Supp. 2d 23, 27 (D.D.C. 2009) (public comments and other documents generated after issuance of final rule but prior to rule's revision were part of the administrative record in action challenging rule and revisions thereto, and the agency was therefore required to produce the documents, even if the agency did not base its revisions on comments received during this period); *Ad Hoc Metals*, 227 F. Supp. 2d at 140 (rejecting the argument that "late-filed comments always can be ignored for purposes of the administrative record" and supplementing the record with a document that was presented at an agency-sponsored workshop, held after the comment period had closed, where evidence suggested that the agency considered the document prior to promulgation of final rule).

Notwithstanding the above-identified shortcomings of certain of the Secretary's arguments in opposition, the Court is cognizant of the fact that the burden rests not with the Secretary to establish affirmatively the completeness of the as-filed administrative record, but rather with Plaintiffs to rebut the presumption of regularity to which that record is entitled. As

discussed *supra*, Part II, to do this, Plaintiffs must show the presence of one of three "unusual circumstances" justifying departure from the general rule against supplementation of the record – specifically, that (1) "the agency deliberately or negligently excluded documents that may have been adverse to its decision, (2) [that] background information was needed to determine whether the agency considered all the relevant factors, or (3) [that] the agency failed to explain administrative action so as to frustrate judicial review." *City of Dania Beach*, 628 F.3d at 590. Additionally, Plaintiffs must introduce "concrete evidence" that the specific materials that are the subject of their motion were considered by the Secretary in taking one or more of the challenged agency actions. *Pac. Shores*, 448 F. Supp. 2d at 6. For reasons discussed below, the Court finds that Plaintiffs have in fact made the requisite showing with respect to some of those materials. Plaintiffs' showing with respect to several others, however, is simply too speculative.

1. *Items 1-3:* Documents Exchanged between the Secretary and OMB

The first category of documents that Plaintiffs seek to add to the record includes documents exchanged between HHS and OMB pursuant to Executive Order 12866, which requires HHS to submit major rulemakings to OMB for review ("E.O. 12866 Submissions").[19] *See* Revised Exhibit A, Items 1-3 & Pls.' Mem., Exs. B & I (E.O. 12866 Submissions). Executive Order 12866 also requires that, after the regulation becomes final, OMB must make available to the public all documents exchanged between it and the agency during the inter-agency review. *See* 58 Fed. Reg. 51735, Exec. Order No. 12866 § 6(b)(4)(D). Accordingly, Plaintiffs were able to obtain from OMB the public docket regarding HHS's submissions to OMB for HHS's rulemakings to revise the Outlier Payment Regulations in early 2003, as well as

[19] OMB is tasked with carrying out coordinated review of agency rulemaking to ensure that regulations are consistent with applicable law, the priorities of the President, and the principles set forth in Executive Order 12866. *See* 58 Fed. Reg. 51735, Exec. Order No. 12866 § 2(b).

its Fixed Loss Threshold Regulations for FYs 2003, 2004, and 2005. For these three FYs, OMB's public docket files contain eight documents that were submitted by HHS, pursuant to Executive Order 12866, all of which Plaintiffs have attached as exhibits to their opening memorandum. *See* Pls.' Mem., Exs. B & I (E.O. 12866 Submissions).

Preliminarily, the Court observes that Plaintiffs' briefing regarding this first category of documents discusses exclusively Item 1, which is attached as Exhibit B to Plaintiffs' renewed motion. At no point do Plaintiffs even describe the content of the other seven documents Plaintiffs allege to have obtained from the OMB's public docket, *see* Revised Exhibit A, Item 2, and they certainly have not attempted to align any of these documents with one of the three "unusual circumstances" required for supplementation. Although Plaintiffs have appended the documents as an exhibit to their motion, *see* Pls.' Mem., Ex. I, the Court cannot and shall not itself attempt to discern whether such unexplained exceptional circumstances do, in fact, exist. *See Nat'l Min. Ass'n*, 856 F. Supp. 2d at 158. Plaintiffs' even broader request for supplementation with "all documents comprising, or relating to, input to and from the OMB with respect to the Outlier Payment Regulations and the Fixed Loss Threshold Regulations for FYS 2003, 2004 and all other years here at issue" must be denied for the same reason – as well as due to Plaintiffs' failure to offer non-speculative grounds for their belief that the requested documents exist and were considered by the Secretary in connection with the rulemakings at issue in this case. *See Franks*, 751 F. Supp. 2d at 73-74. Accordingly, the Court declines to supplement the record with Items 2 and 3 of Plaintiffs' Revised Exhibit A.

The Court comes to the opposite conclusion with respect to Item 1 – a sixty-page Interim Final Rule sent, over the signature of then HHS Secretary, Tommy G. Thompson, to OMB for review and approval in early 2003 ("Interim Final Rule"). *See* Pls.' Mem., Ex. B. By way of

background, of the many agency actions challenged in this case is the Secretary's promulgation and application, in 2003, of invalid amended Outlier Payment Regulations and Fixed Loss Threshold Regulations. *See supra*, Part I.B. Plaintiffs argue that, in the Federal Register sections related to the rulemakings challenged in this case, the Secretary has variously stated that (a) there were no critical flaws in its Outlier Payment Regulations – and then, in 2003, that there were three fatal flaws, (b) that the agency had always used the best available data – and then, in 2003, that other data, which had previously been available and was better, should be used, and (c) that it would not make retroactive corrections to outlier payments – and then, in 2003, that retroactive corrections would be made. Pls.' Mem. at 2. Plaintiffs further contend that in mid-2003, while the agency was in the process of reversing its position on each of these points, the Secretary should have taken the opportunity to lower the fixed loss threshold to correct for what the agency openly acknowledged had been the improper distribution of outlier funds to "turbo charging" hospitals, but instead, in June of 2003, promulgated amended regulations which left the threshold at its previous level, $33,560. *See* Pls.' Mem. at 16-17. *See also* A.R. at 4408 (68 Fed. Reg. 34494 at 34506). As explanation, CMS stated 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." A.R. at 4408 (68 Fed. Reg. at 34506).

