UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DISTRICT HOSPITAL PARTNERS, L.P., d/b/a The George Washington University Hospital, et al.	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 11-0116 (ESH)**
KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiffs own and operate 186 hospitals that participate in the Medicare program. They have sued the Secretary of the Department of Health and Human Services ("Secretary") in her official capacity, alleging that her methodology for setting thresholds for outlier payments to their hospitals, under the Medicare Act, 42 U.S.C. § 1395 *et seq.*, was arbitrary and capricious. Plaintiffs seek a declaration that the Secretary's actions violated the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701, 706, and that they are entitled to additional outlier payments. The Secretary has moved to dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), arguing that the Court lacks jurisdiction to consider those allegations that were not exhausted and that plaintiffs' remaining allegations fail to state a claim upon which relief can be granted. For the following reasons, the motion will be granted in part and denied in part.

STATUTORY FRAMEWORK

I. MEDICARE

A. Outlier Payments and the Outlier Threshold

Medicare is a federally funded system of health insurance for the aged and disabled. It is administered by Centers for Medicare and Medicaid Services, under the direction of the Secretary. 42 U.S.C. § 1395kk; 42 C.F.R. § 400.200 *et seq.* When Medicare providers treat the program's beneficiaries, they receive coinsurance and deductible payments from the patient and then seek reimbursement for remaining costs from the Medicare program. *Foothill Hosp. — Morris L. Johnston Mem'l v. Leavitt*, 558 F. Supp. 2d 1, 2 (D.D.C. 2008).

Rather than pay hospitals for the specific cost of treating each Medicare patient, Medicare uses a "Prospective Payment System" ("PPS"), which compensates them at a fixed "federal rate" that is based on the "average operating costs of inpatient hospital services." *Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999). Because Medicare payments are standardized in this way, hospitals may be over- or under-compensated for any given procedure. The Secretary therefore provides hospitals with additional "outlier payments" to compensate for patients "whose hospitalization would be extraordinarily costly or lengthy." *Id.* at 1009. This case is about these outlier payments.

The Secretary enters into contracts with private firms to "review provider reimbursement claims and determine the amount due." *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 491 (D.C. Cir. 2010). Formerly known as "fiscal intermediaries," these "Medicare administrative contractors" determine the outlier payments awarded to the hospitals. *See id.* & n.1. Outlier payments are intended to "approximate the marginal cost of care beyond certain

thresholds." *Lenox Hill Hosp. v. Shalala*, 131 F. Supp. 2d 136, 138 (D.D.C. 2000) (internal quotation marks omitted). The Medicare statute provides that

> (ii) . . . [A hospital paid under the PPS] may request additional payments in any case where charges, adjusted to cost . . . exceed the sum of the applicable DRG[1] prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.
> (iii) The amount of such additional payment . . . shall be determined by the Secretary and shall . . . approximate the marginal cost of care beyond the cutoff point applicable . . . .

42 U.S.C. § 1395ww(d)(5)(A). The phrase "charges, adjusted to cost" refers to the Secretary's duty to "estimate a hospital's costs based on the charges the hospital has billed for covered services in the case." (Mot. to Dismiss for Lack of Subject Matter Jurisdiction & Failure to State a Claim ("Def.'s Mot.") at 5.) Cost is estimated by multiplying the amount that the hospital charges by a "cost to charge ratio," which is a number that represents a "hospital's average markup." *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1052 (D.C. Cir. 1997). The estimate of the hospital's costs in a given case is then compared to the sum of two other factors (the "outlier threshold"). 42 U.S.C. § 1395ww(d)(5)(A)(ii). If the estimate of the costs is greater than the outlier threshold, the hospital is eligible for an outlier payment.[2] *See id.*

The amount of the outlier payment is proportional to the amount by which the hospital's loss exceeds the outlier threshold. Currently, hospitals are entitled to reimbursement of eighty percent of costs above the outlier threshold. 42 C.F.R. § 412.84(k). Thus, if the outlier threshold is $20,000 and a hospital's cost estimate is $80,000, the hospital will be entitled to eighty percent of $60,000 (the difference between the costs and the outlier threshold).

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[1] "DRG" stands for "diagnosis related group." There are 470 DRGs, each of which is intended to cover a medical condition. *Cnty. of Los Angeles*, 192 F.3d at 1008. The "DRG prospective payment rate" is the standardized rate paid by the Secretary to a hospital after it has been adjusted for various factors, including the "wage index" and the "weight assigned to the patient's DRG." *Id.* at 1009.

[2] Several other factors may affect the calculation of the outlier threshold but, as they are not at issue in this case, they are omitted from this discussion. (*See* Def.'s Mot. at 5-6 n.3.)

In calculating the fixed loss threshold, the Secretary is also governed by 42 U.S.C. § 1395ww(d)(5)(A)(iv), which requires the "total amount of the additional" outlier payments to be not "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." *See Cnty. of Los Angeles*, 192 F.3d at 1013. The Secretary has interpreted this provision to require her to "select outlier thresholds which, when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected or estimated DRG-related payments." *Id.* She has also interpreted the provision to mean that "she has no obligation to ensure that actual outlier payments for the year total five percent of projected DRG-related payments." *Id.*

To fund outlier payments, ordinary Medicare payments made to hospitals are reduced by a percentage equal to the projected percentage of outlier payments (*i.e.*, by between five and six percent). 42 U.S.C. § 1395ww(d)(3)(B). Plaintiffs refer to the funds deducted from ordinary payments as the "outlier pool." (Compl. Ex. A at 1.) However, because the percentage deducted is based on the Secretary's projections, the amount deducted "may be—and indeed, almost certainly will be—either greater than or less than the total amount of funds subtracted from payments." (Def.'s Mot. at 11; *see also* Pls.' Mem. of P. & A. in Opp'n to Def.'s Mot. ("Pls.' Opp'n") at 5.) *See Cnty. of Los Angeles*, 192 F.3d at 1017-18.

B. Judicial Review

Plaintiffs invoke the agency review process detailed in section 1395oo(f)(1) of the Medicare Act. This provision allows any hospital that receives payments in "amounts computed" under § 1395ww(d) and that has submitted timely reports to obtain a hearing with respect to those payments by a Provider Reimbursement Review Board ("Board"), if the amount

in controversy is $10,000 or more and the provider is dissatisfied with the "final determination" of the "fiscal intermediary . . . as to the amount of total program reimbursement due." 42 U.S.C. § 1395oo(a). A group of hospitals may also bring a case to the Board if the matter in controversy "involve[s] a common question of fact or interpretation of law or regulations" and the amount in controversy is more than $50,000. *Id.* § 1395oo(b). The Board lacks the authority to rule on certain issues, such as the legality of agency regulations. *See* 42 C.F.R. § 405.1867. Thus, providers may "file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matter in controversy." 42 U.S.C. § 1395oo(f)(1). If the Board determines that it lacks the authority to decide the question, it will certify the question for "expedited judicial review." *See id.*; *see also Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24, 27 (D.C. Cir. 2005). If the Board certifies the question, the providers have sixty days to bring a civil action in a district court of the United States. 42 U.S.C. § 1395oo(f)(1).

Section 1395ii of the Medicare Act "generally forecloses other avenues of review by incorporating" § 405(h) of the Social Security Act. *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 809 (D.C. Cir. 2001). Together, the statutes provide that "[n]o action against the United States" or the Secretary or the Department of Health and Human Services "shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under" subchapter II of the Medicare Act. *See* 42 U.S.C. §§ 405(h), 1395ii. Thus, "[p]arties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge." *Three Lower Cnties Cmty. Health Servs., Inc. v. Dep't of Health & Human Servs.*, 317 F. App'x 1, 1 (D.C. Cir. 2009).

II. THE APA

The Court reviews the Secretary's actions under the APA, "pursuant to which [it] will uphold them unless they are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Se. Ala. Med. Ctr. v. Sebelius*, 572 F.3d 912, 916-17 (D.C. Cir. 2009) (quoting 5 U.S.C. § 706(2)(A)); *see also St. Elizabeth's Med. Ctr. of Boston, Inc. v. Thompson*, 396 F.3d 1228, 1233 (D.C. Cir. 2005) ("judicial review of HHS reimbursement decisions shall be made under APA standards"). "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. FCC*, Nos. 10-1062, 10-1088, 2011 WL 2277217, at *16 (D.C. Cir. June 10, 2011) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court's inquiry must focus on the "reasonableness of the agency's decisionmaking process," and the Court "will not substitute [its] judgment for that of the agency." *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009). The Court has a "limited" role and its review is "particularly deferential" where the agency's decision is "primarily predictive." *Id.* Thus, the Court "require[s] only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive." *Id.*

FACTUAL BACKGROUND

Plaintiffs are providers of hospital services under the Medicare program. (Compl. ¶ 7.) Plaintiffs received "outlier payments" in fiscal years 2004-2006, but allege that they would have received larger sums if the outlier thresholds had been more accurately estimated. (*Id.* ¶ 20.) On October 29, 2010, plaintiffs submitted requests to the Board for expedited judicial review of the

"validity of the methodology used" by the Secretary. (*Id.* ¶ 22.) On November 17, 2010, the Board approved expedited judicial review of the Secretary's methodology in fiscal years 2004-2006, certifying review of whether the "elements used to project the outlier thresholds were arbitrary and capricious." (*See id.* & Exs. A-C.)

Plaintiffs filed suit on January 19, 2011, claiming that HHS's determination of outlier payments from 2004-2006 was "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." (*Id.* ¶ 24.) They allege that, "when setting the outlier thresholds and calculating outlier payments for federal fiscal years 2004, 2005 and 2006," the Secretary: 1) "failed to take into account the established pattern of declining cost-to-charge ratios . . . despite this problem being repeatedly pointed out in comments and despite proposed methods to account for this phenomenon and to more accurately estimate outlier payments;" 2) "failed to consider use of the 'cost methodology,' rather than the 'charge methodology,' in setting the outlier thresholds" even though the cost methodology had been more accurate in the past; 3) "failed to require mid-year adjustments;" and 4) "failed to consider adjustments to the reconciliation process." (*Id.*) The Secretary has moved to dismiss the "mid-year adjustment" claim based on lack of jurisdiction[3] (Def.'s Mot. at 14) and plaintiffs' other three claims for failure to state a claim upon which relief can be granted. (*Id.* at 17; Reply Mem. in Support of Def.'s Mot. ("Def.'s Reply") at 10.)

ANALYSIS

I. RULE 12(b)(1): LACK OF SUBJECT MATTER JURISDICTION

The Secretary moves to dismiss plaintiffs' claims relating to mid-year adjustments under Fed. R. Civ. P. 12(b)(1), arguing that they were not brought before the Board and, therefore,

[3] The Secretary originally moved to dismiss the "reconciliation process" claim based on a lack of jurisdiction, but has since withdrawn her jurisdictional objection and now moves to dismiss under Fed. R. Civ. P. 12(b)(6). (Def.'s Reply at 9-10.)

were not exhausted. (Def.'s Reply at 2-9.) "Judicial review" of any claim under the Medicare Act "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). This "bar . . . applies to all claims that have their standing and substantive basis in the Medicare Act." *Id.* (internal quotation marks omitted).

Only claims relating to the Secretary's method for projecting outlier thresholds were properly exhausted and may be raised before the Court. The Board, under 42 U.S.C. § 1395oo(f)(1), is responsible for determining whether it has the authority to decide "the question of law or regulations relevant to the matters in controversy . . . ." Thus, the Board only approved review of issues that were "relevant" to plaintiffs' action. *See* 42 C.F.R. § 405.1842(a)(1) (provider may seek review of "a *legal question* relevant to a *specific matter* at issue in a Board appeal" (emphasis added)); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000) (each "'action' arising under the Medicare Act . . . must be channeled through the agency"). The question the Board certified was whether the "various elements used to project the outlier thresholds were arbitrary and capricious." (Compl. Ex. A at 1.) Thus, any claims that do not relate to the Secretary's method for projecting outlier thresholds were not properly exhausted and must be dismissed.

A. Mid-Year Adjustments

Plaintiffs argue that the Secretary could have corrected the underpayment of outlier payments "operationally through 'mid-year adjustments'" of the outlier threshold and that she acted arbitrarily and capriciously by failing to do so. (Pls.' Mot. at 7.) The Secretary argues that plaintiffs failed to assert to the Board that she was "required to make mid[-]year adjustments to the fixed loss thresholds," and, therefore, the Board did not authorize expedited review of this

issue. (Def.'s Mot. at 16.) Thus, she contends that the Court lacks jurisdiction over this claim because plaintiffs did not request that the Board certify the issue for review. (*Id.* at 14; Def's Reply at 2-8.) The Court agrees that "mid-year adjustments" are not a part of the "action" plaintiffs have brought under the Medicare Act. *See Ill. Council on Long Term Care, Inc.*, 529 U.S. at 23. The Board approved review of the "elements used to project the outlier thresholds." (Compl. Ex. A at 1.) By challenging the Secretary's failure to make "mid-year adjustments," plaintiffs challenge the actions the Secretary took after she had already projected the thresholds. Plaintiffs make this clear by arguing that the Secretary could use mid-year adjustments "to correct a flawed methodology used to establish the outlier thresholds." (Pls.' Opp'n at 15.) Thus, adjustments were a corrective tool that the Secretary could use, not a factor she took into account when projecting the outlier thresholds. The issue was neither "encompassed" nor "subsumed" (Pls.' Opp'n at 7) within the action that plaintiffs have brought under the Medicare Act.

Plaintiffs respond by arguing that the Board lacks jurisdiction over "mid-year adjustments," and, therefore, they were not required to appeal the issue separately. (Pls.' Opp'n at 7.) They rely on a series of cases which cite to *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), where the Supreme Court noted the "strong presumption that Congress intends judicial review of administrative action." (Pls.' Opp'n at 8.) More recently, the D.C. Circuit observed that the Supreme Court "appears to have left open a door" in 42 U.S.C. § 1395ii for judicial review under 28 U.S.C. § 1331 "to fill jurisdictional gaps it presumes Congress did not intend." *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 859 (D.C. Cir. 2007). *See also Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 115 (D.D.C. 2009) ("Section 1395ii is inapplicable, however, when a plaintiff could not otherwise

obtain administrative review of its claims"). However, a plaintiff may not evade the administrative review channel simply because the agency "might not provide a hearing" for a "*particular contention*, or may lack the power to provide one." *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 23. So long as the plaintiff can channel the "action" through the agency, a federal court may later consider "any statutory or constitutional contention that the agency does not, or cannot decide." *Id.*

Plaintiffs also argue that the Secretary's decision not to use "mid-year corrections" was not a "final determination," and therefore was not separately appealable under 42 U.S.C. § 1395oo. (Pls.' Opp'n at 8.) However, despite their argument that the Secretary lacked the power to provide a hearing for this "*particular contention*," plaintiffs have not suggested that they faced "the practical equivalent of a total denial of judicial review." *Ill. Council on Long Term Care*, 529 U.S. at 20, 22-24. As a result, plaintiffs have failed to carry their burden of establishing that the Court has subject matter jurisdiction and "the bar of § 405h applies."[4] *Id.* at 25. Since the Board did not grant expedited judicial review of the actions the Secretary took after projecting the outlier thresholds, plaintiffs cannot raise the issue now, and it will be dismissed.

B. Mathematical Errors

Plaintiffs also argue in their opposition brief that it is "apparent" that the Secretary made mathematical errors in calculating final outlier thresholds. (Pls.' Opp'n at 19.) The Court may not consider this allegation because it appears nowhere within the Complaint. (*See* Compl. ¶ 24.) Plaintiffs have not sought to amend their Complaint and "[i]t is axiomatic that a complaint may not be amended by the briefs in opposition to a motion to dismiss." *Arbitraje Casa de Cambio,*

[4] Although plaintiffs note the "strong presumption that Congress intends judicial review of administrative action" (Pls.' Opp'n at 8 (quoting *Mich. Acad. of Family Physicians*, 476 U.S. at 670)), they fail to mention that "federal question jurisdiction is generally unavailable for 'any claim arising under' the Medicare Act," and that the presumption applies only when there would otherwise be "no review at all." *Action Alliance of Senior Citizens*, 483 F.3d at 858-59 (quoting *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 11, 17).

S.A. de C.V. v. U.S. Postal Serv., 297 F. Supp. 2d 165, 170 (D.D.C. 2003). Secondly, this issue does not fall within the scope of the question that was approved, as it does not relate to the "various elements used to project the outlier thresholds." *See supra*, Part II.A. Nor did the Board approve expedited judicial review of any agency determination relating to the Secretary's potential "mathematical errors." (*See* Compl. Ex. A, at 1-2.) Thus, even if plaintiffs had properly raised the issue in their Complaint, it would likely be subject to dismissal for lack of jurisdiction.

II. RULE 12(b)(6): FAILURE TO STATE A CLAIM

Plaintiffs have advanced three other reasons why the Secretary's method for calculating outlier thresholds was arbitrary and capricious. First, they suggest that the Secretary wrongly failed to account for the "established pattern of declining cost-to-charge ratios," even though there were proposed methods to "account for this phenomenon and to more accurately estimate outlier payments." (Compl. ¶ 24.) Second, they argue that the Secretary failed to consider using the "cost methodology" rather than the "charge methodology," even though the cost methodology had been more accurate in the past. (*Id.*) Lastly, they argue that the Secretary "failed to consider adjustments to the reconciliation process." (*Id.*) The Secretary argues that all three claims must be dismissed under Rule 12(b)(6).

To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face,'" such that a court may "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). The plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* Thus, "[f]actual allegations must

be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (citations omitted). In ruling on a 12(b)(6) motion, a court may consider facts alleged in the complaint, documents attached to or incorporated in the complaint, matters of which courts may take judicial notice, and documents appended to a motion to dismiss whose authenticity is not disputed, if they are referred to in the complaint and integral to a claim. *U.S. ex rel. Folliard v. CDW Tech. Servs., Inc.*, 722 F. Supp. 2d 20, 24-25 (D.D.C. 2010).

A. The Federal Register and the Administrative Record

The Secretary argues that the notices she issued in the Federal Register "thoroughly explain" her decisionmaking "with respect to each of the issues that the plaintiffs have complained about."[5] (Def.'s Mot. at 17; Def.'s Reply at 13.) Thus, she suggests, she has "advanced reasonable explanations for the methods she used in making payment projections," and plaintiffs' claims must be dismissed because, as a matter of law, her acts "cannot be considered arbitrary or capricious." (Def.'s Mot. at 30; Def.'s Reply at 17-18.) Plaintiffs do not challenge the explanations offered in the Federal Register. (Pls.' Opp'n at 17-20.) Rather, they argue that the Court may not consider the Federal Register in the context of a motion to dismiss. (*Id.* at 17-18.) Contrary to this argument, it is settled law that "statements in the Federal Register can be examined on 12(b)(6) review." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 n.6 (D.C. Cir. 1993); *Nat'l Treasury Emps. Union v. Whipple*, 636 F. Supp. 2d 63, 78

[5] The Secretary argues that plaintiffs cannot claim that total outlier payments fell short of a minimum level required by the Medicare Act (Def.'s Reply at 11-12) or that the differences between the projected and actual payments are evidence that her methodology was arbitrary or capricious. (Def.'s Mot. at 20.) *See Cnty. of Los Angeles*, 192 F.3d 1005 (rejecting argument that Secretary was required to "recalibrate" outlier thresholds and "disburse a second round of payments"). Plaintiffs have clarified that they "do not allege that actual outlier payments *must* equal the minimum set forth . . . or the outlier payment target set by the Secretary." (Pls.' Opp'n at 9 (emphasis added).) Rather, they suggest that the actual payments show that they suffered damages as a result of the Secretary's arbitrary and capricious methodology. (*Id.*) Thus, to the extent the Complaint could be read to claim that the Secretary was required to ensure that the actual outlier payments reached a minimum level, the Court will treat that claim as abandoned.

n.8 (D.D.C. 2009) ("Public records, such as the Federal Register, can be considered in a motion to dismiss under Rule 12(b)(6) without converting the motion to a motion for summary judgment."). Since the Court may refer to the Federal Register without converting plaintiffs' motion to one for summary judgment, it must now turn to plaintiffs' second claim — that review under the "arbitrary and capricious" standard in this case requires review of the "complete administrative record." (Pls.' Opp'n at 17-18.)

Even though the Court may refer to the Federal Register, it concludes that dismissal based solely on its contents would be premature here because a review of the administrative record is necessary to a determination of whether the Secretary's methodology was arbitrary and capricious. "[T]o review an agency's action fairly, [the Court] should have before it neither more *nor less* information than did the agency when it made its decision . . . and so the APA requires review of 'the whole record.'" *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (emphasis added). Thus, in *Swedish American Hospital v. Sebelius*, the Court refused to grant a motion to dismiss, holding that the plaintiff was entitled to the administrative record because the plaintiff was "challenging not just whether the Secretary's regulations were consistent with the statute, but also whether the Secretary's adjudicatory process was reasonable and whether the decision was consistent with Congressional intent." 691 F. Supp. 2d 80, 89 (D.D.C. 2010). The Court found that it could not "'evaluate the agency's rationale at the time of [its] decision'" or "assess the merits of these arguments without considering the administrative record." *Id.* at 88-89 (quoting *Appleby v. Harvey*, 517 F. Supp. 2d 253, 260 (D.D.C. 2007)).

The Secretary argues that *Swedish American Hospital* does not *rule out* the possibility of resolving an APA claim without examining the administrative record and that the case merely

suggests that the Court should require that the administrative record be produced where it is necessary.[6] (Def.'s Mot. at 15.) But Circuit precedent strongly counsels in favor of administrative review in this case. The Circuit has ruled on the merits without an administrative record where the argument "can be resolved with nothing more than the statute and its legislative history," such as where a plaintiff alleges that a regulation is inconsistent with a statute, *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 271 F.3d 262, 266 (D.C. Cir. 2001), or where a plaintiff alleges that an agency's action was not a "formal administrative determination" under ERISA. *Allied Pilots Ass'n v. Pension Benefits Guar. Corp.*, 334 F.3d 93, 97-98 (D.C. Cir. 2003). The Circuit, however, urged a different approach where plaintiff challenges the "manner in which the Administration has applied [a] rule in specific cases." *See Am. Bankers Ass'n*, 271 F.3d at 267 (no administrative record was required because the Circuit found no "challenge to the Administration's rule-making process" and no challenge to a rule's application that did not "depend entirely" on the argument that the rule violated the statute); *see also Amfac Resorts, L.L.C. v. Dep't of Interior*, 282 F.3d 818, 830 (D.C. Cir. 2002) (noting that the administrative record was unnecessary in *American Bankers* because the case involved a "facial attack on the regulation"), *vacated on other grounds by Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803 (2003).

The Circuit's decision in *American Bioscience, Inc. v. Thompson*, 243 F.3d 579 (D.C. Cir. 2001), illustrates the distinction between these two types of cases. In that case, plaintiffs requested an injunction against the Food and Drug Administration. *Id.* at 581-82. The district

[6] The Secretary cites *Marshall County Health Care Authority* for the proposition that the Court may resolve plaintiffs' claims by "simply 'examining the Secretary's published responses to comments in the rulemaking proceeding.'" (Def.'s Reply at 15 (quoting *Marshall Cnty. Health Care Auth.*, 988 F.2d at 1226).) However, that decision only held that a court may examine published responses to comments and the agency record when ruling on a 12(b)(6) motion and may "reach[] the merits at the 12(b)(6) stage." *See id.* at 1226. Indeed, *Marshall County* held that, in addressing "whether the agency adhered to the standards of decisionmaking required by the APA," the district court "can consult the [agency] record." *Id.* Thus, *Marshall County* does not provide support for defendant's position here.

court denied the request, holding, in part, that that the agency's interpretation and application of a regulation were not plainly erroneous or inconsistent. *Id.* at 582. The Circuit reversed, holding that the district court had improperly failed to "call[] for the administrative record," and had instead "relied on the parties' written or oral representations to discern the basis on which the FDA acted." *Id.* "Surely that was not sufficient," the Circuit concluded, noting that the Supreme Court held that "even sworn affidavits" could not adequately explain the agency's actions. *Id.* (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419 (1971)). The Circuit reiterated that the APA directs courts to perform judicial review "by review[ing] the whole record or those parts of it cited by a party . . . ." *Id.* (citing 5 U.S.C. § 706). Thus, because the Agency's reasons for interpreting and applying a regulation were at issue, the Circuit required the court to consider the administrative record.

The Secretary also argues that her statements in the Federal Register render the claims in plaintiffs' Complaint implausible and that, therefore, plaintiffs have failed to state a claim upon which relief can be granted. (Def.'s Mot. at 21-30.) Specifically, she suggests that the Federal Register explains why she did not account for declining "cost to charge" ratios and why she employed a "charge methodology" instead of a "cost methodology." (Def.'s Reply at 16.) Moreover, she states that the Register also explains why she did not account for the possibility of reconciliation. (*Id.* at 17-18.) Had plaintiffs alleged that the Secretary never explained her actions or that the Secretary never published responses to comments, the Court might have been able to "resolve[]" the argument "with nothing more than" the Federal Register. *See Am. Bankers Ass'n*, 271 F.3d at 267. But plaintiffs have also alleged in their Complaint that the Secretary failed to take "declining cost-to-charge ratios" into account, even though more accurate methods were proposed and even though the problems with the cost-to-charge ratios

were repeatedly pointed out. (Compl. ¶ 24.) Moreover, plaintiffs argue that the Secretary did not "consider use" of the "cost methodology," even though the methodology had been more accurate in the past, and "inadequately considered the impact" of the reconciliation process on the outer threshold. (*Id.*; Pls.' Opp'n at 11.) While plaintiffs recognize that the Secretary wrote about these issues in the Federal Register, they argue that she inadequately considered them, and ignored data and comments that were made during the public comment period. (Pls.' Mot. at 10-11.) Thus, plaintiffs have directly challenged the Secretary's "methodology," suggesting that it was arbitrary and capricious because of her failure to account for a significant decline in cost-to-charge ratios, her use of inaccurate, inferior predictive methods when better ones were available, and her failure to properly account for the reconciliation process. (Compl. ¶ 24.) This is an attack on the adequacy of the Secretary's decisionmaking, not a facial attack on a rule's compliance with a statute. *See Am. Bankers Ass'n*, 271 F.3d at 267. As a result, the Court is obligated to compare the Secretary's statements in the Register with the evidence in the administrative record. *See Cnty. of Los Angeles*, 192 F.3d at 1021 (comparing the Secretary's notices in the Federal Register with evidence in the administrative record to determine whether her method for setting outlier thresholds was arbitrary and capricious).

The Court's eventual review of the Secretary's decisionmaking will be "particularly deferential," *Rural Cellular Ass'n*, 588 F.3d at 1105, and it may well be, given the notices in the Federal Register that she has quoted, that she adequately considered the issues raised by plaintiffs and did not act arbitrarily and capriciously. But the Secretary has failed to cite, and the Court has not found, any case in which a court granted a motion to dismiss with similar APA claims solely on the basis of agency comments in the Federal Register. Since the Court cannot "fairly" review the outlier threshold methodology used by the Secretary without the information

that was before her when she made her decisions, defendant's motion to dismiss will be denied. *See Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792.

CONCLUSION

For the foregoing reasons, the Secretary's motion to dismiss will be granted in part and denied in part. Plaintiffs' claim relating to mid-year adjustments was not exhausted and will therefore be dismissed. The Secretary's motion to dismiss plaintiffs' other claims under Fed. R. Civ. P. 12(b)(6) will be denied. An Order consistent with this Memorandum Opinion will be issued on this date.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: July 5, 2011