UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LEE MEMORIAL HEALTH SYSTEM f/b/o LEE MEMORIAL HOSPITAL, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 13-cv-643 (RMC)**
SYLVIA M. BURWELL, Secretary of the U.S. Department of Health & Human Services	)	
Defendant.	)	

OPINION

In these consolidated cases, Plaintiff hospitals challenge the methods used by the Department of Health & Human Services to calculate the "fixed-loss threshold," a term integral to reimbursement under the Medicare program. Because the Center for Medicare and Medicaid Services, a constituent agency of HHS, followed the notice and comment rulemaking process and is entitled to a highly deferential standard of review, the Court cannot say that it has acted arbitrarily or capriciously. The regulations will stand.

I. FACTS

Plaintiffs, a group of non-profit organizations that own and operate acute care hospitals participating in the Medicare program (Hospitals),[1] contend that the Center for

[1] Plaintiffs are: Billings Clinic, Charleston Area Medical Center, Good Samaritan Hospital, Sarasota Memorial Hospital, Valley View Hospital, West Virginia University Hospital, Lee Memorial Health System, Banner Health, Halifax Community Health System, University of Colorado Health at Memorial Hospital, Allina Health, Denver Health Medical Center, Billings Clinic Hospital, Parkview Medical Center, Good Samaritan Hospital, and Boulder Community Hospital.

Medicare and Medicaid Services (CMS), led by Secretary Sylvia Burwell (the Secretary), has underpaid them for Medicare services provided during the fiscal years ending in 2008, 2009, 2010, and 2011. Plaintiffs challenge CMS's administration of the outlier payment system, which pays eligible hospitals a percentage of their costs above the typical threshold for treating a Medicare patient. Plaintiffs challenge the "fixed loss threshold" rulemakings promulgated in fiscal years 2008 through 2011, as well as the 2003 amendment to the outlier payment regulations.

Presently before the Court are Defendant's Motion to Dismiss or, in the alternative, for Summary Judgment, Dkt. 73, and Plaintiffs' Motion for Summary Judgment, Dkt. 74.

A. Statutory Background

Medicare is a federal program that provides health insurance to the elderly and the disabled. *See generally* 42 U.S.C. §§ 1395 *et seq.* Generally speaking, hospitals provide care to Medicare beneficiaries and then seek reimbursement from CMS.

Reimbursement is not a precise exercise. Instead of reimbursing the providers dollar for dollar, CMS pays fixed rates through the Inpatient Prospective Payment System (IPPS).[2] Under IPPS, inpatient services are divided into categories called "diagnosis related groups" or "DRGs." *See* 42 U.S.C. § 1395ww(d). Each DRG merits a standard payment rate, intended to reflect the estimated average cost of treating the service(s) provided. *See id.*

[2] The program originally reimbursed hospitals for the "reasonable costs" of services provided to Medicare patients. *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999). That system deteriorated over time because it provided "little incentive for hospitals to keep costs down," since "[t]he more they spent, the more they were reimbursed." *Id.* (internal quotations and citations omitted).

Because these DRGs correspond to the given patient's diagnosis upon discharge, the rates may vary from the costs actually incurred by the provider.

In some cases, the rates may drastically understate a hospital's costs. To compensate providers for exceptionally costly cases, Congress established the "outlier" payment system. *See generally* 42 U.S.C. § 1395ww(d)(5)(A). If the cost of health care in a given case exceeds the DRG payment "plus a fixed dollar amount determined by the Secretary," then the hospital is eligible for an outlier payment. *Id.* § 1395ww(d)(5)(A)(ii).[3] Taken together, the DRG plus the "fixed dollar amount determined by the Secretary" represents the "outlier threshold." 42 U.S.C. § 1395ww(d)(5)(A)(ii); *see also Cnty. of L.A.*, 192 F.3d at 1010. If a case qualifies, the provider receives 80% of the costs that exceed the outlier threshold. 42 C.F.R. § 412.84(k). This 80% is called the "additional payment" or "outlier payment." *E.g., id.* §§ 412.80(a)(3), (c).[4]

[3] The cost must also exceed "any amounts payable under subparagraphs (B) and (F)." 42 U.S.C. § 1395ww(d)(5)(A)(ii). Those subparagraphs generally cover additional payments to compensate for indirect costs of medical education (often abbreviated as IME); and for serving a significantly disproportionate number of low-income and urban populations (often abbreviated as DSH). *See generally* 42 U.S.C. §§ 1395ww(d)(5)(B), (F). These provisions need not be parsed for the purposes of this case; the questions presented here can be answered by considering the outlier threshold as a combination of the DRG rate and the "fixed dollar amount."

[4] The D.C. Circuit has succinctly summarized this process in a hypothetical:

> Assume that the Secretary sets the fixed loss threshold at $10,000. Assume also that a hospital treats a Medicare patient for a broken bone and that the DRG rate for the treatment is $3,000. The Medicare patient required unusually extensive treatment which caused the hospital to impose $23,000 in cost-adjusted charges. If no other statutory factor is triggered, the hospital is eligible for an outlier payment of $8,000, which is 80% of the difference between its cost-adjusted charges ($23,000) and the outlier threshold ($13,000).

Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 50-51 (D.C. Cir. 2015).

The key phrase for present purposes is the "fixed dollar amount," which is to be "determined by the Secretary" and "specified by CMS." 42 U.S.C. § 1395ww(d)(5)(A)(ii); 42 C.F.R. § 412.80(a)(3). The parties refer to this as the "fixed-loss threshold" or "FLT." The Fixed Loss Threshold functions as an "insurance deductible" of sorts. *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1229 (11th Cir. 2009). When the cost of care exceeds the predetermined DRG payment, the provider must absorb the entire Fixed Loss Threshold amount before it can recoup any outlier payments from CMS. The parties' interests are thus diametrically opposed: CMS benefits from a higher Fixed Loss Threshold and the Hospitals benefit from a lower Fixed Loss Threshold.

Finally, the Medicare Act requires that in any fiscal year "[t]he total amount of the [outlier] payments . . . 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). Thus, although the Fixed Loss Threshold is "determined by the Secretary," she must set a Fixed Loss Threshold high enough to ensure that projected outlier payments do not exceed 6% of the projected DRG payments, but not so high that projected outlier payments are less than 5% of the projected DRG.[5] Although the statute's command is unequivocal, Fixed Loss Threshold rulemakings are predictive. *Id.* (requiring outlier payments to be within 5-6 "percent of the total payments *projected or estimated* to be made based on DRG *prospective* payment rates for discharges") (emphasis added); 42 C.F.R. § 412.80(c) ("CMS will issue threshold criteria for determining outlier

[5] The numbers are inversely proportional. As the Fixed Loss Threshold rises, so does the outlier threshold. The result is a decrease in an outlier payment, which is 80% of what exceeds the outlier threshold. So as the Fixed Loss Threshold rises, outlier payments decrease, and vice versa.

payment in the annual notice of the prospective payment rates published in accordance with § 412.8(b).”). As a result, there is no obvious way for CMS to *guarantee* that annually prescribed rates and thresholds will yield outlier payments that are between 5% and 6% of total DRG payments in the next federal fiscal year. Nor must it take corrective action if its predictions fall short. *See Cnty. of L.A.*, 192 F.3d at 1020. The D.C. Circuit has upheld this practice. *See Dist. Hosp. Partners*, 786 F.3d at 51.

B. Regulatory Background

2003 was a watershed year for the outlier-payment system. The system had been manipulated in the late 1990s by some hospitals which exploited certain regulatory vulnerabilities, arising from “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,” which predated current charges. Notice of Proposed Rulemaking, 68 Fed. Reg. 10,420, 10,423 (Mar. 5, 2003) (3/5/03 NPRM). The outlier payment system depends on calculating “charges, *adjusted to* cost,” including overhead and capital costs. 42 U.S.C. § 1395ww(d)(5)(A)(ii) (emphasis added). That adjustment is made using the “cost-to-charge ratio” (CCR) mentioned in the Notice of Proposed Rulemaking. Because hospitals knew that CCRs were based on *past* cost reports, some hospitals increased their charges for patient care between past cost reports and current reimbursement requests, yielding a CCR that would “be too high” and thus “overestimate the hospital’s costs.” 3/5/2003 NPRM at 10,423. Some 123 hospitals were found to have increased their charges by 70 percent, while only decreasing their CCRs by two percent. *Id.* at 10,424. This became known as “turbo-charging.” *Dist. Hosp. Partners*, 786 F.3d at 51 (describing turbochargers).

1. The February 2003 Draft Interim Final Rule

The Hospitals rely heavily on a Draft Interim Final Rule proposed in February 2003—before the Notice of Proposed Rulemaking cited above—and obtained by them through a Freedom of Information Act (FOIA) request. Hosp. Mot. [Dkt. 74] at 11 (citing AR S3595-S3659) (Draft); *see also* Joint Appendix, Ex. 4 [Dkt. 81-4] at 97-161 (same). The 63-page Draft included a number of findings and proposed various solutions.[6] The Draft found that turbocharging caused "nearly all of the increase in the FY 2003 threshold from FY 2002 ($21,025 to $33,560)." AR S3610. It also described the effect of turbocharging on the Fixed Loss Threshold: "Because the fixed-loss threshold is determined based on hospitals' historical charge data, hospitals that have been inappropriately maximizing their outlier payments have caused the threshold to increase dramatically for FY 2003." AR S3610.

To prevent future turbocharging, the Draft said that CMS "need[ed] to make revisions to [its] outlier payment methodology," primarily by "updating cost-to-charge ratios [CCRs]." 3/5/2003 NPRM at 10,421, 10,423. *See also generally* AR S3612-15. More specifically, the Draft proposed to amend CMS's payment regulations so that "fiscal intermediaries"—insurance companies who examine Medicare payment claims under contract with CMS—could "use either the most recent settled or the most recent tentative settled cost report, whichever is from the latest cost reporting period." AR S3614. But reducing the lag time alone would not be enough, because some hospitals could still "increase charges much faster

[6] The Court will ascribe the findings and recommendations to "the Draft" and not to "CMS." While the Hospitals argue that the Draft was CMS's "first official act" in the rulemaking process, Hosp. Mot. at 11, a draft rule that is circulated internally and then abandoned does not constitute anything but a discarded first effort. Although the Court previously ordered that the Draft be added to the Administrative Record—a decision that was upheld by the D.C. Circuit in a related appeal, *Dist. Hosp. Partners*, 786 F.3d at 55 n.3—the Draft never became an official proposal by CMS. *See generally id.* at 58.

than costs during the time between the tentative settled cost report period and the time when the claim is processed. . . . [T]here will still be a lag of 1 to 2 years." AR S3614-15. To counter this possibility, the Draft proposed a new regulatory provision that would allow CMS to increase a hospital's CCR if "more recent charge data indicate that a hospital's charges have been increasing at an excessive rate (relative to the rate of increase among other hospitals)." AR S3615. The hospitals could also have requested a modified CCR if they presented substantial evidence that the ratios were inaccurate. AR S3615.

Further, the Draft reconsidered CMS's previous policy "that payment determinations [were] made on the basis of the best information available at the time a claim is processed and [were] not revised, upward or downward, based upon updated data." AR S3620. Acknowledging that "some hospitals have taken advantage of the current outlier policy," AR S3620, the Draft resolved to reconcile processed payments with hospital cost reports once they were ultimately settled. AR S3621; *see also* AR 3626 ("[W]e believe the only way to eliminate the potential for such overpayments is to provide a mechanism for final settlement of outlier payments using actual cost-to-charge ratios from final, settled cost reports."). That proposal would trigger another problem, however: "in the event of a decline in the [CCR], some cases would no longer qualify for *any* outlier payments while other cases would qualify for lower outlier payments." AR S3622 (emphasis added). In other words, the reconciliation might show that an instance of patient treatment was never eligible for an outlier payment to begin with. And because CMS must predict the "total amount" of outlier payments before the fiscal year begins to comply with the 5-6% requirement, "the only way to accurately determine the net effect of a decrease in [CCRs] on a hospital's total outlier payments is to assess the impact on a claim-by-

claim basis." *Id*. The Draft admitted candidly that CMS was "still assessing the procedural changes necessary to implement this change." *Id*.

The proposed amendments to the outlier payment scheme would have also made it "necessary," according to the Draft, to lower the Fixed Loss Threshold. AR S3629. After excluding the 123 offending turbochargers from the CCR pool; applying actual CCRs (from settled cost reports) to the hospitals that were previously assigned statewide averages; extrapolating future CCRs from the national progression over the previous three years; and reestimating charge inflation without the 123 turbochargers, the Draft recommended reducing the Fixed Loss Threshold from $33,560 to $20,760. *See* AR S3629-33.

2. FY 2003 Proposed and Final Rules Amending Payment Regulation

The Draft was never published. Although the Hospitals suggest that CMS "bow[ed] to pressure from [the Office of Management and Budget]," Hosp. Mot. at 11, that proposition finds no support in the record and may be inconsequential since both agencies are in the Executive Branch and headed by presidential appointees exercising their discretion. Whatever the reason, the Draft was abandoned.

Instead, CMS on March 5, 2003 published a Notice of Proposed Rulemaking, 3/5/03 NPRM, 68 Fed. Reg. 10,420-29. The NPRM contained the same modifications listed above to the outlier payment scheme, but did not propose a corresponding reduction in Fixed Loss Threshold.

After comments, the Final Rule was largely unchanged. *See* Final Rule, 68 Fed. Reg. 34,494 (June 9, 2003) (Final Rule). "Many commenters recommended that [CMS] lower the outlier threshold." Final Rule at 34,505. CMS acknowledged having "reestimated the fixed-loss threshold reflecting the changes implemented in this final rule that will be in effect during a

portion of FY 2003." *Id.* Specifically, CMS inflated charges in the FY 2002 Medical Provider Analysis and Review (MedPAR) file[7] by the two-year average annual rate of change in charges. *Id.* Had its analysis stopped there, the Fixed Loss Threshold would have been $42,300. *Id.* "However, *after accounting for the changes implemented in this final rule*, we estimate the threshold would be only slightly higher than the current threshold (by approximately $600)." *Id.* (emphasis added). Nonetheless, despite concluding that the Fixed Loss Threshold should be higher, CMS found it "appropriate not to change the FY 2003 outlier threshold at this time" because "[c]hanging the threshold for the remaining few months of the fiscal year could disrupt the hospitals' budgeting plans and would be contrary to the overall prospectivity of the [inpatient prospective payment system]." *Id.* at 34,506. The Fixed Loss Threshold stayed at $33,560 for the remainder of FY 2003. *Id.*

3. The FY 2004 Regulations

By the time CMS set the Fixed Loss Threshold for FY 2004, the changes to the outlier payment regulations were fully in effect. *See generally* Final Rule, 68 Fed. Reg. 45,346 (Aug. 1, 2003) (FY 2004 FLT Reg.). Extrapolating from 2002 MedPAR data, CMS applied "the 2-year average annual rate of change in charges per case," as opposed to costs per case, "to establish the FY 2004 threshold." *Id.* at 45,476. CMS then took three steps to update the CCR:

> [1] for each hospital, we matched charges-per-case to costs-per-case from the most recent cost reporting year; [2] we then divided each hospital's costs by its charges to calculate the cost-to-charge ratio for each hospital; and [3] we multiplied charges from each case in

[7] The MedPAR file "contains data from claims for services provided to beneficiaries admitted to Medicare certified inpatient hospitals and skilled nursing facilities." CMS.gov, *Medicare Provider Analysis and Review (MEDPAR) File* (Feb. 18, 2015 5:11 PM), https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/MedicareProviderAnalysisandReviewFile.html.

> the FY 2002 MedPAR (inflated to FY 2004) by this cost-to-charge ratio to calculate the cost per case.

Id.

The FY 2004 Fixed Loss Threshold regulation also reviewed and evaluated the reconciliation process established by the 2003 amendment to the outlier payment threshold.[8] 68 Fed. Reg. at 45,476-77. The novel reconciliation process had presented a roadblock. *See id.* ("Without actual experience with the reconciliation process, it is difficult to predict the number of hospitals that will be reconciled."). CMS resolved to "assess the appropriate number of hospitals to be reconciled" once "later data bec[a]me available." *Id.* CMS did identify, however, 50 of the turbocharging hospitals as likely subjects of reconciliation. *Id.* at 45,476-77.

Based on all of this, CMS set an FY 2004 Fixed Loss Threshold of $31,000. *Id.* at 45,477.

4. The FY 2005-2007 Fixed Loss Threshold Regulations

This pattern largely repeated itself until the years challenged in this case. *See generally* 69 Fed. Reg. 48,916, 49,276, 49,278 (Aug. 11, 2004) (FY 2005 FLT Reg.) (lowering the Fixed Loss Threshold to $25,800, after initially proposing $35,085, in response to comments suggesting that CMS revise its methodology); 70 Fed. Reg. 47,278, 47,493-94 (Aug. 12, 2005) (FY 2006 FLT Reg.) (lowering the Fixed Loss Threshold to $23,600, after initially proposing $26,675, by using the same methodology but updated data); 71 Fed. Reg. 47,870, 48,151 (Aug. 18, 2006) (FY 2007 FLT Reg.) (raising the Fixed Loss Threshold to $24,475, after initially

[8] The FY 2003 amendment to the Payment Regulations instituted a process to reconcile outlier payments for hospitals that were overpaid due to the "time lag in updating their cost-to-charge ratios." 68 Fed. Reg. at 34,504. Outlier "[p]ayments will be processed throughout the year using the appropriate historical . . . cost-to-charge ratios" and after "the cost report is settled," outlier payments can be reconciled using the cost-to-charge ratio determined at the time the report is settled. *Id*.

proposing $25,530). To sum up: the Fixed Loss Threshold was set at $25,800 in FY 2005; $23,600 in FY 2006; and $24,475 in FY 2007.

Throughout these rulemakings, commenters continually complained that the Fixed Loss Thresholds were too high, both out of self-interest and a concern over statutory compliance by CMS. *E.g.*, FY 2005 FLT Reg. at 49,276 ("Some commenters explained that this increase to the threshold would make it more difficult for hospitals to qualify for outlier payments and put them at greater risk when treating high cost cases. . . . The commenters further noted that, in the proposed rule, [CMS] estimated total outlier payments for FY 2004 to be 4.4 percent of all inpatient payments."); FY 2006 FLT Reg. at 47,974; FY 2007 FLT Reg. at 48,149.

Commenters cited previous years' outlier payments, which had not fallen within the 5-6% statutory window. *E.g.*, FY 2007 FLT Reg. at 48,149 ("The commenters noted that total estimated outlier payments in FY 2004 and FY 2005 were well under the 5.1 percent target."). CMS conceded this as a factual matter. *Id.* at 48,150 ("As the commenters noted, the outlier thresholds we have projected in the last several years have resulted in payments below the 5.1 percent target."). CMS also noted that in earlier years, payments had been significantly higher than 5.1% because of turbocharging. *Id.* ("[I]n the early years of th[e] decade, outlier payments were significantly higher than the 5.1 percent target we projected.").

More specifically, commenters decried CMS's failure to (1) apply an adjustment factor to the CCRs; or (2) account for the effect of reconciliation. *E.g.*, FY 2006 FLT Reg. at 47,494 ("Several commenters suggested an alternative to the methodology we proposed": CMS "should adjust cost-to-charge ratios that will be used to calculate the FY 2006 outlier threshold."); FY 2005 FLT Reg. at 49,277 ("One of the commenters also noted that none of the

calculations above factored in the impact of reconciliation that would result in an even lower outlier threshold.").

On the first point, CMS eventually relented. *See* FY 2007 FLT Reg. at 48,150 ("[W]e now agree with the commenters that it is appropriate to apply an adjustment factor to the CCRs so that the CCRs we are using in our simulation more closely reflect the CCRs that will be used in FY 2007."). CMS agreed to "apply only a one year adjustment factor" of 99.73%. *Id.* The Hospitals refer to this as a "negative 0.27%." Hosp. Mot. at 14.

On the second point, CMS held firm and did not account for the potential effect of reconciliation when setting the outlier threshold. FY 2007 FLT Reg. at 48,149 ("As we did in establishing the FY 2006 outlier threshold, in our projection of FY 2007 outlier payments, we proposed not to make an adjustment for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.") (citation omitted).

5. The FY 2008-2011 Fixed Loss Threshold Regulations

We come now to the Fixed Loss Threshold regulations at issue in this case. *Cf.* Hosp. Mot. at 15 ("In Each of FYs 2008-2011 Here at Issue . . . ."). The Hospitals allege generally that CMS "continued to use the flawed FLT model that had resulted in substantial underpayment in FY 2007." *Id.* With the benefit of hindsight, CMS has reported that the total outlier payments (as a percentage of total DRG payments) were **4.8% for FY 2008**, *see* 74 Fed. Reg. at 44,012 (AR 7084); **5.3% for FY 2009**, *see* 75 Fed. Reg. 50,042, 50,431 (Aug. 16, 2010) (AR 10187)[9]; **4.7% for FY 2010**, *see* 76 Fed. Reg. 51,476, 51,795-96 (Aug. 18, 2011); and **4.8% for FY 2011**, *see* 77 Fed. Reg. 53,258, 53,697 (Aug. 31, 2012).

[9] The Hospitals dispute this figure, claiming that commenters have since showed outlier payments totaled only 4.9 %. Hosp. Mot. at 15 (citing AR 9473). The reference is to a June 2010 memorandum from the Federation of American Hospitals. *See* AR 9420-79 [Dkt. 81-3 at

a. FY 2008

For FY 2008, CMS used the same methodology as it had used for FY 2007 to calculate the outlier threshold. *See* 72 Fed. Reg. 47,130, 47,417 (Aug. 22, 2007) (FY 2008 FLT Reg.). The agency applied a one-year CCR adjustment factor (99.12%) to the CCRs in the October 2006 update to the hospitals' Provider Specific File, which is a file for each provider that contains the unique information relevant to that provider that is used by CMS to compute payments and repayments for services provided. CMS also artificially inflated (by 15.04%) the 2006 MedPAR claims by two years. *Id.* The result was a proposed Fixed Loss Threshold of $23,015. *Id.* Several commenters thought that amount was too high. *See generally id.* at 47,417-18. These commenters noted that outlier payments had been only 4.63% of overall FY 2007 payments; faulted CMS for not using more recent CCR data; and suggested applying the CCR adjustment factor over different periods of time (longer or shorter than one year). *Id.*

CMS did not budge. *See id.* at 47,418 ("Because we are not making any changes to our methodology for this final rule with comment period, for FY 2008, we are using the same methodology we proposed to calculate the outlier threshold."). It did use more recent data, however, which resulted in a lower final Fixed Loss Threshold of $22,635. *Id.* at 47,419.[10] One commenter implored CMS to use even more recent data. *Id.* at 47,418 ("The commenter urged CMS to use the June 2007 update [to the hospital CCRs] instead of the March 2007 update for the final rule."). CMS declined because the June CCR update would not be ready until the end

130-38]. The Federation cites an accompanying Vaida Health Data Consultants study that concluded: "The actual FY 2009 outlier payment level was estimated at 4.9 percent; the CMS estimate published in the Proposed Rule is 5.3 percent." AR 9480.

[10] A notable product of the updated data was the swing in CCR adjustment factor, from a negative in the proposed rule (0.9912) to a positive in the final rule (1.0027). *Id.* at 47,418.

of July, "which is beyond the timetable necessary for us to compute the outlier threshold and publish this final rule with comment period by August 1st." *Id.*

b. FY 2009

The process was the same for FY 2009. *See* 73 Fed. Reg. 48,434, 48,763 (Aug. 19, 2008) (FY 2009 FLT Reg.) ("For FY 2009, we proposed to continue to use the same methodology used for FY 2008 to calculate the outlier threshold.") (citation omitted). CMS again proposed a one-year CCR adjustment factor (99.2%) to CCRs calculated from the previous December's Provider Specific File update. *Id.* Once again, the previous year's MedPAR data were extrapolated out by two years. *Id.* The result was a proposed Fixed Loss Threshold of $21,025. *Id.*

This proposal found a slightly more welcoming reception than its predecessors. *Id.* at 48,764 ("The commenters commended CMS for making refinements such as applying an adjustment factor to CCRs when computing the outlier threshold but noted that, because CMS is still not reaching the 5.1 percent target, there is still room for improvement."). Commenters again called the CCR adjustment calculation "unnecessarily complicated"; again urged CMS to use more recent, historical, and industry-wide rates of change; again asked CMS to vary the CCR adjustment factor to more or less than one year; and again asked CMS to apply the June Provider Specific File update instead of the March version. *Id.*

Once again, CMS was implacable. *See generally id.* (providing largely the same reasons as in FY 2008). Applying the same methodology as in the proposed rule—but with more recent data—CMS settled on a Fixed Loss Threshold of $20,185. *Id.*[11] As it had done

[11] This was later revised, for unrelated reasons, to $20,045. *See* 73 Fed. Reg. 57,888, 57,891 (Oct. 3, 2008).

previously, CMS refused to make "any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement." *Id.* at 48,765.

c. FY 2010

"For FY 2010, [CMS] proposed to continue to use the same methodology used for FY 2009 to calculate the outlier threshold." 74 Fed. Reg. 43,754, 44,007 (Aug. 27, 2009) (FY 2010 FLT Reg.) (citation omitted). The previous year's MedPAR files were used, and a one-year CCR adjustment factor (98.4%) was applied to the CCRs as contained in the previous December's Provider Specific File update. *See generally id.* at 44,007-08. CMS proposed a Fixed Loss Threshold of $24,240, which represented a 21% increase from the previous fiscal year. *Id.* at 44,008.

The FY 2010 proposed increase spurred further protest. *See generally id.* Commenters could not understand why—when CMS had met its target in FY 2009—there should be any change. *Id.* at 44,009. Others accused CMS of purposefully erring on the low end of the 5-6% target or below it altogether. *Id.* Another asked CMS to make a mid-year change to the Fixed Loss Threshold if it appeared that the 5-6% target would not be met. *Id*. Still others repeated the requests to use June data instead of March data in the Final Rule, to account for reconciliation. *Id*. at 44,009-10.

CMS insisted in its response that it had "use[d] the most recent data available to set the outlier threshold." *Id.* at 44,009. A mid-year course correction was rejected. *Id.* (citing 70 Fed. Reg. at 47,495). All other suggestions were denied for the same reasons as in previous years. *See generally* FY 2010 FLT Reg. at 44,010.

d. FY 2011

Fiscal year 2011—the last at issue in this case—proved to be no different. *See* 75 Fed. Reg. 50,042, 50,427 (FY 2011 FLT Reg.) (Aug. 16, 2010) ("For FY 2011, [CMS] proposed to continue to use the same methodology used for FY 2009 to calculate the outlier threshold.") (citation omitted). CMS proposed a one-year CCR adjustment factor of 98.9% with a resulting Fixed Loss Threshold of $24,165, a 4.5% increase from the previous year. *Id.* at 50,428.

Commenters again pointed out that the previous year had missed the mark (outlier payments were merely 4.7% of total payments) and reiterated the previous years' suggestions about how to fix that. *See generally id.* at 50,428-29. Commenters also made several discrete suggestions, addressed in the analysis below. *See infra* at 38-39.

CMS rejected each of the suggestions. FY 2011 FLT Reg. at 50,429 ("Because we are not making any changes to our methodology for this final rule, for FY 2011, we are using the same methodology we proposed to calculate the outlier threshold."). Applying that methodology to the updated data yielded a final Fixed Loss Threshold of $23,075. *Id.* at 50,430.

C. Procedural History

Hospitals can challenge the payments they receive as reimbursements for Medicare services by appealing to the Medicare Provider Reimbursement Review Board (PRRB). *See* 42 U.S. C. § 1395oo(a), (b) (allowing consolidated appeals by multiple hospitals). When raising questions of law challenging the validity of a regulation, hospitals can request that the PRRB authorize expedited judicial review in federal district court. *Id*. § 1395oo(f)(1). During an appeal to the PRRB, Plaintiffs requested expedited judicial review of the following question pertaining to the Threshold Regulations during FY 2008 through FY 2011 and the 2003 amendments to the Payment Regulations:

> Whether the specific regulations governing Outlier Case Payments as set forth in the two regulatory sources—the Outlier Payment Regulations and the fixed loss threshold ("FLT") Regulations (collectively, the "Medicare Outlier Regulations")—as promulgated by the Secretary of Health and Human Services ("HHS" or the "Secretary") and the Centers for Medicare and Medicaid Services ("CMS"), and in effect for the appealed years are contrary to the Outlier Statute and/or are otherwise substantively or procedurally invalid?

PRRB R 87 (Case No. 13-0593GC) [Dkt. 81-1]. The PRRB granted expedited review and Plaintiffs filed this action on May 3, 2013. *See* Compl. [Dkt. 1].

On September 2, 2014, this case was consolidated with three others. *See* Order Consolidating Cases [Dkt. 25] (consolidating this case with *Allina Health v. Burwell*, Case No. 13-cv-775; *Allina Health v. Burwell*, Case No. 13-cv-776; and *Denver Health Medical Center v. Burwell*, Case No. 14-cv-553). Plaintiffs have since amended the operative complaint in Dkt. 65, *see* Fourth Amended Complaint, [Dkt. 65], and the parties have filed cross motions for summary judgment. Plaintiffs' Mot. for Summary Judgment [Dkt. 74] (Hosp. Mot.); Gov't Mot. for Summary Judgment [Dkt. 73] (Gov't Mot.).[12]

II. LEGAL STANDARD

The Medicare statute incorporates the standards of the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.* (APA). *See* 42 U.S.C. § 1395oo(f)(1) ("Such action[s] . . . shall be tried pursuant to the applicable provisions under chapter 7 of Title 5."). "[W]hen a party seeks review of agency action under the APA, 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). This Court will review CMS's actions under the APA and decide

[12] The Court also previously ruled on Plaintiffs' Motion to Compel the Administrative Record, Dkt. 51, granting in part and denying in part. *See Lee Mem'l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 51 (D.D.C. 2015).

"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." *Se. Conference v. Vilsack*, 684 F. Supp. 2d 135, 142 (D.D.C. 2010). This Court will uphold CMS's actions unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "An agency decision is arbitrary and capricious if it 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" *Cablevision Sys. Corp. v. Fed. Commc'ns Comm'n*, 649 F.3d 695, 714 (D.C. Cir. 2011) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

Under the APA, an agency must "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 and citation 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 Court's review is "narrow[,] 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*, 463 U.S. at 43)), and the reviewing court must not "substitute its judgment for that of the agency." *Id.* (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43)). However, a court may uphold agency action that is not fully explained "if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(b)(1) allows a defendant to move to dismiss a complaint, or any portion thereof, for lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). No action of the parties can confer subject matter jurisdiction on a federal court because subject matter jurisdiction is both a statutory requirement and an Article III requirement. *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003). The party claiming subject matter jurisdiction bears the burden of demonstrating that such jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); *see Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (noting that federal courts are courts of limited jurisdiction and "[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction") (internal citations omitted).

When reviewing a motion to dismiss for lack of jurisdiction under Rule 12(b)(1), a court must review the complaint liberally, granting the plaintiff the benefit of all inferences that can be derived from the facts alleged. *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). Nevertheless, "the Court need not accept factual inferences drawn by plaintiffs if those inferences are not supported by facts alleged in the complaint, nor must the Court accept plaintiffs' legal conclusions." *Speelman v. United States*, 461 F. Supp. 2d 71, 73 (D.D.C. 2006). A court may consider materials outside the pleadings to determine its jurisdiction. *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005); *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003). A court has "broad discretion to consider relevant and competent evidence" to resolve factual issues raised by a Rule 12(b)(1) motion. *Finca Santa Elena, Inc. v. U.S. Army Corps of Eng'rs*, 873 F. Supp. 2d 363, 368 (D.D.C. 2012) (citing 5B Charles Wright & Arthur Miller, *Fed. Prac. & Pro., Civil* § 1350 (3d ed. 2004)); *see also*

Macharia v. United States, 238 F. Supp. 2d 13, 20 (D.D.C. 2002), *aff'd*, 334 F.3d 61 (2003) (in reviewing a factual challenge to the truthfulness of the allegations in a complaint, a court may examine testimony and affidavits). In these circumstances, consideration of documents outside the pleadings does not convert the motion to dismiss into one for summary judgment. *Al-Owhali v. Ashcroft*, 279 F. Supp. 2d 13, 21 (D.D.C. 2003).

B. Motions for Summary Judgment

Under Federal Rule of Civil Procedure 56, summary judgment is appropriate "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." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Moreover, summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255.

When evaluating cross-motions for summary judgment, each motion is reviewed "separately on its own merits to determine whether [any] of the parties deserves judgment as a matter of law." *Family Trust of Mass., Inc. v. United States*, 892 F. Supp. 2d 149, 154 (D.D.C. 2012) (internal quotation and citation omitted). Neither party is deemed to "concede the factual assertions of the opposing motion." *CEI Wash. Bureau, Inc. v. Dep't of Justice*, 469 F.3d 126, 129 (D.C. Cir. 2006) (citation omitted)). "[T]he court shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not

genuinely disputed." *GCI Health Care Centers, Inc. v. Thompson*, 209 F. Supp. 2d 63, 67 (D.D.C. 2002). A genuine issue exists only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248.

III. ANALYSIS

The Hospitals cite "five flaws" in the Threshold Regulations described above for FYs 2008 through 2011. Hosp. Mot. at 27. First, the Hospitals accuse CMS of employing merely a "token CCR adjustment factor," a miniscule amount compared to the true decline in CCRs nationally. *Id*. Second, the Hospitals find it anomalous that CMS's positive, substantial inflation factors resulted in *decreased* Fixed Loss Thresholds. Third, the Hospitals impugn CMS's modeling of historical outlier payments, which were "represented as having been made in prior FYs." *Id.* Fourth, the Hospitals say it is "[c]ontrary to its established past practices" for CMS to have ignored prior years' underpayments. *Id.* And fifth, the Hospitals say that CMS violated its own regulations and guidance when it failed to consider reconciliation when setting the Fixed Loss Threshold and failed to respond to comments urging the same. With the exception of the second argument, which is not advanced against the FY 2010 Threshold Regulation, all five arguments apply to all four years at issue. The Court will therefore address them categorically instead of taking each year in turn.

The Hospitals also argue that the Payment Regulations, amended in 2003, are invalid both because they were promulgated in violation of the APA's procedural requirements (under 5 U.S.C. § 553) and because, as applied, they are arbitrary, capricious or otherwise not in accordance with law (under 5 U.S.C. § 706).

A. Applicable Case Law

1. District Hospital Partners, L.P. v. Burwell (Dist. Hosp. Partners II)

This Court does not paint on a blank canvas. In *District Hospital Partners, L.P. v. Burwell*, the D.C. Circuit recently rejected several challenges to rulemakings concerning Fixed Loss Thresholds. 786 F.3d 46 (D.C. Cir. 2015) (*Dist. Hosp. Partners II*). In that case, 186 hospitals challenged the Fixed Loss Thresholds for FYs 2004, 2005, and 2006. *Id.* at 48.

The Circuit rejected the broad proposition "that the Secretary was obligated to use the best available data in formulating the outlier thresholds," *id.* at 56, because the court could find no statute, regulation, or precedent to support it. *See generally id.* at 56-57; *but see id.* at 56 ("To be clear, agencies do *not* have free rein to use inaccurate data.") (emphasis in original); *id.* at 57 ("These requirements underscore that an agency cannot *ignore* new and better data.") (emphasis in original). The Circuit reviewed the data used and explanations given in each rulemaking because "[w]hether an agency has arbitrarily used deficient data depends on the specific facts of a particular case." *Id.*

For each year—2004, 2005, and 2006—plaintiffs in *Dist. Hosp. Partners* argued that CMS had "acted arbitrarily and capriciously by setting the outlier thresholds too high." *Id.* The Circuit reviewed each year individually because of the varying considerations addressed in each rulemaking. The challenge to the FY 2004 rulemaking focused on CMS's failure to exclude data from the 123 turbocharging hospitals that were identified in the NPRM. *Id.* at 58. The *Dist. Hosp. Partners* plaintiffs focused their argument on the variations between a draft rule, which was never published for notice and comment, and the final rule. In the draft rule, CMS had excluded data from the turbochargers, but in the final rule the data was included. The plaintiffs argued that CMS was arbitrary and capricious because it did not explain the differences

between the internal draft and final rule. *Id*. The Circuit determined that federal courts are empowered to review final action of an agency; since the FY 2004 draft was never part of the final rule, it was not reviewable. "[T]he published regulations did not 'repeal or modify' anything because the draft 'never became a binding rule requiring repeal or modification.'" *Id*. at 58 (quoting *Kennecott Utah Copper Corp. v. DOI*, 88 F.3d 1191, 1208 (D.C. Cir. 1996)). The Circuit found that CMS was not required to address an internal draft, as part of notice and comment, because it was not part of formulating the proposed new rule. *Id*.

Although the Circuit found CMS was not arbitrary or capricious by failing to comment on the FY 2004 draft rule, it found the 2004 rulemaking otherwise deficient because CMS had failed to address all of the 123 turbocharging hospitals and had only accounted for 50 turbocharging hospitals. *Id*. at 58-59. The Circuit found this omission to be significant because accounting for only 50 turbocharging hospitals decreased the FY 2004 outlier threshold significantly, which presumably meant that factoring in all 123 hospitals would have further decreased the threshold and resulted in more outlier payments to the plaintiffs. *Id*. at 59. Thus, the Circuit held that CMS failed to "examine the relevant data and articulate a satisfactory explanation for its action," because the inconsistency between the 123 turbochargers identified in the NPRM and 50 turbochargers identified in the outlier threshold rulemaking "went unresolved in the 2004 rulemaking." *Id*. The Circuit remanded to the Secretary to "explain why [it] corrected for only 50 turbo-charging hospitals in the 2004 rulemaking rather than for the 123 [it] had identified in the NPRM." *Id*. at 60.

The Circuit rejected plaintiffs' arguments that the Secretary also acted arbitrarily and capriciously in the 2005 and 2006 rulemakings by "setting the outlier thresholds too high" due to the effect of the turbo-charging hospitals. *Id*. at 57. The Circuit found that, in the FY

2005 and 2006 rulemakings, CMS used a new methodology for calculating the charge inflation factor, which obviated the need to factor in any turbocharging hospitals, and avoided the issues present in the 2004 rulemaking. *Id*. at 61. The Circuit held that CMS adequately explained its new methodology and "used the most recent data that accounted for the outlier correction rule's effects." *Id*. at 62.

2. District Hospital Partners, L.P. v. Sebelius

District Hospital Partners II was a partial appeal from the district court's decision in *District Hospital Partners, L.P. v. Sebelius*, 973 F. Supp. 2d 1 (D.D.C. 2014) (*Dist. Hosp. Partners I*). The remaining holdings of the district court are instructive to the current case. The Court considered a challenge to CMS's cost-to-charge ratio in 3 ways: (1) its failure to account for a continued trend of declining cost-to-charge ratios; (2) its removal of the "floor" with its default to statewide average cost-to-charge ratios; and (3) its failure to account for the effects of reconciliation on an individual hospital's Fixed Loss Threshold. The district court found that CMS had not been arbitrary or capricious by relying on actual historical data and not projecting continuing declines in cost-to-charge ratios. *Id*. at 15-16.

The district court also found that CMS had adequately considered the effect of terminating its practice of defaulting to statewide averages when a hospital's cost-to-charge ratio was lower than a predetermined threshold. *Id*. at 16. Plaintiffs argued that CMS "never addressed . . . how [it] accounted for the change in policy regarding default to statewide averages." *Id*. The Court found, however, that despite CMS's lack of a direct response, the rulemaking "clearly accounted for the change in policy" and the Court would not substitute its judgment for CMS's decision "not to undertak[e] the task of modeling the undoubtedly complex and attenuated effects of the [change in] policy on hospital behavior." *Id*. at 16-17.

Finally, Plaintiffs argued that CMS "acted arbitrarily and capriciously by not accounting for the effect of reconciliation on the fixed loss threshold calculation." *Id*. at 17. The Court again considered CMS's findings and explanations and found that CMS did not ignore the issue. CMS "explained that it was impossible to predict the full effects of reconciliation" and attempted to project reconciled cost-to-charge ratios for those hospitals CMS anticipated would face reconciliation. *Id*. at 17-18. In light of the new nature of the reconciliation procedure, the Court found CMS's action "reasonable and adequately responsive to plaintiffs' [] concerns." *Id*. at 18.

3. Banner Health v. Burwell

In addition to the two *District Hospital Partners* cases, *Banner Health v. Burwell*, 126 F. Supp. 3d 28 (D.D.C. 2015) is relevant to this case. In *Banner Health*, 29 organizations that owned or operated hospitals challenged the Fixed Loss Thresholds in FYs 1997 through 2007 and challenged the outlier payment regulations of 1988, 1994, and 2004. The Court summarizes only the potentially relevant holdings.

First, *Banner Health* found it was reasonable for CMS to "adjust[ ] charges to cost to determine whether those cost-adjusted charges were above the applicable [fixed loss] threshold, and then ma[ke] a payment based on the amount by which the cost-adjusted charges exceeded that threshold." *Id*. at 75. *Banner Health* also found CMS did not violate the APA by "failing to conduct reconciliation or to account for reconciliation in setting the fixed loss thresholds for FY 2004 through FY 2007," because "nowhere does the statute require the agency to undertake reconciliation." *Id*. at 78-79. The challenged regulations also did not require reconciliation, but instead indicated that some payments could be "subject to adjustment." *Id*. at 79. "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." *Id*.

CMS's outlier payment determinations were found to be reasonable in that CMS "use[d] the actual cost-to-charge ratios in order to set the FY 2004 through FY 2006 fixed loss threshold, rather than adjusting those ratios to account for possible continued declines" in the cost-to-charge ratios. *Id*. The statute only required CMS to set the threshold as "tested against historical data," not considering current trends. *Id*.

The *Banner Health* plaintiffs had lodged separate challenges to the Fixed Loss Threshold rulemakings in FYs 1998 through 2003 and FYs 2004 through 2007. For the earlier years, they argued that CMS acted arbitrarily and capriciously by not reacting to its own continued failure to meet the targeted amount of outlier payments. The district court concluded that "[j]ust because the agency was aware that actual outlier payments exceeded the predicted levels for these years [ ] does not mean that it was arbitrary or capricious to continue implementing this model." *Id*. at 90 (internal citation omitted).

Additionally, for FYs 2001 through 2003, the *Banner Health* plaintiffs challenged what they called "fudge factors" used to set the Fixed Loss Threshold. The district court rejected the argument, finding that the challenged factors were uncertain inflation factors used to project outlier charges. "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 [ ] figure." *Id*. at 91 (citing *Tex. Mun. Power v. EPA*, 89 F.3d 858, 869-70 (D.C. Cir. 1996) ("[T]he 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.")). The district court also found that it was not arbitrary and capricious for CMS to move from a cost

inflation to a charge inflation methodology when setting the Fixed Loss Threshold.[13] *Id*. at 93. Although CMS switched to the cost inflation methodology in 1994 and then back to the charge inflation method in 2003, the district court determined that "the agency [had] adequately explained its decision in both circumstances" so that it was not arbitrary and capricious. *Id*.

Finally, the *Banner Health* plaintiffs argued that the FYs 2005-2007[14] Fixed Loss Threshold rulemakings were arbitrary and capricious because: (1) "the agency failed to adjust the cost-to-charge ratios to account for continuing declines" and (2) "the agency failed to account for reconciliation." *Id*. at 96-97. The district court found that those plaintiffs impermissibly relied on the Draft to challenge the cost-to-charge ratios; it ultimately held that CMS's decision to use historical data and not projection adjustments to calculate the cost-to-charge ratios was reasonable. *Id*. at 98. The district court rejected the arguments concerning reconciliation because CMS had adequately explained its reasons. *Id*. at 101.

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[13] The difference between the two methodologies was explained as follows:

> 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. 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.

Banner Health, 126 F. Supp. 3d at 92.

[14] Consistent with the Circuit's holding in *District Hospital Partners*, the *Banner Health* court remanded the 2004 rulemaking to CMS for more explanation regarding the effect of turbocharging, but rejected each of the plaintiffs' other arguments. 126 F. Supp. 3d at 98.

B. This Case: Challenges to the FY 2008 through 2011 Fixed Loss Threshold Rulemakings

The Plaintiff Hospitals here cite "five flaws" in the FY 2008 through 2011 threshold regulations described above. Hosp. Mot. at 27. The Court will address them categorically instead of taking each year in turn.

Before addressing the specific "flaws" raised, the Court considers the jurisdictional argument advanced by CMS. CMS argues that some of Plaintiffs' claims should be dismissed for lack of subject matter jurisdiction because the issues were not approved by the PRRB for judicial review and were not initially made during the relevant comment period. The Court finds it has subject matter jurisdiction over all of the claims presented. The question presented by Plaintiffs for judicial review was very broad:

> Whether the specific regulations governing Outlier Case Payments as set forth in the two regulatory sources—the Outlier Payment Regulations and the fixed loss threshold ("FLT") Regulations (collectively, the "Medicare Outlier Regulations")—as promulgated by the Secretary of Health and Human Services ("HHS" or the "Secretary") and the Centers for Medicare and Medicaid Services ("CMS"), and in effect for the appealed years are contrary to the Outlier Statute and/or are otherwise substantively or procedurally invalid?

PRRB R 87 (Case No. 13-0593GC). The PRRB certified this entire question.

In addition, Plaintiffs bring an as-applied challenge to the Medicare regulations, questioning their validity. CMS argues Plaintiffs have waived their right to challenge the consistency between inflation and the Fixed Loss Thresholds because they did not submit relevant comments to each FYs rulemaking. CMS describes Plaintiffs' challenges to the validity of its rulemakings as "facial," requiring explicit exhaustion during the administrative proceeding. However, the Court finds that Plaintiffs properly challenged each rulemaking through challenges to the application of the earlier rules. *See Banner Health*, 126 F. Supp. 3d at 68 ("The Secretary

has not pointed to any authority suggesting that, just because a plaintiff argues that a regulation is invalid, such plaintiff has waived any arguments not raised in 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 also Weaver v. Fed. Motor Carrier Safety Admin.*, 744 F.3d 142, 145 (D.C. Cir. 2014); *National Res. Def. Council. v. EPA*, 513 F.3d 257, 260 (D.C. Cir. 2008). Therefore, Plaintiffs' claims are properly before this Court.

1. CCR adjustment factor

Plaintiffs argue CMS's use of a "token" CCR adjustment factor was arbitrary and capricious because CMS: (1) failed to use the best available data to calculate the adjustment factor, that is, the historic rate of change of CCR; (2) elected to use a complex proxy to calculate the year-over-year change in CCR, which was contrary to CMS's earlier preference for using historical data; and (3) failed to respond to comments regarding its method for calculating the adjustment factor.

Plaintiffs argue CMS failed to use the best available data to calculate the yearly CCR adjustment factor because it relied on a projection, rather than historical data. Defendant responds that CMS "reasonably exercised [its] discretion in deciding on the data to use" and agencies "have no generic obligation to use the best available data." Gov't Opp'n at 18-19. *Dist. Hosp. Partners II* rejected the theory "that the Secretary was obligated to use the best available data." 786 F.3d at 56. Instead, the D.C. Circuit reviewed the data that was actually used and CMS's explanation to determine whether the agency "arbitrarily used deficient data." *Id*. at 57. This Court, therefore, rejects Plaintiffs' argument that the regulation was arbitrary and

capricious for failing to use the best available data and will review the reasonableness of the data used in this particular instance.

Plaintiffs also argue that the "token" adjustment factor was arbitrary and capricious because CMS "concocted [it] from projected cost inflation." Hosp. Mot. at 33. Plaintiffs criticize the use of a projected factor in lieu of historical trends in CCRs.

CMS established its methodology to calculate the CCR adjustment factor during the FY 2007 rulemaking, working with the Office of the Actuary. 72 Fed. Reg. at 47,417 (FY 2008 FLT Reg.). The method used in FYs 2008 through 2011 is the same as that established FY 2007. CMS calculated the CCR using estimated cost and charge inflation for the upcoming year. *Id*. Potential cost inflation was measured using two sets of data: (1) the market basket rate-of-increase and (2) the increase in the average cost per discharge from hospital cost reports. *Id*. The charge inflation factor is simply the average change in charges. *Id*. In response to comments urging CMS "to adopt a methodology that uses recent historical industry wide average rate of change," CMS explained the decision to use two alternative data sets to project cost inflation:

> [W]e believe this calculation of an adjustment to the CCRs is more accurate and stable than the commenter's methodology because it takes into account the costs per discharge and the market basket percentage increase when determining a cost adjustment factor. There are times where the market basket and the cost per discharge will be constant, while other times these values will differ from each other, depending on the fiscal year. Therefore . . . , using the market basket in conjunction with the cost per discharge uses two sources that measure potential cost inflation and ensures a more accurate and stable cost adjustment factor.

Id. at 47,418. CMS considered the option of using the historical average rate of change, but determined that the projected calculation using the market basket and cost per discharge method was superior. CMS is not required to use the best data, but "cannot ignore new or better data."

Dist. Hosp. Partners, 786 F.3d at 57 (emphasis omitted). Here, CMS considered all available data and explained its reasons for not using the historical average rate of change data.[15] CMS "articulate[d] a satisfactory explanation for its action including 'a rational connection between the facts and the choice made.'" *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

Finally, Plaintiffs argue CMS failed to respond adequately to comments regarding the CCR adjustment factor. As CMS notes, an "agency's response to public comments need only 'enable [the court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did." *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (quoting *Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 335 (D.C. Cir. 1968)). "The agency need only state the main reasons for its decision and indicate that it has considered the most important objections." *Simpson v. Young*, 854 F.2d 1429, 1435 (D.C. Cir. 1988).

Each year CMS received comments regarding the CCR adjustment factor and each year CMS responded by indicating its reasons for not altering the adjustment factor methodology. *See* 72 Fed. Reg. at 47, 418 (FY 2008 FLT Reg.); 73 Fed. Reg. at 48,764 (FY 2009 FLT Reg.); 74 Fed. Reg. at 44,010 (FY 2010 FLT Reg.); 75 Fed. Reg. at 50,429 (FY 2011 FLT Reg.). This Court finds CMS's acknowledgement and consideration of the comments reasonable. CMS's responses identified the major issues raised by the commenters and stated the main reasons for its decisions. Consequently, use of the CCR adjustment factor was not arbitrary and capricious.

[15] CMS also acted reasonably in continuing to use the 2007 methodology until multiple years of data were available to assess its value. *See* Gov't Opp'n at 17.

2. Inconsistent relationship between rising inflation factor and deflated Fixed Loss Threshold

Plaintiffs argue the FY 2008, 2009, and 2011 Fixed Loss Threshold rulemakings are arbitrary and capricious because of the inconsistencies between the CMS deflation of the Fixed Loss Threshold and the increased inflation factor. Specifically, they argue that if CMS were assuming a positive (upward) trend in hospital costs, it was inconsistent for the Fixed Loss Threshold to be experiencing consistent deflation. *Id*. at 45. As discussed above, the Court finds Plaintiffs' argument is properly presented without comment during the rulemaking process.

Although Plaintiffs' argument is proper, CMS adequately explained its calculation of the Fixed Loss Threshold and the factors that it considers when setting the Threshold. Admittedly, CMS failed to address specifically the inconsistency between the positive inflation in hospital charges and costs and the deflation in Fixed Loss Threshold. However, CMS met its burden of "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the facts found and the choices made." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Despite Plaintiffs' arguments, there are no unexplained inconsistencies in the Fixed Loss Threshold rulemakings. *See also Dist. Hosp. Partners*, 786 F.3d at 59 ("We have often declined to affirm an agency decision if there are unexplained inconsistencies in the final rule.").

CMS sets the Fixed Loss Threshold "in advance of each fiscal year" by projecting what "aggregate outlier payments [will] total[] 5.1% of projected total DRG payments" and setting the Fixed Loss Threshold at the level required to achieve those projected outlier payments. Gov't Opp'n at 6-7. The Fixed Loss Threshold is based on a projection of future payments, not a previous year's outlier payments. Plaintiffs argue that CMS fails to consider the year-to-year inflation of hospital charges and costs. However, the inflation factor is simply one

of many factors evaluated and incorporated into simulations used to determine the aggregate outlier payments that will total 5.1% of aggregate DRG payments in the forthcoming fiscal year. *Id*. at 31. The simulated outlier payment calculations used to project the Fixed Loss Threshold also incorporate additional inputs, including:

> cost-to-charge ratios, an adjustment factor to project changes in cost-to-charge ratios, the mix of DRGs and national standardized amounts of labor and nonlabor set forth in tables published in the Federal Register notices, and other hospital-specific information for the upcoming fiscal year that is set forth in the annual impact file, e.g., wage index, medical education, disproportionate share hospital status.

Gov't Opp'n at 31 (citing 68 Fed. Reg. at 34,495). Contrary to Plaintiffs' arguments, CMS did explain the inconsistency between the decreasing Fixed Loss Threshold and increasing inflation rate: the Fixed Loss Threshold is a product of more than just the inflation of hospital costs and charges.

Plaintiffs also critique the failure of CMS to provide the formulas it used to calculate the Fixed Loss Threshold after this Court granted their motion to compel and supplement the administrative record. Plaintiffs mischaracterize this Court's holding, which only required CMS to produce formulas "if such formulas exist." *Lee Mem'l Hosp.*, 109 F. Supp. 3d at 51. CMS responded that no additional formulas existed, but that the process for determining the Fixed Loss Threshold was incorporated in the original administrative record, *see* Gov't Opp'n at 32, and each year commenters were able to use that explanation to confirm the accuracy of CMS's calculations. *See, e.g.*, 72 Fed. Reg. at 47,417-18 (FY 2008 FLT Reg.); 73 Fed. Reg. at 48,766 (FY 2009 FLT Reg.); 75 Fed. Reg. at 50,431 (FY 2011 FLT Reg.).

This Court finds that CMS has provided a "satisfactory explanation" of its process and the factors considered when it projected the aggregate outlier payments and set the Fixed Loss Threshold in each year.

3. Failure to consider past outlier payments

Plaintiffs also argue CMS acted arbitrarily and capriciously by not considering past outlier payments, which "demonstrated the historical failure of [the CMS] model," when calculating the Fixed Loss Threshold for each year. Hosp. Mot. at 48. Specifically, because the CMS estimate of outlier payments was consistently higher than the actual amount in these years, CMS continually missed the statutory 5.1% target of outlier payments. Nevertheless, it continued to employ the same methodology to set the Fixed Loss Threshold. *Id*. at 49.

Plaintiffs inaccurately interpret the CMS response to their motion to compel, claiming that CMS, through a declarant, admits that it failed to consider past outlier payments during the rulemaking for each following year. Actually, the Acting Director of CMS, Donald Thompson, explained that in each FY's rulemaking CMS included "an estimate of total outlier payments as a percentage of total IPPS (or diagnosis related group ("DRG")) payments made during each of the prior two years." Declaration of Donald Thompson [Dkt. 68-1] ¶ 13. The declaration (and the rulemakings themselves) indicate that CMS reviewed estimates of the past two years' outlier payments during each year's rulemaking process. *See* 72 Fed. Reg. at 47,420 (FY 2008 FLT Reg.) ("Our current estimate, using available FY 2006 bills, is that actual outlier payments for FY 2006 were approximately 4.65 percent of actual total DRG payments. Thus, the data indicate that, for FY 2006, the percentage of actual outlier payments relative to actual total payments is lower than we projected before FY 2006."); 73 Fed. Reg. at 48,766 (FY 2009 FLT Reg.) ("Our current estimate [ ] is that actual outlier payments for FY 2007 were approximately 4.64 percent of actual total DRG payments."); 74 Fed. Reg. at 44,012 (FY 2010 FLT Reg.) ("Our current estimate [ ] is that actual outlier payments for FY 2008 were approximately 4.8 percent of actual total DRG payments."); 75 Fed. Reg. at 50,431 (FY 2011

FLT Reg.) ("Our current estimate [ ] is that actual outlier payments for FY 2009 were approximately 5.3 percent of actual total DRG payments."). Plaintiffs are, therefore, incorrect that CMS did not identify past outlier payments.

Plaintiffs' argument that it is arbitrary and capricious for CMS to fail to adjust the Fixed Loss Threshold based on the multi-year trend of it falling below the 5.1% mandated by statute is also without merit. As CMS explains, it considers past outlier payments during each year's rulemaking, responds to comments regarding past payments, and, as it thinks appropriate, adjusts the model to set the next Fixed Loss Threshold. *See* 71 Fed. Reg. at 48,150. During the FY 2007 rulemaking, CMS proposed a change to the Fixed Loss Threshold model to account for the trend in "payments below the 5.1 percent target." *Id*. CMS stated:

> As the commenters noted, the outlier thresholds we have projected in the last several years have resulted in payments below the 5.1 percent target. However, we have been hesitant to change our model because, in the early years of this decade, outlier payments were significantly higher than the 5.1 percent target we projected because the charging practices of some hospitals resulted in overestimation of hospitals' cost-per-case. However, now that data for later years in which charging practices were stabilized are available, after careful consideration, we agree that a refinement to the proposed methodology to account for the rate of change in the relationship between costs and charges would likely increase the precision of our model and we believe this would be an appropriate refinement to adopt in determining the FY 2007 outlier threshold.

Id. Based on CMS's decision to adjust the model in the FY 2007 rulemaking and inclusion of the estimates of prior payments in each year's rulemaking, it is evident CMS has not disregarded accurate and reliable information or adopted an estimate it knew at the time to be inaccurate. *See Guindon v. Pritzker*, 31 F. Supp. 3d 169, 195-96 (D.D.C. 2014). CMS "was not required to 'meet' those targets." *Banner Health*, 126 F. Supp. 3d at 90 (citing *Cnty. of L.A.*, 192 F.3d at 1013). "Just because the agency was aware that actual outlier payments [did not meet] the

predicted levels for these years . . . does not mean that it was arbitrary or capricious to continue implementing this model." *Id*.

CMS has not, as Plaintiffs claim, turned a blind eye to a system that does not work. Hosp. Mot. at 52-53. Instead, it adjusted the model in the FY 2007 rulemaking and has since been monitoring the payouts and "consider[ing] and evaluat[ing] commenters comments on modifying the outlier threshold methodology." 73 Fed. Reg. at 48,766. It is not arbitrary and capricious to continue with the newly revised model for FYs 2008 through 2011 to determine its efficacy. Due to the complexity of the Medicare payment system and the data collection at issue, it is not unreasonable for CMS to continue to use the model revised in 2007 during FYs 2008 through 2011, especially considering CMS reported that outlier payments in FY 2009 fell within the 5-6% threshold. *See* 75 Fed. Reg. at 50,431 (FY 2009 outlier threshold calculated as 5.3%). CMS's continued identification of the outlier payments and consideration of possible revisions and suggestions raised by commenters is reasonable.

For the foregoing reasons, the Court finds CMS acted reasonably and complied with the requirements of the APA in considering past outlier payments.

4. Past outlier payment estimates

Plaintiffs also lodge three challenges to CMS's estimate of total outlier payments in each year: CMS (1) failed to provide sufficient notice about how prior outlier payments were determined; (2) failed to respond adequately to comments in FYs 2008 through 2011 regarding the estimated past outlier payments; and (3) failed to respond to a commenter's recommendation for an estimated adjustment factor in FY 2011.

Plaintiffs compare this case to *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240 (D.D.C. 2015), in which this Court found that CMS had failed to provide sufficient

notice of "actuarial assumptions and methodology," due to CMS's failure to provide its methods for estimating total outlier payments made in prior years in violation of the APA. *Id.* at 261. CMS argues that its rulemakings adequately described its methodology, announcing each year that CMS used the same methodology to simulate outlier payments for upcoming fiscal years as it used to estimate past outlier payments. The difference is in the data used. When determining the upcoming Fixed Loss Threshold, CMS used projected payments, while it used the latest available claims information, or bills, to estimate past payments. *See, e.g.*, 72 Fed. Reg. at 47,420 (FY 2008 FLT Reg.) (indicating CMS used "the FY 2005 MedPAR file" to estimate the 2006 past outlier payments during the FY 2007 rulemaking and used the 2006 file to estimate the same 2006 past outlier payments during the FY 2008 rulemaking).

In *Shands*, the Court considered CMS's creation of an "across-the-board reduction in payments to hospitals for inpatient services." 139 F. Supp. 3d at 247. *Shands* found that CMS "did not provide sufficient notice of the actuarial assumptions and methodology [it] employed and that disclosure of this information was essential to communicate the basis for the proposed adjustments and to permit meaningful public comment." *Id*. at 261. "[A]n agency cannot rest a rule on data that, [in] critical degree, is known only to the agency." *Time Warner Entm't Co., L.P. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (internal quotation and citation omitted). CMS only disclosed some of the necessary information in the final rule at issue in *Shands*. *See* 139 F. Supp. 3d at 262. Disclosing the data sets used alone was insufficient; CMS needed to "disclose what the actuaries did with that data." *Id*. at 263.

Hospital Plaintiffs in this case similarly argue that CMS pointed to the data sets used to calculate prior years' outlier payments, but failed to identify how the estimates were ultimately calculated. Despite Plaintiffs' insistence, the CMS explanation of its outlier payment

methodology is available. Prior FY outlier payment estimates are calculated using the same method as CMS uses to predict future payments. The only difference between past and future estimates is the data sets used. *See* 68 Fed. Reg. at 34,495. Unlike *Shands*, CMS has provided the data set and the formula used in each year. *See id*. The only information not provided was the specific set of hospitals CMS used to do its simulations, but that alone does not render its explanations or data inadequate. Plaintiffs had the "critical factual material" necessary to review the agency's method, *Owner-Operator Indep. Drivers Ass'n Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007), as evidenced by the ability of commenters to replicate CMS's calculations. *See, e.g.*, 75 Fed. Reg. at 50,431 (FY 2011 FLT Reg.). The rulemakings adequately explained the method used to estimate past outlier payments.

Second, Plaintiffs argue that CMS failed to respond to "relevant and significant comments" from the Federation. Hosp. Mot. at 55. Defendant responds that CMS answered the Federation comments with an explanation about the data used to calculate the outlier payments and indicated that it had not used the data set recommended by the Federation. As explained above, in each year, the estimated past outlier payments for the previous two years were included in the rulemaking analysis. For example, in the FY 2008 rulemaking CMS included an estimate of the 2007 outlier payments, which was calculated using FY 2006 data. 72 Fed. Reg. at 47,420. Then in the FY 2009 rulemaking, CMS updated the estimate of 2007 payments using FY 2007 data. 73 Fed. Reg. at 48,766. Plaintiffs challenge the specific data sets used by CMS, arguing they were not the most recent available data. But, CMS is not required to use the best available data, *see Dist. Hosp. Partners*, 786 F.3d at 56, and CMS adequately explained why it chose to use the earlier data. *See* 72 Fed. Reg. at 47,418.

CMS clearly responded to Federation comments, explaining the data sets used. The requirement to respond to comments is "not particularly demanding." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 441-42 (D.C. Cir. 2012) (internal quotation and citation omitted). CMS's responses to Federation comments in FYs 2008 through 2011 identified the reasons earlier data was selected, thereby demonstrating that CMS considered the comments. Thus, the responses to the comments satisfied the APA requirements.

Third, Plaintiffs raise a second argument with respect to the 2011 Fixed Loss Threshold regulation, asserting that CMS failed to respond to different comment from the Federation that recommended an estimate adjustment factor to the outlier threshold. To the contrary, CMS summarized and responded to the Federation's comment in the 2011 Final Rulemaking. *See* 75 Fed. Reg. at 50,428-29. CMS explained that it would not apply an estimate adjustment factor—as requested by the Federation—because it believed the current model used to predict the outlier threshold necessary to meet the target of 5.1% of DRG payments was adequate. The Court finds that CMS adequately considered and responded to the comment, even though it expressed no willingness to change its model.

5. Failure to account for reconciliation

Plaintiffs' final challenge to the Fixed Loss Threshold rulemakings is that CMS acted arbitrarily and capriciously in failing to factor the impact of reconciliation into the Fixed Loss Threshold projections for FYs 2008-2011. Plaintiffs argue that CMS failed to conduct any reconciliations and did not adequately respond to comments submitted during the NPRMs for the Fiscal Years at issue. Defendant argues that CMS adequately explained its reasons for not factoring reconciliation into the projections for each year's Fixed Loss Threshold.

Banner Health found that neither consideration of reconciliation, nor accounting for reconciliation, was required by the 2003 Payment Regulation when setting the Fixed Loss Threshold each year. *See* 126 F. Supp. 3d at 78-79. This holding was not appealed. The 2003 amendments to the Payment Regulations created a system for reconciling outlier payments that were made using a "significantly inaccurate cost-to-charge ratio." 68 Fed. Reg. at 34,502. The 2003 Payment Regulation created the reconciliation procedure by which outlier payments are subject to reconciliation when hospitals' cost reports are finalized. *See id*. at 34,501. The Payment Regulation stated that "if [CMS] deem[s] it necessary as a result of a hospital-specific data variance to reconcile outlier payments of an individual hospital, such action . . . would not affect the predictability of the entire system." *Id*. at 34,502. Nothing in the 2003 rulemaking indicated that reconciliation was required.

Banner Health also found it was not arbitrary and capricious for CMS not to consider the effects of reconciliation on the projections of the Fixed Loss Threshold for FY 2004 through 2006. 126 F. Supp. 3d at 99, 101, 103. Just as in those years, CMS explained in the Fixed Loss Threshold rulemakings for FYs 2008 through 2011, at issue here, why it did not account for reconciliation. Each year CMS has explained:

> As we did in establishing the [previous year's] outlier threshold, in our projection of [the current year's] outlier payments, we are not making any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the outlier final rule, CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement.

72 Fed. Reg. at 47,419 (FY 2008 FLT Reg.); *see also* 73 Fed. Reg. at 48,763 (FY 2009 FLT Reg.); 74 Fed. Reg. at 44,007-08 (FY 2010 FLT Reg.); 75 Fed. Reg. at 50,427 (FY 2011 FLT Reg.).

Plaintiffs argue that the reasons given by CMS were not its real reasons: They posit that CMS did not account for reconciliation in the Fixed Loss Threshold projections because CMS never conducted any reconciliations. However, this Court cannot question the legitimacy of the reasoning provided without evidence that CMS was acting in bad faith. *See In re Subpoena Duces Tecum Served on Office of the Comptroller of the Currency*, 156 F.3d 1279, 1279-80 (D.C. Cir. 1998) ("[T]he actual subjective motivation of agency decisionmakers is immaterial as a matter of law—unless there is a showing of bad faith or improper behavior."). Plaintiffs have provided no evidence of bad faith or improper behavior. Therefore, this Court finds CMS has provided adequate reasoning for its decision not to account for reconciliation when setting the outlier threshold.

Finally, Plaintiffs argue that in 2010 and 2011 CMS failed to respond to comments requesting it to report the amount of money recovered through reconciliation. An agency is not required to respond to every comment, but instead must "only 'enable [the court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Public Citizen*, 988 F.2d at 197 (quoting *Boyd*, 407 F.2d at 335). In each rulemaking CMS considered and responded to a host of other comments related to reconciliation, which allows the Court to view the "major issues being ventilated" and the agency's thinking. *See* 72 Fed. Reg. at 47,419 (FY 2008 FLT Reg.); 73 Fed. Reg. at 48,763 (FY 2009 FLT Reg.); 74 Fed. Reg. at 44,007-08 (FY 2010 FLT Reg.); 75 Fed. Reg. at 50,427 (FY 2011 FLT Reg.). The lack of response to the specific comment asking how much has been collected through reconciliation does not render the rulemaking arbitrary and capricious.

C. The 2003 Payment Regulations

Plaintiffs also argue that the Payment Regulations, as amended in 2003, are invalid because they were promulgated in violation of the APA's procedural requirements (under 5 U.S.C. § 553) and because, as applied, they are arbitrary, capricious or otherwise not in accordance with law (under 5 U.S.C. § 706).

1. APA procedural requirements

Plaintiffs argue that CMS failed to comply with the disclosure requirements of the APA by failing to include the 2003 draft Interim Final Rule (Draft) in the NPRM and notice of final amendments to the 2003 Payment Regulations. Plaintiffs rely on this Court's holding requiring the Draft to be included as part of the administrative record here, arguing that because the Draft was missing from this record, it was also missing from the notice and comment process. *Id*. at 67-68. Despite this Court's inclusion of the Draft in the administrative record for this proceeding, an agency is only required to identify in a NPRM the studies and other materials on which the agency "actually relies." 5 U.S.C. § 553. While it is "especially important for the agency to identify and make available technical studies and data that it has employed," *see Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982), an agency is not required to disclose materials or drafts upon which it did not rely. *See Banner Health v. Burwell*, 55 F. Supp. 3d 1, 9 (D.D.C. 2014).

This Court's order to include the Draft in the administrative record followed prior cases in this District regarding the same Draft. As in *Banner Health*, Plaintiffs met their burden of showing the agency considered the Draft and that CMS had no legitimate deliberative process argument for shielding the Draft from inclusion. *Lee Mem'l Hosp.*, 109 F. Supp. 3d at 47-49; *see Banner Health v. Burwell*, 945 F. Supp. 2d 1, 24-27 (D.D.C. 2013).

However, the Court in *Banner Health* later denied a motion to amend the complaint because the claims, identical to the claim here, were against Circuit precedent. *See id.* at 12. This Court agrees.

While the D.C. Circuit has repeatedly found agency NPRM's lacking for failure to disclose "*critical* material, on which [the agency] relies," or redacting studies relied upon by an agency, the Circuit's rule is centered upon the principle that only those studies and materials relied upon must be disclosed. *See id.* at 9 (emphasis in original) (citing *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). Plaintiffs' attempt to equate this case to *Shands* and *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227 (D.C. Cir. 2008), is unpersuasive. In both *Shands* and *American Radio*, it was apparent that the agency had relied on the reports and data that were either not included or redacted. *See Shands*, 139 F. Supp. 3d at 263 (finding that "the Secretary's failure to disclose the critical assumptions *relied upon* by the HHS actuaries deprived Plaintiffs and other members of the public of a meaningful opportunity to comment") (emphasis added); *American Radio*, 524 F.3d at 239 ("[T]he Commission can point to no authority allowing it to rely on the studies in a rulemaking but hide from the public parts of the studies that may contain contrary evidence, inconvenient qualifications, or relevant explanations of the methodology employed."). Plaintiffs' only basis for alleging that CMS relied on the Draft is this Court's order to include the Draft in the administrative record. That is not enough.

With the benefit of a full record and briefing, it is now clear that CMS did not rely on the Draft. Although this Court found CMS initially considered the Draft as an alternative to the later Payment Regulations at issue here, that holding does not require a finding that CMS relied on the Draft in these rulemakings. It is noteworthy that, Plaintiffs' Fourth Amended

Complaint agrees. It makes no allegation that CMS relied on the Draft in the 2003 rulemaking, but instead faults CMS for not disclosing the "alternatives" it "considered but rejected." Fourth Am. Compl. [Dkt. 65] at 27.

For the reasons stated above, the Court concludes that the 2003 Payment Regulations were promulgated in a manner that was consistent with the procedural requirements under 5 U.S.C. § 553.

2. APA substantive requirements

In addition to its procedural claims, Plaintiffs argue the 2003 rulemaking was arbitrary and capricious because CMS failed to address the known data indicating 123 hospitals were turbocharging. Plaintiffs' argument relies on the Circuit's finding in *Dist. Hosp. Partners* that CMS's FY 2004 Threshold Rulemaking was arbitrary and capricious for failure to account for the 123 turbochargers.

Plaintiffs failed to adequately raise their substantive APA claims concerning the 2003 Outlier Payment Regulation in the Fourth Amended Complaint. Plaintiffs claim that a single allegation stating "[w]hile . . . amending the Outlier Payment Regulations . . . the Secretary had both the obligation and the opportunity to reset her [Fixed Loss Threshold], which she had improperly inflated by more than 246%, but she did not" and the broad statement in the request for relief that the Court find "the Outlier Statute and [CMS's] application of same were, for the FYs here at issue, . . . (B) arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law" were sufficient to plead a substantive APA claim. Fourth Am. Compl. ¶ 50, Request for Relief ¶ 1. Neither statement sufficiently articulates a substantive APA claim. Plaintiffs cannot rely on a conclusory and ambiguous allegation that CMS was supposed to act in

a certain manner "but [ ] did not" alert Defendant that a substantive APA claim was raised.[16] *Id.* at ¶ 50. Plaintiffs' argument that CMS gave express or implied consent by arguing against these claims in its opposition is unpersuasive. Tellingly, CMS's own motion to dismiss or for summary judgment omits any discussion of a substantive APA claim regarding the 2003 Payment Regulations, indicating it was unaware of the claim.

Even if this Court found Plaintiffs had adequately raised a substantive APA claim regarding the 2003 Payment Regulations, summary judgment would be entered for CMS. First, Plaintiffs cannot rely on the Draft, which was never finalized or relied upon by CMS to impugn subsequent rulemakings. *See Dist. Hosp. Partners*, 786 F.3d at 58; *Banner Health*, 126 F. Supp. 3d at 69, 94. Second, CMS clearly considered all 123 turbo-charging hospitals in the 2003 amendments to the Payment Regulations. *See* 68 Fed. Reg. at 34,496 ("We proposed these changes in the payment methodology . . . in order to correct situations in which rapid increases in charges by certain hospitals have resulted in their cost-to-charge ratios being set too high."). CMS not only considered all the turbochargers, but they were the basis for altering the Payment Regulations in the first place. To the extent that Plaintiffs are also challenging the decision not to make a mid-year adjustment to the Fixed Loss Threshold in 2003, this Court finds that CMS was not required to make a mid-year adjustment and its explanation for "why it concluded that a mid-year adjustment was not warranted" was adequate.[17] *Banner Health*, 126 F. Supp. 3d at 96.

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[16] "Judges are not expected to be mindreaders. Consequently, a litigant has an obligation to spell out its arguments squarely and distinctly, or else forever hold its peace." *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) (quoting *Rivera-Gomez v. de Castro*, 843 F.2d 631, 635 (1st Cir. 1988) (internal quotations omitted).

[17] CMS explained:

> 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

IV. CONCLUSION

For the foregoing reasons, the Court will grant Defendant's motion for summary judgment and deny Plaintiffs' motion for summary judgment. The Court will also enter judgment in favor of the Secretary and the consolidated cases, *Abbott Northwestern Hospital, et al. v. Sebelius*, Case No. 13-cv-775; *Buffalo Hospital, et al. v. Sebelius*, Case No. 13-cv-776; and *Denver Health Medical Center, et al. v. Sebelius*, Case No. 14-cv-553, will be closed.

A memorializing Order accompanies this Opinion.

Date: September 7, 2016

/s/
ROSEMARY M. COLLYER
United States District Judge

> considerations that lead us to conclude the 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.

68 Fed. Reg. at 34,506.