Plaintiffs contend that the Interim Rule, which was approved by Secretary Thompson on February 6, 2003 and submitted for OMB's review on February 12, 2003, tells a different story. *See* Pls.' Mem. at 3, 15. Specifically, Plaintiffs explain that the Interim Final Rule contains HHS's conclusion, with supporting facts and analysis, that the public interest required it, mid-year, to lower its FY 2003 fixed loss threshold from $33,560 to $20,760 – in other words, that

the threshold was approximately 62% higher than it should have been. *See id*. at 3 (citing Ex. B). Upon the Court's own review of the document, HHS does appear to have proposed to OMB a reduction of the outlier threshold to $20,760, to be effective as of the date of publication of the interim rule. *See* Pls.' Mem., Ex. B at 33-38. Further, HHS acknowledged that the prior increase in the threshold was due to relatively few hospitals with extraordinary rates of increase in their charges, *see id*. at 15-18, causing many truly high-cost cases not to qualify for outlier payments, *see id.* at 58; HHS therefore proposed that the Interim Final Rule reducing the threshold be implemented without prior notice and comment procedures, so as not to extend the duration of these payment inequities, *see id*.

Plaintiffs observe, however, that the Secretary's proposed rule, issued on February 28, 2003 – just over two weeks after HHS submitted the Interim Final Rule to OMB – makes no mention of the data and analysis stated in the Interim Final Rule. *Id*. at 16-17. *See also* A.R. at 4386-4395 (68 Fed. Reg. at 10420-10429).[20] Therefore, Plaintiffs argue, inclusion of the Interim Final Rule in the administrative record is necessary to show significant alternatives, facts, other data and analyses that HHS considered in the rulemaking process, but that were directly contrary to its published regulations which maintained the threshold at $33,650. Plaintiffs also 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. *See id.* at 3, 15-17.

[20] The proposed rule was issued by HHS for publication on February 28, 2003, and subsequently published on March 5, 2003. *See* A.R. at 4395 (68 Fed. Reg. at 10429).

In view of the foregoing, the Court finds that Plaintiffs have made a sufficient showing that "unusual circumstances" warrant supplementation of the administrative record – namely, that "the agency deliberately or negligently excluded documents that may have been adverse to its decision." *City of Dania Beach*, 628 F.3d at 590. *See also, e.g., Public Citizen v. Heckler*, 653 F. Supp. 1229, 1237 (D.D.C. 1986) (supplementing the record with draft of a proposed regulation because the documents were "known to HHS at the time of their decisionmaking, are directly related to the decision made, and are adverse to the agency's position"); *Ad Hoc Metals*, 227 F. Supp. 2d at 139 (requiring the agency to supplement the administrative record with a transcript reflecting presentations of technical issues at a workshop sponsored by the agency, where the transcript was "directly related to the issue decided in the final rule" and "adverse to the agency's position").

Further, Plaintiffs have proffered reasonable, non-speculative evidence that the Interim Final Rule was in fact considered by the Secretary in connection with the 2003 amended Outlier Payment Regulations. The document was signed by the CMS Administrator and the Secretary on the exact same dates they signed the proposed rule (January 24, 2003 and February 6, 2003, respectively); both documents 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), *compare, e.g.*, Pls.' Mem., Ex B, at 33-38, *with* A.R. at 4392-93 (68 Fed. Reg. at 10426-10427). Additionally, Plaintiffs have pointed to Congressional testimony by Thomas Scully, then CMS Administrator, which corroborates the fact that HHS's decision not to lower the fixed loss threshold was a result of input received from OMB. *See* Pls.' Mem., Ex. H

(Tr. of Hearing before Subcomms. on Appropriations and Labor, Health & Human Servs, and Educ., 108th Cong. 108-268, at 12-13 (Mar. 11, 2003)).

Notably, the Secretary offers no substantive rebuttal to any of Plaintiffs' evidence but instead offers two arguments as to why the Interim Final Rule is not properly considered part of the administrative record. First, the Secretary appears to argue that the document is not part of the administrative record because it was transmitted to OMB before HHS even opened rulemaking proceedings for the 2003 amendments to the Outlier Payment Regulations, and that Plaintiffs have made no showing that the document was considered in connection with the final, as opposed to the proposed, regulations, *see* Def.'s Opp'n at 19, 25. However, for reasons explained *supra*, Part III.C, the mere fact that a document predates the notice of proposed rulemaking does not require exclusion from the record.

Second, the Secretary relies on *Sierra Club v. Costle*, 657 F.3d 298 (D.C. Cir. 1981), to argue that all communications with the White House in connection with interagency reviews are excluded from the administrative record, except when the agency explicitly relies on such communications to support its actions. *See* Def.'s Opp'n at 24. But *Sierra Club v. Costle* does not support such a blanket rule, as that case concerned intra-executive branch meetings – not the exchange of written documentation or rules or proposed rules to OMB (or any other documents, for that matter). Further, the Secretary fails to explain why the Circuit's holding in that case – that oral communications between the agency and the President need not be publicly docketed – should be extended to written statements of agency policy, such as the Interim Final Rule, which are in fact required to be made publicly available pursuant to Executive Order 12866. *Cf. Ad Hoc Metals*, 227 F. Supp. 2d at 139 (finding supplementation of the record appropriate in action challenging agency's final rule that lowered reporting thresholds for lead compounds to include

publicly available report by General Accounting Office responding to an agency request for inter-agency review of economic issues pertaining to the lead rule).

In summary, 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. For this reason, and because the Court finds unavailing the Secretary's arguments as to why the document is not part of the administrative record, Plaintiffs' motion to supplement shall be granted with respect to Item 1, the sixty-page Interim Final Rule.[21]

2. *Items 4-17:* Data and Data Analysis

Plaintiffs also seek to compel the Secretary to supplement the administrative record with various categories of data and data analysis, including (a) certain data, formulas, and algorithms allegedly used by the Secretary in connection with the rulemakings, *see id*., Items 4-11; (b) certain raw electronic data generally known as "LDS MedPAR" data (the "Electronic MedPAR data"), *see id*., Items 12-13; (c) certain Microsoft Excel spreadsheets and related documents containing assumptions used in determining the Inpatient Payment System outlier payment reimbursement rates (the "Impact Files"), *see id*., Items 14-15; and (d) certain data tables included in the Federal Register pertaining to the Fixed Loss Threshold Regulations and the underlying data considered to calculate the data tables, *see id*., Items 16-17.

[21] The Court shall take the opportunity to clarify, however, that Plaintiffs' broad request, asserted only in passing in their brief, that the Court also supplement the record with "data and other facts used, and analysis undertaken, by HHS in reaching its conclusions in the Interim Final Rule," *see* Pls.' Mem. at 18, must be denied for the same reason the Court denies Plaintiffs' request, stated in Item 3, for all documents relating to input to and from the OMB – because Plaintiffs have offered no concrete evidence supporting their belief that these unnamed materials exist and were considered by the Secretary in connection with the rulemakings at issue in this case. *See Franks*, 751 F. Supp. 2d at 73-74.

Before addressing each of these categories, the Court shall take the opportunity to note that data files and data analysis considered during agency rulemaking are necessarily subject to the same standards governing supplementation of the administrative record as reports, draft rules, or any other item of information. That is, the agency is entitled to a strong presumption that the record properly designates all data directly or indirectly considered by the decisionmakers (save for data which "so expose[s] the deliberative process within an agency that it must be deemed exempt by [the deliberative process privilege]," *see Mead Data v. Dep't of the Air Force*, 566 F.2d 242, 256 (D.C. Cir. 1977)). And in order to rebut this presumption, a plaintiff must introduce "concrete evidence" showing that the data files or data analysis allegedly missing from the record were considered by the relevant decisionmakers. *See supra* Part II. As with any other material, Plaintiffs must identify alleged omissions with sufficient specificity, as opposed to merely proffering broad categories of data or analysis that are "likely" to exist as a result of documents or other data that are included in the administrative record. *See Blue Ocean*, 503 F. Supp. 2d at 369. *See also, e.g.*, *Styrene*, 851 F. Supp. 2d at 66 (denying plaintiff's request to supplement the record with unspecified "statistical analysis" underlying expert report upon which the agency relied because the request "lack[ed] concrete detail and specificity"). Further, while it is true that data and analysis compiled by subordinates may be properly part of the administrative record despite not having actually passed before the eyes of the Secretary, the data or analysis must be sufficiently integral to the final analysis that was considered by the Secretary, and the Secretary's reliance thereon sufficiently heavy, so as to suggest that the decisionmaker constructively considered it. *See, e.g.*, *Styrene*, 851 F. Supp. 2d at 64 (supplementing the administrative record with expert panel subgroup draft reports because such reports were

specifically identified and were an integral part of the expert panel's recommendations to the agency, upon which the agency based its decision).

Separately, a plaintiff seeking to supplement the record with data or data analysis – as with any other materials – must also demonstrate the presence of one of the three aforementioned "unusual circumstances" justifying a departure from the general prohibition against supplementation. *See City of Dania Beach*, 628 F.3d at 590. Accordingly, the Court shall not order supplementation unless Plaintiffs have made a satisfactory showing that either the allegedly missing data or data analysis may have been adverse to the Secretary's final decisions, that the data or data analysis is necessary to determine whether the agency considered all of the relevant factors, or that the absence of the data or data files results in a failure by the agency to explain the administrative action so as to frustrate judicial review. *Id.* Plaintiffs' desire to replicate each calculation contained within the agency's analysis – without more – will not suffice, as "[t]here is no general requirement that the agency include in the record the data underlying each factor" considered in its decision. *Todd v. Campbell*, 446 F. Supp. 149, 152-53 (D.D.C. 1978), *aff'd* 593 F.2d 1372 (D.C. Cir. 1979) (holding that arbitrary and capricious review did not require an examination of raw data upon which staff recommendations were based where the recommendations contained sufficient detail to alert the decisionmakers to the underlying factual data and the nature of the judgment decisions to be made). Indeed, 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. *See Occidental Petroleum Corp.*, 873 F.2d at 338 ("[I]n order to allow for meaningful judicial review, the agency must produce an administrative record that delineates the path by which it reached its decision.").

Having outlined the applicable framework, the Court shall proceed to its consideration of the various categories of data and data analysis requested by Plaintiffs.

a. *Items 4-11*: Data, Formulas, and Algorithms

As the Plaintiffs acknowledge, the Federal Register excerpts filed by the Secretary describe in basic terms how the Secretary calculated fixed loss thresholds and performed other analyses. *See* Pls.' Mem. at 19. Further, the Secretary represents, through counsel, that she has supplied the data used to make the final fixed loss threshold and outlier payment calculations in dispute. *See, e.g.*, Def.'s Opp'n at 22; Def.'s Resp. to Pls.' Second Supp. Mem. at 4. But Plaintiffs contend that this is not enough. Specifically, Plaintiffs request that the Secretary provide all of the "data, formulas, and algorithms" the agency "used to model and perform calculations" to determine the annual fixed loss thresholds, cost and charge inflationary factors, and perform other calculations underlying the regulations. *See* Revised Exhibit A, Items 4-6,[22] 11. Plaintiffs also request all "data, equations, assumptions[,] analyses" and "computer runs" that "support or refute" the policies implemented through the final regulations, or alternative options thereto. *See id.*, Items 7, 9; *see also id.*, Item 8 (requesting "all data, equations, assumptions, and analyses" underlying the cost-benefit regulatory impact analysis sections of the Federal Register for the proposed and final Fixed Loss Threshold Regulations and amendments to the Outlier Payment Regulations). Most broadly of all, Plaintiffs request "all other studies, data, reports, communications, memoranda, and other documents that were before the agency with respect to each of the administrative records at issue." *Id.*, Item 10.

[22] The Court notes that Item 6 also contains more pointed requests for the "December and March updates to the Provider Specific File" and the "December updates to the MedPAR files." These items overlap with Plaintiffs' requests, in Items 15 and 13, respectively, and shall be addressed in the context of the Court's discussion of the latter.

For all of these requests, Plaintiffs fail to identify specific documents – or even kinds of documents – that might reveal the various formulas, algorithms, and other analysis. Instead, Plaintiffs seem to assume, based upon the basic descriptions of the agency's methodology contained in the Federal Register, that the agency must have documented or memorialized in some way the computations and other analysis underlying that methodology. *See also* Pls.' Reply at 24 (arguing, with respect to their request for data underlying the agency's regulatory impact analyses, that Plaintiffs cannot be expected to identify the exact documents or data files created and relied upon but that "one would hope" the agency's cost-benefit assessments were based upon data and analysis). Simply put, such assumptions do not rise to the level of "concrete evidence" that the underlying analysis allegedly missing from the record was considered by the Secretary.

Equally fatal to their request, for every item within this category, Plaintiffs have not even attempted to demonstrate the presence of any extraordinary circumstances justifying a departure from the general rule against supplementation. The Federal Register excerpts in the record describe the factors considered by the Secretary in establishing the methodology for calculating outlier payments, and beyond an apparent intent to replicate the agency's analysis of source data, Plaintiffs have proffered no explanation as to why the unspecified additional data or analysis they request is necessary to determine whether the agency acted arbitrarily or capriciously in their estimations. While Plaintiffs loosely assert that the absence of the source data and related methodologies "will prevent a full explanation" by HHS of the path it took in taking the challenged agency actions, *see* Pls.' Reply in Supp. of Second Supp. Mem. at 4; Pls.' Second Supp. Mem. at 10, they neglect to explicate as to why this is so. Further, whether the Secretary

has adequately explained and supported her decision is a question more suited for the Court's merits review.

Because Plaintiffs have not provided the "concrete evidence" necessary to overcome the strong presumption of regularity with respect to Items 4 through 11, the Court declines to compel the Secretary to add those items to the record.

b. *Items 12-13:* Electronic MedPAR Data

The Secretary has produced to Plaintiffs certain raw Electronic MedPAR Data files, which Plaintiffs describe as containing records, by FY, relating to claims paid on all Medicare beneficiaries using hospital inpatient services. Plaintiffs contend, however, that the Secretary has not provided any representation that the data produced is the data on which the agency relied for any particular discrete agency action, much less which action. Pls.' Mem. at 11. Plaintiffs also assert that the Secretary has produced only approximately one-half of the Electronic MedPAR Data files it has stated it used in drafting the Fixed Loss Threshold Regulations. *Id*. Accordingly, Plaintiffs request the following: "[t]he missing Electronic MedPAR Data files, together with a representation as to the requisite documentation of the record layouts and field codes for use with the Electronic MedPAR Data already produced (and to be produced) and a representation that each of the Electronic MedPAR Data files produced is the file that was actually used by HHS for one (and which one) of the specific rulemakings here at issue," *see* Revised Exhibit A, Item 12; and "[t]he December update of the MedPAR files used to calculate the annual [fixed loss threshold] in the proposed Inpatient Payment System rulemakings," *see id*., Item 13; *see also id.*, Item 6 (repeating Plaintiffs' request for the December updates to the MedPAR files).

The Court shall first address Plaintiffs' request for the "missing" MedPAR Data files themselves. As is clear from the Secretary's briefing in response, the Secretary has only produced the MedPAR Data files used by the agency in connection with the *final* rulemakings for each year at issue (*i.e.*, March/June updates). The Secretary has not provided Plaintiffs with the data sets used for the *proposed* rules (*i.e.*, December updates). By way of background, the Secretary explains that each year, when the agency issues proposed rules for the Inpatient Prospective Payment System, it uses data available at that time to calculate a proposed fixed loss threshold for outlier payments. *See* Def.'s Opp'n at 26; Def.'s Resp. to Pls.' Second Supp. Mem. at 4. When the Secretary issues the final rules several months later, she calculates the final fixed loss threshold using newer, more up-to-date data that was not yet available at the time the proposed rule was issued. Def.'s Resp. to Pls.' Second Supp. Mem. at 4. The deposition testimony elicited in connection with the discovery proceedings in *District Hospital Partners* confirms that when CMS calculates a final fixed loss threshold, it does not consider data or calculations from formulation of the proposed rule, but rather starts "from scratch" using the more recent data. *See* Def.'s Resp. to Pls.' Second Supp. Mem., Ex. 2 (Tr. of Dep. of Tzvi Hefter, at 161:13-162:11 (Nov. 1, 2012)).

Although the Court has rejected the Secretary's attempt to categorically exclude information from the record merely because such information was considered in connection with a proposed, as opposed to final, rule, *see supra* Part III.C., it does not follow that every informational input considered in connection with promulgation of a proposed rule necessarily belongs in the record. Rather, the key inquiry remains whether Plaintiffs have demonstrated the presence of one of the three previously listed "unusual circumstances" warranting supplementation. Here, the evidence before the Court makes clear that the data set used to

calculate the final thresholds was merely a more current version of the same data set used to calculate the proposed rules. There is no indication that the final data sets considered different factors or otherwise differed qualitatively (as to opposed to merely quantitatively); accordingly, Plaintiffs have not, and indeed could not, demonstrate that the raw data underlying the proposed rules is adverse to the final agency actions, required background information, or otherwise necessary for effective judicial review. *See City of Dania Beach*, 628 F.3d at 590. For this reason, the Court declines to order supplementation of the record with the MedPAR Data files used in connection with the proposed rules.

With respect to the MedPAR Data files used to calculate the final thresholds, which have been produced to Plaintiffs, Plaintiffs contend that the deposition testimony in *District Hospital Partners* revealed that the MedPAR data files in the record "are not the data that HHS actually used." Pls.' Second Supp. Mem. at 9. Plaintiffs base this contention on testimony from one of the Secretary's Rule 30(b)(6) designees, Tzvi Hefter, who explained that the MedPAR data files are "raw data" that HHS "trims" before running it through a series of iterative calculations. *See id*. at 10. However, as the Secretary clarifies in response, "trimming," as that term was used in the deposition testimony, refers to the practice of disregarding data records that are invalid or otherwise may unduly distort the analysis. *See* Def.'s Resp. to Pls.' Second Supp. Mem. at 9. To illustrate, the Secretary points to Mr. Hefter's testimony that one example of "trimming" would be to disregard all entries in a data set that contain a cost value of $1.00, which is more likely to be a placeholder than an actual cost value. *Id.* (citing Ex. 2 (Tr. of Dep. of Tzvi Hefter at 160:4-11 (Nov. 1, 2012))). Mr. Hefter further testified that such numerical thresholds are reflected in the data contained in the as-filed administrative record in the Impact Files. *See id.*, Ex. 2 (Tr. of Dep. of Tzvi Hefter at 160:11-13 (Nov. 1, 2012)). Most notably, Mr. Hefter's

testimony makes indisputably clear that the "trimming" process does not entail modification of data files or production of new data. *See id.* at 149:20-21 ("[T]he file doesn't change: we don't change the data."). Mr. Hefter also confirmed that the MedPAR files contained in the administrative record are the identical files used by the Secretary in determining the fixed loss thresholds at issue in this lawsuit. *See id*. at 53:21-54:5 ("The MedPAR file is … the file that we gave to you. That entire file is used in a data run. In that data run certain elements are pulled from that. But the data file that you were presented is the data that was before the decision maker.").

The Court has reviewed the pertinent deposition testimony and agrees with the Secretary that Plaintiffs are in possession of the MedPAR Data that was considered by the agency when making the pertinent decisions at issue. Plaintiff has failed to provide anything more than speculation that a separate data set or document memorializing the MedPAR data as modified by the "trims" exists, and, for reasons stated *supra*, Part III.C.2, the Secretary's obligation to produce an administrative record does not require the Secretary to provide instructions that can be used to replicate the Secretary's analysis in minute detail.

Accordingly, for all of the foregoing reasons, Plaintiffs' requests to supplement the record with Items 12 and 13 are denied.[23]

[23] Although Item 12 also requests that the Secretary provide the "record layouts and field codes" accompanying the Electronic MedPAR Data, Plaintiffs appear to have withdrawn this request, indicating that they would use certain documentation from 1996, so long as the Secretary does not challenge reliance on the 1996 Documentation. *See* Pls.' Mem. at 23 n.17. As the Secretary sidesteps providing a direct response as to whether it may challenge the Secretary's reliance on the 1996 Documentation, *see* Def.'s Opp'n at 23-24 n.10, the Court shall assume, based upon the present record that Plaintiffs' use of the 1996 documentation to analyze the Electronic MedPAR Data is not contested by the Secretary. Accordingly, the Court need not address Plaintiffs' request for "record layouts and filed codes" for the MedPAR data at this time.

c. *Items 14-15:* Impact Files

Plaintiffs also request that the Court order the Secretary to supplement the record with what the parties have referred to as the "Impact Files" – Microsoft Excel spreadsheets and related documents containing assumptions used in determining the Inpatient Payment System outlier payment reimbursement rates. Specifically, Plaintiffs request: "[t]he Impact Files related to HHS's proposed [Inpatient Prospective Payment System] rulemakings and for the 1988 and 2003 amendments to the Outlier Payment Regulations (proposed and final)," *see* Revised Exhibit A, Item 14; and "[a]ll of HHS's underlying assumptions and associated data used to compute the conclusory assumptions contained in the Impact Files, including the Provider Specific Files, Cost Reports, and Provider Statistical and Reimbursement Reports," *see id*., Item 15.

For the same reasons stated *supra*, Part III.C.2.b, Plaintiffs have failed to demonstrate the presence of "unusual circumstances" warranting supplementation of the record with the Impact Files considered in connection with the *proposed*, as opposed to the *final* rules, and the Court shall reject their request for the Impact Files underlying the proposed regulations on that ground alone. However, for the following reasons, the Court finds that Plaintiffs have satisfied their burden with respect to their request for both the Impact Files relating to the agency's 1988 and 2003 final amendments to the Outlier Payment Regulations, as well as for the underlying data used to compute the assumptions contained in the Impact Files used in connection with all of the final regulations at issue.

Clearly, the Impact Files are a fundamental part of the administrative record, as the Secretary herself has described the Impact Files produced in this action as "containing the assumptions used in determining the Inpatient Prospective Payment System outlier payment reimbursement rates." *See, e.g.*, Indices to Administrative Records, ECF Nos. [45-3], [45-12],

[45-13]. Indeed, the Secretary has appeared to have filed Impact Files relating to all of the final rulemakings at issue, except for those used in connection with the agency's 1988 and 2003 final amendments to the Outlier Payment Regulations. As the Secretary has provided no explanation for her failure to file the latter, the Court agrees with Plaintiffs that they should be added to the record. *See, e.g., Ad Hoc Metals*, 227 F. Supp. 2d at 141 (supplementing the record with comments submitted during agency sponsored meeting where exclusion could not be reconciled with presence in the record of analogous materials from a similar meeting).

Further, as Plaintiffs explain, and the Secretary does not dispute, the Impact Files which the agency has filed with the Court – which are mostly Microsoft Excel files – present data that are largely derivative of underlying data from other files, some of which appears to be publicly available. *See* Pls.' Mem. at 24-25. *See also, e.g.*, 64 Fed. Reg. at 24747 ("This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the Federal Register."). The Court finds the foregoing description constitutes sufficiently reasonable, non-speculative showing that the Secretary, at least indirectly, considered the data underlying the Impact Files.

The Court also finds that Plaintiffs have sufficiently shown the presence of "unusual circumstances" warranting supplementation with the derivative data. For example, Plaintiffs explain that the Impact Files contain data on each hospital's assumed specific cost-to-charge ratio, which is used to calculate projected outlier case payments. However, Plaintiffs contend that for certain years at issue, it cannot be determined from the as-filed Impact Files whether the

assumed cost-to-charge ratio for each hospital states its actual computed hospital-specific ratio, or whether the assumed ratio is the product of an automatic default to the statewide average ratio. While the Secretary has apparently indicated that the ratios in the Impact Files were drawn from data contained in its publicly available "Provider Specific File," Plaintiffs have pointed to material discrepancies between the ratios assumed in the Impact Files and those set forth in the Provider Specific File database. The Secretary has not addressed any of these alleged discrepancies, which, as Plaintiffs fairly contend, may be problematic in view of the fact that one of the claims made in this matter is that the agency failed to use the best available data, as well as the fact that the inaccuracy of the cost-to-charge ratios was identified as the source of several key "vulnerabilities" in prior Outlier Payment Regulations, *see* A.R. at 4398-4404 (68 Fed. Reg. 34496-34502). *See* Pls.' Mem. at 25-26; Pls.' Reply at 18-19. *See also* Pls.' Second Supp. Mem., Ex. F (Tr. of Dep. of Tzvi Hefter at 119:12-120:18 (Nov. 1, 2012)) (indicating that the cost-to-charge ratios for FY 2004 were calculated from data other than the Provider Specific File database). In view of the foregoing explanation, the Court finds that supplementation of the record with the data underlying the Impact Files is necessary under the unique circumstances of this case "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.

Accordingly, the Court shall deny-in-part and grant-in-part Plaintiffs' request for an order directing the Secretary to supplement the record with Items 14 and 15. Specifically, the Secretary shall not be compelled to add to the record the Impact Files related to the agency's proposed rulemakings, but the Secretary shall be ordered to supplement the record with the Impact Files relating to the agency's final 1988 and 2003 amendments to the Outlier Payment Regulations, as well as with all of the agency's underlying assumptions and associated data used

to compute the assumptions contained in the Impact Files – including the Provider Specific Files, Cost Reports, and Provider Statistical and Reimbursement Reports.

d. *Items 16-17:* Data Tables in the Federal Register

Plaintiffs contend that although the Secretary has filed select excerpts from the Federal Register relating to the rulemakings at issue in this case, certain key sections are missing from the record – specifically "Tables 8a and 8b," which were included as appendices to the annual proposed and final Fixed Loss Threshold Regulations for the years 1997 through and including 2003. Pls.' Mem. at 26-27. *See also* Revised Exhibit A, Row 16. Plaintiffs explain that each year, "Tables 8a and 8b" contain updated statewide averages of hospitals' operating and capital cost-to-charge ratios and that, until the Secretary revised the Outlier Payment Regulations in 2003 (effective for FY 2004 and beyond), the Secretary used the statewide average cost-to-charge ratios in Tables 8a and 8b when hospital-specific ratios either were not available or were more than three standard deviations above or below the mean of the log distribution of ratios for all hospitals. Pls.' Mem. at 2 n.20. Indeed, as Plaintiffs correctly observe, the Secretary's notices of proposed and final rulemaking with respect to the Fixed Loss Threshold Regulations contain several express references to Tables 8a and 8b. *See id*. *See also, e.g.*, A.R. at 4916 (66 Fed. Reg. at 22727).

The Secretary does not dispute that Tables 8a and 8b belong in the administrative record. Rather, the Secretary asserts that Plaintiffs' request is meaningless and a waste of the Court's time because the Secretary has repeatedly indicated, in correspondence with Plaintiffs and in filings with the Court, that the contents of the Federal Register are subject to judicial notice and can be considered in the Court's review. *See* Def.'s Opp'n at 32. However, as Plaintiffs appropriately retort, that is not the point. *See* Pls.' Reply at 30. The point is that Tables 8a and

8b are admittedly part of the administrative record in this case, and the Court shall therefore compel the Secretary to file them as part of the administrative record and for the Court's convenient reference.

While the Court agrees with Plaintiffs that the record should be supplemented to include Tables 8a and 8b, Plaintiffs' non-specific request to also add to the record the "underlying data considered to calculate Tables 8a and 8b" will be denied for the same reasons discussed *supra*, Part II.C.2.a. Accordingly, the Court shall grant Plaintiffs' request to compel the Secretary to supplement the administrative record with Item 16, but shall deny Plaintiffs' request to compel the Secretary to add to the record Item 17.

3. *Items 18-20:* Publicly Available OIG Report and Documents Referenced Therein

Attached as Exhibit J to Plaintiffs' renewed motion is a September 9, 2005 memorandum from the HHS Office of Inspector General ("HHS-OIG") to the CMS Administrator entitled, *Audit of the Effectiveness of the Revised Medicare Outlier Payment Regulations for Inpatient Acute Care Hospitals* ("OIG Report"). Therein, the HHS-OIG reports that "[a]s a result of the revised [outlier regulations], CMS estimated that the Medicare program would save at least $9 billion over 5 years (2004 through 2008). This cost savings is based on CMS's estimate of excess outlier payments for FYs 1998 through 2002." Pls.' Mem., Ex J (OIG Report), at 8. The cover letter transmitting the OIG Report states that the HHS-OIG "previously raised concerns to [CMS] about excessive outlier payments in an early alert memorandum dated December 23, 2002." *Id*. at 1. Plaintiffs request that the Court supplement the administrative record with the OIG Report, the "early alert memorandum" referenced in the cover letter to the report, and all documents comprising or relating to the analysis of excess outlier payments referenced in the report. *See* Revised Exhibit A, Items 18-20.

The Court finds that Plaintiffs have failed to rebut the presumption of regularity accorded to the record with respect to these documents. Plaintiffs argue only that, given the "on-point subject matter" and the temporal proximity of the documents to the promulgation of the revised Outlier Payment Regulations, it is clear that the documents were before the agency and were considered, or should have been considered. *See* Pls.' Mem. at 27-28; Pls.' Reply at 22-24. Plaintiffs further argue that the notion that HHS did not consider its own analysis of billions of dollars in cost savings is implausible. *See* Pls.' Mem. at 27-28; Pls.' Reply at 22-24. However, as explained repeatedly throughout this Memorandum Opinion, Plaintiffs cannot meet their burden by merely asserting that certain documents and data are relevant, were possessed by the entire agency at or before the time the agency action was taken, and were inadequately considered. *See Pac. Shores*, 448 F. Supp. 2d at 7; *accord Franks*, 751 F. Supp. 2d at 67. Because Plaintiffs have failed to introduce any reasonable, non-speculative evidence that the report or the analysis or documents referenced therein were actually considered by the Secretary in connection with any of the rulemakings at issue, supplementation is not appropriate. Moreover, as the Federal Register is replete with estimates regarding excess outlier payments resulting from certain hospitals' inappropriately overcharging, *see, e.g.*, A.R. 4389 (68 Fed. Reg. at 10423), it does not appear to be the case that the requested documents contain adverse information not otherwise disclosed. *Cf. Ad Hoc Metals*, 227 F. Supp. 2d at 142 ("Where an agency has considered an issue and included relevant material on the record, supplementation with similar or identical documents is not always required."). Nor have Plaintiffs attempted to show the presence of any other "unusual circumstance" warranting supplementation even if they could demonstrate that the documents were considered by the Secretary.

Accordingly, for the foregoing reasons, Plaintiffs' request for an order compelling the Secretary to supplement the record with Items 18, 19, and 20 is denied.

4. *Items 21-25:* Public Comments

Plaintiffs also request that the Court compel the Secretary to supplement the record with the following public comments and related materials: three documents attached as Exhibit N to Plaintiffs' motion, *see* Revised Exhibit A, Items 22-24; "[t]he public comment logs prepared by the recordkeeping office with respect to each of the administrative records at issue;" *see id.*, Item 21; and "all other missing comments, including those for the FY 2004 and FY 2005 Loss Threshold Regulations," *see id.*, Item 25.

Regarding the documents attached as Exhibit N, because the Secretary does not object to supplementation with respect to two of the three documents, *see* Def.'s Opp'n at 32-33, the Court will order the Secretary to supplement the record with those two documents – specifically, letters from the Medicare Payment Advisory Commission and the American Hospital Association relating to the FY 2004 fixed loss threshold determination, *see* Revised Exhibit A, Items 22, 24. Regarding Item 23 – a February 28, 2003 letter from the United States House of Representative Ways and Means Committee to the CMS Administrator – Plaintiffs make no attempt to explain why this document should be viewed as "public comment" materials, and in fact do not even specifically discuss the document in their briefing at all. The mere fact that the document existed and was in the possession of CMS at or around the time of the relevant rulemakings is itself not enough to require that the document be added to the record. Accordingly, the Court declines to order supplementation of the record with respect to Item 23.

Regarding Plaintiffs' request for the public comment logs, Plaintiffs cite to deposition testimony elicited from Mr. Wickliffe as part of the discovery ordered in *District Hospital*

Partners, that "[n]ormally the organizational component developing a regulation will keep a log of all the comments." *See* Pls.' First Supp. Mem. at 5 (citing Ex. 5 (Tr. of Dep. of James Wickliffe at 127:16-21 (June 14, 2012)). Preliminarily, the Court notes that even if it is true that HHS kept public comment logs for each of the rulemakings at issue, Plaintiffs have offered no authority or argument suggesting that such logs belong in the administrative record. Furthermore, in her briefing, the Secretary represents that she has searched for logs or similar documents listing comments received during the rulemaking proceedings referenced in Mr. Wickliffe's deposition and that the Secretary has provided the results of such search to Plaintiffs – namely, three internal documents that appear to contain partial lists of public comments received during the rulemaking proceedings. *See* Def.'s Resp. to Pls.' First Supp. Mem. at 5 n.3. Because Plaintiffs have proffered no argument as to why the logs are properly part of the administrative record in the first instance, nor any evidence to suggest that the Secretary has not produced all of the logs that she has been able to locate, the Court shall decline to order the Secretary to supplement the record with Item 21.

In a similar vein, as detailed *supra*, Part III.B, the Secretary has represented that she has conducted a thorough search for all public comments and has exhausted all reasonable avenues for attempting to locate the admittedly lost public comments. Because Plaintiffs offer neither argument nor evidence to suggest that the Secretary is concealing or otherwise aware of public comments that have not already been filed as part of the record, Plaintiffs' request for an order compelling the Secretary to supplement the record with "all other missing comments" is denied.

In summary, the Court shall grant as conceded Plaintiffs' request to supplement the record with Items 22 and 24. However, because Plaintiffs have failed to offer non-speculative grounds for their belief that the Secretary considered the remaining items in this category (or that

certain of the items even exist), the Court shall deny Plaintiffs' request for an order compelling the Secretary to supplement the record with Items 21, 23, and 25.

5. *Items 26-35:* Documents Referenced in Federal Register

Next, Plaintiffs request that the Court supplement the record with various documents which Plaintiffs contend are specifically referenced, or otherwise identified, in the Federal Register as having been considered in the process of its rulemakings here at issue. *See* Revised Exhibit A, Items 26-35. Before addressing these documents, the Court first pauses to observe that, as several courts in this district have held, reference to a document in the administrative record does not itself constitute "concrete evidence" that the document was considered by the agency. *See, e.g.*, *Franks*, 751 F. Supp. at 70; *Wildearth Guardians*, 670 F. Supp. 2d at 6; *Cape Hatteras Access Preservation Alliance v. U.S. Dep't of Interior*, 667 F. Supp. 2d 111, 114 (D.D.C. 2009). Plaintiffs therefore cannot meet their burden by pointing to the mere mention of Items 26-35 in the Federal Register; rather, they must offer non-speculative argument for their belief that the Secretary actually considered the materials.

In this regard, several of the documents and categories of documents listed in Revised Exhibit A under this category are nowhere specifically discussed in Plaintiffs' briefing – namely, Items 27, 31, 32, 34, and 35. Instead, Plaintiffs simply list citations to portions of the Federal Register and deposition transcripts from the *District Hospital Partners* discovery proceedings. But for reasons just stated, mere mention in a Federal Register notice is not enough, and the Court need not, and shall not, itself plow through the record in an attempt to determine whether the documents were in fact considered by the Secretary in making the pertinent decisions. Even if it were self-evident from the content of the Federal Register excerpts that the documents exist and were before the agency in connection with the challenged rulemaking(s), Plaintiffs have

made no attempt to align any of these items with one of the three "unusual circumstances" required for supplementation. *See City of Dania Beach*, 628 F.3d at 590. Accordingly, the Court declines to order the Secretary to supplement the record with Items 27, 31, 32, 34, and 35. *See Nat'l Min. Ass'n*, 856 F. Supp. 2d at 158 ("If the plaintiffs do not take their argument seriously enough to do more than mention it in a passing footnote, the Court will not on its own accord attempt to discern whether such unnamed and unargued exceptional circumstances do, in fact, exist.").

Turning to the documents which Plaintiffs do specifically address in their briefing, the Court finds that Plaintiffs have made a satisfactory showing that supplementation is required with respect to the following documents: "the April 22, 2002 Joint Letter from CMS' Center for Medicare Management, Office of Financial Management to the fiscal intermediaries," *see* Item 26, and two of the four CMS documents listed under Item 33. Regarding the April 22, 2002 joint letter, the final FY 2003 Inpatient Prospective Payment System rule publication clearly indicates that the agency considered and rejected a number of comments filed regarding this letter – which purportedly addressed the effect of incorrect cost-to-charge ratios on the annual fixed loss thresholds. *See* A.R. at 4810 (67 Fed. Reg. at 50125). Given the fact that the agency expressly discussed its consideration of the April 22, 2002 letter, as well as the apparently adverse nature of its contents, the Court finds that supplementation is warranted.

Regarding the CMS documents, the Court has reviewed the excerpts of the Federal Register to which Plaintiffs cite and agrees with Plaintiffs that two of these documents – specifically, Program Memoranda A-02-122 and A-02-126 – were addressed in responses to comments expressly referencing the Program Instructions and recommending that the agency adopt the parameters set therein for determining when a hospital's cost-to-charge ratio should be

updated. *See* A.R. at 4401 (68 Fed. Reg. at 34499). Considering the fact that the agency expressly discussed its consideration of these memoranda, as well as the potentially adverse nature of their contents (which relates to the accuracy of the cost-to-charge-ratio data), the Court finds that supplementation is warranted. By contrast, Plaintiffs have failed to make a reasonable, non-speculative showing that the other two CMS documents – specifically Program Memoranda A-03-058 and Transmittal 707 – were considered by the Secretary; in fact, they do not even appear to be specifically referenced in the Federal Register. *See* Pls.' Second Supp. Mem. at 8-9. Plaintiffs' argument that the documents were "implicitly considered" or should be considered as the agency's subsequent "interpretations" of the Outlier statute are unavailing, as this is simply not the standard governing compilation of an administrative record.

Finally, the Court shall turn to Items 28, 29, and 30. As explained *supra*, Part III.B in connection with the Court's discussion about documents lost by HHS, the Secretary concedes that the Federal Register notice regarding the 1988 amendments to the Outlier Payment Regulations suggests that the Secretary considered research materials created by the RAND Corporation (as well as by the Congressional Research Service and the Urban Institute). *See* Def.'s Notice of Filing Supplements to Administrative Rs. 2, ECF No. [58]; *see also* Def.'s Opp'n at 7. However, the Secretary represents that she has been unable to locate and identify any such research materials, despite having made all reasonable efforts to search for them. *See* Def.'s Opp'n at 7; *see also* Def.'s Notice of Filing Supplements to Administrative Rs. 2, ECF No. [58]. While Plaintiffs, in a footnote, indicate that the Secretary has produced (but not filed) two studies – one by the RAND Corporation and the second by the Congressional Research Service, *see* Pls.' Mem. at 29 n.21, Plaintiffs have failed to proffer reasonable, non-speculative evidence from which the Court could conclude that the two studies were indeed considered in

connection with any of the rulemaking(s) at issue to rebut the Secretary's representation that they were not. Accordingly, Plaintiffs' request for an order directing the Secretary to supplement the record with Items 28, 29, and 30 is denied.

In summary, the Court denies Plaintiffs' request to add the following materials to the administrative record: Items 27, 28, 29, 30, 31, 32, 34, and 35, and two of the documents listed under Item 33 – specifically, Program Memoranda A-03-058 and Transmittal 707. Conversely, the Court shall grant Plaintiffs' request to order the Secretary to supplement the record with the following materials: Item 26 and two of the documents listed under Item 33 – specifically, Program Memoranda A-02-122 and A-02-126.

6. *Item 36:* Studies/Reports/Analyses

Finally, the Court shall address Plaintiffs' request that the Court compel the Secretary to supplement the record with "[a]ll internal and external studies, reports and analysis directly or indirectly considered by HHS, or that were otherwise before the agency, when promulgating the Fixed Loss Threshold Regulations and Outlier Payment Regulations here at issue, including those that support, refute or provide alternative options to the policies implemented through the final Regulations." Revised Exhibit A, Item 36. This sweeping request need not detain the Court long. Simply stated, Plaintiffs provide no evidence that such additional studies, reports, or analyses exist, thus giving the Court no grounds to grant their request. *See Franks*, 751 F. Supp. 2d at 73-74. Instead, Plaintiffs argue that it is "virtually unthinkable" that the Secretary did not consider many other studies in promulgating the regulations here at issue and that "in light of HHS's admitted overpayments of more than $10 billion, the failure to consider other studies, analyses and reports would be evidence of a failure (or refusal) to grapple with the adverse effects of its regulations." Pls.' Mem. at 30. Plaintiffs are essentially making a merits argument

in a discovery motion: that the Secretary's failure to sufficiently consider relevant studies, reports, and analyses would be arbitrary and capricious. Any such determination, however, is at this stage in the litigation premature. *See Midcoast Fishermen's Ass'n v. Gutierrez*, 592 F. Supp. 2d 40, 44 (D.D.C 2008).

IV. CONCLUSION

For all of the reasons stated herein, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Plaintiffs' [60] motion to compel the Secretary to file the complete administrative record and to certify the same. An appropriate Order accompanies this Memorandum Opinion.

Date: May 16, 2013

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge