UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BANNER HEALTH f/b/o BANNER GOOD SAMARITAN MEDICAL CENTER, *et al.*,
Plaintiffs
v.
SYLVIA M. BURWELL, Secretary of the U.S. Department of Health and Human Services,
Defendant

Civil Action No. 10-1638 (CKK)

MEMORANDUM OPINION
(September 2, 2015)

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"), purporting to challenge various actions taken by the Secretary in the course of administering Medicare's "outlier" payment system, the system which provides additional payments to hospitals for extremely high cost cases. Plaintiffs challenge a series of regulations that, together, govern outlier payments for federal fiscal year ("FY") 1997 through FY 2007. Specifically, they challenge 14 regulations: outlier payment regulations promulgated in 1988, 1994 and 2003, and 11 annual fixed loss threshold regulations issued for FY 1997 through FY 2007.[1] As explained in more detail below, the combination of the applicable outlier payment

[1] Plaintiffs' claims in this action have long been wide ranging, and the Court previously dismissed those claims that exceed the scope of the proper judicial review of agency action. *See Banner Health v. Sebelius*, 797 F. Supp. 2d 97, 110-11 (D.D.C. 2011). Over the course of the lengthy procedural history of this case, it has become clear that Plaintiffs in fact challenge 14 regulations, promulgated between 1988 and 2007. Notwithstanding this clarification and narrowing of this action, Plaintiffs continue to use broad language addressed at flaws of the outlier program overall, in addition to identifying certain purported legal flaws with the regulations challenged. Nonetheless, in addition to addressing Plaintiffs' claims that are directed at specific regulations, where the connections between Plaintiffs' other arguments and individual

regulations and the applicable annual fixed loss threshold establishes the formula for calculating the outlier payments made to individual hospitals, including payments to Plaintiffs and to the facilities controlled by Plaintiffs, during each fiscal year. Plaintiffs challenge the individual outlier payments made by applying those 14 regulations, as well.[2]

Presently before the Court are Defendant's [126] Motion to Dismiss for Lack of Subject Matter Jurisdiction and for Summary Judgment, Plaintiffs' [127/142] Motion for Summary Judgment, and Plaintiffs' [128] Motion (Related to Their Motion For Summary Judgment) for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief. Upon consideration of the pleadings,[3] the relevant legal authorities, and the record as a whole,

---

rulemakings are apparent, the Court addresses those arguments in this Memorandum Opinion as well.

[2] Plaintiffs do not claim that the agency applied the regulations incorrectly in calculating the individual outlier payments; they claim that, because of flaws with the underlying regulations, the resultant outlier payments were necessarily incorrect.

[3] The Court's consideration has focused on the following documents:

- Def.'s Mot. to Dismiss for Lack of Subject Matter Jurisdiction and for Summary Judgment ("Def.'s Mot."), ECF No. 126;
- Pls.' Corrected Opp'n to Def.'s Mem. in Support of Mot. to Dismiss for Lack of Subject Matter Jurisdiction and for Summary Judgment ("Pls.' Opp'n"), ECF No. 143;
- Def.'s Reply Mem. in Support of Mot. to Dismiss for Lack of Subject Matter Jurisdiction and for Summary Judgment ("Def.'s Reply"), ECF No. 134;
- Pls.' Corrected Mot. for Summary Judgment ("Pls.' Mot."), ECF No. 142;
- Def.'s Mem. in Opp'n to Pls.' Mot. for Summary Judgment ("Def.'s Opp'n"), ECF No. 132;
- Pls.' Corrected Reply in Support of Pls.' Mot. for Summary Judgment ("Pls.' Reply"), ECF No. 144;
- Pls.' Motion (Related to their Motion for Summary Judgment) for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief ("Pls.' Extra-Record Mot."), ECF No. 128;
- Def.'s Mem. in Opp'n to Pls.' Mot. to Supplement Administrative Records With Extra-Record Evidence and for Leave to Exceed Page Limit ("Def.'s Extra-Record Opp'n"), ECF No. 129; and

the Court DENIES Defendant's [126] Motion to Dismiss for Lack of Subject Matter Jurisdiction, GRANTS IN PART and DENIES IN PART Defendant's [126] Motion for Summary Judgment, GRANTS IN PART and DENIES IN PART Plaintiffs' [127/142] Motion for Summary Judgment, and GRANTS IN PART and DENIES IN PART Plaintiffs' [128] Motion for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief.

As an initial matter, the Court concludes that it has subject matter jurisdiction over all of the claims in this action. With respect to the FY 2004 fixed loss threshold rule, the Court REMANDS the rule to the agency to allow the agency to explain its decision regarding its treatment of certain data—or to recalculate the fixed loss threshold if necessary—as explained further below. In all other respects, the Court DENIES Plaintiffs' challenges to all of the regulations at issue in this case.

With respect to Plaintiffs'[128] Motion for Judicial Notice and/or Extra-Record Consideration of Documents and Other Related Relief, the Court DENIES Plaintiffs' request to supplement the record and for extra-record consideration of documents, but the Court GRANTS the motion insofar as the Court will take judicial notice of the publicly available materials subject to the motion, as relevant. The Court DENIES Plaintiffs' request to submit three additional tables and STRIKES from the record exhibits 5, 7, and 8 to Plaintiffs' Motion for

---

- Pls.' Reply in Support of Mot. for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief ("Pls.' Extra-Record Reply"), ECF No. 130.

In light of the voluminous administrative record pertaining to numerous regulations, the Court cites to the administrative record by referring to the specific agency action for which that portion of the administrative record was assembled, e.g., "A.R. (FY 2004)" or "A.R. (2003 amendments)." In an exercise of its discretion, the Court finds that holding oral argument in this action would not be of assistance in rendering a decision. *See* LCvR 7(f).

Summary Judgment. The Court will retain jurisdiction pending the limited remand to the agency regarding the FY 2004 rulemaking.

I. BACKGROUND

A. Factual Background

While this action emerges from Plaintiffs' challenge to the outlier payments they received for FY 1997 through FY 2007, the hospitals do not challenge the calculation of the individual outlier payments; instead, they level their substantive challenges at the 14 regulations that established the formulas for outlier payments in each of the relevant years. Plaintiffs challenge two sets of interrelated regulations that, taken together, create a formula that generates the actual outlier payments paid each year. With these regulations in hand, the calculations of the actual outlier payments are effectively a ministerial task. The first set of regulations consists of three rules—promulgated in 1988, 1994, and 2004—revising the outlier payment regulations, which are codified at 42 C.F.R. § 412.84. As presented below in greater detail, these regulations set a formula for how individual outlier payments will be calculated for each fiscal year, a formula that was revised over the course of time by these regulations. For all of the years after 1994, including the years for which outlier payments are at issue in this litigation, that formula involved a fixed loss threshold that was set annually. As described below in greater detail, the fixed loss threshold represents the dollar amount of loss that a hospital must absorb in any case in which the hospital incurs estimated costs for treating a patient above and beyond the payment rate set for that type of case. Accordingly, the second set of regulations challenged in this action consists of 11 annual fixed loss threshold rulemakings issued for FY 1997 to FY 2007. In each of those annual rulemakings, the agency established a methodology for setting a fixed loss

threshold and set the dollar value of the fixed loss threshold itself.[4] The outlier payment regulations that were applicable for the relevant fiscal year are effectively inputs for the fixed loss threshold rulemakings. That is, using the methodology selected for the fiscal year, the agency uses the applicable outlier payment regulations together with selected past data to generate an annual fixed loss threshold that complies with the statutory requirements.

Because of the wide-ranging nature of Plaintiffs' challenge—challenging 11 annual fixed loss threshold regulations and outlier payment regulations issued over the course of three decades—and because of the technical complexity of the program involved—it is necessary to review the history of the program in some detail.[5] Moreover, it is important that significant changes to the program occurred over the course of the years covered in this challenge. Because Plaintiffs challenge rulemakings that occurred as early as 1988, it is necessary to explain the changes that occurred as the outlier payment program unfolded over time. That said, the Court provides the greatest detail on fiscal years 1997 through 2007 that are the core of the claims in this case. The Court reserves certain details for its discussion of the discrete issues presented by the parties below.

The Statutory 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

[4] For FY 2007, the agency only set a *tentative* final fixed loss threshold in the rule that finalized the methodology for setting the fixed loss threshold because of uncertainty about certain other data. *See infra* note 16. The agency later set the actual final fixed loss threshold for that year. *See id.* That distinction is of no moment to this litigation.

[5] The Court notes that, by contrast, Plaintiffs persist in taking a blunderbuss approach to this challenge, despite the Court's previous opinions indicating that doing so was not permissible, eliding certain key differences between the variety of regulations they challenge and the years in which they were promulgated.

"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.

Under the Prospective Payment System, Hospitals are reimbursed "based on the average rate of 'operating costs [for] inpatient hospital services.'" *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015) (quoting *Cnty. of Los Angeles*, 192 F.3d at 1008). "Because different illnesses entail varying costs of treatment, the Secretary uses diagnosis-related groups (DRGs) to 'modif[y]' the average rate." *Id.* (quoting *Cape Cod Hosp.*, 630 F.3d at 205). "A DRG is a group of related illnesses to which the Secretary assigns a weight representing 'the

relationship between the cost of treating patients within that group and the average cost of treating all Medicare patients.'" *Id.* (quoting *Cape Cod Hosp.*, 630 F.3d at 205–06). "To calculate a specific reimbursement, the Secretary 'takes the [average] rate, adjusts it [to account for regional labor costs], and then multiplies it by the weight assigned to the patient's DRG.'" *Id.* (quoting *Cnty. of Los Angeles*, 192 F.3d at 1009) (alteration in original).

"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.* While relatively simple in concept—hospitals receive additional payments for extremely high cost treatments—implementing the outlier payment concept entails a complex process, which has evolved substantially in the more than three decades since outlier payments were introduced. Because Plaintiffs challenge aspects of the implementation of the scheme that cover all three decades, it is necessary to review how the program has evolved over time.

Pursuant to the 1983 legislation, the program provided for outlier payments for "day outliers" and "cost outliers." *Cnty. of Los Angeles*, 192 F.3d at 1009 (citing 42 U.S.C. § 1395ww(d)(5)(A)(i)-(ii) (Supp. IV 1986)). Day outliers are those patients whose "length of stay exceeded the mean length of stay for that particular DRG by a fixed number of days or standard deviations." *Cnty. of Los Angeles*, 192 F.3d at 1009 (citing 42 U.S.C. § 1395ww(d)(5)(A)(i) (Supp. IV 1986)). In other words, day outlier payments cover patients with extraordinarily lengthy hospital stays. Day outlier payments for extraordinary lengthy stays were subsequently eliminated by Congress and are not at issue in this litigation. *See* 42 U.S.C.

§ 1395ww(d)(5)(A)(i) (day outlier payments only available for discharges occurring "during fiscal years ending on or before September 30, 1997"). As specified by Congress in 1983, cost outlier payments covered situations where "a hospital's cost-adjusted charges surpassed either a fixed multiple of the applicable DRG prospective-payment rate or such other fixed dollar amount that the Secretary established."[6] *Cnty. of Los Angeles*, 192 F.3d at 1009 (citing 42 U.S.C. § 1395ww(d)(5)(A)(ii) (Supp. IV 1986)). The 1983 statute further specified that the amount of the outlier payments "shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable" to day outliers or to cost outliers. 42 U.S.C. § 1395ww(d)(5)(A)(iii); *see also Cnty. of Los Angeles*, 192 F.3d at 1009. Finally, the statute provides that "[t]he total amount of the additional [outlier] payments made under this subparagraph 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)(A)(iv). In *County of Los Angeles*, the D.C. Circuit Court of Appeals approved the Secretary's interpretation of that final provision—regarding the 5 to 6 percent range—under which the agency was required to set the outlier threshold in advance such that the projected outlier payments would be between 5 and 6 percent of the total projected payments. *See* 192 F.3d at 1020. The Court of Appeals concluded

[6] As explained further below, this provision of the statute was subsequently amended such that outlier payments are made for "discharges in fiscal years beginning on or after October 1, 1994"—that is, the first day of FY 1995—where "charge, adjusted to cost, … exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a *fixed dollar amount determined* by the Secretary." 42 U.S.C. § 1395ww(d)(5)(A)(iii) (emphasis added). It is the annually-set "fixed dollar amount" and factors related to the agency's method of setting that amount that are the core of the dispute in this case.

that the agency was not required to retroactively adjust the outlier thresholds such that the *actual* outlier payments would be between 5 and 6 percent of the total payments. *See id.* at 1019-20.

Since the introduction of the Prospective Payment System, the applicable statutory provision has provided for cost outlier payments only when "charges, adjusted to cost," exceed a certain cutoff. 42 U.S.C. § 1395ww(d)(5)(A)(ii). Because hospitals "markup" their costs in their billing, a calculation is necessary in order to estimate the actual costs of a given treatment based on the amount charged by a medical facility. *See Dist. Hosp. Partners*, 786 F.3d at 50. Until 1988, the agency used a standard cost-to-charge ratio for all facilities. *See* 53 Fed. Reg. 38,476, 38,502 (Sept. 30, 1988) ("We currently determine the cost of the discharge to be equal to 66 percent of the billed charges for covered services based on the average ratio of operating costs to charges for Medicare discharges nationwide."). However, in 1988 the agency decided to shift to using hospital-specific cost-to-charge ratios, reasoning that "[t]he use of hospital-specific cost-to-charge ratios should greatly enhance the accuracy with which outlier cases are identified and outlier payments are computed, since there is wide variation among hospitals in these cost-to-charge ratios." *Id.* at 38,503. Accordingly, the agency codified that change by adding the following provision to the Code of Federal Regulations specifying that that hospital-specific cost-to-charge ratios would be used:

> The cost-to-charge ratio used to adjust covered charges is computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. Statewide cost-to-charge ratios are used in those instances in which a hospital's cost-to-charge ratio falls outside reasonable parameters. HCFA sets forth these parameters and the Statewide cost-to-charge ratios in each year's annual notice of prospective payment rates published under § 412.8(b).

53 Fed. Reg. at 38,529 (providing text of provision codified at 42 C.F.R. § 412.84(h)). In explaining the choice to use the "latest available settled cost report," the Secretary reasoned that "the hospital-specific cost-to-charge ratios should be developed using the most current and

accurate data available." 53 Fed. Reg. at 38,507. Furthermore, the Secretary reasoned that, "[w]hile the latest filed cost report represents the most current data, we have found that Medicare costs are generally overstated on the filed cost report and are subsequently reduced as a result of audit." *Id.* The agency considered the range of reasonable cost-to-charge ratios to be "3.0 standard deviations (plus or minus) from the mean of the log distribution of cost-to-charge ratios for all hospitals." *Id.* The agency explained that it "believe[d] that ratios falling outside this range are unreasonable and are probably due to faulty data reporting or entry." *Id.* at 38,507-08. In other words, pursuant to the 1988 regulation, to determine whether a hospital's cases qualified for outlier payments, the agency would use the ratio between the latest available settled cost report—that is, the most recent audited cost report—and the associated charges. But if the cost-to-charge ratio was either extremely high or extremely low in comparison to the other hospitals, the agency would use the statewide average cost-to-charge ratio in determining whether outlier payments were warranted. These two aspects of the formula for calculating outlier payments—the use of the latest available settled cost reports and the statewide average default—remained applicable until they were modified by regulation in 2003. *See* 68 Fed. Reg. 34,494, 34,497-500 (June 9, 2003); 42 C.F.R. § 412.84(i)(3) (2003).

In 1993, Congress amended the statutory provisions establishing the outlier payment framework—for FY 1995 and beyond—through Section 13501(c) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66). 59 Fed. Reg. 45,330, 45,368 (Sept. 1, 1994). Previously a "hospital [could] receive payment for a cost outlier if the adjusted costs for a discharge exceed the greater of a fixed dollar amount or a fixed multiple of the DRG payment for the case." *Id.* Pursuant to the 1993 legislation, for discharges on or after October 1, 1994, a hospital can request an outlier payment when the charges, adjusted to cost, "exceed the sum of

the applicable DRG prospective payment rate … plus a fixed dollar amount determined by the Secretary."[7] 42 U.S.C. § 1395ww(d)(5)(A)(ii); *see also* 59 Fed. Reg. at 45,368. The "fixed dollar amount" is known as the fixed loss threshold. "In effect, this threshold 'acts like an insurance deductible because the hospital is responsible for that portion of the treatment's excessive cost' above the applicable DRG rate." *Dist. Hosp. Partners*, 786 F.3d at 50 (quoting *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1229 (11th Cir. 2009)). The fixed loss threshold is set by the Secretary each fiscal year. *Id.* The agency must set that fixed loss threshold such that the projected outlier payments are between 5 and 6 percent of the total projected DRG-based payments for the applicable fiscal year. *See Cnty. of Los Angeles*, 192 F.3d at 1020.

To implement the amended statutory provisions, the agency amended its outlier payment regulations—promulgating the second regulation challenged by Plaintiffs in this action. For all discharges on or after October 1, 1994, cost outlier payments would be available when charges, adjusted to cost, "exceed the DRG payment for the case plus a fixed dollar amount." 59 Fed. Reg. 45,330, 45398 (Sept. 1, 1994) (amending 42 C.F.R. § 412.80). The agency acknowledged that the language of the statutory amendment contained some ambiguity as to whether the new formula was required for future discharges or whether it provided an optional alternative to the previous outlier payment formula. *See id.* at 45,370. But the agency concluded that adopting the new fixed loss cost methodology exclusively was both substantively appropriate and consistent with the intent of Congress in amending the relevant statutory provisions. *See id.*

[7] The 1993 Act also eliminated the day outlier payment provision, discussed above, for all discharges after September 30, 1997. 59 Fed. Reg. at 45,367. The Act also specified that the day outlier payments must be a declining percentage of the total outlier payments for FY 1995, FY 1996, and FY 1997. *See id.*

In this same regulation, the agency set the fixed loss threshold for FY 1995 at $20,500. *See id.* at 45,407. Pursuant to section 1395ww(d)(5)(A)(iii), there is a requirement that the outlier payment "approximate the marginal cost of care beyond the cutoff point." For FY 1995, the agency set the marginal cost factor for cost outliers at 80 percent.[8] 59 Fed. Reg. at 45,407. Accordingly, cost outlier payments would be provided where a charge, adjusted to cost, was greater than the applicable DRG rate plus $20,500. In such a circumstance, the amount of the cost outlier payment would be 80 percent of the difference between the charges, adjusted to cost, and the sum of the DRG rate and $20,500. For FY 1995, the agency set the fixed loss threshold such that "estimated outlier payments equal 5.1 percent of estimated DRG payments." *Id.* The 5.1 percent level satisfies the statutory requirement that the predicted outlier payments be between 5 and 6 percent of the total DRG payments. *See Cnty. of Los Angeles*, 192 F.3d at 1020. In order to set the fixed loss threshold such that outlier payments would meet this 5.1 percent level, it was necessary to model the outlier and DRG payments for the upcoming fiscal year. Whereas the agency had used a charge inflation methodology through FY 1993, the agency used a cost inflation methodology for FY 1995 as it had done the previous fiscal year.[9] *See* 59 Fed. Reg. at 45,407. In modeling the outlier payments for FY 1994, the agency concluded that a cost inflation methodology would be more accurate than a charge inflation methodology. 58 Fed. Reg. 46,270, 46,347 (Sept. 1, 1993). Specifically, the agency reasoned that, because charges were rising faster than costs and because the cost-to-charge ratios used could be "as much as 2 years old" due to the use of the latest available settled cost reports, a charge inflation

[8] The marginal cost factor is not at issue in this litigation.

[9] Prior to FY 1994, the agency had used a charge inflation methodology, which involved inflating a prior year's charges by the level of charge inflation, and *then* adjusting those inflated charges to costs using hospital-specific cost-to-charge ratios. 59 Fed. Reg. at 45,407.

methodology could be leading to "overestimating outlier payments in setting the thresholds." *Id.* The agency continued to use the cost inflation methodology in FY 1995 and through FY 2002. *See* 68 Fed. Reg. 45,346, 45,476 (Aug. 1, 2003). Under the cost inflation methodology, to generate a data set of projected costs for FY 1995, the agency first took the FY 1993 charge data and adjusted the charges by the applicable cost-to-charge ratios. *Id.* Then the agency inflated those costs to account for two years of cost inflation. *Id.* The agency then used this data set to determine what fixed loss threshold would generate projected outlier payments that were 5.1 percent of the total projected DRG payments for FY 1995.

The final prong of the statutory scheme is that the payments based on the DRG prospective payment rates—non-outlier payments—are reduced each year by a percentage equal to the percentage established by the Secretary for outlier payments for that year. *See* 42 U.S.C. § 1395ww(d)(3)(B). This reduction offsets, approximately, the cost of the outlier payments for each year. Accordingly, for those years where the Secretary set the fixed loss threshold such that outlier payments were projected to be 5.1 percent of the total DRG-based payments, the payments based on the DRG prospective payment rates were reduced by 5.1 percent. *See* 62 Fed. Reg. 45,966, 46,011 (Aug. 29, 1997) ("Thus, for example, we set outlier thresholds so that the outlier payments for operating costs are projected to equal 5.1 percent of total DRG operating payments, and we adjust the operating standardized amounts correspondingly. We do not set aside a pool of money to fund outlier cases."). However, there is no guarantee that the actual total outlier payments will equal the reduction in DRG payments. *See Cnty. of Los Angeles*, 192 F.3d at 1019-20.

Outlier Payments and Fixed Loss Thresholds: FY 1997 through FY 2003

Because Plaintiffs challenge each of the fixed loss thresholds set for FY 1997 through FY 2007, the Court reviews each of the rulemakings in which those thresholds were set. As explained above, 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. For each of these fiscal years, the agency modeled the expected payments for that upcoming fiscal year and set the fixed loss threshold at a rate such that the level of outlier payments was predicted to be 5.1 percent of the anticipated total payments based on the DRG rates, which is within the 5 to 6 percent range of total DRG-based payments set by the statute. *See Cnty. of Los Angeles*, 192 F.3d at 1009. As explained in further detail below, the year 2003 was a critical pivot point in the outlier payment program. Based on the discovery of abusive charging practices by certain hospitals, the agency set out to change the rules for outlier payments to curb these abuses, ultimately modifying the regulations governing outlier payments in a regulation promulgated in June 2003. *See Dist. Hosp. Partners*, 786 F.3d at 51-52. Accordingly, for the annual fixed loss threshold rulemakings between FY 1997 and FY 2003, the agency applied the outlier payment regulations promulgated in 1988 and in 1994, both discussed above. For the annual fixed loss threshold rulemakings for FY 2004 through FY 2007, the agency applied the outlier payment regulations as modified by the June 2003 regulation. The Court first reviews, briefly, each of the fixed loss threshold rulemakings for FY 1997 through FY 2003. After reviewing the 2003 changes to the outlier payment regulations, the Court turns to the four challenged fixed loss threshold rulemakings following those changes, for FY 2004 through FY 2007.

Fixed Loss Threshold Rulemaking for FY 1997[10]

In a proposed rule published in the Federal Register on May 31, 1996, the agency proposed a fixed loss threshold of $11,050 and proposed to maintain the marginal cost factor for cost outliers at 80 percent.[11] 61 Fed. Reg. 27,444, 27,495 (May 31, 1996). The agency calculated the outlier thresholds so that outlier payments were projected to equal 5.1 percent of the total projected DRG payments. *Id.* In a final rule promulgated on August 30, 1996, the agency concluded that a fixed loss threshold of $9,700 was appropriate in order to satisfy the 5.1 percent projection. *See* 61 Fed. Reg. 46,166, 46,228 (Aug. 30, 1996). The agency maintained the 80 percent marginal cost factor as proposed. *Id.* The agency concluded that a $9,700 fixed loss threshold was appropriate because of updated cost inflation data. Specifically, the agency noted that "[t]he latest available Medicare cost reports indicate that hospital cost per case decreased from FY 1993 to FY 1994 as well as from FY 1994 to FY 1995." *Id.* The agency concluded that the data "suggests a continued trend in cost *deflation*," whereas the agency had assumed zero cost inflation in the proposed rule. *Id.* (emphasis in original). Accordingly, in order to project the costs and the associated Medicare payments for FY 1997, the agency used a negative annual inflation factor of 1.906 percent. *Id.* Specifically, the agency deflated the cost data for 1995 by 1.906 percent, twice, to generate a set of projected cost data for FY 1997. Because of the

[10] Pursuant to the 1993 legislation amending the outlier payment program, FY 1997 was the final year that the outlier program included both day outliers and cost outliers. The Court does not address certain complexities of the fixed loss threshold calculation for FY 1997 that result from the relationship of the day outlier provisions and the cost outlier provisions because the parties have not indicated that any issues result from the inclusion of day outliers in the calculations for FY 1997.

[11] The agency proposed a lower fixed loss threshold of $10,075 for those hospitals that had not yet entered the Prospective Payment System for capital related costs. *See* 61 Fed. Reg. at 27,495. The Court does not discuss the lower thresholds set for such hospitals further because it does not affect the analysis below, nor do the parties emphasize this distinction.

predicted cost deflation, it was necessary to lower the fixed loss threshold, in comparison to the proposed threshold, so that the outlier payments would be 5.1 percent of the total DRG-based payments. *See id.* at 46,228-29.

Fixed Loss Threshold Rulemaking for FY 1998

In a proposed rule issued on June 2, 1997, the agency proposed a fixed loss threshold for cost outliers of $7,600. *See* 62 Fed. Reg. 29,902, 29,946 (June 2, 1997). The agency proposed to maintain the marginal cost factor for cost outliers of 80 percent. *Id.* Once again, the agency set the threshold so that the projected outlier payments would be 5.1 percent of the projected total DRG-based payments. *See id.* The proposed fixed loss threshold was premised on continued cost deflation—which the agency derived by analyzing cost data from previous years—and the agency used an annual cost deflation factor of 1.969 percent to project costs for FY 1998. *See id.* In a final rule issued August 29, 1997, the agency selected a fixed loss threshold of $11,050, such that outlier payments were projected to be 5.1 percent of the projected total DRG-based payments.[12] 62 Fed. Reg. at 46,040. The increase in comparison to the proposed threshold was due, in part, to amendments to the outlier payment provisions of the statute, which required adjusting the outlier payment model to account for other factors not relevant to the issues in this action.[13] *Cf. Dist. Hosp. Partners*, 786 F.3d at 50, n.1 (noting that these factors were immaterial

[12] The agency retained the proposed marginal cost factor of 80 percent. 62 Fed. Reg. at 46,040.

[13] Between the issuance of the proposed rule and the issuance of the final rule on August 29, 1997, Congress amended the applicable statutory provision such that the cost outlier threshold would be "based on 'the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) [IME payments] and (F) [DSH payments] plus a fixed dollar amount determined by the Secretary.'" 62 Fed. Reg. at 46,040 (quoting Balanced Budget, Pub. Law 105–33, August 5, 1997, 111 Stat. 251). IME payments are for indirect medical education, and DSH payments are for disproportionate share hospitals. As a result of this change, the agency no longer adjusted hospital costs to exclude these payments. *See id.* The IME and DSH payments themselves are not at issue in this action.

to the analysis of challenges to outlier payments). Based on more recent data available at the time of the promulgation of the final rule, which showed continued declining costs, the agency used an annual cost inflation factor of minus 2.005 percent. *See* 62 Fed. Reg. at 46,041. Accordingly, for FY 1998, the fixed loss threshold was set at $11,050.

Fixed Loss Threshold Rulemaking for FY 1999

In a proposed rule issued on May 8, 1998, the agency proposed a fixed loss threshold for cost outliers of $11,350. 63 Fed. Reg. 25,576 (May 8, 1998). The agency proposed maintaining the marginal cost factor of 80 percent. *Id.* The agency calculated the proposed outlier threshold so that the projected outlier payments would be 5.1 percent of the total projected DRG-based payments. *Id.* As in previous years, these calculations were made using a cost inflation methodology. *See id.* at 25,611. In the agency's proposed rule, the projections were based on an annual cost inflation factor of minus 1.831 percent. *See id.* In a final rule promulgated on July 31, 1998, the agency established a fixed loss threshold for FY 1999 of $11,100 and maintained the marginal cost factor at 80 percent. 63 Fed. Reg. 40,954, 41,008 (July 31, 1998). The agency continued to use a cost inflation methodology but used an updated cost inflation factor of minus 1.724 percent, which was suggested by the more recent data available at the time of the promulgation of the final rule. *See id.* The agency calculated that the projected cost outlier payments using the fixed loss threshold of $11,100 would be 5.1 percent of the total projected DRG-based payments. *See id.*

Fixed Loss Threshold Rulemaking for FY 2000

In a proposed rule issued on May 7, 1999, the agency proposed a fixed loss threshold of $14,575. 64 Fed. Reg. 24,716, 24,754 (May 7, 1999). The agency also proposed maintaining the marginal cost factor of 80 percent. *Id.* The agency calculated the proposed outlier threshold so

that the projected outlier payments would be 5.1 percent of the total DRG-based payments. *Id.* Once again, these calculations were made using a cost-inflation methodology. *See id.* For FY 2000, the agency proposed using a zero inflation factor. The use of a zero inflation factor "reflects [the agency's] analysis of the best available cost report data as well as calculations (using the best available data) indicating that the percentage of actual outlier payments for FY 1998, is higher than [] projected before the beginning of FY 1998, and that the percentage of actual outlier payments for FY 1999 will likely be higher than [] projected before the beginning of FY 1999." *Id.* In a final rule promulgated on July 30, 1999, the agency established a fixed loss threshold for FY 2000 of $14,050 and maintained the marginal cost factor at 80 percent. 64 Fed. Reg. 41,490, 41,546 (July 30, 1999). The agency used a zero inflation factor, as proposed, reflecting the latest cost report data, as well as the relationship of actual outlier payments to the previously projected outlier payments for FY 1998 and FY 1999, as discussed in the FY 2000 proposed rule. *Id.* The agency noted that it was "attempting to improve [its] estimate of payments for FY 2000 by using a cost inflation factor of zero percent rather than a negative inflation factor," as the agency had done for several years prior to FY 2000. *Id.* at 41,547.

Fixed Loss Threshold Rulemaking for FY 2001

In a proposed rule issued on May 5, 2000, the agency proposed a fixed loss threshold of $17,250. 65 Fed. Reg. 26,282, 26,329 (May 5, 2000). The agency also proposed maintaining the marginal cost factor of 80 percent. *Id.* The agency calculated the proposed outlier threshold so that the projected outlier payments would be 5.1 percent of the total DRG-based payments. *Id.* Once again, these calculations were made using a cost-inflation methodology. *See id.* For FY 2001, the agency proposed using a 1.0 percent inflation factor. The use of a 1.0 percent inflation factor "reflects [the agency's] analysis of the best available cost report data as well as

calculations (using the best available data) indicating that the percentage of actual outlier payments for FY 1999, is higher than [] projected before the beginning of FY 1999, and that the percentage of actual outlier payments for FY 2000 will likely be higher than [] projected before the beginning of FY 2000." *Id.* In a final rule promulgated on August 1, 2000, the agency established a fixed loss threshold for FY 2001 of $17,550 and maintained the marginal cost factor at 80 percent. 65 Fed. Reg. 47,054, 47,113 (Aug. 1, 2000). The agency used a 1.8 percent inflation factor—as opposed to the proposed inflation factor of 1.0 percent—reflecting the latest cost report data, as well as the relationship of actual outlier payments to the previously projected outlier payments for FY 1999 and FY 2000, as discussed in the FY 2001 proposed rule. *Id.*

Fixed Loss Threshold Rulemaking for FY 2002

In a proposed rule issued on May 4, 2001, the agency proposed a fixed loss threshold of $21,000. 66 Fed. Reg. 22,646, 22,726-27 (May 4, 2001). The agency also proposed maintaining the marginal cost factor of 80 percent. *Id.* at 22,727. The agency calculated the proposed outlier threshold so that the projected outlier payments would be 5.1 percent of the total DRG-based payments. *Id.* Once again, these calculations were made using a cost-inflation methodology. *See id.* For FY 2002, the agency proposed using a 5.5 percent inflation factor. The use of the 5.5 percent inflation factor "reflects [the agency's] analysis of the best available cost report data as well as calculations (using the best available data) indicating that the percentage of actual outlier payments for FY 2000, is higher than [] projected before the beginning of FY 2000, and that the percentage of actual outlier payments for FY 2001 will likely be higher than [] projected before the beginning of FY 2001." *Id.* In a final rule promulgated on August 1, 2001, the agency established a fixed loss threshold for FY 2002 of $21,025 and maintained the marginal cost factor at 80 percent. 66 Fed. Reg. 39,828, 39,941 (Aug. 1, 2001). The agency used a 2.8 percent

inflation factor—as opposed to the proposed inflation factor of 5.5 percent—reflecting the latest cost report data, as well as the relationship of actual outlier payments to the previously projected outlier payments for FY 2000 and FY 2001, as discussed in the FY 2002 proposed rule.

Fixed Loss Threshold Rulemaking for FY 2003: Shift from Cost Inflation to Charge Inflation Methodology

In a proposed rule issued on May 9, 2002, the agency proposed a fixed loss threshold of $33,450. 67 Fed. Reg. 31,404, 31,510 (May 9, 2002). The agency also proposed maintaining the marginal cost factor of 80 percent. *Id.* at 22,727. The agency calculated the proposed outlier threshold so that the projected outlier payments would be 5.1 percent of the total DRG-based payments. *Id.* While these calculations were made using a cost-inflation methodology, the agency proposed a calculation that differed from those employed in previous years because of the data that was available at the time of the FY 2003 proposed rule. *See id.* The agency noted that, previously, "inflation factors have been calculated by measuring the percent change in costs using the two most recently available cost report files." *Id.* For example, for FY 2002, those were the FY 1998 and FY 1999 cost reports. *Id.* However, when the agency was proposing the threshold for FY 2003, the FY 2000 cost reports were not available because of processing delays. *See id.* Therefore, the agency proposed projecting the cost inflation factor by constructing an averaging model based on the changes to the data available from FY 1995 through FY 1999, the most recent cost data available. *See id.* The agency emphasized that this proposal was based on the unavailability of the FY 2000 data. *See id.* As a result of the model, the agency proposed applying a 15 percent cost inflation factor to the FY 2001 data to generate the projected FY 2003 data. *See id.*

After receiving a significant numbers of comments regarding the methodology proposed for accounting for inflation—which was proposed in light of the unavailability of the FY 2000

cost data—the agency declined to adopt the proposed cost inflation methodology in the final FY 2003 fixed loss threshold regulation. 67 Fed. Reg. 49,982, 50,124 (Aug. 1, 2002). Instead, in the final rule promulgated on August 1, 2002, the agency adopted a charge inflation methodology. *See id.* The agency reasoned that, because of substantial increases in the growth of charges, which were increasing faster than costs, predicting future payments using a charge inflation methodology would be more accurate than using a cost inflation methodology. *See id.* Accordingly, in order to determine the fixed loss threshold for FY 2003, the agency calculated the rate of charge inflation from FY 1999 to FY 2000 and from FY 2000 to FY 2001 and applied this two-year rate of inflation—a total of 17.6398 percent—to the FY 2001 charge data to generate a set of projected FY 2003 charge data. *See id.* The agency adjusted these projected charges to cost for use in modeling outlier payments for FY 2003. *See id.* Using this charge inflation methodology, as well as continuing to use a marginal cost factor of 80 percent, the agency set the fixed loss threshold at $33,560 for FY 2003. *See id.* With this fixed loss threshold, the agency predicted that outlier payments would be 5.1 percent of the total DRG-based payments. *See id.*

Changes to the Outlier Payment Program in 2003

By 2003, it appeared that the outlier payment system was breaking down. *See Dist. Hosp. Partners*, 786 F.3d at 51. In particular, concerns emerged that hospitals "could manipulate the outlier regulations if their charges were 'not sufficiently comparable in magnitude to their costs.'" *Id.* (quoting 68 Fed. Reg. 10,420, 10,423 (Mar. 5, 2003)). In February 2003, the Secretary transmitted a draft interim final rule discussing several possible changes to the outlier

payment system to the Office of Management and Budget ("OMB").[14] *See* AR (2003 amendments) 4417.338. Based on analysis of trends in the cost and charge data, the draft also would have revised the previously-established fixed loss threshold for FY 2003, lowering it to $20,760 for discharges occurring between the would-be date of publication of the interim final rule and the end of FY 2003. *See* AR (2003 amendments) 4417.376. Specifically, the draft highlighted 123 hospitals that had rapidly increased their charges between FY 1999 and FY 2001 and whose outlier payments were a disproportionately high percentage of their total DRG payments. *See* AR (2003 amendments) 4417.373. However, the Secretary later abandoned this draft rule and never published it in the Federal Register. *See Dist. Hosp. Partners*, 786 F.3d at 54, 58.

Instead, on March 5, 2003, the agency published a notice of proposed rulemaking that proposed several of the same changes to the outlier payment system suggested in the draft interim final rule. *See* 68 Fed. Reg. at 10,420. In the notice of proposed rulemaking, the agency described how a hospital could take advantage of "the time lag between the current charges on a submitted bill and the cost-to-charge ratio taken from the most recent settled cost report." *Id.* at 10,423. As the D.C. Circuit Court of Appeals described in *District Hospital Partners*, "[a] hospital knows that its cost-to-charge ratio is based on data submitted in past cost reports. If it dramatically increased charges between past cost reports and the patient costs for which reimbursement is sought, its cost-to-charge ratio would 'be too high' and would 'overestimate the hospital's costs.'" 786 F.3d at 51 (quoting 68 Fed. Reg. at 10,423). Reviewing actual outlier payments from several previous years, the agency discovered "123 hospitals whose percentage

[14] By executive order, agencies taking "significant regulatory action" are required to send OMB "[t]he text of the draft regulatory action" before publishing that action in the Federal Register. Exec. Order No. 12,866 § 6(a)(3)(B)(i), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

of outlier payments relative to total DRG payments increased by at least 5 percentage points" from FY 1999 to FY 2001. 68 Fed. Reg. at 10,423. Furthermore, for those 123 hospitals, "the mean rate of increase in charges was 70 percent." *Id.* at 10,424. Yet, cost-to-charge ratios for these hospitals, which were based upon cost reports from *prior* periods, declined by only 2 percent." *Id.* (emphasis added). While charges were increasing rapidly, the cost-to-charge ratios did not reflect this change because they were based on earlier time periods. These hospitals, with rapidly increasing charges, have become called turbo-chargers. *Dist. Hosp. Partners*, 786 F.3d at 51.

To address these concerns, the agency proposed three changes to the outlier payment regulations. *First*, whereas previously the regulations—promulgated in 1988—required using the most recent *settled* cost report when determining the cost-to-charge ratios for hospitals, the agency proposed to use either the *tentatively* settled cost report or the *final* settled cost report, whichever would be from the later cost reporting period. *Id.* at 10,423-24. Because it can take 12 to 24 months between the tentative settling of a cost report and the final settling of that cost report, allowing the use of the tentatively settled cost reports would allow more up-to-date data to be used in determining the outlier payments. *See id.* at 10,424. *Second*, the agency proposed that it would no longer default to statewide average cost-to-charge ratios for hospitals with low cost-to-charge ratios. *See id.* Previously the regulations—again, promulgated in 1988—specified that, for hospitals with extremely high or extremely low cost-to-charge ratios, the statewide average cost-to-charge ratio would be used in determining outlier payments. *See id.* The agency proposed that the statewide average would still be used for hospitals that had not yet filed cost reports and situations where the hospital-specific cost-to-charge ratios would exceed the upper threshold, *id.*, which had previously been set at three standard deviations above the mean of the

log distribution of cost-to-charge ratios for all hospitals. *See* 53 Fed. Reg. at 38,507. But for hospitals that had low cost-to-charge ratios, they would "receive their actual cost-to-charge ratios, no matter how low their ratios fall." 68 Fed. Reg. at 10,424. *Third*, the agency proposed reconciling outlier payments after settled cost reports were issued. *Id.* at 10,424-25. The agency proposed adding a provision to the regulations such that outlier payments would "become subject to adjustment when hospitals' cost reports are settled." *Id.* at 10,425. Beyond three major changes, in contrast to the draft interim final rule, the agency *did not* propose a mid-year correction for the FY 2003 fixed loss threshold because of uncertainty regarding charging practices during FY 2003. *See id.* at 10,426-27.

On June 9, 2003, the agency promulgated a final rule, which included the three major changes to the outlier payment regime proposed in the March 2003 notice of proposed rulemaking. *See* 68 Fed. Reg. 34,494, 34,497-503 (June 9, 2003). First, for all discharges on or after October 1, 2003, the cost-to-charge ratios would be based on more recent data—based on tentatively settled cost reports rather than on final settled cost reports. *See id.* at 34,497-99, 34,515 (codified at 42 C.F.R. § 412.84(i)(1)-(2)). Second, for discharges on or after August 8, 2003, the agency would not default to statewide averages for hospitals with low cost-to-charge ratios. *See id.* at 34,500 (codified at 42 C.F.R. §§ 412.84(h) and (i)(1)). Third, for discharges on or after August 8, 2003, outlier payments would "become subject to adjustment when hospitals' cost reports coinciding with the discharge are settled."[15] *Id.* at 34,504 (codified at 42 C.F.R. § 412.84(i)(4)). Finally, consistent with the agency's suggestion in the notice of proposed

[15] For discharges between August 8, 2003, and October 1, 2003, the outlier payments were only partially subject to reconciliation in light of the fact that the use of tentatively settled cost reports was not yet in effect. *See* 42 C.F.R. § 412.525(a)(4); 68 Fed. Reg. at 34,515.

rulemaking, the agency concluded that adjusting the fixed loss threshold for the remainder of FY 2003 was not warranted. *See id.* at 34,506.

Fixed Loss Threshold Rulemakings for FY 2004 through 2007

Plaintiffs challenge four annual fixed loss threshold rules—for FY 2004 through FY 2007—issued *after* the agency promulgated the 2003 regulations that changed the methodology for calculating outlier payments. As with the fixed loss thresholds for FY 1997 through FY 2003, the agency was required to set the fixed loss threshold in order that the projected outlier payments would be between 5 and 6 percent of the total projected DRG-based payments for the applicable fiscal years. *See Cnty. of Los Angeles*, 192 F.3d at 1020. Each of the annual fixed loss thresholds for FY 2004 through FY 2007 was set using the outlier payment methodology updated in 2003. In setting each of these thresholds, the agency used a charge inflation methodology, which had been reintroduced in 2003. For each of these years, the agency set the fixed loss threshold so as to result in outlier payments being 5.1 percent of total DRG-based payments and, for each of these years, the agency adopted a marginal cost factor of 80 percent. *See* 68 Fed. Reg. 45,346, 45,478 (Aug. 1, 2003); 69 Fed. Reg. 48,916, 49,278 (Aug. 11, 2004); 70 Fed. Reg. 47,278, 47,495 (Aug. 12, 2005); 71 Fed. Reg. 47,870, 48,151 (Aug. 18, 2006). However, there are differences in the setting of each of these fixed loss thresholds, particularly regarding the data sets that were used to calculate the threshold for each year. The Court, therefore, reviews how the fixed loss threshold was set for each of these fiscal years.

Fixed Loss Threshold Rulemaking for FY 2004

In a proposed rule issued May 19, 2003, the agency proposed setting the fixed loss threshold for FY 2004 at $50,645. 68 Fed. Reg. 27,154, 27,235 (May 19, 2003). The agency proposed using a charge inflation rate of 12.8083 percent annually (27.3 percent over two years).

Id. The agency also proposed maintaining the marginal cost factor at 80 percent. *Id.* Notably this proposed rule was published *prior* to the promulgation of the revised outlier payment regulations—finalized on June 9, 2003—and therefore used the methodology that was in place before the 2003 changes to the outlier payment regulations. *See id.* In issuing the proposed fixed loss threshold rule, the agency noted that "any final rule subsequent to the March 5, 2003 proposed rule that implements changes to the outlier payment methodology is likely to affect how we will calculate the final FY 2004 outlier threshold." *Id.* The agency further noted that "the final FY 2004 threshold is likely to be different from this proposed threshold, as a result of any changes subsequent to the March 5, 2003 proposed rule." *Id.*

The final fixed loss threshold rule for FY 2004 was issued on August 1, 2003—two months after the changes to the outlier payment regulations were promulgated. 68 Fed. at 45,346. The final fixed loss threshold rule took account of the revised outlier payment regulations, which would govern outlier payments for discharges occurring in FY 2004 and beyond. *See id.* Specifically, using the charge inflation methodology that the agency had re-introduced in the FY 2003 rulemaking, the agency used charge data from 2002 and inflated it by a two-year charge inflation rate to project charges for FY 2004. *Id.* The agency used "the 2-year average annual rate of change in charges per case," from FY 2000 to FY 2001 and from FY 2001 to FY 2002, which was 12.5978 percent annually (or 26.8 percent over two years). *Id.* To calculate projected *costs* for FY 2004, the agency adjusted the projected charges by hospital-specific cost-to-charge ratios. In doing so, the agency implemented changes introduced by the 2003 revisions to the outlier payment regulations. First, the agency adjusted its methodology to use more recent data to generate the cost-to-charge ratios because, in issuing the outlier payments for FY 2004, the latest *tentatively settled* cost reports would be used rather than the *latest settled* cost reports. *See id.*

Therefore, whereas the agency had previously used cost-to-charge ratios from the Provider Specific File to calculate the fixed loss threshold, the agency instead "matched charges-per-case to costs-per-case from the most recent cost reporting year" and "then divided each hospital's costs by its charges to calculate the cost-to-charge ratio for each hospital." *Id.* Second, whereas previously the agency had used a statewide average cost-to-charge ratio for hospitals with low cost-to-charge ratios, the revised outlier payment regulations specified that the hospital-specific cost-to-charge ratio would be used "no matter how low their ratios actually fall." *Id.* The agency used the resultant hospital-specific cost-to-charge ratios to adjust the projected FY 2004 charges to costs for that fiscal year. *See id.*

The final change introduced by the 2003 outlier payment regulations was that outlier payments would become subject to reconciliation "at the time of cost report final settlement if a hospital's actual … cost-to-charge ratios are found to be substantially different from the cost-to-charge ratios used during that time period to make outlier payments." *Id.* The agency noted that it was "difficult to project which hospitals will be subject to reconciliation of their outlier payments using available data." *Id.* The agency also noted that "resources necessary to undertake reconciliation will ultimately influence the number of hospitals reconciled." *Id.* For all of those reasons, it was "difficult to predict the number of hospitals that [would] be reconciled." Nonetheless, based on previous data, the agency "identified approximately 50 hospitals [it] believe[d] will be reconciled." *Id.* For these hospitals, the agency attempted to integrate the effects of reconciliation in the predictive model for FY 2004 by using a modified methodology for projecting outlier payments for FY 2004. *See id.* at 45,476-77. Using this revised methodology, in light of the changes to the outlier payment regulations in 2003, the agency established a fixed loss outlier of $31,000. *Id.* at 45,477.

Fixed Loss Threshold Rulemaking for FY 2005

In a proposed rule issued May 18, 2004, the agency proposed a fixed loss threshold of $35,085. 69 Fed. Reg. 28,196, 28,376 (May 18, 2004). To arrive at this proposed threshold, the agency once again used a charge inflation methodology. The agency took FY 2003 charge data and inflated it two years—based on the two-year average annual rate of change in charges from FY 2001 to FY 2002 and FY 2002 to FY 2003, which was 14.5083 percent annually. *See id.* Pursuant to the 2003 changes to the outlier payment regulations, the agency then used hospital-specific cost-to-charge ratios that reflected the most recent settled or the most recent tentatively settled cost reports, whichever was more recent, for each hospital. *See id.* In proposing this threshold, the agency acknowledged that the inflation data "derive[d] from the years just prior to the adoption of the policy changes, when some hospitals were increasing charges at a rapid rate in order to increase their outlier payments." *Id.* As a result, the agency noted that they "represent rates of increase that may be higher than the rates of increase under our new policy." *Id.* Accordingly, the agency welcomed suggestions that might enable predictions that "better reflect current trends in charge increases." *Id.*

Given these concerns, as well as comments received in response to the proposed rule, the agency adjusted the methodology for predicting FY 2005 data in order to set the final FY 2005 fixed loss threshold. *See* 69 Fed. Reg. at 49,277. In the final rule promulgated on August 11, 2004, the agency used the FY 2003 charge data as a baseline. *Id.* To derive an inflation factor, the agency took the "unprecedented step of using the first half-year of data from FY 2003 and comparing this data to the first half year of FY 2004." *Id.* The agency concluded that "this comparison will result in a more accurate determination of the rate of change in charges per case between FY 2003 and FY 2005." *Id.* Using this data, the agency calculated a one-year annual rate of charge inflation of 8.9772, or 18.76 percent over two years, and then inflated the FY 2003 data

by this two-year charge inflation figure. *Id.* The agency then converted the projected charge data to costs using hospital-specific cost-to-charge ratios from the April 2004 update of the Provider Specific File. *Id.* As with the calculation of the cost-to-charge ratios for the setting of the FY 2004 fixed loss threshold, this analysis incorporated the changes introduced by the 2003 revisions to the outlier payment regulations, specifically the use of tentatively settled cost reports and the use of hospital-specific ratios even for hospitals with extremely low cost-to-charge ratios. *See id.* However, unlike the FY 2004 fixed loss threshold calculation, the agency did not change its methodology to explicitly account for the possibility of reconciliation in setting the FY 2005 threshold. *See id.* at 49,278. The agency concluded that "due to changes in hospital charging practices following implementation of the new outlier regulations in the June 9, 2003 final rule, the majority of hospitals' cost-to-charge ratios will not fluctuate significantly enough between the tentatively settled cost report and the final settled cost report to meet the criteria to trigger reconciliation of their outlier payments." *Id.* Moreover, the agency noted that it would be "difficult to predict which specific hospitals may be subject to reconciliation in any given year." *Id.* Using this methodology, the agency established a fixed loss threshold of $25,800 for FY 2005. *Id.*

Fixed Loss Threshold Rulemaking for FY 2006

In a proposed rule issued May 4, 2005, the agency proposed a fixed loss threshold of $26,675. 70 Fed. Reg. 23,306, 23,469 (May 4, 2005). In order to account for changes in the rate of charge inflation, the agency generated projected data for FY 2006 using FY 2004 charge data as a baseline. *See id.* The agency calculated the rate of charge inflation from the combination of the last quarter of FY 2003 and the first quarter of FY 2004 to the combination of the last quarter of FY 2004 and the first quarter of FY 2005. *See id.* For this period, the agency calculated an

annual rate of charge inflation of 8.65 percent, or 18.04 percent over two years. *See id.* The agency then inflated the FY 2004 charge data by this two-year inflation factor. *See id.* To derive projected cost data, the agency adjusted the projected charge data by the hospital-specific charge ratios from the most recent update to the Provider Specific File (for December 2004), which reflected the 2003 changes to the outlier payment regulations. *See id.*

For the final rule, promulgated August 12, 2005, the agency calculated the FY 2006 fixed loss threshold "using the methodology proposed in the proposed rule, but using updated data." 70 Fed. Reg. at 47,494. Specifically, the agency calculated a charge inflation factor based on a comparison between the first six months of FY 2004 and the first six months of FY 2005. *Id.* Using this data, the agency calculated a two-year charge inflation factor of 14.94 percent. *Id.* The agency used this inflation factor to inflate charges from FY 2004, *id.* at 47,495, and then adjusted the projected charges to projected costs using hospital-specific cost-to-charge ratios from the March 2005 update of the Provider Specific File, which included cost-to-charge ratios based on the most recent tentatively settled cost reports, *id.* at 47,494. Just as in calculating the FY 2005 fixed loss threshold, the agency did not adjust its methodology to explicitly account for reconciliation in establishing the FY 2006 threshold. *Id.* at 47,495. Based on this methodology, the agency established a fixed loss threshold of $23,600. *Id.*

Fixed Loss Threshold Rulemaking for FY 2007

In a proposed rule issued on April 25, 2006, the agency proposed a fixed loss threshold of $25,530. 71 Fed. Reg. 23,996, 24,150 (Apr. 25, 2006). The agency proposed to use the same methodology to calculate the fixed loss threshold as it had in the past. Specifically, it proposed to inflate FY 2005 charge data by two years of charge inflation. *Id.* at 24,149. The agency calculated the rate of charge inflation by calculating the one-year average annual rate of change

from the combination of the last quarter of FY 2004 with the first quarter of FY 2005 to the combination of the last quarter of FY 2005 with the first quarter of FY 2006. *Id.* at 24,149-50. For this period, the agency calculated a one-year inflation rate of 7.57 percent, or 15.15 percent over two years. *Id.* at 24,150. The agency inflated the FY 2005 charge data by this two-year rate and then adjusted it to cost using the hospital-specific cost-to-charge ratios from the most recent update to the Provider Specific File. *Id.*

For the final rule, promulgated on August 18, 2006, the agency calculated the FY 2007 fixed loss threshold "using the same methodology [] proposed, except [] using more recent data to determine the charge inflation factor." 71 Fed. Reg. at 48,150. In addition, however, the agency also "appl[ied] an adjustment factor to the [cost-to-charge ratios] to account for cost and charge inflation." *Id.* Specifically, the agency calculated a charge inflation factor based on a comparison between the first six months of FY 2005 and the first six months of FY 2006. *Id.* Using this data, the agency calculated a two-year charge inflation factor of 16.42 percent. *Id.* The agency used this inflation factor to inflate charges from FY 2005. *Id.* As in previous years, the agency used hospital-specific cost-to-charge ratios to adjust the projected FY 2007 charges to cost. *Id.* However, in response to comments submitted, the agency agreed "that it is appropriate to apply an adjustment factor to the [cost-to-charge ratios] so that the [cost-to-charge ratios] we are using in our simulation more closely reflect the [cost-to-charge ratios] that will be used in FY 2007." *Id.* The agency calculated the ratio between the one-year change in costs and the one-year change in charges, and derived an adjustment factor of 0.9973. *Id*. The agency applied this adjustment factor to the cost-to-charge ratios contained in the Provider Specific File, which itself was based on the most recent tentatively settled cost reports. *Id.* The agency then used these *adjusted* cost-to-charge ratios to adjust the projected FY 2007 charges, generating projected FY

2007 costs. *See id.* Finally, just as in calculating the FY 2005 and FY 2006 fixed loss thresholds, the agency did not adjust its methodology to explicitly account for reconciliation in establishing the FY 2007 threshold. *Id.* at 48,149. Following this methodology, the agency adopted a tentative fixed loss threshold of $24,475. *Id.* at 48,151.[16]

* * *

In sum, for each fiscal year between 1997 and 2007, the Secretary determined the fixed loss threshold, a fixed dollar amount that, when added to the DRG prospective payment rate, serves as the cutoff point triggering eligibility for outlier payments. *See* 42 U.S.C. § 1395ww(d)(5)(A)(ii), (iv); 42 C.F.R. § 412.80(a)(2)-(3). When a hospital's approximate costs actually incurred in treating a patient exceed the sum of the DRG prospective payment rate applicable to that patient and the fixed loss threshold, the hospital would be 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

[16] The agency adopted the actual final dollar amount in a subsequent rule. *See* 71 Fed. Reg. at 48,151. As the agency explained in full:

> [T]he wage index tables, rates, and impacts will not be final in this final rule because we are yet to determine occupational mix adjusted wage indices. Therefore, we are only able to provide tentative standardized amounts, relative weights, offsets, and budget neutrality factors in this final rule. Once we have the final occupational mix data, we will recalculate these amounts to reflect the final occupational mix adjusted wage indices. The same circumstances apply to the outlier threshold. Without final wage index data, final standardized amounts, final offsets and final budget neutrality factors, we are only able to provide a tentative fixed loss outlier threshold in this final rule. Subsequent to this final rule, we will publish a final fixed loss outlier threshold that will be effective for discharges on and after October 1, 2006 for FY 2007. However, in this final rule, we are adopting as final the methodology we will use to calculate the final outlier fixed-loss cost threshold.

Id. at 48,149. Although the final fixed loss threshold was set at a later time, the methodology, which is at issue in this case, was final as of the promulgation of the August 2006 regulation.

in any case in which the hospital incurs estimated actual costs for treating a patient that are above the DRG prospective payment rate. 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). Accordingly, an increase in the fixed loss threshold reduces the number of cases that will qualify for outlier payments, as well as the amounts of such payments for qualifying cases. In light of this scheme, Plaintiffs challenge the rulemakings revising the outlier payment regulations and the annual fixed loss threshold rulemakings that are applicable to the payment determinations—for FY 1997 through FY 2007—that are challenged in this action.

B. Procedural Background

The procedural history is long and complex, and the Court limits its presentation of the procedural history to the relevant facts for resolving the motions before the Court. Additional procedural history can be found in the Court's previous opinions in this case. *See Banner Health v. Sebelius* ("*Banner Health I*"), 797 F. Supp. 2d 97 (D.D.C. 2011); *Banner Health v. Sebelius* ("*Banner Health II*"), 905 F. Supp. 2d 174 (D.D.C. 2012); *Banner Health v. Sebelius* ("*Banner Health III*"), 945 F. Supp. 2d 1 (D.D.C. 2013).

Plaintiffs in this case challenge outlier payment determinations for fiscal years 1997 through 2007. As required by statute, Plaintiffs filed various appeals with the Provider Reimbursement Review Board ("PRRB"), each challenging the Secretary's final outlier payment determinations for the fiscal years in question, and Plaintiffs requested expedited judicial review in those appeals. All but two of Plaintiffs' requests for expedited judicial review were made in a

consolidated filing dated June 25, 2010. *See* PRRB Rs. at 27, 172, 428, 647, 980, 1304, 1771, 2410, 2831, 3125, 3556, 4091, 4594, 5037, 5383. Two additional requests were filed, on June 25, 2010, and on September 7, 2011, that were subsequently consolidated in this action. *See* PRRB Rs. at 5633; PRRB R. (Case No. 11-0026) at 211. The June 25, 2010, request identified the legal question at issue as follows:

> Whether the Medicare Outlier Regulations, and the "fixed loss thresholds" thereunder established by the Secretary of Health and Human Services (the "Secretary"), and its Center for Medicare and Medicaid Services ("CMS") and as in effect for the Appealed Years, are substantively and/or procedurally invalid?

PRRB Rs. at 29. The legal requests presented in the two other separate requests for expedited review did not differ in any substantive matter from the consolidated request. *See* PRRB Rs. at 5633; PRRB R. (Case No. 11-0026) at 211. 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 authorized expedited judicial review pursuant to 42 U.S.C. § 1395*oo*(f)(1). *See* PRRB Rs. at 1-3; PRRB R. (Case No. 11-0026) at 208-10.

Plaintiffs commenced this action on September 27, 2010, claiming that this Court has jurisdiction under the Medicare Act, 42 U.S.C. § 1395*oo*(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 (with a minor exception discussed below). *See* Am. Compl., ECF No. 16. As this Court has previously observed, Plaintiffs' Amended Complaint was "sprawling," containing over two hundred paragraphs, spanning fifty-nine pages, and including two lengthy exhibits. *See Banner Health III*, 945 F. Supp. 2d at 9-10. 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 I, 797 F. Supp. 2d at 97. Specifically, the Court first concluded that Plaintiffs' allegations were sufficient, for the pleading stage, to establish their standing to challenge the several actions at issue in this case. *See id.* at 109. The Court noted that this conclusion was not intended to foreclose the Secretary from raising standing arguments upon filing motions for summary judgment, after the record had been developed. *See id.* However, the Court dismissed—for failure to state a plausible claim for relief—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. Looking forward, 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, in order to gain further clarity as to the precise contours of Plaintiffs' claims, the Court ordered Plaintiffs to file a "notice of claims," identifying, in bullet-point format, each circumscribed, discrete agency action that Plaintiffs intended to challenge. *Id.* at 117-18.

On July 27, 2011, Plaintiffs filed their Notice of Claims, which enumerated the claims Plaintiffs were bringing in this action. Plaintiffs' Notice of Claims likewise listed among the challenged agency actions "the Secretary's directions, starting in late 2002, to CMS's fiscal intermediaries to reopen hospital 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))." 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 I,* 797 F. Supp. 2d at 97; *Banner Health II*, 905 F. Supp. 2d at 174. 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 more appropriately addressed in the context of the Court's consideration of Plaintiffs' motion to compel. *Id.* In light of the Notice of Claims, 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 rulemakings revising the outlier payment regulations, which were promulgated in 1988, 1994, and 2003; and eleven rulemakings establishing the annual fixed loss threshold for federal fiscal years 1997 through 2007. *See Banner Health III*, 945 F. Supp. 2d at 13.

After Plaintiffs filed their Notice of Claims, the Court ordered the Secretary to file the complete administrative record—which did not include any record relating to Plaintiffs' 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 Banner Health III*, 945 F.

Supp. 2d at 13 (citing ECF filings).[17] 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. All together, the 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.

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 requesting that the Court 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, ECF No. 60, at 37. After the filing of several supplements by the parties, the Court granted in part and denied

[17] The Secretary also filed the records of Plaintiffs' proceedings before the PRRB. *See Banner Health III*, 945 F. Supp. at 13 n.14.

in part the motion. *See Banner Health III*, 945 F. Supp. 2d at 39. The Court granted the motion and ordered supplementation with respect to all or part of eight of the 36 discrete items subject to Plaintiffs' motion.[18] *See id.* at 24-39. The Court denied Plaintiffs' motion in all other respects. *See id.*

After the Secretary filed the required supplementation of the Administrative record, the Court granted the Secretary's [99] Motion for Leave to File Motion to Dismiss for Lack of Subject Matter Jurisdiction. However, instead of allowing Defendant to file the motion separately, the Court ordered Defendant to file the motion simultaneously and, in the alternative to, its motion for summary judgment. *See* Order and Docket Entry, dated August 13, 3013, ECF No. 102. On July 7, 2014, the Court granted in part and denied in part Plaintiffs' [108] Motion for Leave to Further Amend and Supplement First Amended Complaint. Specifically, the Court denied Plaintiffs' request to include claims that the Secretary's failure to disclose the draft 2003 interim final rule violated 5 U.S.C. § 553, but granted Plaintiffs' request to amend their Complaint to include factual allegations concerning the draft interim final rule. *See Banner Health v. Burwell*, 55 F. Supp. 3d 1, 3 (D.D.C. 2014). Specifically, the Court allowed Plaintiffs to

[18] Specifically, the Court ordered supplementation regarding the following items: the 2003 draft interim final rule (item 1), *Banner Health III*, 945 F. Supp. at 27; the Impact Files relating to the 1988 and 2003 amendments to the outlier payment regulations, including the underlying assumptions and associated data (items 14 and 15), *id.* at 33-34; Tables 8a and 8b for the fixed loss threshold regulations for FY 1997 through FY 2007 (item 16), *id.* at 34; letters from the Medicare Payment Advisory Commission and the American Hospital Association relating to the FY 2004 fixed loss threshold determination (items 22 and 24), *id.* at 35; the April 22, 2002 Joint Letter from CMS' Center for Medicare Management, Office of Financial Management to the fiscal intermediaries (item 26), *id.* at 37-38; and Program Memoranda A-02-122 and A-02-126 (item 33), *id*. Subsequently, the Court granted in part and denied in part the Secretary's Motion for Reconsideration, ECF No. 93. *See* Mem. Order, dated July 30, 2013, ECF No. 96. The Court granted the motion with respect to the cost-to-charge data underlying the Impact Files and vacated the previous order to supplement the record with the source data for those files. *See id.* at 19. In all other respects, the Court denied the Motion for Reconsideration and did not disturb its previous decisions regarding the supplementation of the administrative record. *See id.* at 20.

amend their Complaint to include the allegations contained in sub-paragraphs 198.5(a)-(e) of their Proposed Amendments. *See id.* at 14.

On September 9, 2014, Defendant filed her [126] Motion to Dismiss for Lack of Subject Matter Jurisdiction and for Summary Judgment, and Plaintiffs filed their [127] Motion for Summary Judgment. That same day, Plaintiffs also filed their [128] Motion (Related to Their Motion For Summary Judgment) for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief. The parties briefed these motions and both, subsequently, filed notices of supplemental authority. These motions are now ripe for resolution.

II. LEGAL STANDARD

Judicial review of Plaintiffs' claims under the Medicare Act rests on 42 U.S.C. § 1395*oo*(f)(1), which incorporates the APA. *See* 42 U.S.C. § 1395*oo*(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).

A. Supplementation of the Record

The Administrative Procedure Act directs the 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). 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) (citation omitted). "In other words, the administrative record 'should not include materials that were not considered by agency decisionmakers.'" *Id.*

(citation omitted). "[A]bsent clear evidence, an agency is entitled to a strong presumption of regularity, that it properly designated the administrative record." *Id.* at 5.

"Supplementation of the administrative record is the exception, not the rule." *Pac. Shores*, 448 F. Supp. 2d at 5 (quoting *Motor & Equip. Mfrs. Ass'n, Inc. v. EPA*, 627 F.2d 1095, 1105 (D.C. Cir. 1979)); *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)). However, an agency "may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made." *Blue Ocean Inst. v. Gutierrez,* 503 F. Supp. 2d 366, 369 (D.D.C. 2007). 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 omitted). "[W]hile 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," to be included in the Administrative Record, "the data or

analysis must be sufficiently integral to the final analysis that was considered by the [agency], and the [agency's] reliance thereon sufficiently heavy, so as to suggest that the decisionmaker constructively considered it." *Banner Health III*, 945 F. Supp. 2d at 28.

B. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(h)(3) provides that "[i]f the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3). In assessing its jurisdiction over the subject matter of the claims presented, a court "must accept as true all of the factual allegations contained in the complaint" and draw all reasonable inferences in favor of the plaintiff, *Brown v. District of Columbia*, 514 F.3d 1279, 1283 (D.C. Cir. 2008) (internal quotation marks omitted), but courts are "not required … to accept inferences unsupported by the facts alleged or legal conclusions that are cast as factual allegations." *Rann v. Chao*, 154 F. Supp. 2d 61, 64 (D.D.C. 2001). Ultimately, the plaintiff bears the burden of establishing the Court's subject matter jurisdiction, *Arpaio v. Obama*, No. 14-5325, 2015 WL 4772774, at *5 (D.C. Cir. Aug. 14, 2015), and where subject-matter jurisdiction does not exist, "the court cannot proceed at all in any cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998).

C. Motions for Summary Judgment

Under Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." However, "when a party seeks review of agency action under the APA [before a district court], the district judge sits as an appellate tribunal. The 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Accordingly, "the standard set forth in Rule 56[ ] does not

apply because of the limited role of a court in reviewing the administrative record.... Summary judgment is [ ] the mechanism for deciding whether as a matter of law the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review." *Southeast Conference v. Vilsack*, 684 F. Supp. 2d 135, 142 (D.D.C. 2010).

The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "This is a 'narrow' standard of review as courts defer to the agency's expertise." *Ctr. for Food Safety v. Salazar*, 898 F. Supp. 2d 130, 138 (D.D.C. 2012) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (internal quotation omitted). "Moreover, an agency cannot 'fail[ ] to consider an important aspect of the problem' or 'offer[ ] an explanation for its decision that runs counter to the evidence' before it." *Dist. Hosp. Partners*, 786 F.3d at 57 (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43). The reviewing court "is not to substitute its judgment for that of the agency." *Id.* Nevertheless, a decision that is not fully explained may be upheld "if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas–Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

III. DISCUSSION

This action entails Plaintiffs' challenges to 14 rulemakings, three rulemakings revising the outlier payment regulations and 11 annual fixed loss threshold rulemakings. The parties filed

cross-motions for summary judgment, and Defendant moved to dismiss for lack of subject matter jurisdiction with respect to certain claims. In addition, Plaintiffs moved the Court to take judicial notice and/or extra-record consideration of certain other materials, as well as specified other relief. The Court begins by considering Plaintiffs' motion requesting the consideration of additional materials because the resolution of that motion determines the scope of the materials examined with respect to the other motions resolved today. The Court then turns to Defendant's arguments that this Court lacks subject matter jurisdiction over certain claims. Finally, having resolved those issues, the Court addresses the cross-motions for summary judgment and resolves the merits of this dispute.

A. Plaintiffs' Motion Regarding Consideration of Additional Materials

On the same date that the parties filed their dispositive cross-motions—on the deadline previously set by the Court for those cross-motions, *see* Scheduling and Procedures Order, ECF No. 122—Plaintiffs filed a motion asking the Court to consider additional materials in resolving the cross-motions filed that day. Plaintiffs asked the Court (1) to take judicial notice of six identified documents, or in the alternative to consider them as extra-record materials, (2) to supplement the administrative record with a comment to the FY 2004 fixed loss threshold rulemaking, and (3) to "receive" three tables as demonstrative exhibits that exceed the allowed page limits set by the Court for the briefing. Defendant opposes each of these requests.

As an initial matter, the Court notes that it considers this request to be tardy. Asking the Court for permission to consider additional materials on the very day on which the dispositive motions are filed is simply too late. Doing so meant that Plaintiffs precluded Defendant from effectively objecting to the inclusion of these materials before Plaintiffs relied on them in their briefing. At the same time, by waiting until the last moment to present these materials, Defendant

was prevented from being able to rely on them in her initial briefing. To say that Defendant could file an opposition to this motion after the fact and could respond to the proposed materials in the subsequent briefing is no answer at all. The orderly management of this litigation requires the resolution of questions regarding the materials on which the parties may rely—and on which the Court will base its ultimate decision—before the submission of the parties' arguments regarding the merits. Last minute surprises regarding materials on which Plaintiffs hope to rely are neither efficient nor fair. With that in mind, the Court considers each of Plaintiffs' requests.

Judicial Notice or Extra-record Consideration of Six Documents

Plaintiffs ask the Court to take judicial notice "as a matter of adjudicative fact" or, in the alternative, to consider as extra-record evidence six documents (falling into four categories): (1) two versions of a statement given by Thomas A. Scully, former Administrator of the Centers for Medicare and Medicaid Services ("CMS"), on March 11, 2003, before a Senate subcommittee; (2) a report of the Office of Inspector General of the Department of Health and Human Services regarding the reconciliation of outlier payments[19]; (3) the declaration of Peter Reisman, a CMS official, that was submitted in a case filed in the Southern District of New York; and (4) two *amicus* briefs submitted by the United States in a case relating to outlier payments in the Southern District of Florida.

The Court agrees—as does Defendant—that parties may cite to publicly available documents and that the Court may take judicial notice of such documents. *See Pharm. Research & Manufacturers of Am. v. United States Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 33

[19] The full title of the report in question is as follows: *The Centers for Medicare and Medicaid Services Did Not Reconcile Medicare Outlier Payments In Accordance with Federal Regulations and Guidance* (2012), *available at* https://oig.hhs.gov/oas/reports/region7/71002764.pdf (last visited July 23, 2015).

(D.D.C. 2014). Each of the identified documents is publicly available, and the Court considers it proper to take judicial notice of them. While Plaintiffs frame their request for judicial notice as an alternative to their request for extra-record consideration of these documents, Plaintiffs have revealed their hand. It appears that, regardless of Plaintiffs' framing, Plaintiffs are effectively asking the Court to consider these materials as extra-record evidence serving as the basis for the Court's review of the agency actions challenged here. Insofar as Plaintiffs seek to base their challenge upon these extra-record materials, even those available to the public of which the Court could take judicial notice, the Court concludes that it is necessary to apply the standard for considering extra-record evidence.

It is "black-letter administrative law that in an [Administrative Procedure Act] case, a reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.' " *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) (quoting *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984)). As the D.C. Circuit Court of Appeals has recently reiterated, "exceptions to that rule are quite narrow and rarely invoked." *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014). "They are primarily limited to cases where 'the procedural validity of the agency's action remains in serious question,' or the agency affirmatively excluded relevant evidence." *Id.* (citations omitted). Plaintiffs have not even attempted to show that this standard is met in this case. Plaintiffs emphasize that these documents should be considered because they are "needed to assist the court's review." Pls.' Extra-Record Mot. at 9 (quoting *Nat'l Mining Ass'n v. Jackson*, 856 F. Supp. 2d 150, 156-57 (D.D.C. 2012). But that is not enough. As the D.C. Circuit has emphasized, consideration of such extra-record materials "at most [] may be invoked to challenge gross procedural deficiencies—such as where the administrative record itself is so deficient as to

preclude effective review." *Hill*, 709 F.3d at 47. This is not such a case. Plaintiffs are not using these materials to "challenge gross procedural deficiencies." *CTS Corp.*, 759 F.3d at 64. While some procedural deficiencies undoubtedly exist in this case—such as missing comments from the FY 2004 fixed loss threshold rulemaking—the Court has adequately accounted for those deficiencies in resolving the parties' previous motions regarding the scope of the administrative record. *See Banner Health III*, 945 F. Supp. 2d at 19. Contrary to Plaintiffs' characterization, the record readily permits "effective review" without adding the requested materials to the record. The Court concludes that, pursuant to the standard for consideration of extra-record evidence, it would not be proper to consider the presented materials along with the already-voluminous administrative record. In other words, Plaintiffs cannot evade that strict standard by appealing to the standard for judicial notice. Although the Court will take judicial notice of these documents as necessary in resolving this matter, the documents cannot serve as the foundation for Plaintiffs' claims.

Supplementation with Federation of American Hospitals Comment

Plaintiffs seek to supplement the administrative record for the FY 2004 fiscal loss threshold rulemaking with a comment by the Federation of American Hospitals. The Court concludes that it is too late to—once again—expand the administrative record in this case. The Court previously set a deadline of March 23, 2012, for Plaintiffs' motion to compel regarding the contents of the administrative record in this case. *See* Minute Order dated February 24, 2012. After numerous supplemental filings, the Court resolved Plaintiffs' motion to compel on May 16, 2013, addressing a wide variety of challenges to the administrative record filed. *See Banner Health*, 945 F. Supp. 2d at 6. Subsequently, the Court granted Defendant's [93] Motion for Partial Reconsideration or Clarification and modified its previous order compelling the

supplementation of the administrative record with respect to certain materials. *See* Order dated July 30, 2013, ECF No. 96. Meanwhile, on September 19, 2013, another judge in this district accepted the comment in question into the administrative record in an outlier case proceeding in parallel to this one. *See Dist. Hosp. Partners, L.P. v. Sebelius*, 971 F. Supp. 2d 15, 27 (D.D.C. 2013) *aff'd in part and rev'd in part* sub nom. *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46 (D.C. Cir. 2015). It is undisputed that the parties in this case were aware of the proceedings in *District Hospital Partners*; indeed, from time to time, the parties reported to this Court regarding those parallel proceedings, particularly regarding disputes over the administrative record in that case. *See, e.g.*, Plaintiffs' Notice of the Conclusion of Previously Reported Discovery Proceedings in the *District Hospital Partners* Case, dated April 12, 2013, ECF No. 81. Despite the fact that Federation of American Hospitals comment was added to the record in *District Hospital Partners* approximately one year before the dispositive motions in this case were due, Plaintiffs never sought leave to add the Federation of American Hospitals comment to this case until the day they filed their dispositive motion.

Plaintiffs argue that Defendant cannot be prejudiced because the agency knew about this comment, but that misses the point. Defendant had no reason to believe that Plaintiffs would—at the very last minute—seek to add this particular comment to the record given that the administrative record had been extensively litigated in this case and given the lag between the addition of the comment in question to the *District Hospital Partners* record and the filing of the dispositive motions in this case. Accordingly, the Court concludes that it would be improper to add the Federation of American Hospitals comment to the administrative record.[20]

[20] In any event, as the Court explains below, even if the Federation of American Hospitals comment were added to the administrative record, the outcome in this case would not be altered.

Three Additional Tables

Plaintiffs ask the court to "receive" three tables that are appended to Plaintiffs' Motion for Summary Judgment. Plaintiffs explain that "[a]ll three tables summarize data in the Impact Files that are already part of the administrative record and concisely encapsulate what would otherwise require resorting to a voluminous portion of the administrative records." Pls.' Extra-Record Mot. at 7. They argue that, because these tables "merely restate information already contained in the administrative record," they should not be included in the page limitations previously ordered by the Court. *Id.* at 7-8. Plaintiffs further state that the "tables are intended to aid the parties and the Court by presenting visually concise data that would otherwise only be accessible in cumbersome spreadsheets." *Id.* at 8. Defendant responds that Plaintiffs' request to submit the tables was untimely, that the additional pages should not be exempt from the page limit because they effectively present argument rather than materials from the administrative record, and that the Court should not allow an expansion of the page limits. The Court agrees with Defendant.

First, pursuant to Local Civil Rule 7(e), Plaintiffs should have requested leave to exceed the page limits—or to submit what they believe should not be counted towards the page limits—prior to the deadline for filing their briefs. Presenting this request simultaneous with the filing of those briefs is neither fair—Defendant did not have an opportunity to file an expanded brief—nor conducive to the orderly administration of this action.

Second, the Court concludes that the appended tables are not exempt from the page limit. Contrary to Plaintiffs' suggestion, the exhibits are not like a Joint Appendix. A Joint Appendix contains excerpts of the *unadorned* administrative record to facilitate the Court's review of those portions of the administrative record on which the parties rely, which is particularly useful in cases like this one with a voluminous record. *See* LCvR 7(n). A Joint Appendix does not provide

an opportunity for the parties to add analysis or commentary regarding the meaning of the administrative record. The Court agrees that, as a general matter, charts or graphs may be a helpful way to present complex information. *See generally* Edward Tufte, *Beautiful Evidence* (2006). They also can be an effective way to present an argument. *See id.* However, the question is not whether or not the charts are helpful. Any material describing the administrative record that is not a faithful reproduction of the unadorned administrative record belongs in a memorandum of points and authorities in support of, or in opposition to, a motion. Indeed, that is essentially what a factual or background section of a memorandum is: it is a description of a voluminous record to set the groundwork for a party's legal arguments about the meaning of that record. Whether the charts themselves are more like a background section of a brief or the argument section itself is immaterial for present purposes; it is plain that they are not like portions of the administrative itself and that they should be counted towards the page limit for the briefing.

In that light, the Court arrives at the page limitation itself. The Court's Scheduling and Procedures Order, dated July 17, 2014, established a 70-page limit for Plaintiffs' motion for summary judgment. *See* ECF No. 122, at 3. In that Order, the Court also stated that the "page limits identified above are similarly generous and equally firm," just as the briefing schedule set that day was generous and firm. *Id.* at 4. The Court also "caution[ed] the parties that any attempt to subvert these page limits by including additional briefing in appendices will be rejected, and such appendices will be stricken from the record." *Id.* (citing *Hajjar-Nejad v. George Washington Univ.*, 37 F. Supp. 3d 90, 114 (D.D.C. 2014)). Despite their arguments to the contrary, Plaintiffs have done precisely that. Plaintiffs submitted a memorandum of points and authorities in support of their motion for summary judgment of 70 pages. In *addition*, they submitted three tables—

exhibits 5, 7, and 8—that purport to summarize relevant data in the administrative record. These exhibits are properly considered portions of Plaintiffs' memorandum and, therefore, exceed the page limit.

Plaintiffs' suggestion—as a basis for submitting the separate exhibits—that they could not have effectively cited to the administrative record is immaterial. Insofar as they believe they effectively cited to the record in their charts, and then relied on these charts in their briefing, they could have simply included these charts within their briefing itself.[21] Parties always face tradeoffs in choosing what to include in a page-limited filing. If Plaintiffs had concluded that including the tables was valuable in presenting their arguments—more valuable than other materials they did include—the Court is confident that Plaintiffs could have devised a way to include those materials in their memorandum itself. Instead, Plaintiffs are trying to have it both ways, but the Court will not allow them to do so. Accordingly, the Court will not grant Plaintiffs' belated request to submit the tables, which is effectively a request to expand the page limit for the briefing of this action. The Court denies Plaintiffs' request to submit these additional exhibits and strikes exhibits 5, 7, and 8 from the record.

Having resolved these preliminary issues, the Court proceeds to consider the Secretary's arguments that this Court does not have subject matter jurisdiction over certain claims in this action.

[21] It is similarly immaterial that they had space within the final page of the brief to list all of the citations to the administrative record on which those three tables rely.

B. Secretary's Motion to Dismiss for Lack of Subject Matter Jurisdiction

The Secretary argues that several of Plaintiffs' claims should be dismissed for lack of subject matter jurisdiction. The Court reviews each of those arguments in turn and concludes that it has jurisdiction over the claims in this action.

First, the Secretary argues that Plaintiffs lack standing to pursue claims that rely on speculation about how hospitals—other than Plaintiffs—would behave under a different set of regulations. To satisfy the standing requirements of Article III, a plaintiff "must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). Essentially the Secretary argues that a subset of Plaintiffs' claims—although the Secretary does not identify specifically which claims—rely on assumptions about how hospitals would, generally, respond to the regulations in question. Therefore, the Secretary argues, the injury was not "fairly traceable" to the challenged agency action. Plaintiffs respond that their injuries are directly linked to each of the challenged regulations. The Court agrees that Plaintiffs have standing to challenge the 14 regulations at issue in this case.

As described above, in *Banner Health I*, in resolving the Secretary's motion to dismiss, the Court concluded that Plaintiffs' allegations were sufficient, for the pleading stage, to establish their standing over all of the claims that survived the motion to dismiss stage.[22] *See* 797 F. Supp. 2d at 109. At that time, the Court noted that this conclusion was not intended to foreclose the Secretary from raising standing arguments upon filing a motion for summary judgment, after the

[22] Whether Plaintiffs have standing over claims that the Court dismissed for failure to state a claim is immaterial at this stage of the proceedings. *See Banner Health I*, 797 F. Supp. 2d at 109.

record had been developed. *See id.* The Secretary now does so. However, neither the subsequent development of the record nor the gradual refining of Plaintiffs' claims alters the Court's previous conclusion that Plaintiffs have standing. As the Court noted in resolving the Secretary's motion to dismiss, "[i]n many cases, a plaintiff's 'standing to seek review of administrative action is self-evident,' including where, as here, 'the complainant is an object of the action (or forgone action) at issue—as is the case usually in review of a rulemaking and nearly always in review of an adjudication.'" *Id.* at 108 (quoting *Sierra Club v. Envtl. Prot. Agency,* 292 F.3d 895, 900 (D.C. Cir. 2002)) (internal quotation marks and citation omitted). As the Court stated previously, Plaintiffs certainly have standing to challenge the outlier payments that Plaintiffs themselves received for FY 1997 through FY 2007 and, accordingly, Plaintiffs also have standing to challenge the validity of the regulations on which those payments were based—i.e., three rulemakings revising the outlier payment regulations and 11 annual fixed loss threshold regulations. *See id.*

Essentially, the Secretary's standing argument amounts to a claim that the challenged regulations were not arbitrary or capricious, or otherwise not in accordance with law, because Plaintiffs' arguments rely on predictions about actions of third parties. As the Court said previously, this argument is best considered on the merits because, even if the Secretary's arguments are correct, they would not undermine Plaintiffs' standing to bring the challenges in this action in the first instance. *See id.* at 108 n.11. Notwithstanding the subsequent development of the record and of the parties' arguments, the Court's conclusion that the Plaintiffs have standing to bring the claims in this action is unchanged.

Second, the Secretary argues that this Court has no subject matter jurisdiction over Plaintiffs' claim that it was arbitrary and capricious for the agency to fail to make a mid-year

adjustment to the FY 2003 fixed loss threshold because the PRRB had not approved that question for judicial review. Plaintiffs respond that the question of the propriety of a mid-year adjustment to the FY 2003 fixed loss threshold was within the scope of judicial review approved by Plaintiffs. Regarding this question, the Court agrees with Plaintiffs.

Under the Medicare Act, "[j]udicial review may be had only after the claim has been presented to the Secretary and administrative remedies have been exhausted." *Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005). In this case, Plaintiffs presented requests for judicial review with respect to all of the payment determinations at issue in this case. The question for which Plaintiffs requested judicial review was framed broadly:

> Whether the Medicare Outlier Regulations, and the "fixed loss thresholds" thereunder established by the Secretary of Health and Human Services (the "Secretary"), and its Center for Medicare and Medicaid Services ("CMS") and as in effect for the Appealed Years, are substantively and/or procedurally invalid?"

PRRB Rs. 28. Plaintiffs' request made it clear that they were challenging the 2003 rulemaking promulgating amendments to the outlier payment regulations. *See id.* It is that rulemaking that encompasses Plaintiffs' mid-year adjustment claim—whereby Plaintiffs argue that the decision not to lower the FY 2003 fixed loss threshold in a mid-year adjustment was arbitrary and capricious. The Secretary argues that Plaintiffs' request for judicial review does not include the mid-year adjustment claim because Plaintiffs' request included discussion of several other specific questions—not including the mid-year adjustment question—and references to several specific Federal Register pages—which did not include the pages on which the decision not to adjust the FY 2003 fixed loss threshold was explained. However, the Court does not read Plaintiffs' request so narrowly so as to exclude a challenge to the decision to refrain from a mid-year adjustment to the FY 2003 threshold.

The decision in *District Hospital Partners*, 794 F. Supp. 2d at 162, is not to the contrary. In *District Hospital Partners*—another outlier case—another judge in this district concluded that the court did not have subject matter jurisdiction over the claims of the hospital-plaintiffs in that case, arguing that the agency had failed to adjust the fixed loss thresholds for FY 2004 through FY 2006, because those plaintiffs had not presented the mid-year adjustment claims to the agency, as required. *See id.* at 168-69. At the outset, it is important that different mid-year adjustments were challenged in the two cases: the FY 2003 threshold in this case, and the FY 2004, FY 2005, and FY 2006 thresholds in *District Hospital Partners*. *See id.* at 167. In that case, "[t]he question the Board certified was whether the 'various elements used to project the outlier thresholds were arbitrary and capricious.'" *Id.* at 168 (citing Complaint Ex. A at 1). That court determined the plaintiffs' request did not encompass any decisions not to adjust the thresholds after the fact—which necessarily occurred after the setting of the fixed loss thresholds for the applicable years. *See id.* In this case, however, Plaintiffs' challenge encompassed a challenge to the validity of the 2003 regulation, which promulgated changes to the outlier payment regulations and encompassed the decision not to lower the FY 2003 fixed loss threshold after the fact. The two cases, therefore, are distinguishable. Accordingly, the Court concludes that Plaintiffs' challenge to the June 9, 2003, decision to forego a mid-year adjustment of the FY 2003 fixed loss threshold was within the scope of the questions approved by the PRRB and, therefore, that it is within the scope of this Court's subject matter jurisdiction. The Court returns to the merits of Plaintiffs' claims regarding the agency's decision not to undertake a FY 2003 mid-year adjustment below.

Furthermore, insofar as the Secretary's argument that this Court lacks subject jurisdiction is directed at "any other claims that were not properly channeled through the PRRB," that

argument is unavailing as well. Def.'s Mot. at 30. Not only has the Secretary failed to identify any other claims in this action that were not presented to the PRRB, but the Court concludes, because it must assure itself of jurisdiction over the claims in this action, that each was adequately presented to the PRRB. As explained above, the legal question presented to the PRRB was framed broadly, referring to each of the revisions to the outlier payment regulations and each of the fixed loss threshold regulations at issue for the payment years in question—that is, each of the regulations challenged in this action. *See* PRRB Rs. at 29. Accordingly, Plaintiffs have complied with the jurisdictional requirements of the Medicare Act, and the Court has subject matter jurisdiction over each of the claims in this action.

Third, and finally, the Secretary argues that claims aimed at increasing Plaintiffs' outlier payments rather than at correcting an identifiable error would be barred by sovereign immunity. It is true that Plaintiffs cannot bring a claim under the Medicare Act, which incorporates the APA's standard of review, in order to simply increase Plaintiffs' payments that they receive from the government. However, Plaintiffs are not doing so: they have brought claims identifying what they argue are legal errors in each of the 14 rulemakings at issue in this case. That is enough to fall within the government's waiver of sovereign immunity.

Having concluded that the Court has subject matter jurisdiction over the claims in this action, the Court turns to those claims—the legal errors Plaintiffs purport to identify with respect to the 14 regulations in question—in the remainder of this Memorandum Opinion. However, before addressing the individual claims, in light of the multitude of arguments that Plaintiffs present with respect to the 14 regulations at issue in this case and the variety of arguments that the Secretary presents in response, the Court reviews several fundamental principles regarding the parameters of its review.

C. Framing Issues

Essentially, Plaintiffs present two sets of challenges in this case. First, Plaintiffs argue that certain of the challenged regulations—specifically the outlier payment regulations from 1988 and 1994 and all of the fixed loss threshold regulations at issue—are at odds with the language of the Medicare Act.[23] Plaintiffs refer to this set of arguments as their *Chevron* challenge—under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See* Pls.' Mot. at 25. Second, Plaintiffs argue that each of the regulations at issue in this case was arbitrary and capricious. While Plaintiffs' claims pertain to 14 different regulations over the course of a thirty year period, there are several legal questions that recur in the parties' briefing. In the interest of clarity, the Court first addresses several recurring legal issues before addressing Plaintiffs' individual challenges. The resolution of these issues sets the stage for the Court's discussion of Plaintiffs' specific claims below.

Of these several framing questions, the Court first addresses Defendant's argument that Plaintiffs are barred from raising various arguments by failing to raise them in comments before the agency at the time of the various rulemakings or, at a minimum, being able to point to other parties who raised those arguments before the agency at the proper time. The Court disagrees. The Medicare Act allows judicial review of legal issues pertaining to regulations pursuant to the scheme described above: by filing timely appeals of payment determinations with the PRRB and seeking judicial review on legal issues outside the scope of the PRRB's authority. *See* 42 U.S.C. § 1395oo(a)(3); *id.* § 1395oo(f)(1). Plaintiffs have done so here. Indeed, Defendant does not contest the timeliness of Plaintiffs' challenges to the payment determinations from the relevant

[23] Plaintiffs also argue that the failure to engage in reconciliation in FY 2004 through FY 2007 also violates the clear language of the statute. As discussed further below, the Court understands this argument as linked to Plaintiffs' arguments regarding the fixed loss threshold regulations for those years.

fiscal years. Nor does Defendant contend that a challenge to those payment determination cannot be the appropriate vehicle for challenging the regulations on which those payment determinations depend. However, Defendant argues, nonetheless, that various *arguments* by Plaintiffs are barred because they were never placed before the agency during the various rulemaking proceedings subject to challenge in this action. In support of this proposition, they cite to various cases that stand for the proposition that arguments must be raised before an agency before they can be raised in court. *See, e.g.*, *Nuclear Energy Inst., Inc., v. EPA*, 373 F.3d 1251, 1298 (D.C. Cir. 2004). But those cases do not tell the whole story. Even where a party has waived its opportunity to pursue facial review of a regulation by failing to comment during a rulemaking proceeding,[24] such a party can raise its arguments when the agency applies the rule. *See Koretoff v. Vilsack*, 707 F.3d 394, 399 (D.C. Cir. 2013) (citing *Murphy Exploration & Production Co. v. U.S. Department of Interior*, 270 F.3d 957, 958 (D.C. Cir. 2001)). The Secretary responds, in turn, that this is a facial challenge because Plaintiffs are arguing that the regulations in question cannot be validly applied in calculating any hospital's payments—not simply in calculating payments due to Plaintiffs. *See* Def.'s Reply at 17. For that proposition, the Secretary looks to the oft-repeated standard for success on a facial challenge: "'To prevail in such a facial challenge, [a party] 'must establish that no set of circumstances exists under which the [regulations] would be valid.'" *Ass'n of Private Sector Colleges & Universities v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012) (citation omitted). However, in doing so, the Secretary has transformed the standard for success on a facial challenge into the definition of a facial

[24] The Court notes that, even in the facial challenge posture, "the waiver rule would not bar a facial challenge if the agency has actually addressed the issue, either sua sponte or at the behest of another party." *Koretoff*, 707 F.3d at 400 n.3 (Williams, J., concurring) (citing *Ohio v. EPA*, 997 F.2d 1520, 1529 (D.C. Cir. 1993)).

challenge. They are not the same. The Secretary has not pointed to any authority suggesting that, just because a plaintiff argues that a regulation is invalid, such a plaintiff has waived any arguments not raised in a prior rulemaking proceeding. To the contrary, a series of cases from the D.C. Circuit Court of Appeals indicate that a party may challenge the very validity of a regulation when that regulation is applied without waiving arguments that were not raised before the agency in the underlying rulemaking proceedings. *See Weaver v. Fed. Motor Carrier Safety Admin*., 744 F.3d 142, 145 (D.C. Cir. 2014) (citing cases where the Court of Appeals "considered the *validity* of rules that an agency applied" "despite want of a prior timely attack" to the regulations in question) (emphasis added); *see also Natural Res. Def. Council v. EPA*, 513 F.3d 257, 260 (D.C. Cir. 2008) (describing "established doctrine that parties claiming substantive invalidity of a rule for which direct statutory assault is time-barred are nonetheless free to raise their claims in actions against agency decisions *applying* the earlier rule") (emphasis in original). That is precisely what Plaintiffs have done here. They have raised a timely challenge to the outlier payments they received for FY 1997 through FY 2007, which entailed applying the 14 regulations subject to challenge in this action. Accordingly, they may raise arguments challenging the validity of those regulations regardless of whether those arguments were raised before the agency in the challenged rulemakings.

However, this conclusion is not the end of the story. Just because Plaintiffs are not barred from raising at this time arguments that were not previously raised before the agency does not mean that they will prevail on them. Indeed, whether comments have been presented to the agency matters in applying the arbitrary and capricious standard of review. In addition to other potential bases for determining that an agency action was arbitrary or capricious, discussed further below, this Court cannot "uphold agency action if it fails to consider 'significant and

viable and obvious alternatives.'" *Dist. Hosp. Partners*, 786 F.3d at 59 (quoting *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (internal quotation marks omitted)). Determining whether comments have been presented to the agency regarding a specific challenge is thus part—but not all—of the calculus entailed in determining whether the agency has failed to consider "significant and viable and obvious alternatives." The Court will apply that standard below, as required, in resolving Plaintiffs' arbitrary and capricious claims.

One particular application of that rule is worth explaining at this point because of its general relevance to this case. Many of Plaintiffs' arguments are dependent, in some form, on the differences between the draft interim final rule sent to the Office of Management and Budget in 2003 and the subsequent rulemakings undertaken by the agency. However, the Court of Appeals has determined that Plaintiffs cannot "[r]ely[] on the OMB draft rule to impugn the 2004 rulemaking." *Dist. Hosp. Partners*, 786 F.3d at 58. Because "the OMB draft was never 'on the books' in the first place"—that is to say, never published in the Federal Register—the Court of Appeals concluded that the agency had no obligation to explain its departure from the provisions of that internal draft. *Id.* That conclusion is wholly applicable here.

Furthermore, as the Court of Appeals recently clarified in *District Hospital Partners*, contrary to Plaintiffs' arguments here, the agency does not have an obligation to use the "best available data" above and beyond the requirements of arbitrary and capricious review. *See id.* at 56 (rejecting argument that *Gas Appliance Manufacturers Ass'n, Inc. v. DOE*, 998 F.2d 1041 (D.C. Cir. 1993), "imposed a generic obligation on agencies to always use the best available data").

Next, the Court turns to the basis for its review of the various agency actions challenged here. A fundamental principle of judicial review of agency actions is that such review is based

on—and limited to—the record before the agency at the time of the action. *See Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792 ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision."); *see also* 5 U.S.C. § 706 (for review under the APA, "the court shall review the whole record or those parts of it cited by a party"). The Supreme Court has cautioned that the record must be limited to that which existed at the time of the decision. *See Citizens to Preserve Overton Park*, 401 U.S. at 420 ("[R]eview is to be based on the full administrative record that was before the Secretary *at the time* he made his decision.") (emphasis added). Accordingly, information that was not yet before the agency at the time of a particular agency decision cannot provide the ammunition for challenging that decision.

Here, Plaintiffs are challenging 14 discrete regulations. Only the information that was before the agency at the time of each of those individual rulemakings can be used to challenge that action. In evaluating each rulemaking, the Court must exclude all information that pertains to events after that rulemaking, including information in the administrative records for subsequent rulemakings. For example, in evaluating the FY 2004 fixed loss threshold rulemaking, anything outside of the administrative record for *that* rulemaking—including information in the administrative records for subsequent fixed loss threshold rulemakings—cannot be considered. The same result applies to the Court's evaluation of each of the three outlier payment rulemakings and the 11 fixed loss threshold rulemakings challenged in this action.

Furthermore, notwithstanding Plaintiffs' suggestions to the contrary, the mere fact that a subsequent rulemaking relied on a prior rulemaking does not mean that the earlier rulemaking becomes open to challenge as a result of information before the agency at the time of the

subsequent rulemaking. *See Biggerstaff v. FCC*, 511 F.3d 178, 184 (D.C. Cir. 2007) (describing reopening doctrine). Plaintiffs are correct that the issue directly before the Court of Appeals in *Biggerstaff* was whether the petitioners in that case were time barred from challenging an earlier agency action, which those petitioners claimed was encompassed in a later rulemaking. As Plaintiffs argue, the issue of timeliness is not before this Court because Plaintiffs' challenges to each of the 14 regulations on which the challenged payment determinations rely are timely, as explained above. However, the Court concludes that the reasoning in *Biggerstaff,* and the associated line of reopening cases, is equally applicable here. In *Biggerstaff*, the Court of Appeals concluded that, "for the court to examine the merits of his contention, [plaintiff] must demonstrate that in the [subsequent] rulemaking the Commission reopened consideration of its authority to adopt the [earlier-adopted] exemption, for otherwise his challenge is untimely." *Biggerstaff*, 511 F.3d at 185. The Court of Appeals also concluded that the agency's "intention to initiate a reopening must be clear from the administrative record." *Id.* It is sensible to apply this standard to determine whether actions taken in an earlier rulemaking can be evaluated in light of the information in front of the agency at a later date. If the agency effectively reopened an earlier rulemaking, such earlier decisions can be subject to challenge as a result of the later rulemaking. Similarly, it is sensible that decisions made earlier can be challenged based on information before the agency at the time of a later rulemaking only if the later rulemaking actually considered and adopted, anew, the results of the earlier rulemaking—and only with respect to applications of that decision *after* the later rulemaking.[25]

[25] To be clear, a subsequent re-adoption of a prior rule could not make that earlier rule retroactively invalid as of the time it was originally adopted; but it could potentially make the re-opened and re-adopted rule invalid as of the later adoption based on judicial evaluation of the information before an agency at the time of the later adoption.

Despite Plaintiffs' suggestions that the reopening line of cases is inapposite, Plaintiffs have pointed to no authority suggesting an exception to the general rule that judicial review of an agency action is limited to the record before the agency at the time of the agency action. Accordingly, in the analysis below, the Court will evaluate the decisions made in each rulemaking by analyzing the record before the agency at the time of each of those rulemakings. Only in the limited circumstance where Plaintiffs have shown that one of the rules challenged has been reopened and adopted through a later rulemaking will the Court review the later adopted rule pursuant to the record before the agency at that later time, as well.[26]

A final word is necessary regarding Plaintiffs' framing of their challenges. While Plaintiffs frame their *Chevron* arguments as a separate set of challenges, distinct from their arbitrary and capricious arguments, *Chevron* does not provide an independent basis for reviewing the agency's actions. *See Ass'n of Private Sector Colleges & Universities*, 681 F.3d at 441. Pursuant to the APA standard of review that is adopted by the Medicare Act, the Court reviews agency actions, as relevant here, to determine whether they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(a), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).[27] *Chevron* provides the two-step rubric for determining whether the agency actions were "not in

[26] Somewhat analogously, Plaintiffs argue in several contexts that, in setting the fixed loss threshold for a given year, the agency was aware of the relationship between actual outlier payments from a previous year and previous projections as to outlier payments used in setting the fixed loss threshold for that previous year. Although that claims recurs several times, it requires a fact-specific inquiry—particular to the specific record before the agency at the time of the respective challenged regulations. Accordingly, the Court will consider those arguments in the context of Plaintiffs' specific claims discussed below.

[27] Notably, Plaintiffs never once cite the relevant statutory provisions that establish the parameters for judicial review over agency action, which they seek in this case.

accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."[28] *See Ass'n of Private Sector Colleges & Universities*, 681 F.3d at 441; *Military Toxics Project v. EPA*, 146 F.3d 948, 954 (D.C. Cir. 1998). Accordingly, this Court applies the analytic framework of *Chevron* in the context of Plaintiffs' claims that the rulemakings at issue in this case are inconsistent with the provisions of the Medicare Act.[29]

Finally, even though *Chevron* does not provide an independent basis for review, in the interest of clarity, the Court will address Plaintiffs' challenges according to the manner in which Plaintiffs organized them: first, a set of statutory challenges invoking *Chevron* with respect to various regulations and, then, a series of claims that each of the regulations at issue in this case was arbitrary and capricious. It is to the challenges invoking *Chevron* that the Court turns first.

D. Plaintiffs' *Chevron* Arguments

Plaintiffs argue that the outlier payment model as a whole in effect for the fiscal years in question was inconsistent with the outlier payment provisions of the Medicare Act, 42 U.S.C. § 1395ww(5)(A). Specifically, Plaintiffs claim that the payment model was inconsistent with what they claim was the statute's mandate to reimburse only for high *cost* cases because, they claim, the agency actually reimbursed hospitals for high *charge* cases. Pls.' Mot. at 25. Defendant argues that the agency's actions were a reasonable means of implementing the

[28] Under the familiar *Chevron* standard, "[i]f the court determines 'Congress has directly spoken to the precise question at issue,' and 'the intent of Congress is clear, that is the end of the matter.'" *S. Carolina Pub. Serv. Auth. v. FERC*, 762 F.3d 41, 54 (D.C. Cir. 2014) (quoting *Chevron*, 467 U.S. at 842). "If, however, 'the statute is silent or ambiguous with respect to the specific issue,' then the court must determine 'whether the agency's answer is based on a permissible construction of the statute.'" *Id.* (quoting *Chevron*, 467 U.S. at 843).

[29] The Courts notes, as well, that Plaintiffs have pointed to nothing that suggests that this Court's analysis of their so-called *Chevron* challenges, including the *Chevron* step two determination of whether an agency's interpretation of a statute is permissible, is not limited to the record before the agency the time of the respective rulemakings.

statutory provisions. Defendant also argues that Plaintiffs' challenges are barred because they were not presented to the agency previously. With respect to the latter argument, the Court concludes that, for the reasons stated above, Plaintiffs may raise these arguments here even if they were not presented in comments to the agency because this is a timely challenge to the regulations as applied in outlier payment determinations challenged in this action. *See Koretoff*, 707 F.3d at 399 (arguments not raised before agency may be raised in timely challenge to application of rule). With respect to the former argument, the Court agrees with Defendant: each of the agency actions challenged as inconsistent with the statute entailed a reasonable, interpretation of the statute. The Court reviews Plaintiffs' arguments to the contrary here.

1. Challenge to Outlier Payments for FY 1997 through FY 2003

With respect to FY 1997 through FY 2003, the gravamen of Plaintiffs' claim appears to be that the agency made outlier payments for these years where the hospitals' actual costs were below the "cut off point," 42 U.S.C. § 1395ww(5)(A)(iii), and that such payments are barred by the language of the statute. There are several fatal flaws with Plaintiffs' argument. First, Plaintiffs persist in referring to the outlier payment regulations and the fixed loss threshold rulemakings applicable in these fiscal years as a bundle. Plaintiffs do not pinpoint explicit decisions in the nine agency rulemakings at play for this set of fiscal years—the revisions to the outlier payment regulations promulgated in 1988 and 1994, as well the fixed loss threshold rulemakings for these seven fiscal years—that are inconsistent with the requirements of the statute. As the Court has stated previously, Plaintiffs' challenges must be tethered to specific agency actions. *See Banner Health I*, 797 F. Supp. 2d at 106. Plaintiffs' failure to do so adequately at this point would be enough, without more, to make Plaintiffs' statutory challenge fail. However, in the interest of thoroughness, the Court considers whether the underlying

rulemakings are inconsistent with the statute. For the reasons stated below, the Court concludes that they are not inconsistent because the statute does not require what Plaintiffs claim it requires.

The Court begins, as it must, with the language of the statute itself. The statute requires that the agency make payments, upon request, "in any case where charges, adjusted to cost" exceed a certain cutoff point. 42 U.S.C. § 1395ww(5)(A)(ii). As a result of amendments to the statute enacted in 1993, that cutoff point—for discharges after October 1, 1994, including all the years at issue in this action—is the "sum of the applicable DRG prospective payment rate … plus a fixed dollar amount determined by the secretary."[30] *Id.* That fixed dollar amount is the amount that has been referred to throughout this Memorandum Opinion as the fixed loss threshold. As a reminder, the DRG prospective payment rate is the rate set for a particular year for a particular category of medical diagnoses. The statute does not directly tell the agency how to set the fixed loss threshold. However, the statute does require that "[t]he total amount of the additional payments made under this subparagraph 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." *Id.* § 1395ww(5)(A)(iv). The D.C. Circuit Court of Appeals has determined that the agency complies with this requirement by "selecting outlier thresholds that, 'when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments.'" *Dist. Hosp. Partners*, 786 F.3d at 51 (quoting *Cnty. of Los Angeles*, 192 F.3d at

[30] As explained above, the calculus also includes other payments not subject to this challenge—"any amount payable under subparagraphs (B) and (F)"—but leaving those payments to the side simplifies the narrative but does not subtract anything from the relevant analysis. 42 U.S.C. § 1395ww(5)(A)(ii); *see Dist. Hosp. Partners*, 786 F.3d at 50 n.1.

1013). Finally, the statute directs the agency that the "amount of such additional payment … shall … approximate the marginal cost of care beyond the cutoff point applicable." *Id.* § 1395ww(5)(A)(iii).

With these remarkably few words, Congress established the framework for the outlier payment scheme, leaving the details to be fleshed out by the agency. *Cf. Cnty of L.A.*, 192 F.3d at 1016 ("Where, as here, Congress enacts an ambiguous provision within a statute entrusted to the agency's expertise, it has 'implicitly delegated to the agency the power to fill those gaps.'") (quoting *National Fuel Gas Supply Corp. v. FERC*, 811 F.2d 1563, 1569 (D.C. Cir. 1987)). Specifically, the statute establishes the framework for determining both *when* outlier payments should be made and *what amounts* those payments should be. But the details necessary to implement the statutory framework and to fulfill the statutory mandate are left to the agency.

Plaintiffs argue that the agency wrongly based outlier payments on cases with high charges rather than high costs. *See, e.g.*, Pls.' Mot. at 25. However, notwithstanding Plaintiffs' cut-and-paste citations of the statute, they ignore key language in the relevant statutory provision. The statute specifies that outlier payments are available where "charges, adjusted to cost" exceed the cutoff point. 42 U.S.C. § 1395ww(5)(A)(ii). In other words, the statute *requires* the agency to make the determination of when an outlier payment should be made based on "charges, adjusted to cost," not based on hospital costs in the abstract. The statute does not specify *how* to adjust charges to cost, but the statute clearly requires the agency take charges and adjust them to cost, in some manner, in order to make that determination. In 1988, in a rulemaking challenged in this action, the agency determined that it would adjust charges to cost by using hospital-specific cost-to-charge ratios. 53 Fed. Reg. at 38,503. These cost-to-charge ratios would be derived by using historical data, specifically using the latest settled cost reports.

Id. at 38,529. The agency also concluded that, for hospitals where the data indicated extremely high or extremely low cost-to-charge ratios, the agency instead would use the relevant statewide average cost-to-charge ratio to adjust charges to cost for those hospitals. *Id.* at 38,507-08. Through that rulemaking, the agency amended the applicable regulations, codified at 42 C.F.R. § 412.84(h). These decisions were not revisited, nor were the relevant provisions of the regulations amended, until later proceedings in 2003, discussed elsewhere in this Memorandum Opinion. Therefore, these provisions were applicable for the fixed loss threshold rulemakings for FY 1997 through FY 2003.

None of these conclusions are inconsistent with the statute. The statute plainly indicates that charges adjusted to cost should be used to determine whether an outlier payment is applicable for an individual case. *See* 42 U.S.C. § 1395ww(5)(A)(ii). The statute is just as plainly ambiguous regarding the method of adjusting charges to cost. Because the statute is ambiguous, the Court "defers to the agency's interpretation as long as it is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. "The question for a reviewing court is whether in doing so the agency has acted reasonably and thus has 'stayed within the bounds of its statutory authority.'" *Natural Res. Def. Council v. EPA*, 777 F.3d 456, 463 (D.C. Cir. 2014) (quoting *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013)). The Court concludes that each decision in the 1988 regulation regarding the adjustment of charges to cost was reasonable.[31]

The agency's decision to adjust charges to cost by looking at hospital-specific data was reasonable. *See* 53 Fed. Reg. at 38,503 (describing conclusion that "use of hospital-specific cost-to-charge ratios should greatly enhance the accuracy with which outlier cases are identified and

[31] The Court addresses Plaintiffs' specific arguments that the agency did not adequately explain certain decisions in analyzing, below, Plaintiffs' claims that each regulation at issue in this case was arbitrary and capricious.

outlier payments are computed, since there is wide variation among hospitals in these cost-to-charge ratios"). So, too, was the agency's decision to adjust charges to cost using historic cost-to-charge ratios that are based on the latest settled cost reports. *See* 53 Fed. Reg. at 38,507 (explaining decision to use this dataset). As explained further below, just because the agency later concluded—in 2003—that using somewhat more recent data (the tentatively settled cost reports) was more sensible in light of the agency's experience does not make the earlier decision to use settled cost reports unreasonable. *See* 68 Fed. Reg. at 34,497-99. Similarly, the agency's decision to use statewide average data for hospitals with extremely high or low cost-to-charge ratios was also reasonable. *See* 53 Fed. Reg. at 38,507-08 (explaining agency's assessment that "that ratios falling outside this range are unreasonable and are probably due to faulty data reporting or entry"). Just because the agency later concluded—in 2003—that it would be more sensible in light of the agency's experience to use hospital-specific charge ratios for hospitals with low cost-to-charge ratios rather than statewide averages, *see* 68 Fed. Reg. at 34,497-99, does not mean that the decision to use statewide averages in 1988 was an unreasonable construction of the statute. The Court notes that the agency never revisited these several decisions until 2003 when the agency ultimately revised the outlier payment regulations. Accordingly, the Court has no occasion to evaluate the reasoning behind these decisions in light of events that occurred in those intervening years.

The same considerations apply with respect to the "amount of such additional payment" under section 1395ww(5)(A)(iii). The statute requires that that amount "approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or clause (ii)." 42 U.S.C. § 1395ww(5)(A)(iii). In a 1983 regulation *not challenged* in this action, the agency determined that the amount of a cost outlier payment would be determined by applying a

marginal cost factor to the difference between charges, adjusted to cost, and the applicable threshold.[32] *See* 48 Fed. Reg. 39,752, 39,777 (Sept. 1, 1983). The Court notes that it does not appear that the agency actually reconsidered the decision to use cost-adjusted charges to determine the amount of the outlier payment in promulgating the 1988 revisions to the outlier payment. *See* 53 Fed. Reg. at 38,502 (describing the consideration of the level of the marginal cost factor without reconsidering the use of cost-adjusted charges). In any event, Court concludes that it is reasonable to determine the *amount* of an outlier payment based on cost-adjusted charges derived by the same methodology of cost-adjustment as used to determine *whether* a case qualifies for an outlier payment.

It is important that this clause requiring that the "amount of such additional payment … shall approximate the marginal cost of care beyond the cutoff point applicable" is applicable both to day outliers and to cost outliers. 42 U.S.C. § 1395ww(5)(A)(iii). The language of this clause is necessarily capacious enough to accommodate both forms of outliers.[33] It is reasonable that the agency treated "cost of care" similarly to the calculation of "charges, adjusted to cost" used to determine whether a cost outlier payment was applicable for an individual case—in accordance with the provisions regarding the outlier threshold just discussed. Pursuant to the regulations that

[32] In the 1983 rulemaking, the agency explained why it was necessary to use a marginal cost factor: "Marginal cost is the change in total cost associated with a one unit change in output. Due to the presence of fixed costs, the marginal cost of care is generally less than the average cost." 48 Fed. Reg. at 39,776. The use of a marginal cost factor to transform the average costs above the threshold into the marginal costs above that threshold is not in dispute. Nor are the individual marginal cost factors that the agency used in the fiscal years relevant to this dispute.

[33] "For day outliers, an additional per diem payment is made for each covered day of care beyond the length of stay threshold." 53 Fed. Reg. at 38,502; *see* 42 C.F.R. § 412.82. "The per diem payment is equal to 60 percent of the average per diem Federal rate for the DRG, which is calculated by dividing the wage-adjusted Federal rate for the DRG by the geometric mean length of stay for the DRG." 53 Fed. Reg. at 38,502. The applicable percentage was set annually. 42 C.F.R. § 412.82. Day outliers are not at issue in this action.

the agency promulgated, the agency adjusted charges to cost to determine whether those cost-adjusted charges were above the applicable threshold, and then made a payment based on the amount by which the cost-adjusted charges exceeded that threshold. *See* 53 Fed. Reg. at 38,503. Although the statute does not refer to "cost of care" in clause (iii) as being derived from "charges, adjusted to cost," as it did in clause (i) regarding the determination of whether an outlier payment is applicable, the agency's interpretation that cost-adjusted charges should be used to determine the amount of the cost outlier payment—just as cost-adjusted charges were used to determine whether a case exceeds the threshold for payment—is wholly reasonable. *See Nat'l Credit Union Admin. v. First Nat. Bank & Trust Co.*, 522 U.S. 479, 501 (1998) (describing "established canon of construction that similar language contained within the same section of a statute must be accorded a consistent meaning"); *see also Janko v. Gates*, 741 F.3d 136, 141 (D.C. Cir. 2014) *cert. denied*, 135 S. Ct. 1530 (2015). So, too, is the agency's determination that it should use the same methodology for cost-adjustment in determining the amount of the outlier payment as in determining the applicability of the outlier payment. Not only does consistency in this context have the virtue of simplicity, it is also plainly reasonable.

In *District Hospital Partners*, the D.C. Circuit Court of Appeals used an example to explain how outlier payments were generated for FY 2004 through FY 2006 and to explain the relationship among fixed loss thresholds, cost-adjusted charges, and outlier payments for those fiscal years. 786 F.3d at 50-51 (citing 62 Fed. Reg. at 45,997). Similarly, an example may be helpful in explaining the relationship between the determination *whether* a specific case qualifies for an outlier payment and the determination of the *amount* of any such outlier payment—with

respect to the years at issue in this action.[34] Assume that the "cutoff point" for a certain DRG category is $20,000. Pursuant to the regulations, the agency would adjust charges to cost based on the applicable cost-to-charge ratio. If that cost-adjusted charge was above $20,000, a payment would be available. If the charge for an individual case were $40,000 and the applicable cost-to-charge ratio were 0.75 (or 75 percent), the cost-adjusted charge would be $30,000. Because that amount is above $20,000, a payment would be available. The amount of the payment would be the difference between the cost-adjusted charge ($30,000 in this example) and the threshold ($20,000)—after applying a marginal cost factor. If the marginal cost factor were 0.80, the payment would be $8,000, or 80 percent of the difference between the cost-adjusted charge and the threshold. It is reasonable to use the same the cost-adjusted charge—here a $40,000 charge adjusted to a $30,000 estimated cost—to determine the amount of the payment as used to determine whether a payment was warranted in the first place. Accordingly, the court concludes that using cost-adjusted charges, pursuant to the methodology outlined above, to determine the amount of the payment is a reasonable interpretation of the statutory requirement that the "amount of the payment … shall … approximate the marginal cost of care beyond the cutoff point applicable." 42 U.S.C. § 1395ww(5)(A)(iii). In other words, the 1988 rulemaking was a reasonable construction of the statute and is therefore consistent with the statute's terms.

Turning to the 1994 rulemaking, only a brief discussion is necessary. In 1993, Congress introduced the fixed loss threshold as the method of determining the applicable cutoff point used to determine whether an outlier payment is available for a given case and to determine the

[34] This analysis is equally applicable with respect to the statutory scheme extant in 1988 and with respect to the statutory scheme as revised in 1993, when the "fixed loss threshold" was introduced. For the purposes of this example, it is not necessary to review the calculation of the threshold itself under those two schemes.

amount of the outlier payments for such a case.[35] *See* 59 Fed. Reg. at 45,368. The following year, the agency revised the outlier payment regulations to use the altered methodology specified by statute for determining when payments would be available and the amounts of such payments. *See id*. The changes to the outlier payment regulations in this rulemaking were limited to implementing the 1993 statutory changes. *See id.* Although Plaintiffs name the 1994 rulemaking as a source of the inconsistency between the statute and the regulations applicable for fiscal years 1997 through 2003, Plaintiffs point to nothing about the 1994 rulemaking that would create that inconsistency. Perhaps Plaintiffs mean to suggest that the 1994 regulation implicitly re-adopted the decisions promulgated in the 1988 regulation—although they do not identify anything in the record suggesting that the agency had done so. Moreover, Plaintiffs do not point to anything that would make those 1988 regulations unreasonable in 1994—but would not have made them unreasonable in 1988. Accordingly, just as the Court concluded that the 1988 revisions to the outlier payment regulations were consistent with the Medicare Act, the Court concludes that the 1994 regulations are consistent with the Medicare Act, as amended in1993.

Finally, the Court turns to the seven fixed loss threshold rulemakings for FY 1997 through FY 2003—when the 1988 and 1994 regulations were operative. Critically, each of those rulemakings took the formula for outlier payments established by the applicable outlier payment regulations—as amended in 1988 and then in 1994—as a given. For each year, taking those formulas as given, the agency calculated a fixed loss threshold that was predicted to generate

[35] Prior to the 1993 statutory amendments, outlier payments were made where "charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater." 42 U.S.C. § 1395ww(5)(A)(ii). Going forward, outlier payments would be made "exceed the sum of the applicable DRG prospective payment rate … plus a fixed dollar amount determined by the Secretary." *Id.* That fixed dollar amount is known as the fixed loss threshold.

outlier payments that would be 5.1 percent of total DRG-based payments. *See* 61 Fed. Reg. at 46,228 (FY 1997 rulemaking); 62 Fed. Reg. at 46,040 (FY 1998 rulemaking); 63 Fed. Reg. at 41,008 (FY 1999 rulemaking); 64 Fed. Reg. at 41,546 (FY 2000 rulemaking); 65 Fed. Reg. at 47,113 (FY 2001 rulemaking); 66 Fed. Reg. at 39,941 (FY 2002 rulemaking); 67 Fed. Reg. at 50,124 (FY 2003 rulemaking). This approach was approved by the D.C. Circuit Court of Appeals in *County of Los Angeles*, 192 F.3d at 1013. The agency is not required to adjust the fixed loss thresholds in retrospect to ensure that actual outlier payments are between 5 and 6 percent of actual DRG-based payments. *Id.* The agency is only required to select threshold that "when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments." *Id.* Although the D.C. Circuit did not address this particular issue in *County of Los Angeles*, it is plainly reasonable to use the then-applicable formula for generating outlier payments, which would be used to calculate the actual outlier payments for these several fiscal years, to determine the fixed loss threshold for those years.

Plaintiffs argue that outlier payments during FY 2003, in particular, were inconsistent with the statute because the agency was aware of "turbo-charging" practices by certain hospitals. *See* Pls.' Mot. at 30. The only evidence of this awareness on which Plaintiffs rely is the draft interim final rule sent to the Office of Management and Budget. *See id.* (citing A.R. at 4417.372, 4417.396). However, that draft was dated February 12, 2003—approximately six months after the August 1, 2002, promulgation of final FY 2003 fixed loss threshold rule. *See* 67 Fed. Reg. at 50,124. Plaintiffs cannot rely on information that was only before the agency after the promulgation of the FY 2003 rulemaking to impugn that rule. Moreover, like each of the other fixed loss threshold rulemakings from FY 1997 through FY 2003, the FY 2003 rulemaking was

based on the established methodology for outlier payments applicable to that fiscal year, and the agency did not reconsider the methodology in the FY 2003 rulemaking. Accordingly, the FY 2003 fixed loss threshold rulemaking is consistent with the statute just as its predecessors were. Insofar as Plaintiffs are claiming that the failure to implement a mid-year adjustment to the FY 2003 fixed loss threshold was inconsistent with the statute, that claim fails as well. There is no authority supporting Plaintiffs' suggestion that a mid-year adjustment is required. To comply with the statute, all that is required is for the agency to "select[] outlier thresholds that, 'when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments.'" *Dist. Hosp. Partners*, 786 F.3d at 51. The agency did so in selecting the FY 2003 fixed loss threshold on August 1, 2002. Moreover, as explained in more detail below, in its final rule issued June 9, 2003, the agency adequately explained it decision not to implement a mid-year adjustment to the FY 2003 fixed loss threshold. *See* 68 Fed. Reg. at 34,505. The statute requires no more.

In sum, for the fiscal years between 1997 and 2003, the agency made outlier payments based on the methodology established by the then-applicable outlier payment regulations, revised in both 1988 and 1994; pursuant to that methodology, the fixed loss threshold chosen in an annual fixed loss threshold rulemaking was a key input in determining the actual outlier payments. As described above, each of those regulations is consistent with the statute. Plaintiffs have identified no other ways in which the outlier payments for these years were inconsistent with the statute. With respect to these seven fiscal years, Plaintiffs' arguments amount to a claim that the agency ultimately ended up making outlier payments to hospitals that had high charges rather than hospitals that had high costs. As regrettable as that result may be, insofar as it is true, that result does not show that the agency actions challenged here were incompatible with the

statute.[36] To the contrary, the Court concludes that outlier payment regulations applicable during this period and the fixed loss thresholds established during this period were based on reasonable constructions of the statute and, accordingly, the outlier payments during these fiscal years were consistent with the statute, as well.

2. Failure to Conduct Reconciliation and to Account for Reconciliation

Next, Plaintiffs make a cursory argument that the agency violated the statute's requirement that outlier payments "shall … approximate the marginal cost of care beyond the cutoff point applicable," 42 U.S.C. § 1395ww(5)(A)(iii), by failing to conduct reconciliation or to account for reconciliation in setting the fixed loss thresholds for FY 2004 through FY 2007. This argument fails because nowhere does the statute require the agency to undertake reconciliation. In 2003, the agency promulgated revisions to the outlier payment regulations that, among other changes, stated that outlier payments would "become subject to adjustment when hospitals' cost reports coinciding with the discharge are settled." 68 Fed. Reg. at 34,504 (codified at 42 C.F.R. § 412.84(i)(4)). The agency reasoned that, even with other changes to the regulations promulgated that year, hospitals would be able to "manipulate the system to maximize outlier payments" by "dramatically increas[ing] its charges by far above the rate-of-increase in costs during any given year." *Id.* at 34,501. To prevent manipulation of outlier payments through dramatic charge increases, the agency introduced the possibility of reconciliation. Through reconciliation, outlier payments that were already made—based on the cost-to-charge ratios available at the time of the determination of those payments—could be adjusted in light of the actual cost-to-charge ratios for the period in question. However, the

[36] Insofar as Plaintiffs argue that the regulations on which the outlier payments relied were arbitrary and capricious, the Court considers those arguments below.

agency's regulations do not *require* reconciliation: they simply state that payments would "become subject to adjustment," rather than affirmatively requiring that they be adjusted. *Id.* at 34,504. Nor do the regulations indicate that reconciliation was necessary in order to ensure consistency with the statute. Indeed, there is nothing to indicate that the failure to reconcile would be inconsistent with the statutory requirement that outlier payments "shall … approximate the marginal cost of care beyond the cutoff point applicable." 42 U.S.C. § 1395ww(5)(A)(iii). While reconciliation appears to be a plausible way to effectuate the statutory purpose in combination with other changes made to the regulations, given the "turbo-charging" behaviors that were discovered by the agency as of 2003, *see* 68 Fed. Reg. at 34,501, failing to conduct reconciliation was not unreasonable and is therefore consistent with the statute.

Just as reconciliation itself is not mandated by the statute, neither does the statute mandate that the agency account for reconciliation in setting the annual fixed loss threshold. Because reconciliation became simply an option rather than a requirement, it would be irrational to conclude that the statute actually required the agency to account for reconciliation explicitly in calculating the fixed loss threshold. In addition, Plaintiffs wholly ignore the fact that, for FY 2004, the agency considered the impact of reconciliation in setting the fixed loss threshold. *See* 68 Fed. at 45,476-77. The agency's methodology for that fiscal year integrated its estimate that reconciliation would occur for approximately 50 hospitals—based on past hospital behavior and based on the resources that would be available for reconciliation. *Id.* For FY 2005 through FY 2007, the agency reasonably concluded that, given other changes introduced by the 2003 revisions to the outlier payment regulations and given uncertainty regarding future behavior, considering reconciliation in setting the fixed loss threshold was not warranted. *See* 69 Fed. Reg. at 49,278 (FY 2005 rulemaking); 70 Fed. Reg. at 47,495 (FY 2006 rulemaking); 71 Fed. Reg. at

48,151 (FY 2007 rulemaking). In sum, the agency's failure to reconcile and its failure to explicitly account for reconciliation in fixed loss rule rulemakings for these years do not make those rulemakings—or the outlier payments calculated pursuant to them—inconsistent with the statute.

3. Challenge to Outlier Payment Determinations for FY 2004 through FY 2006

With respect to the fixed loss threshold rulemakings for FY 2004 through FY 2006, Plaintiffs' statutory argument is that the rulemakings did not comply with the requirement that the agency choose "outlier thresholds that, 'when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments.'" *Dist. Hosp. Partners*, 786 F.3d at 51 (quoting *Cnty. of Los Angeles*, 192 F.3d at 1013). Specifically, Plaintiffs argue that these three rulemakings did not comply with that requirement because the agency did not adjust the cost-to-charge ratios used for those predictions to account for continued declines in cost-to-charge ratios. *See* Pls.' Mot. at 34-37. Accordingly, Plaintiffs argue that it was predictable that the agency would choose fixed loss thresholds that were too high and thus would result in outlier payments below the 5 to 6 percent range set by section 1395ww(5)(A)(iv).

The Court notes that Plaintiffs repeat this claim in their argument that each of these three fixed loss threshold rulemakings were arbitrary and capricious. The Court fully addresses the agency's responses to proposed alternatives regarding the adjustment of cost-to-charge ratios in discussing Plaintiffs' arguments that these fixed loss threshold rulemakings were arbitrary and capricious. But in evaluating the consistency of these three annual rulemakings with the statute, it is important that the agency thoroughly explained why it chose not to adjust the methodology to account for any declines in cost-to-charge ratios:

> We do not believe that it is necessary to make a specific adjustment to our methodology for computing the outlier threshold to account for any decline in cost-to-charge ratios in FY 2005, as the commenter has requested. We have already taken into account the most significant factor in the decline in cost-to-charge ratios, specifically, the change from using the most recent final settled cost report to the most recent tentatively settled cost report. Furthermore, we strongly prefer to employ actual data rather than projections in estimating the outlier threshold because we employ actual data in updating charges, themselves.

69 Fed. Reg. at 49,277. With respect to FY 2005, the agency concluded that other changes to the outlier payment regulations and to the fixed loss threshold methodology adequately accounted for the decline in cost-to-charge ratios such that an additional adjustment of the cost-to-charge ratios was not necessary. As explained below, the agency adequately explained similar choices for FY 2004 and FY 2006. *See* 68 Fed. Reg. at 45,476-77; 70 Fed. Reg. at 47,495. Moreover, it is proper to "'defer to the agency's decision on how to balance the cost and complexity of a more elaborate model against the oversimplification of a simpler model,'" *West Virginia v. EPA*, 362 F.3d 861, 868 (D.C. Cir. 2004) (quoting *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 535 (D.C. Cir. 1983)). Therefore, the Court will defer to the agency's choice to use actual historical data for the cost-to-charge ratios rather than to add an unknown adjustment factor. *See Disp. Hosp. Partners*, 973 F. Supp. 2d at 16. The Court concludes that the agency's decision to use the actual cost-to-charge ratios in order to set the FY 2004 through FY 2006 fixed loss thresholds, rather than adjusting those ratios to account for possible continued declines, was reasonable. Accordingly, in these rulemakings, the agency has fulfilled the requirement that it set "outlier thresholds that, 'when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments.'" *Dist. Hosp. Partners*, 786 F.3d at 51 (quoting *Cnty. of Los Angeles*, 192 F.3d at 1013).

* * *

In sum, the Court concludes that each of Plaintiffs' statutory arguments fails because the regulations challenged are consistent with the requirements of the Medicare Act. Each regulation promulgated by the agency represents a reasonable interpretation of the outlier provisions of the Medicare Act. Therefore, the outlier payments determined pursuant to these regulations are necessarily consistent with the statute, as well. The Court now turns to Plaintiffs' arguments that the regulations challenged here were arbitrary and capricious.

E. Plaintiffs' Arbitrary and Capricious Arguments

In addition to Plaintiffs' claim that the several agency actions challenged here are inconsistent with the statute, Plaintiffs argue that each of the regulations challenged here—the revisions to the outlier payment regulations and the annual fixed loss threshold rulemakings—were arbitrary and capricious.[37] At the outset, the Court reiterates that the Court's review is limited to the individual administrative records for each rulemaking—that is, the information that was before an agency at the time of the respective rulemakings—and it cannot invalidate a rulemaking because it subsequently becomes clear that a rulemaking was unwise. The Court reviews each of Plaintiffs' numerous arguments and concludes that, with one exception, none are successful.

1. Challenges to the 1988 Revisions to the Outlier Payment Regulations

Plaintiffs present three challenges to what they call the "Outlier Payment Model." As explained above, the outlier payment regulations—amended in 1988, 1994, and 2003—establish the methodology for the determination of annual payments. Plaintiffs challenge two features of

[37] However, the Court notes that Plaintiffs' arguments do not address the 2003 amendments to the outlier payment regulations—with the exception of Plaintiffs' argument regarding a mid-year adjustment to the FY 2003 fixed loss threshold—notwithstanding Plaintiffs' statement that they challenge each of the outlier payment and fixed loss threshold rulemakings subject to this action.

the outlier payment regulations that were introduced in 1988 and then eliminated in revisions to the outlier payment regulations in 2003. First, they challenge the use of "older" data—that is, the use of the latest settled cost reports—to establish the hospital-specific cost-to-charge ratios, which are used to adjust charges to cost.[38] Second, Plaintiffs challenge the use of statewide average cost-to-charge ratios in lieu of hospital-specific cost-to-charge ratios for hospitals with extremely low cost-to-charge ratios. Third, Plaintiffs present a challenge related to the use of statewide average data: they argue that the statewide averages were outdated and based on incorrect data. The Court considers each argument and concludes that none are successful.

Use of Latest Settled Cost Reports

In 1988, the agency concluded that, because cost-to-charge ratios differed among hospitals, it would be preferable to use hospital-specific cost-to-charge ratios rather than a single nationwide estimate, as the agency has done before. *See* 53 Fed. Reg. at 38,503 (reasoning that "[t]he use of hospital-specific cost-to-charge ratios should greatly enhance the accuracy with which outlier cases are identified and outlier payments are computed, since there is wide variation among hospitals in these cost-to-charge ratios."). The agency was, thus, faced with the choice of what data to use to compute those cost-to-charge ratios. The agency explained its choice to use the latest settled cost reports: "[w]hile the latest filed cost report represents the most current data, we have found that Medicare costs are generally overstated on the filed cost report and are subsequently reduced as a result of audit." *Id.* The agency concluded that the greater accuracy of audited cost-data outweighed the time lag necessitated by using that audited data. *See id.*

[38] As explained above, the agency then determines whether this cost-adjusted charge exceeds the applicable threshold. If so, a payment is made based on the amount by which this cost-adjusted charge exceeds the threshold.

The agency's choice to use the latest settled cost reports was codified in amendments to the regulations governing outlier payments. 53 Fed. Reg. at 38,529 (codified at 42 C.F.R. § 412.84(h) ("The cost-to-charge ratio used to adjust covered charges is computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report."). The agency did not revisit this choice until 2003, when the agency ultimately decided to made a different choice—using the latest *tentatively settled* cost reports (when they were more recently updated than the *settled* cost reports). *See* 68 Fed. Reg. at 34,497-99. Plaintiffs challenge only the earlier choice, and, as stated above, this Court's review is limited to the record before the agency in 1988. Nothing that occurred later or that was presented to the agency later—even if it ultimately convinced the agency to make a different policy choice—can be ammunition for challenging the 1988 decision to use the latest settled cost reports. In that light, the Court reviews Plaintiffs' several arguments in support of their claim that this decision was arbitrary and capricious.

Plaintiffs claim that the agency ignored the warning of commenters that using settled cost report data—rather than more recent data—would introduce inaccuracies into the calculation of outlier payments. *See* AR (1988 Rulemaking) 7156, 7387. However, the agency responded to this concern, acknowledging that settled cost reports did not represent the most recent data but explaining that the agency "found that Medicare costs are generally overstated on the filed cost report and are subsequently reduced as a result of audit." 53 Fed. Reg. at 38,503. Therefore, the agency chose the older-but-audited data instead of the most recent raw data. *See id.*

Plaintiffs next argue that, in choosing to use the settled cost reports, the agency disregarded comments indicating that charges were rising faster than costs.[39] However, each of the comments to which Plaintiffs cite for this proposition were submitted after the promulgation of the final 1988 outlier payment regulations. *See* Pls.' Mot. at 41 (citing 58 Fed. Reg. at 46,347 (1993); A.R. (1993 amendments) 6590; A.R. (1993 amendments) 6685; A.R. (FY 2003) 4809; A.R. (2003 amendments) 4390; A.R. (2003 amendments) 4392; A.R. (2003 amendments) 4399; A.R. (2003 amendments) 4401; A.R. (2003 amendments) 4407; A.R. (2003 amendments) 4417.357; A.R. (FY 2005) 1032; A.R (FY 2006) 609). Accordingly, Plaintiffs may not rely on these comments in challenging the 1988 regulation, and the Court may not rely on them in determining whether that regulation was arbitrary or capricious.

Plaintiffs also argue that the choice to use settled cost reports was unreasonable because, even using settled cost reports, the agency's calculation would necessarily involve unaudited data. Plaintiffs point out that calculating outlier payments involves adjusting current charges, which are unaudited, by a ratio that is calculated from historic cost data, which has been audited, and historic charge data, which has not been audited. Accordingly, Plaintiffs argue that it was irrational to choose older data, which includes audited cost data, at the expense of the timeliness of the data, when they would nonetheless be using some unaudited data. The Court first notes that the Secretary had no need to respond to this concern because Plaintiffs do not point to anything in the record suggesting that this concern was before the agency at the time of the 1988 rulemaking. Moreover, as the Secretary argues, it was not irrational to use a data source that

[39] The gravamen of the claim is that, if charges are rising faster than costs, the actual cost-to-charge ratios would necessarily be falling over time. In turn, that trend would imply that using an older cost-to-charge ratio—all things being equal—would mean using a cost-to-charge ratio that was higher than the actual cost-to-charge ratio for the relevant time period.

included some audited data and some unaudited data. In particular, the agency emphasized the importance of using the audited *cost* data in light of its finding "that Medicare costs are generally overstated on the filed cost report and are subsequently reduced as a result of audit." 53 Fed. Reg. at 38,503. Accordingly, it was reasonable to choose to use an older data source on account of the fact that it included audited cost data even while the charge data used was not audited.

Next, Plaintiffs argue that the agency disregarded its own previous statements—in years prior to adopting the hospital-specific cost-to-charge ratio methodology—that "using hospital-specific [cost-to-charge ratios] came with the risks of introducing data with poor predictive value." Pls.' Mot. at 42. However, the several statements that Plaintiffs cite do not show that the agency's 1988 decision was arbitrary or capricious.

The first set of statements that Plaintiffs identify is a pair of statements in the 1986 rulemaking, in which the agency declined to shift from using a national cost-to-charge ratio to using hospital-specific cost-to-charge ratios, as a commenter had then suggested. *See* 51 Fed. Reg. 31,454, 31,526 (1986). First, the agency noted that "[t]he use of hospital-specific cost-to-charge ratios to compute outlier payments would require that they be frequently revised to account for changes in the mix and scope of services provided." *Id.* This statement reflects the (undisputed) additional administrative burden entailed by calculating hospital-specific ratios. Notwithstanding the administrative burden associated with the methodology, in 1988, the agency ultimately chose to adopt hospital-specific cost-to-charge ratios because it concluded that they would be more accurate than a single nationwide ratio. *See* 53 Fed. Reg. at 38,503. The agency's 1986 statement does not reveal anything arbitrary or capricious about the 1988 decision.[40] Also,

[40] Notably, Plaintiffs do not suggest it would be preferable to use a nationwide rate (and indeed vociferously contest the use of statewide averages).

in the 1986 rulemaking, the agency noted that "[a]n additional source of inaccuracy could arise from the fact that the hospital-specific cost-to-charge ratios would presumably be from completed cost reports, which means that they would lag behind the current period for which they would be used in computing outlier payments." 51 Fed. Reg. at 31,526. In later adopting the use of hospital-specific cost-to-charge ratios, the agency did not ignore this lag, it simply embraced the tradeoff entailed: it concluded that (1) using older but more accurate settled cost reports was preferable to using more recent unaudited cost reports, and (2) using hospital-specific ratios was more accurate than using a nationwide cost-to-charge ratio. *See* 53 Fed. Reg. at 38,503. Accordingly, the agency adequately responded to the concern that it itself had voiced in the 1986 rulemaking.

The second statement that Plaintiffs identify is a statement in the 1987 rulemaking in which the agency explained why it decided once again not to adopt hospital-specific cost-to-charge ratios at that time. It is important to set this decision in its context. The decision not to adopt hospital-specific cost-to-charge ratios in 1987 was part of a larger decision to delay broader changes to the outlier program, which would have shifted the emphasis from day outliers (patients with extremely long stays in the hospital) to cost outliers (extremely high cost cases), until the agency could complete its analysis of the relevant factors. *See* 52 Fed. Reg. at 33,047-48. The agency described its reasoning as follows:

> While the use of hospital-specific cost-to-charge ratios may be more accurate for purposes of computing cost outlier payments, there are a number of significant administrative and data problems associated with using these ratios. For example, estimating future outlier payments in order to establish appropriate outlier thresholds becomes more of a problem, since hospital specific cost-to-charge ratios used in the estimate would not be the same as those used for actually paying outliers. In addition, major changes in PRICER software (the program used to calculate each hospital's payment per discharge) and the Medicare cost report would be necessary in order for cost-to-charge ratios to be developed for payment purposes.

52 Fed. Reg. at 33,048. In part, the agency was highlighting an administrative and technical problem regarding transitioning to a new system. Just as with the administrative burdens highlighted in the 1986 rulemaking, these administrative and technical details were not simply brushed aside in the 1988 rulemaking; rather, the agency concluded that the administrative burden was worthwhile and decided that it was necessary to overcome the technical difficulties entailed in the transition. The agency also identified a specific challenge with using hospital-specific data: that the ratios used in setting the thresholds for outlier payments, in advance, would not be the same as those used to calculate the actual outlier payments. *Id.* In retrospect, there is no doubt this phenomenon has been a challenge for the agency, and the agency ultimately changed several policy choices in 2003 in light of its experience over the past three decades. However, in deciding to use hospital-specific ratios in 1988, the agency adequately addressed the issue it has raised the previous year. The agency did not conclude that using the settled cost reports would be a perfect solution, but as described above, the agency reasonably concluded that it would be better than the available alternatives. *See* 53 Fed. Reg. at 38,503; *cf. Dist. Hosp. Partners*, 786 F.3d at 59 (agency must address "significant and viable and obvious alternatives").

The third statement that Plaintiffs identify is a statement in the 1988 rulemaking promulgating changes to the outlier payment regulations, which Plaintiffs claim shows that the agency did not adequately address problems with the decision to use hospital-specific cost-to-charge ratios. *See* Pls.' Mot. at 42-43 (citing 53 Fed. Reg. at 38,509). Because Plaintiffs' claim regarding this statement extracts it from its essential context, it is worth reproducing in full the agency's summary of the comment to which it was responding and the agency's response:

> *Comment*: Some commenters were concerned that the increased emphasis on cost outliers in the proposed policy would provide an incentive for hospitals to increase their charges and to manipulate their charge structures.
>
> *Response*: Cost outliers are identified by, and the amount of cost outlier payment determined by, comparing the charges for the case, adjusted by a cost-to-charge ratio, to the cost outlier threshold. Since both the cost-to-charge ratio (whether national or hospital-specific) and the threshold are constant for the payment period, the payment received by the hospital can be increased by increasing charges. In addition, hospitals can conceivably change their charge structures, just as is the case at present, to maximize their outlier payments.
>
> Although concern over this type of incentive is appropriate, we believe that there are several factors that will mitigate its effects. First, increases in a hospital's overall charges relative to costs will be reflected in the cost-to-charge ratio assigned to the hospital in the future. This is one of the strong arguments for the use of hospital-specific cost-to-charge ratios. Second, many hospitals are restricted in their ability to arbitrarily increase their charges by the fact that they must deal with other third-party payers, some of which base their payments on charges. Also, several States place restrictions on hospital charge increases. Third, a general acceleration in hospital charge increases can be incorporated into the setting of thresholds in future years, which would limit the potential benefit to hospitals.
>
> Fourth, outlier payments comprise a small percent of total hospital payments under the prospective payment system, diluting the incentive for hospitals to disrupt their operations by drastically and continually manipulating charges.
>
> It must be pointed out that this incentive to manipulate charges is not new; in fact, any measure of cost (including length of stay) that is based on an indicator that is within the control of the provider provides an incentive to manipulate that indicator. As previously stated, we will continue to investigate potential improvements in the measurement of case level costs.

53 Fed. Reg. at 38,510. Most importantly, in this response, the agency appears to be responding to a comment regarding a major shift to the outlier payment regime introduced in 1988 that is not challenged in this action: a shift from a system focused on day outliers (extremely lengthy stays) to cost outliers (extremely costly cases). The agency appears to be responding to a comment that suggests that a shift to cost outliers would encourage system participants to manipulate the system to increase their own payments—undermining a core purpose of shifting to the Prospective Payment System in 1983 in the first place. In essence, in response, the agency

(1) acknowledges why the changes could allow participants to manipulate the system, (2) explains why the agency believed that such manipulation was less likely than it appeared, and (3) emphasized that there were incentives to manipulate both a day outlier and a cost outlier system, such that manipulation per se was not a reason to refrain from shifting from a focus on day outliers to a focus on cost outliers. The Court concludes that the agency sufficiently responded to the issues presented and explained its decision to, as relevant here, adopt an approach using hospital-specific cost-to-charge ratios based on the latest settled cost reports.

One final point is worth emphasizing with respect to this excerpt from the 1988 rulemaking. As the Court has reiterated before, judicial review of the 1988 regulation requires using the judicial time machine and focusing on the record before the agency in 1988. Plaintiffs interpret this comment as if the statement in the 1988 Federal Register about potential manipulation referred to a small set of hospitals that could manipulate the system by raising charges. However, that interpretation appears infected by hindsight. While the agency discovered in 2003 that a small set of 123 hospitals had manipulated outlier payments by increasing charges—hospitals that became known as "turbo-chargers," *see Dist. Hosp. Partners*, 786 F.3d at 51—there is no indication that the agency, in 1988, was referring to a subset of bad actor hospitals. Instead, it appears equally possible—if not likely—that the agency was referring to the possibility that the new system would incentivize hospitals, as a whole, to increase their charges. Indeed, that would be consistent with the problem that Congress attempted to solve just five years beforehand in introducing the Prospective Payment System—the incentives in a cost-based system to encourage hospitals *generally* to increase their costs in order to increase their payments. *See Cnty. of Los Angeles*, 192 F.3d at 1008. Particularly in light of this possibility, the agency rationally explained how it understood that increases in charges would be mitigated and

why, under this understanding, it chose to shift towards an approach focusing on cost outliers, including the use of hospital-specific cost-to-charge ratios, rather than on day outliers.

Finally, in addition to pointing to comments by the agency that Plaintiffs' claim are inconsistent with the use of settled cost reports, Plaintiffs argue that the agency could have made outlier payments subject to adjustment after cost reports for the applicable payment period were finally settled—a process that the agency adopted in 2003 under the label reconciliation. However, once again, Plaintiffs point to nothing in the record that shows that this possibility was before the agency in 1988. Because Plaintiffs have not shown that this proposal was a "significant and viable and obvious alternative[]" at the time of the 1988 rulemaking, this claim fails. *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d at 215.

In sum, the agency's decision to use hospital-specific cost-to-charge ratios based on the latest settled cost reports was neither arbitrary nor capricious. The agency rationally concluded that this choice was the best among the "significant and viable and obvious alternatives" and sufficiently explained its decision to do so.

Use of Statewide Average Cost-to-Charge Ratios

Plaintiffs argue that it was arbitrary and capricious to use statewide average cost-to-charge ratios for hospitals where their individual cost-to-charge ratios were extremely low. As a reminder, when the agency instituted the use of hospital-specific cost-to-charge ratios in 1988, it concluded that "Statewide cost-to-charge ratios [would be] used in those instances in which a hospital's cost-to-charge ratio falls outside reasonable parameters."[41] 53 Fed. Reg. at 38,529

[41] This provision was eliminated through the revisions to the outlier payment regulations promulgated in 2003 for discharges occurring after August 7, 2003. *See* 68 Fed. Reg. at 34,500.

(codified at 42 C.F.R. § 412.84(h)). The agency would sets both those "parameters" and the statewide cost-to-charge ratios annually. *See id.* (codified at 42 C.F.R. § 412.84(h)).

In the 1988 rulemaking, the agency determined that "[t]he range of reasonable cost-to-charge ratios represents 3.0 standard deviations (plus or minus) from the mean of the log distribution of cost-to-charge ratios for all hospitals." *Id.* at 38,503. The agency also calculated the upper and lower boundaries for cost-to-charge ratios. *Id.* The agency explained its reasoning:

> We believe that ratios falling outside this range are unreasonable and are probably due to faulty data reporting or entry. Therefore, they should not be used to identify and pay cost outliers. We believe that 3.0 standard deviations represents an appropriate range and that the accuracy of cost-to-charge ratios falling outside that range is questionable.

53 Fed. Reg. at 38,507-08. This explanation was reasonable.

Once again, the fact that the agency later came to the conclusion that the use of statewide cost-to-charge ratios allowed "turbo-chargers" to reap benefits from increasing charges does not mean that the decision was arbitrary or capricious when made in 1988. Plaintiffs can point to nothing that suggests that this decision was arbitrary and capricious when the regulation was promulgated. Plaintiffs point only to a comment submitted in the context of the 1994 rulemaking, claiming that the use of statewide ratios for hospitals with extremely low costs created an incentive to inflate charges. *See* 59 Fed. Reg. at 45,407-08. While that concern ultimately appears prescient, a comment raised in 1994 cannot be used, after the fact, to challenge the regulation promulgated in 1988. In the 1994 rulemaking, the agency promulgated changes to the outlier payment regulations to comply with the changes to the Medicare Act that Congress had recently enacted. However, the agency never considered whether to eliminate the use of statewide averages in that rulemaking. *See* 59 Fed. Reg. 27,708, 27,737-69 (May 27, 1994). As explained before, just because the agency received and responded to comments outside of the scope of the rulemaking does not expand the scope of that rulemaking. *See Biggerstaff*, 511 F.3d

at 186. In addition, insofar as the comment was presented in the context of setting the rates for FY 1995, including the "reasonable parameters" outside of which statewide ratios would be used, Plaintiffs have not challenged any payment determinations from FY 1995 in this action. Moreover, Plaintiffs do not show any way in which decisions made specifically for FY 1995 infect subsequent fixed loss threshold rulemakings. Therefore, they are not relevant to Plaintiffs' challenges to payment determinations in subsequent fiscal years. In any event, the agency provided an adequate response to the comment on which Plaintiffs rely. The agency stated that it did "not believe hospitals are setting their charges just to manipulate their cost-to-charge ratios." 59 Fed. Reg. at 45,408. The agency further explained its reasoning, explaining that "contrary to the commenter's contention, the incentives a hospital would have to maximize outlier payments, if any, would be to lower charges in order to increase its cost-to-charge ratio." *Id.* While Plaintiffs claim that the logic behind this explanation is faulty, the Court would conclude—even if this comment were relevant to proceedings at issue in this case—that it was an adequate response to the issue raised, particularly given the agency's expertise in implementing the complex statutory scheme with which the agency is entrusted. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) ("[I]n framing the scope of review, the court takes special note of the tremendous complexity of the Medicare statute. That complexity adds to the deference which is due to the Secretary's decision.").

Data Quality

Plaintiffs also argue that the agency did not implement the statewide cost-to-charge ratio policy correctly. The Secretary responds that Plaintiffs incorrectly understand the record and argue that the agency did not commit the alleged errors. The Court agrees with the Secretary.

First, Plaintiffs argue that the agency improperly used the statewide ratios from *prior* years in calculating the fixed loss thresholds. Plaintiffs state that the Impact Files that the agency used to calculate the fixed loss thresholds include the statewide ratio from a prior year for certain hospitals. The Secretary acknowledges that the Impact Files include prior-year statewide averages. However, she explains that, during the process of calculating the fixed loss threshold, updated statewide averages were calculated and used in setting the fixed loss threshold. While the administrative record does not include the computer programs used to perform the calculations, the Court has no basis to doubt the Secretary's representation. Moreover, the agency adequately described the sources of the data for the model in the challenged rulemakings. For example, the agency explained that to calculate FY 2003 fixed loss threshold, it "simulated payments by applying FY 2003 rates and policies to the March 2002 update of the FY 2001 MedPAR file and the March 2002 update of the Provider-Specific File." 67 Fed. Reg. at 50,122. The agency further explained that, for hospitals where the hospital-specific cost-to-charge ratio was more than 3.0 standard deviations above or below the mean of the log distribution of cost-to-charge ratios for all hospitals, the agency used the statewide average cost-to-charge ratios found in Tables 8A and 8B of the rulemaking. *Id.* at 50,125. In the FY 2002 rulemaking, as with the other annual rulemakings, the agency used input from the several sources enumerated here to calculate the fixed loss threshold and to calculate the statewide averages, all of which were promulgated in that rulemaking. *See id.* at 50,122, 50,263 (promulgating Tables 8A and 8B for FY 2002). This fact is consistent with the agency's explanation in its briefing that the agency calculated the statewide averages in the course of the modeling that generated the fixed loss threshold and then used these revised averages in generating the fixed loss threshold. The agency need not have done any more.

Second, Plaintiffs claim that, for certain hospitals, the agency used the statewide averages themselves, instead of the hospital-specific cost-to-charge ratios, to compute the statewide averages. The agency once again responds that this is incorrect. Plaintiffs do not point to any support in the record for this claim. They point only to a document in the record showing those facilities that defaulted to the statewide cost-to-charge ratios, A.R. (2003 amendments) 4417.332, and to the list of statewide ratios for the FY 2003 rulemaking, A.R. (FY 2003) 4819.001. Once again, the Court has no reason to disbelieve the agency's representation that it did not use statewide averages to calculate those averages themselves.

In sum, while the agency ultimately decided to change the features of the outlier payment scheme that Plaintiffs challenge here—the use of settled cost reports and the use of statewide averages for hospitals with low cost-to-charge ratios—the agency's decision to implement these features in the first instance was neither arbitrary nor capricious. It appears the agency subsequently learned from its experience implementing these decisions, but that does not provide cause for this Court to invalidate the agency's 1988 action. Plaintiffs have pointed to nothing that would show that the outlier payment regulations applicable to any of outlier payment determinations challenged in this action were arbitrary or capricious.

2. Challenge to the FY 1998 through 2003 Fixed Loss Thresholds

Plaintiffs present two groups of challenges to the six fixed loss thresholds for FY 1998 through 2003. First, they claim that, for these fiscal years, the agency kept increasing the fixed loss threshold despite evidence that the model "had no rational relationship to the real world." Pls.' Mot. at 47. Second, Plaintiffs claim that the agency wrongly used "fudge factors" for FY 2001 through FY 2003. Neither arguments succeeds. Before addressing these two claims, the Court notes that, notwithstanding Plaintiffs' claim that they are challenging each fixed loss

threshold rulemaking from FY 1997 through FY 2003, they have clarified that they "do not claim underpayments with respect to the FY 1997 [fixed loss threshold]." Pls.' Mot. 48 n.38. Because they are not claiming underpayments for that fiscal year, the Court does not understand Plaintiffs to be arguing that the FY 1997 fixed loss threshold rulemaking was arbitrary or capricious. In any event, Plaintiffs would have no basis to do so because they are not challenging any payment determinations for that year.

a. Plaintiffs' Tale of Continuing Increases in the Fixed Loss Threshold

In presenting their claim that the agency continued to increase the fixed loss threshold between FY 1997 and FY 2003 despite evidence that the "model had no rational relationship to the real world," *id.*, Plaintiffs have failed to heed the Court's instruction—and the fundamental principle of judicial review of agency action—that their challenges must be directed at discrete agency actions and that they must be based on the administrative record before the agency at the time of the respective actions. Plaintiffs tell a story of continually increasing fixed loss threshold in the face of contradictory data, but do not show how any of these seven rulemakings were arbitrary and capricious based on the record before the agency at the time of the rulemaking.

First, Plaintiffs emphasize how the agency kept missing its target for outlier payments despite the increasing fixed loss thresholds. Plaintiffs are correct that, for several years, the agency increased the fixed loss threshold, but nonetheless the outlier payments for that year exceeded the 5.1 percent estimate.[42] However, this pattern does not show that the fixed loss

[42] For example, for FY 1997, the agency set the fixed loss threshold at of $9,700—such that outlier payments would be 5.1 percent of total DRG-based payments. *See* 61 Fed. Reg. at 46,228-29. As of July 31, 1998, the agency estimated that actual outlier payments for FY 1997 were 5.5 percent of total DRG-based payments. 63 Fed. Reg. at 41,009. For FY 1998, the agency set the fixed loss threshold at $11,050—such that outlier payments would be 5.1 percent of total DRG-based payments. 62 Fed. Reg. at 46,040. As of July 30, 1999, the agency estimated that

rulemakings were arbitrary and capricious. Despite Plaintiffs' repeated emphasis that the agency missed its targets, it was not required to "meet" those targets. As the Court of Appeals held in *County of Los Angeles*, the agency is simply required to calculate the fixed loss thresholds such that "when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected … DRG-related payments." 192 F.3d at 1013. Just because the agency was aware that actual outlier payments exceeded the predicted levels for these years, *see supra* note 42, does not mean that it was arbitrary or capricious to continue implementing this model. Plaintiffs present three arguments to the contrary; each is unavailing.

First, Plaintiffs claim that it should have been obvious to the agency that the increase in outlier payments was caused by increases in charges. As the basis for this argument, Plaintiffs rely on the following syllogism. The agency was aware that charges were rising faster than costs, and thus that cost-to-charge ratios were (necessarily) declining. The agency had previously explained that using a cost-inflation methodology automatically accounted for changes in the cost-to-charge ratios "since the relevant variable is the costs estimated for a given case." 59 Fed. Reg. at 45,407. Therefore, Plaintiffs say, it should have been obvious that the actual increase in outlier payments "was attributable to the principal remaining variable: hospital charges." Pls.' Mot. at 50-51. The Court disagrees. Under this complex statutory and regulatory scheme, the Court would not conclude that the source of the increases was so obvious such that the agency was under an obligation to address it *sua sponte*, without being prompted by a public comment. Yet, despite Plaintiffs' claim that the agency did not address the problem "[d]espite warnings,"

---

actual outlier payments for FY 1998 were 6.5 percent of total DRG-based payments. 64 Fed. Reg. at 41,547. For FY 1999, the agency set the fixed loss threshold at $11,100—such that outlier payments would be 5.1 percent of total DRG-based payments. 63 Fed. Reg. at 41,008. As of August 1, 2000, the agency estimated that actual outlier payments for FY 1999 were 7.6 percent of total DRG-based payments. 65 Fed. Reg. at 47,114.

Plaintiffs do not point to any place in the record where such warnings were made with respect to the relevant fiscal years. Pls.' Mot. at 51.

Second, Plaintiffs claim that there was evidence that the model was producing irrational results because several hospitals were projected to receive outlier payments that would be a high percentage of the DRG-based payments. This argument fails for several reasons. Most fundamentally, Plaintiffs cannot point to anywhere in the record where this phenomenon was brought to the attention of the agency. Simply because the agency possessed data that could reveal this phenomenon does not mean that the agency had an obligation to change its methodology or to explain why it did not do so. In addition, Plaintiffs do not even attempt to explain how they generated the calculations on which they rely for this argument.[43] Lastly, just because agency set the fixed loss threshold such that the projected outlier payments for the entire country would be 5.1 percent of the total projected nationwide DRG-based payments, pursuant to the statutory requirements, does not mean it was arbitrary or capricious to set the threshold on the basis of a prediction that would have generated high payments for individual hospitals. The agency had no obligation to explain this phenomenon absent a relevant comment from a member of the public or other evidence in the record showing that this issue was before the agency.

Third, Plaintiffs claim that the agency asserted, "in total contradiction of the record, that there was no evidence of any problem." Pls.' Mot. at 52. However, it is Plaintiffs' assertion that is "in total contradiction of the record." Plaintiffs' sole citation to the record for this proposition is a single response in the FY 2003 fixed loss threshold rulemaking. While Plaintiffs portray the comment and response as pertaining to general delays in updates to cost-to-charge ratios, it

[43] Plaintiffs cite to an additional exhibit, Exhibit 8, which the Court concluded above could not be considered. In any event, Plaintiffs neither explain in their exhibit nor in the body of their brief how they derived these calculations.

appears from the record that the exchange was limited to specific delays with the processing of the FY 2000 cost reports. *See* 67 Fed. Reg. at 50,124. In that light, the agency responded that it did not expect these additional delays—beyond the usual lag in the data processing—to have detrimental effects.[44] *See id.* at 50,124-25. This response is adequate with respect to the problem presented in the comment and does not show a general obliviousness to problems with the data as Plaintiffs suggest.

In sum, Plaintiffs have failed to show that any of the fixed loss threshold rulemakings from FY 1997 to FY 2003 were arbitrary or capricious because of the purported trend of escalating fixed loss thresholds combined with outlier payments that continued to exceed the agency's projections.

b. Use of "Fudge Factors"

Plaintiffs claim that the agency used unexplained "fudge factors" in setting the fixed loss thresholds for FY 2001 through FY 2003. The Court disagrees.

Plaintiffs first claim that the agency used an unexplained "fudge factor" in setting the FY 2001 fixed loss threshold. This is simply at odds with the record. As the agency recounted in finalizing the FY 2001 fixed loss threshold, the agency had used a cost inflation factor of negative 1.724 percent in projecting the costs for FY 1999, and the agency had used a zero inflation factor in projecting the costs for FY 2000. *See* 65 Fed. Reg. at 47,113. For FY 2001, the agency had proposed an inflation factor of 1.0 percent, but ultimately decided that a factor of 1.8

[44] The following is the agency's full response: "Our analysis shows that, despite the delay in processing cost reports alluded to above, the average cost-to-charge ratios have continued to decline. We note there is always a lag between the timeframe from which the cost-to-charge ratios are taken and the period to which they are applied to charges. We do not have any evidence that the higher than expected outlier payments result from any extra lag in updating cost-to-charge ratios due to the delay in processing the cost reports." 67 Fed. Reg. at 50,124-25.

percent was proper. *See id.* The agency explained the reasoning for using this inflation factor: "This factor reflects our analysis of the best available cost report data as well as calculations (using the best available data) indicating that the percentage of actual outlier payments for FY 1999 is higher than we projected before the beginning of FY 1999, and that the percentage of actual outlier payments for FY 2000 will likely be higher than we projected before the beginning of FY 2000." *Id.* In other words, the agency explained why it used the higher inflation factor in light of its experience in previous years. This is neither arbitrary nor capricious. The agency explained why it used this factor, and it need not explain in any further detail exactly how its analysis of the underlying data generated the 1.8 percent figure. *See Tex. Mun. Power v. EPA*, 89 F.3d 858, 869-70 (D.C. Cir. 1996) ("And though the EPA did not explain its precise method for calculating a rate based on a statewide average that was used in this case until after the close of general proceedings before the agency, the failure of an agency to identify every detail of a process before it is used does not automatically require judicial interference in matters that must be thought to lie within the agency's expertise.").

Plaintiffs present a similar argument regarding the FY 2002 threshold, and it fails for a similar reason.[45] In setting the FY 2002 threshold, the agency recounted the cost inflation factors used for the previous several years. *See* 66 Fed. Reg. at 39,941. While the agency had proposed using a cost inflation factor for FY 2002 of 5.5 percent, the agency ultimately concluded that a cost inflation factor of 2.8 percent was proper. *See id.* Once again the agency explained its conclusion in light of its recent experience: "This factor reflects our analysis of the best available cost report data as well as calculations (using the best available data) indicating that the percentage of actual outlier payments for FY 2000 is higher than we projected before the

[45] The Court notes that Plaintiffs do not cite any record evidence for this claim.

beginning of FY 2000, and that the percentage of actual outlier payments for FY 2001 will likely be higher than we projected before the beginning of FY 2001." *Id.* As with the FY 2001 cost inflation factor, the agency adequately explained the choices behind its decision to choose this factor. No more is necessary to survive arbitrary and capricious review. *See Tex. Mun. Power*, 89 F.3d at 869-70.

Finally, with respect to this set of years, Plaintiffs argue that the decision in the FY 2003 fixed loss threshold rulemaking to switch from cost inflation to charge inflation was arbitrary and capricious. Plaintiffs primarily rely on the agency's prior decision, in 1994, to switch from charge inflation to cost inflation. Neither choice was arbitrary or capricious. To explain why, it is necessary to explain briefly the differences in the two methodologies. Under the charge inflation methodology, which the agency introduced for FY 2003, the agency calculated a measure of past charge inflation based on historical data and used this measure to inflate past charges in order to generate a dataset of projected charges for the fiscal year in question; the agency then adjusted these charges to projected future costs using cost-to-charge ratios. *See* 70 Fed. Reg. at 47,495. By contrast, under the cost inflation methodology, which was used for FY 1994 through FY 2002, the agency adjusted past charges by cost-to-charge ratios to estimate past costs, and then used a cost inflation factor derived from historical data to inflate the estimated costs and generate projected future costs. *See* 58 Fed. Reg. at 46,347. Under either methodology, the agency ultimately used the projected future costs to simulate outlier payments for the fiscal year in question.

In 1994, the agency determined that it was best to switch from a charge inflation methodology to a cost inflation methodology. 58 Fed. Reg. at 46,347. The agency reasoned:

> However, we have noted a continued trend with respect to changes in costs relative to charges. Over time, charges have continued to increase at a faster rate

> than costs, so that cost-to-charge ratios have been declining. Because we use the latest available cost-to-charge ratios (which may be as much as 2 years old) to convert billed charges to costs for purposes of estimating cost outlier payments, we may be overestimating outlier payments in setting the thresholds. As a result, actual payments may be lower than estimated. In order to alleviate this problem, we are using a cost inflation factor rather than a charge inflation factor to estimate FY 1994 costs. In other words, instead of inflating the FY 1992 charge data by a charge inflation factor for 2 years in order to estimate FY 1994 charge data and then applying the cost-to-charge ratio, we will adjust the charges by the cost-to-charge ratio and then inflate the estimated costs for 2 years of cost inflation. In this manner, we will be automatically adjusting for any changes in the cost-to-charge ratios that may occur, since the relevant variable is the costs estimated for a given case.

Id. Plaintiffs do not challenge this choice. Almost ten years later, the agency determined that, in light of the agency's experience, it would be preferable to make the opposite choice and use a charge inflation methodology. *See* 67 Fed. Reg. at 50,124. The agency explained its decision:

> Based on our analysis above, we believe that, due to current trends in hospital charging practices, using inflation factors based on annual cost growth results in underestimating the percentage of outlier payments. That is, if charges are growing at a faster rate than costs, inflating FY 2001 charges by the observed rate of change in costs will underestimate FY 2003 charges, thereby resulting in outlier payments greater than 5.1 percent. … Because charge data are available from claims data in the MedPAR file, they are more up-to-date than cost data taken from the cost reports.

Id. In short, even though the agency was trying to resolve challenges in accounting for cost and charge inflation at both junctures, neither approach was arbitrary or capricious. The agency adequately explained its decision in both circumstances, and the agency's hands were not tied in 2002 simply because it had previously decided to switch from charge inflation to cost inflation. *See Fox Television Studios*, 556 U.S. at 515 ("But [an agency] need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately

indicates."). Accordingly, the agency's decision to adopt a charge inflation methodology in 2003 was neither arbitrary nor capricious.

In sum, none of Plaintiffs' challenges to the fixed loss threshold rulemakings from FY 1997 through FY 2003 are successful. Plaintiffs have not shown, based on the record, that any of those rulemakings were arbitrary or capricious.

3. Challenges to the Fixed Loss Thresholds after the 2003 Changes to the Outlier Payment Regulations

As described above, in 2003, the agency promulgated several changes to the outlier payment regulations to address problems that had been discovered regarding the outlier payment program. In short, the agency introduced three changes: (1) more recent data would be used to derive the cost-to-charge ratios (specifically, tentatively settled cost reports would be used when they were more recent than settled cost reports), (2) the agency would no longer use statewide cost-to-charge ratios for hospitals with extremely low cost-to-charge ratios, and (3) outlier payments would become subject to adjustment, in an after-the-fact reconciliation process, when the actual cost-to-charge ratios deviated substantially from the ratios used to make the outlier payments. *See* 68 Fed. Reg. at 34,497-503. These changes were in effect for FY 2004 and beyond.[46] *See id.* at 34,498, 34,510; *see also* 42 C.F.R. § 412.84(h), (i). Plaintiffs challenge the agency's decision not to implement a mid-year adjustment to the FY 2003 fixed loss threshold

[46] More precisely, the use of statewide cost-to-charge ratios for hospitals with extremely low cost-to-charge ratios was eliminated for discharges occurring on or after August 8, 2003, less than two months before the beginning of FY 2004. 68 Fed. Reg. at 34,510. For discharges occurring on or after October 1, 2003, the latest of the settled or the tentatively settled cost reports would be used to derive the cost-to-charge ratios. *See id.* at 34,498. For discharges between August 8, 2003, and October 1, 2003, outlier payments were only partially subject to reconciliation in light of the fact that the use of tentatively settled cost reports was not yet in effect. *See* 42 C.F.R. § 412.525(a)(4); 68 Fed. Reg. at 34,515. For discharges on or after October 1, 2003, outlier payments would be fully subject to reconciliation. *See id.*

along with these changes to the outlier payment regulations. Plaintiffs also challenge each of the fixed loss threshold rulemakings for the fiscal years for which these new rules were in effect: FY 2004 through FY 2007.

Plaintiffs raise three general arguments with respect to these four rulemakings. First, they claim that, because the charge data on which these rulemakings were based was from the "turbo-charging" era, the agency should have adjusted the data in setting the fixed loss thresholds. Pls.' Mot. at 55. Second, Plaintiffs argue that, even with the use of more recent data to derive the cost-to-charge ratios (from tentatively settled cost reports), because of the lag between the setting of the fixed loss threshold and the calculation of actual outlier payments, the agency should have adjusted the cost-to-charge ratios to account for continuing declines in those ratios. *Id.* at 55-56. Third, Plaintiffs argue that the fixed loss threshold for each of these years was flawed because the agency failed to account for reconciliation. *Id.* at 56. Because each of these arguments applies differently to the four fixed loss threshold rulemakings during this period, it is necessary to evaluate Plaintiffs' specific arguments directed at each of the annual rulemakings in light of the data before the agency at the relevant times. Before doing so, it is necessary to resolve one preliminary issue. Several of Plaintiffs' challenges are based on the draft interim final rule that was sent to the Office of Management and Budget in 2003. *See id.* at 56-57. However, the Court of Appeals confirmed that the draft rule cannot be used to challenge any agency rulemakings because it was never published in the Federal Register. *See Dist. Hosp. Partners*, 786 F.3d at 58. Accordingly, insofar as Plaintiffs' challenges are based on the draft interim final rule, they cannot succeed. With this in mind, the Court first addresses Plaintiffs' challenge to the agency's decision not to undertake a mid-year adjustment to the FY 2003 fixed loss threshold and then

addresses, in turn, Plaintiffs' specific challenges to the fixed loss threshold rulemakings for FY 2004 through FY 2007.

a. Mid-year Adjustment to the FY 2003 Fixed Loss Threshold

In the agency's 2003 rulemaking promulgating changes to the outlier payment regulations, the agency responded to comments suggesting that the agency make a mid-year adjustment to the FY 2003 fixed loss threshold and explained why it decided not to make such an adjustment. 68 Fed. Reg. at 34,505. Plaintiffs now argue that it was arbitrary and capricious for the agency to decline to make such a mid-year adjustment.

Plaintiffs' arguments are largely based on the draft interim final rule that the agency transmitted to the Office of Management and Budget in February 2003. *See* AR (2003 amendments) 4417.338. However, the agency abandoned the plan to promulgate an interim final rule and never published such a rule in the Federal Register. Accordingly, the agency had no obligation to explain its departure from proposals in that draft rule, such as the proposal to implement a mid-year adjustment to the FY 2003 threshold. *See Dist. Hosp. Partners*, 786 F.3d at 58 ("It is true, of course, that an agency cannot 'depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.' But this principle is inapplicable here—the OMB draft was never 'on the books' in the first place.") (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515).

Nonetheless, in response to public comments the agency received, the agency considered the appropriateness of a mid-year adjustment. To determine whether an adjustment was appropriate, the agency re-estimated the fixed loss threshold for FY 2003 using the more recent data then available—FY 2002 data rather than data from earlier fiscal years—and taking into account the fact that some of the changes to the outlier payment regulations promulgated in that

same rule would be in effect during the last two months of FY 2003. 68 Fed. Reg. at 34,505. The agency estimated the "threshold would be only slightly higher than the current threshold [$33,560] (by approximately $600)." *Id.*

Plaintiffs argue that the analysis that generated this conclusion was arbitrary and capricious, but their arguments fail. They argue that the agency improperly applied the "old" fixed loss threshold model, by which they appear to mean the model that was used to calculate the fixed loss thresholds for the fiscal years prior to the 2003 revisions to outlier payment regulations. However, none of the purported flaws that they identify show that the agency's choice of model was arbitrary or capricious. First, Plaintiffs claim that the model provided "statutorily unauthorized payments" to turbo-charging hospitals. However, as the Court explained above with respect to Plaintiffs' challenges invoking *Chevron*, payments to turbo-chargers were not in fact statutorily prohibited. Second, Plaintiffs claim that the agency wrongly included the data pertaining to the turbo-chargers—the hospitals that rapidly increased their charges—in computing its inflation factor. Third, Plaintiffs argue that the agency mistakenly failed to account for continuing declines in the cost-to-charge ratios when it decided not to adjust those ratios. However, with respect to Plaintiffs' second and third arguments, Plaintiffs do not point to anywhere in the administrative record for the 2003 rulemaking where these issues were raised before the agency. While the agency discussed several comments regarding a mid-year adjustment to the FY 2003 threshold, none of the comments raised the specific issues that Plaintiffs now raise. Accordingly, the agency had no obligation to consider these specific issues in re-estimating the FY 2003 fixed loss threshold. Plaintiffs also highlight the agency's statement that it "inflated charges from the FY 2002 Medicare Provider Analysis and Review (MedPAR) file by the 2-year average annual rate of change in charges per case to predict charges for *FY*

2004." 68 Fed. Reg. at 34,505 (emphasis added). As the agency explains, this reference to FY 2004 is self-evidently a typographical error. Every other reference in the discussion was to the proper year, including its statement that the agency concluded "it would be appropriate to use FY 2002 data to reestimate the FY 2003 threshold." *Id.* There is no reason to believe that, contrary to the agency's representation in its briefing, that the agency inflated data in order to project cost for FY 2004 rather than for FY 2003.

Aside from Plaintiffs' specific claims regarding the purported flaws with the agency's re-calculation of the FY 2003 fixed loss threshold, Plaintiffs ignore the fact that the 2003 revisions to the outlier payment regulations were generally not applicable for FY 2003. *See supra* note 46. The only change that became fully applicable during even a part of that fiscal year was the elimination of the use of statewide cost-to-charge ratios for hospitals with extremely low cost-to-charge ratios—and only for discharges occurring on or after August 8, 2003.[47] 68 Fed. Reg. at 34,510. Even this change was applicable for less than two months of FY 2003. Accordingly, notwithstanding Plaintiffs' suggestion to the contrary, *see* Pls.' Mot. at 58 n.44, one would not necessarily expect that applying "the changes implemented in this final rule that will be in effect during a portion of FY 2003" would generate a significant change in the fixed loss threshold for FY 2003.

In light of its conclusion that a re-estimated fixed loss threshold would be slightly higher than the existing threshold for FY 2003, the agency explained why it concluded that a mid-year adjustment was not warranted:

> We believe it is appropriate not to change the FY 2003 outlier threshold at this time. Although our current empirical estimate of the threshold indicates it could be slightly higher, there are other considerations that lead us to conclude the

[47] The outlier payments for the period from August 8, 2003, to September 30, 2003, were only partially subject to reconciliation. *See* 68 Fed. Reg. at 34,498, 34,510.

> threshold should remain at $33,560. Increasing the threshold would result in lower outlier payments for all hospitals, not just those that have been aggressively maximizing their outlier payments. Changing the threshold for the remaining few months of the fiscal year could disrupt hospitals' budgeting plans and would be contrary to the overall prospectivity of the [Prospective Payment System]. We do believe that we have the authority to revise the threshold, given the extraordinary circumstances that have occurred (in particular, the manipulation of the policy by some hospitals). However, 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.

Id. at 34,506. This explanation is adequate on its own terms, and there is no need to consider it further. Indeed, Plaintiffs do not challenge the agency's decision not to *raise* the fixed loss threshold; they only argue that, if the fixed loss threshold had been "properly" re-calculated, it should have been lowered. Accordingly, the Court concludes that the agency's decision not to implement a mid-year adjustment to the FY 2003 fixed loss threshold was not arbitrary or capricious.[48]

b. Challenge to the FY 2004 Fixed Loss Threshold Rulemaking

With respect to the FY 2004—the first full fiscal year where the 2003 revisions to the outlier payment regulations were applicable—Plaintiffs argue that the decision to set the fixed loss threshold at $31,000 was arbitrary and capricious (1) because the data used to set the fixed loss threshold included data infected by turbo-charging, (2) because the agency failed to adjust the cost-to-charge ratios to account for continuing declines in cost-to-charge ratios, and (3) because the agency failed to account for reconciliation. *See* Pls.' Mot at 62.

[48] Because the Court concludes that the agency adequately justified its decision not to implement a mid-year adjustment to the FY 2003 fixed loss threshold, it need not reach Defendant's alternative argument that the decision whether to make such an adjustment is committed to the agency's discretion by law.

Before addressing the individual arguments, the Court notes that, once again, Plaintiffs rely substantially on the draft interim final rule to impugn the FY 2004 fixed loss threshold rulemaking. However, they may not do so because that rule was never published in the Federal Register. *See Dist. Hosp. Partners*, 786 F.3d at 58. Similarly, Plaintiffs may not rely on testimony given by Thomas Scully, Administrator of the Center for Medicare and Medicaid Services, before a Congressional subcommittee to impugn subsequent rulemakings. Plaintiffs cite a statement of Scully in testimony before the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, on March 11, 2003, that "the correct number [for the fixed loss threshold] probably is in the midtwenties." *See Medicare Outlier Payments to Hospitals: Hearing Before Subcomms. On Appropriations and Labor, Health & Human Services, and Education*, 108th Cong. 108-268, at 13 (2003) (statement of Thomas A. Scully, Adm'r, Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs.), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-108shrg85832/pdf/CHRG-108shrg85832.pdf (last visited on Aug. 3, 2015). It appears that this testimony represents Scully's personal opinion rather than the official position of the agency. *See id.* ("*I happen to believe*, and our actuaries believe that the correct number probably is in the midtwenties, if we fix the program abuses, I really think that fixing this will provide the other 97 percent of the hospitals that have not abused more money from it. And so I do think the outlier threshold—*my personal opinion* is that it probably, if we fix the abuses, would be too high, but I can understand the skepticism from our budget analysts to say we have been wrong 5 years in a row by a couple of billion dollars, how could we possibly think we are right now?") (emphasis added). In any event, Scully's speculation about the appropriate level for the fixed loss threshold cannot be used to attack the FY 2004 fixed loss threshold that was ultimately promulgated, particularly when he

testified before the promulgation of the final 2003 revisions to the outlier payment regulations—which governed FY 2004 and beyond—and before the agency conducted the analysis that resulted in the fixed loss threshold promulgated for FY 2004. Furthermore, the agency has no obligation to explain why the fixed loss threshold for this fiscal year deviated from the administrator's previous speculations. *Cf. Dist. Hosp. Partners*, 786 F.3d at 58 (no obligation to explain deviation from policy that was never "on the books"). With that in mind, the Court addresses the substance of Plaintiffs' three challenges regarding the FY 2004 fixed loss threshold.

First, Plaintiffs argue that the agency should have excluded the data that was related to turbo-chargers from the charge inflation calculation. In addition to their reliance on the findings of the draft interim final rule, Plaintiffs argue that the agency never responded to a comment presenting such a suggestion. Indeed, the record reflects that one commenter "requested that CMS factor in the calculation of the threshold the fact that certain hospitals have distorted their charges significantly." 68 Fed. Reg. at 45,477. Plaintiffs argue that the agency did not adequately respond to this comment and did not explain why it chose to include data from the turbo-chargers when calculating the charge inflation factor for FY 2004. In *District Hospital Partners*, the D.C. Circuit Court of Appeals concluded that the agency had not adequately explained why it did not exclude the 123 turbo-charging hospitals from the charge inflation calculation for that fiscal year. *See* 786 F.3d at 58, 59. The Court of Appeals concluded that the FY 2004 rule must be remanded to the agency for further explanation regarding the inclusion of the 123 turbo-charging hospitals that had been referenced in the notice of proposed rulemaking issued by the agency earlier in 2003. *See id.* at 60. This Court is, therefore, constrained to do the same and will remand the FY 2004 rule to the agency to provide the agency an opportunity to explain further why it did not

exclude the 123 identified turbo-charging hospitals from the charge inflation calculation for FY 2004—or to recalculate the fixed loss threshold if necessary. While the Court must remand the FY 2004 rulemaking to the agency because of the gap in its contemporaneous explanation in that rulemaking, the Court nonetheless considers Plaintiffs' other claims regarding the FY 2004 rulemaking to determine the scope of that remand.

Second, Plaintiffs claim that the agency improperly failed to include an adjustment factor in the cost-to-charge ratio despite the fact that cost-to-charge ratios continued to decline. Aside from Plaintiffs' impermissible reliance on the interim final rule, they support this argument by pointing to a single comment submitted by the Federation of American Hospitals on July 8, 2003. Above, the Court concluded that it would not be proper, at this point, to supplement the administrative record with this comment because of its untimely submission. Without that comment, Plaintiffs' cannot point to any evidence in the record showing that the use of an adjustment factor with respect to the cost-to-charge ratios was a "'significant and viable and obvious alternative[]'" at the time of the agency's decision. *Dist. Hosp. Partners*, 786 F.3d at 59 (citation omitted). For that reason alone, the Court concludes that this particular challenge fails.

In any event, even if the Court considered the Federation of American Hospitals comment, which the Court has excluded from the record, the Court would conclude that the agency's decision not to apply an adjustment factor to the cost-to-charge ratios across the board was neither arbitrary nor capricious. *See Dist. Hosp. Partners*, 973 F. Supp. 2d at 15-16. Notably, the agency did, in fact, attempt to account for declining cost-to-charge ratios with respect to a certain subset of hospitals "that ha[d] been consistently overpaid recently for outliers." 68 Fed. Reg. at 45,476. For those hospitals, the agency "attempted to project each hospital's cost-to-charge ratio based on its rate of increase in charges per case based on FY 2002 charges,

compared to costs (inflated to FY 2002 using actual market basket increases)." *Id.* at 45,477. For other hospitals, the agency used the cost data from the most recent cost-reporting year to approximate the cost-to-charge ratios that would be used for actual outlier payments in FY 2004, which would be based on the latest tentatively settled cost reports. *See id.* at 45,476. It was rational for the agency to limit its attempt to project future decreases in cost-to-charge ratios to a small subset of hospitals where recent history strongly suggested that the ratios for those hospitals would continue to decrease—but to continue to use actual data in deriving the cost-to-charge ratios for all other hospitals. In light of the Court's deferential standard of review, *see West Virginia*, 362 F.3d at 868, even if the Court were to consider 2004 Federation of American Hospitals comment as part of the administrative record, the Court would not invalidate the agency's decision to use actual historical data and to limit its projections of future data changes to a small subset of Medicare facilities.

Third, Plaintiffs argue that the agency improperly failed to consider the effects of reconciliation on the projections for FY 2004. Once again, in support of this argument, Plaintiffs rely only on a statement in the Federation of American Hospitals comment—which is not part of the administrative record—and on the draft interim final rule. As explained above, neither can serve as the basis for Plaintiffs' claim that the agency's action was arbitrary and capricious for failing to account for reconciliation. Nonetheless, the Court notes that this challenge would also fail because the agency *did* account for the effects of reconciliation for FY 2004. *See* 68 Fed. Reg. at 45,476-77. The agency noted that it "is difficult to project which hospitals will be subject to reconciliation of their outlier payments using available data." *Id.* at 45,476. Nonetheless, based on the data available, the agency explained how it had accounted for the effects of reconciliation:

> Based on our analysis of hospitals that have been consistently overpaid recently for outliers, we have identified approximately 50 hospitals we believe will be

> reconciled. Therefore, for these hospitals, to account for the fact that the reconciliation will result in different outlier payments than predicted using the cost-to-charge ratios calculated as described above, we attempted to project each hospital's cost-to-charge ratio based on its rate of increase in charges per case based on FY 2002 charges, compared to costs (inflated to FY 2002 using actual market basket increases).

Id. at 45,476-77. The agency also noted that "the amount of fiscal intermediary resources necessary to undertake reconciliation will ultimately influence the number of hospitals reconciled." *Id.* at 45,476. Taken together, these statements adequately explain why the agency accounted for reconciliation with respect to the set of 50 hospitals rather than with respect to all 123 hospitals previously identified as turbo-chargers.

For all of these reasons, the Court remands the FY 2004 fixed loss threshold rulemaking to the agency to allow it to explain further why the agency did not exclude the 123 turbo-charging hospitals from its calculation of charge inflation. *See Dist. Hosp. Partners*, 786 F.3d at 60 (concluding that remand is appropriate to allow agency to articulate better explanation of decision). The Court rejects all of Plaintiffs' other challenges to the FY 2004 fixed loss threshold.

c. Challenge to the FY 2005 Fixed Loss Threshold Rulemaking

With respect to the FY 2005 fixed loss threshold rulemaking, Plaintiffs raise once again the challenges that they raise with respect to the FY 2004 fixed loss threshold rulemaking—that the agency used data infected by turbo-charging when the setting the fixed loss threshold, that the agency should have used an adjustment factor to account for declining cost-to-charge ratios, and that the agency failed to account for reconciliation. In addition, Plaintiffs argue that the agency should have used a cost inflation methodology rather than a charge inflation methodology. The Court addresses these arguments in turn.

First, Plaintiffs argue that the agency failed to address the trend of declining cost-to-charge ratios. However, in responding to a comment suggesting the use of such an adjustment factor, the agency explained why it concluded it was not necessary to use such a factor:

> We do not believe that it is necessary to make a specific adjustment to our methodology for computing the outlier threshold to account for any decline in cost-to-charge ratios in FY 2005, as the commenter has requested. We have already taken into account the most significant factor in the decline in cost-to-charge ratios, specifically, the change from using the most recent final settled cost report to the most recent tentatively settled cost report. Furthermore, we strongly prefer to employ actual data rather than projections in estimating the outlier threshold because we employ actual data in updating charges, themselves.

69 Fed. Reg. at 49,277. While Plaintiffs critique this explanation, the Court concludes it is sufficient. It is not for the Court to second guess the agency's choices when it has, as here, provided a cogent explanation for those choices. Indeed, while Plaintiffs suggest that it was irrational for the agency to prefer to use actual cost-to-charge ratios over projected ratios when it was already using projected data, the Court disagrees. It is reasonable for the agency to prefer to use only projected data for certain factors, as it has explained here. In addition, the agency explained that it had addressed the most significant factor regarding declining cost-to-charge ratios by using more recent data. Altogether the agency sufficiently explained its conclusion that an adjustment factor was not necessary.

Second, Plaintiffs argue that the charge inflation factor used was flawed. Plaintiffs argue that the charge inflation factor was distorted by data from turbo-charging hospitals and that the agency did not adequately address its choice to continue using a charge inflation methodology rather than reverting to a cost inflation methodology.

To assess these arguments, a brief review of the agency's methodology to establish the fixed loss threshold for FY 2005 is necessary. The agency used the FY 2003 charge data as a baseline. 69 Fed. Reg. at 49,277. To develop a charge inflation factor, the agency took the

"unprecedented step of using the first half-year of data from FY 2003 and comparing data to the first half year of FY 2004." *Id.* Using this data, the agency calculated a one-year annual rate of charge inflation of 8.9772, or 18.76 percent over two years, and then inflated the FY 2003 data by this two-year charge inflation figure. *Id.* The agency then converted these projected charges into projected costs by using hospital-specific cost-to-charge ratios from the April 2004 update to the Provider Specific File. *Id.*

The D.C. Circuit Court of Appeals already considered and rejected the argument presented by Plaintiffs here: that it was arbitrary and capricious to fail to exclude the turbo-charging data from the calculation of a charge inflation factor for FY 2005. *See Dist. Hosp. Partners*, 786 F.3d at 61-62. In *District Hospital Partners*, the Court of Appeals noted that, while the data from the first half of FY 2003 was affected by turbo-charging, the charge data from the first half of FY 2004 was not similarly affected because the underlying discharges had occurred after the implementation of the 2003 changes to the outlier payment regulations. *Id.* at 61. The Court of Appeals approved the agency's decision to retain the turbo-chargers in the dataset in order to ensure that the FY 2003 and FY 2004 datasets were comparable. *See id.* So, too, here. As stated by the Court of Appeals in *District Hospital Partners*, it was not arbitrary or capricious to include the turbo-chargers in the datasets used to calculate the charge inflation factor for FY 2005.

Plaintiffs also argue that it was arbitrary and capricious for the agency to reject a suggestion that the agency ought to revert to a cost inflation methodology, which the agency had used through FY 2002. In explaining its choice to continue using a charge inflation methodology, the agency explained that "the use of charges is still appropriate because the basic tendency of charges to increase faster than costs is still evident." 69 Fed. Reg. at 49,277. Plaintiffs argue that

this explanation is insufficient because it was similar to the explanation gave in 1993 when the agency shifted from a charge inflation methodology to a cost inflation methodology. However, as the Court explained above, this explanation is adequate. Neither choice of methodology was arbitrary or capricious, and the agency is not barred from reversing its earlier decision as long as it has explained why it is making the present decision—as it has done here. *See Fox Television Studios*, 556 U.S. at 515.

Third, Plaintiffs argue that the FY 2005 fixed loss threshold rulemaking was arbitrary and capricious because the agency failed to account for reconciliation. However, the agency explained at length why it was not accounting for reconciliation:

> We are not including in the calculation of the outlier threshold the possibility that hospitals' cost-to-charge ratios and outlier payments may be reconciled upon cost report settlement. Reconciliation occurs when hospitals' cost-to-charge-ratios at the time of cost report settlement are different than the tentatively settled cost-to-charge-ratio used to make outlier payments during the fiscal year. However, we believe that due to changes in hospital charging practices following implementation of the new outlier regulations in the June 9, 2003 final rule, the majority of hospitals' cost-to-charge ratios will not fluctuate significantly enough between the tentatively settled cost report and the final settled cost report to meet the criteria to trigger reconciliation of their outlier payments. Furthermore, it is difficult to predict which specific hospitals may be subject to reconciliation in any given year. As a result, we believe it is appropriate to omit reconciliation from the outlier threshold calculation.

69 Fed. Reg. at 49,278. This explanation is more than adequate. Plaintiffs emphasize that reconciliation never occurred for FY 2005. However, that does not undermine the agency's explanation, which emphasizes uncertainty regarding reconciliation and reflects the agency's belief that the other changes to the outlier payment regulations obviated much of the need for reconciliation. The agency has explained why it chose not to account for reconciliation given the data that was available and given uncertainty about the implementation of the reconciliation provision.

For all of these reasons, the Court concludes that none of Plaintiffs' challenges to the FY fixed loss threshold rulemaking succeed and that the FY 2005 fixed loss threshold rulemaking was neither arbitrary nor capricious.[49]

d. Challenge to the FY 2006 Fixed Loss Threshold Rulemaking

Next, the Court turns to Plaintiffs' challenges to the FY 2006 fixed loss threshold rulemaking. Before addressing Plaintiffs' individual challenges, the Court notes that the D.C. Circuit Court of Appeals concluded in *District Hospital Partners* that "the 2006 outlier threshold was plainly reasonable." 786 F.3d at 62. In addition, just like the Court of Appeals, this Court is "perplexed" by Plaintiffs' objection to this fixed loss threshold. *See id.* at 63. Plaintiffs "cite[] favorably a comment submitted during the 2006 rulemaking that advocated a fixed loss threshold of $24,050." *Id.; see* Pls.' Mot. at 66 (citing A.R. (FY 2006) at 658 (comment of Federation of American Hospitals)). In fact, agency set the threshold *lower* than this proposed level—at $23,600—which would therefore would generate outlier payments *higher* than would have resulted from the proposal by the Federation of American Hospitals. *See* 70 Fed. Reg. at 47,494.

Nonetheless, the Court addresses the three arguments Plaintiffs present, which largely recapitulate the arguments they lodged with respect to the FY 2005 fixed loss threshold. Specifically, Plaintiffs argue (1) that the agency did not adequately explain its use of a charge inflation methodology, (2) that the agency did not adequately account for the decline of the cost-to-charge ratios over time, and (3) that the agency did not adequately account for reconciliation.

[49] Plaintiffs also emphasize the fact that it appeared that the outlier payments for FY 2004 would, in fact, be less than 5.1 percent of total DRG-based payments. However, the Court notes that the mere fact that it appeared that FY 2004 outlier payments would be less than 5.1 percent of the DRG-based payments does not make the agency's failure to adjust its methodology arbitrary or capricious. Given that the Court rejects Plaintiffs' other challenges to the FY 2005 rulemaking, it is of no moment that the data available at the time of the FY 2005 rulemaking suggested that FY 2004 outlier payments would be lower than the previous projections suggested.

Pls.' Mot. at 66-68. As with Plaintiffs' challenge to the FY 2005 rulemaking, none of these arguments are persuasive.

First, Plaintiffs argue that the agency did not adequately respond to comments suggesting a return to the use of a cost inflation methodology and did not adequately explain the continued use of a charge inflation methodology. The Court disagrees. The agency responded to those comments and explained that it "continue[d] to believe that using charge inflation, rather than cost inflation, will more likely result in an outlier threshold that leads to outlier payments equaling 5.1 percent of total [Prospective Payment System] payments." 70 Fed. Reg. at 47,495. The agency further explained why it was appropriate to use a charge inflation methodology in establishing the fixed loss threshold. *See id.* Notably, in their brief, Plaintiffs do not argue that a cost inflation methodology would have been superior; they simply argue that the agency failed to adequately explain why it used this methodology when it had previously had concluded that a cost inflation methodology was more accurate. However, the agency adequately explained its use of the charge inflation methodology. Moreover, as the Court explained above, the fact that the agency previously arrived at a different conclusion regarding the optimal inflation methodology does not make arbitrary or capricious its subsequent conclusion that a charge inflation methodology was preferable.

Second, Plaintiffs argue that the agency failed to account for the decline of cost-to-charge ratios over time. However, the agency explained its reasons for, once again, declining to apply an adjustment factor to cost-to-charge ratios. It is worth reproducing the agency's thorough explanation at length:

> We also carefully analyzed the comments suggesting that we also adjust the cost-to-charge ratios that are used in setting the outlier thresholds. We believe it is necessary to inflate the charges from the FY 2004 MedPAR file to project charge levels for FY 2006, but we do not believe it is also necessary to adjust the cost-to-

> charge ratios from the March 2005 Provider-Specific File. The FY 2004 MedPAR charge data include charges for dates of service through August 31, 2003. Although these data are the most recent case-specific charge information we have available for a complete fiscal year, the FY 2004 MedPAR charge data are over 2 years old. We likely would greatly underestimate FY 2006 outlier payments if we did not inflate the MedPAR charge data.
>
> On the other hand, the cost-to-charge ratios from the March 2005 Provider-Specific File reflect much more recent hospital-specific data than the case-specific data in the FY 2005 MedPAR file. The March 2005 Provider-Specific File includes the cost-to-charge ratios from hospitals' most recent tentatively-settled cost report. In many cases, for part of FY 2006, fiscal intermediaries will determine actual outlier payment amounts using the same cost-to-charge ratios that are in the March 2005 Provider-Specific File. Fiscal intermediaries will begin using an updated cost-to-charge ratio to calculate the outlier payments for a hospital only after a more recent cost report of the hospital has been tentatively settled. We note that the cost-to-charge ratios that we are using from the March 2005 Provider-Specific File are approximately 3 percent lower on average than the cost-to-charge ratios from the December 2004 Provider-Specific File that we used in setting the proposed rule outlier threshold.

70 Fed. Reg. at 47,495. This explanation adequately justifies the agency's decision not to adjust the cost-to-charge ratios. As the district court explained in *District Hospital Partners*, "[a]lthough the Secretary's rationale in []FY 2006 was distinct from that given in []FY 2005, it is no less reasonable." 973 F. Supp. 2d at 22. "Indeed, the fact that the cost-to-charge ratios used to calculate the fixed loss threshold are actually used, for some portion of the fiscal year, to calculate outlier payments, is a strong reason to not adjust the cost-to-charge ratios downward based on speculation regarding the continued downward trend in cost-to-charge ratios." *Id.* Although Plaintiffs claim that the agency's statement that lies underneath this conclusion has no basis in the administrative record, it is actually Plaintiffs' claim that cost-to-charge ratios would be updated before the start of FY 2006 that is not tethered to anything in the record. Absent any evidence to the contrary, the agency need not further justify its own understanding, as promulgated in the Federal Register, of the complicated statutory scheme that it administers.

Third, Plaintiffs argue, once again, that the agency failed to account for reconciliation in setting the fixed loss threshold. However, the agency did explain why it did not alter its methodology to account for reconciliation:

> As we did in establishing the FY 2005 outlier threshold (69 FR 49278), in our projection of FY 2006 outlier payments we did not make an adjustment for the possibility that hospitals' cost-to-charge ratios and outlier payments may be reconciled upon cost report settlement. We believe that, due to the policy implemented in the June 9, 2003 outlier final rule, cost-to-charge ratios will no longer fluctuate significantly and, therefore, few hospitals, if any, will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict which specific hospitals will have cost-to-charge ratios and outlier payments reconciled in their cost reports in any given year. We also note that reconciliation occurs because hospitals' actual cost-to-charge ratios for the cost reporting period are different than the interim cost-to-charge ratios used to calculate outlier payments when a bill is processed. Our simulations assume that cost-to-charge ratios accurately measure hospital costs and, therefore, are more indicative of post-reconciliation than pre-reconciliation outlier payments. As a result, we omitted any assumptions about the effects of reconciliation from the outlier threshold calculation.

70 Fed. Reg. 47,495. This thorough explanation is certainly adequate to explain the agency's decision not to account for reconciliation in setting the fixed loss threshold. Indeed, Plaintiffs point to no reason why this explanation is not adequate; they simply make the conclusory claim that the agency's explanation is conclusory and lacking in a factual basis.[50]

In sum, the Court concludes that none of Plaintiffs' challenges to the FY 2006 fixed loss threshold are successful.

e. Challenge to the FY 2007 Fixed Loss Threshold Rulemaking

Lastly, the Court turns to Plaintiffs' more modest challenges to the FY 2007 fixed loss threshold rulemaking. Plaintiffs' primary challenge is that, when the agency finally implemented

[50] As the Court has stated above, the agency's failure to implement reconciliation for this fiscal year does not undermine the Court's conclusion that it is not arbitrary and capricious for the agency to decline to account for reconciliation explicitly.

an adjustment to the cost-to-charge ratios in this year, the level of the adjustment was insufficient. Plaintiffs also argue that it was arbitrary and capricious not to account for reconciliation. With respect to the latter challenge, for the same reasons stated beforehand with respect to the prior fiscal years, the agency adequately explained its decision not to adjust its methodology to account for reconciliation explicitly. *See* 71 Fed. Reg. at 48,149. Because the agency's response is similar to that offered the previous year, and because Plaintiffs have offered no additional reasons why this response is inadequate, no further analysis is necessary for the Court to conclude that the agency's decision was neither arbitrary nor capricious. The Court now turns to the adjustment factor implemented for FY 2007.

For FY 2007, the agency applied an adjustment factor of 0.9973 to the otherwise applicable hospital-specific cost-to-charge ratios. *See* 71 Fed. Reg. at 48,150. To develop this adjustment factor, the agency assessed the relationship between previous changes to costs and previous changes to charges. *See id.* The agency explained thoroughly and adequately how it developed this methodology and applied it in setting the FY 2007 fixed loss threshold. *See id.* In arguing that the adjustment factor was inconsistent with the national average rates of change in cost-to-charge ratios across previous years, Plaintiffs rely on the Exhibit 5, which they submitted along with their motion. However, the Court previously concluded that Plaintiffs may not rely on that exhibit because it is properly considered part of Plaintiffs' brief and because it exceeds the page limit previously set by the Court for briefing in this case. In any event, even if the Court were to consider Plaintiffs' exhibit, Plaintiffs cannot point to any "'significant and viable and obvious alternatives'" regarding the calculation of an adjustment factor that were before the agency at the time of the rulemaking. *Dist. Hosp. Partners*, 786 F.3d at 59 (citation omitted). Plaintiffs' argument that the chosen adjustment factor was arbitrary and capricious is unavailing.

Accordingly, Plaintiffs' claim that the FY 2007 fixed loss threshold rulemaking was arbitrary and capricious fails.

* * *

Ultimately, while the Court concludes that it has jurisdiction over all of the claims in this action, of all of Plaintiffs' claims, only one is successful: the claim that the agency failed to explain why it included the 123 identified turbo-charging hospitals in the charge inflation calculations used to develop the FY 2004 fixed loss threshold. In all other respects, the Court rejects Plaintiffs' challenges to the 14 regulations at stake in this action, including Plaintiffs' statutory challenges and Plaintiffs' claims that the agency acted arbitrarily and capriciously in promulgating each of those 14 regulations.

IV. CONCLUSION

For the foregoing reasons, the Court DENIES Defendant's [126] Motion to Dismiss for Lack of Subject Matter Jurisdiction, GRANTS IN PART and DENIES IN PART Defendant's [126] Motion for Summary Judgment, GRANTS IN PART and DENIES IN PART Plaintiffs' [127/142] Motion for Summary Judgment, and GRANTS IN PART and DENIES IN PART Plaintiffs' [128] Motion for Judicial Notice and/or for Extra-Record Consideration of Documents and Other Related Relief. The Court first concludes that it has subject matter jurisdiction over all of the claims in this action. With respect to Plaintiffs' request for the Court to consider additional documents not part of the administrative record, the Court takes judicial notice of those publicly available documents as necessary, but denies Plaintiffs' request for extra-record consideration of those documents. The Court also denies Plaintiffs' request to add an additional comment to the administrative record because of the untimeliness of the request. The Court denies Plaintiffs' request to submit three additional tables and strikes from the record exhibits 5, 7, and 8 to

Plaintiffs' Motion for Summary Judgment. With respect to the cross-motions for summary judgment, the Court GRANTS Plaintiffs' Motion and DENIES Defendant's Motion with respect to the claim that the agency failed to explain its decision to include 123 turbo-charging hospitals in the dataset used to derive the inflation factor used for calculating the FY 2004 fixed loss threshold; the Court DENIES Plaintiffs' Motion and GRANTS Defendant's Motion in all other respects.

Accordingly, the FY 2004 fixed loss threshold rule is REMANDED to the agency to provide the agency an opportunity to explain why the agency included the turbo-charging hospitals in the data used to derive the inflation factor used to determine the FY 2004 fixed loss threshold—or to recalculate the fixed loss threshold if necessary. In all other respects, summary judgment is GRANTED to Defendant. The Court will retain jurisdiction pending the limited remand to the agency regarding the FY 2004 rulemaking. *See Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001) (district court has authority to retain jurisdiction pending remand to agency).

An appropriate Order accompanies this Memorandum Opinion.

Dated: September 2, 2015

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge