

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

CAPE COD HOSPITAL, et al.,

Plaintiffs

v.

**KATHLEEN SEBELIUS,¹ SECRETARY,
United States Department of Health and
Human Services,**

Defendant.

Civil Action No. 08-1751 (RCL)

MEMORANDUM OPINION

Plaintiffs Cape Cod Hospital, Falmouth Hospital Association, Flushing Medical Center, Brookdale University Hospital Medical Center and Jamaica Hospital Center bring this action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 702 et al., seeking judicial review of two final rules promulgated by the U.S. Department of Health and Human Services. The rules in dispute determined the rates for inpatient hospital services paid under the Medicare prospective payment system. The first motion presently before the Court concerns two documents offered by the plaintiffs that were not included in the official administrative record for Fiscal Year 2007. The defendant moves to strike these documents as improperly supplementing the administrative record. In addition, both parties have filed motions for summary judgment. For reasons set forth in this opinion, the motion to strike is GRANTED in part and DENIED in part. Defendant's cross-motion

¹ Pursuant to Federal Rule of Civil Procedure 25(d), Secretary Sebelius, in her official capacity as the Secretary of the Department of Health and Human Services, is automatically substituted as the named defendant.

for summary judgment is GRANTED. Accordingly, Plaintiff's motion for summary judgment is DENIED.

I. BACKGROUND

A. Medicare Payment for Inpatient Hospital Services

Established in 1965 under Title XVIII of the Social Security Act, 79 Stat. 291, as amended, 42 U.S.C. § 1395 *et seq.* (1988 ed. and Supp. IV), Medicare is a federally funded health insurance program for the elderly and disabled. Subject to a few exceptions, Congress authorized the Secretary of Health and Human Services (Secretary) to issue regulations defining reimbursable costs and otherwise giving content to the broad outlines of the Medicare statute. § 1395x(v)(1)(A). That authority encompasses the discretion to determine both the “reasonable cost” of services and the “items to be included” in the category of reimbursable services. *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 507 (1994). However, experience proved that the “reasonable cost” system provided “little incentive for hospitals to keep costs down” because “[t]he more they spent, the more they were reimbursed.” *Tuscon Med. Ctr. v. Sullivan*, 947 F.2d 971, 974 (D.C. Cir. 1991). In the Balanced Budget Act of 1997, Congress changed the payment system for services from a “reasonable cost” to a prospective payment system (PPS). Under PPS, Medicare pays prospectively-established rates for each patient discharge. 42 U.S.C. § 1395ww(d); 71 Fed. Reg. 47870, 47875-76 (Aug. 16, 2006). Plaintiffs are five non-profit hospitals that participate in the Medicare program.

Under the Medicare Act, the amount of reimbursement to a provider hospital for a given service is dependant on the hospital's “average standardized amount” per discharge and the “area wage index” applicable to the hospital. *See* 42 U.S.C. §

1395ww(d)(2)(C),(D); § 1395ww(d)(3)(E). The standardized amount is the base payment rate per discharge under the PPS according to the particular diagnosis.² 42 U.S.C. § 1395ww(d)(3). It is divided into two parts: a labor-related share and a nonlabor-related share. *See* 42 U.S.C. § 1395ww(d)(3)(E). The Secretary adjusts the labor-related portion of the standardized amount for differences in hospital wage levels in different geographic areas.³ *See* 42 U.S.C. § 1395ww(d)(3)(E). In order to calculate the relative wage-level adjustment, the Secretary calculates and assigns an area wage index value to each hospital reflecting the relative wage levels in the hospital's geographic location. *See* 71 Fed. Reg. at 48005; 71 Fed. Reg. 59886, 59903-68 (Oct. 11, 2006). Beginning in 1994, Congress required that the Department of Health and Human Services, through the Centers for Medicare and Medicaid Services (CMS), update wage indexes annually based on wage data information submitted by participating hospitals.

B. The Rural Floor Adjustment

The disparity in payments between urban and rural hospitals caused by differences in the applicable wage indexes has resulted in congressional adjustments. In 1997, Congress enacted legislation requiring the wage index for hospitals located in an urban area to not be less than the wage index for hospitals located in rural areas in the same state. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4410(a) (BBA), 42 U.S.C. § 1395ww note. The legislation provided that “the area wage index applicable . . . to any hospital which is not located in a rural area . . . may not be less than the area wage

² The Secretary has established a system for classifying inpatient hospital discharges by diagnosis by assigning each diagnosis to a diagnosis-related group (DRG). The PPS payment rates are adjusted to account for differences in resources required to care for patients in different DRGs. *See* 42 U.S.C. § 1395ww(d)(4).

³ All “hospitals participating in the Medicare program are classified as located in ‘large urban areas,’ ‘other urban areas,’ or ‘rural areas.’” *Universal Health Servs of McAllen v. Sullivan*, 770 F.Supp. 704, 707 (D.D.C. 1991).

index applicable . . . to hospitals located in rural areas in the State in which the hospital is located.” *Id.* In other words, where a state’s rural hospitals would otherwise have a higher applicable wage index than an urban hospital in the same state, Congress provided that the urban hospital’s wage index be raised to match that of the rural hospitals. This adjustment, commonly called the “rural floor,” is required to be performed in a budget neutral manner, so that payments in a given fiscal year “are not greater or less than those which would have been made in [that] year” had the rural floor provision not applied. *Id.* The effect of the rural floor is to provide payments to some urban hospitals that are greater than would have otherwise been provided to those hospitals. The budget neutrality provision means that any increases in the wage indexes for urban hospitals due to the rural floor must be offset by a corresponding reduction to the wage indexes for rural hospitals so that the total Medicare payments are no greater and no less than they would have been had the rural floor not existed.

Each year, the Secretary publishes proposed changes in the PPS policies and calculations for the upcoming fiscal year in the Federal Register. The Secretary’s final changes are published “after such consideration of public comment . . . as is feasible in the time available.” 42 U.S.C. § 1395ww(e)(5). The CMS’s standard procedure is to issue a Proposed Rule that identifies any changes that it proposes to make along with an Addendum to the Proposed Rule that describes the changes. The agency also provides information on “how to obtain data related to the PPS changes and provides the raw wage data to be used for calculations in the current year, as well as hospital wage indexes, and a PPS payment impact file that contains payment adjustment variables that CMS uses when estimating . . . payments.” Cross-Mot., Summ. J. (citing R08:148-50; R07:143-45).

C. Fiscal Year 2007 Rulemaking Process

CMS issued a proposed rule for FY 2007 on April 25, 2006. The proposed rule set forth specific instructions for submission of comments to those who wished to deliver comments by hand to CMS's Baltimore address. R07:2. The FY 2007 proposed rule directs those who wish to submit comments by hand delivery to the Baltimore office to call staff in advance to schedule their arrival with one of the CMS's regulations staff members so that proper receipt of comments can be assured. Specifically, the proposed rule instructed:

By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or 7500 Security Boulevard, Baltimore, MD 21244-1850. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.)

R07:2. According to the FY 2007 rulemaking record submitted by the Secretary, no comments addressing the rural floor adjustment were properly submitted during the FY 2007 comment period.

However, plaintiffs contend there are two additional items that should have been included in the FY 2007 rulemaking record and were left out. The first is an e-mail exchange between the plaintiffs' consultant, Theodore Giovanis, and a CMS employee, Nora Fleming, in which Giovanis asked questions regarding the calculation of rural floor budget neutrality for the acute care prospective payment system in May 2006. The

employee responded to the inquiry with a description of how CMS calculates the wage and budget neutrality factor and Giovanis responded by raising a question about the neutrality floor and later requesting a formula that is used in the calculation.

The second document that the plaintiffs submitted in the partial administrative record that is not included in the administrative record certified by the defendant is a comment letter dated June 9, 2006, which was submitted by the plaintiff's same consultant. While the letter has an acknowledgement of receipt by a CMS employee, the defendants did not include the letter as part of the administrative record for FY 2007.

The FY 2007 Final Rule did not adopt any changes to the rural floor adjustment methodology. R07:1225 (71 Fed. Reg. 47870). It also did not address Giovanis' observations about the rural floor adjustment. Instead, it stated that it used the "same method" to calculate the rural floor budget neutrality adjustment that it used in prior years. 71 Fed. Reg. at 48147. The same method described by CMS referred to the simulation model that had been used from 1998 to 2007. The model was used to determine each year's budget neutrality adjustment to the standardized amount for the effect of the rural floor. The model compared the projected aggregate payments resulting from the next year's wage indexes with the aggregate payments resulting from applying the prior year's wage indexes. In the Final Rule for 2007, CMS described the model as follows:

[W]e used FY 2005 discharge data to simulate payments and compared aggregate payments using the FY 2006 relative weights and wage indexes to aggregate payments using the FY 2007 relative weights and wage indexes. The same methodology was used for the FY 2006 budget neutrality adjustment. . . . These budget neutrality adjustment factors are applied to the standardized amounts without removing the effects of the FY 2006 budget neutrality adjustments.

71 Fed. Reg. at 48147. Previous years had similar descriptions of the simulation model. *See, e.g.*, 70 Fed. Reg. at 47493; 69 Fed. Reg. at 49275; 68 Fed. Reg. at 45475-76. However, additional data was not provided in the calculation of the budget neutrality adjustments.⁴

D. Fiscal Year 2008 Rulemaking Process

CMS issued a proposed rule for FY 2008 on May 3, 2007. After the 2007 final rule had been issued, CMS reevaluated the rural floor adjustment methodology and the e-mail exchange which occurred during the FY 2007 period was included in the FY 2008 administrative record. Under the new proposed methodology, CMS would apply the budget neutrality adjustment factor to the wage index rather than to the standardized amount as it had done in the past. R08:109-14.

CMS stated that “the statute supports either an adjustment to the standardized amount or the wage indices because under either methodology, the rural floor would not result in aggregate payments that were greater or less than those that would have been made in the absence of a rural floor.” R08:114. However, CMS noted that new adjustment to the “wage index would have slightly different effects from an adjustment to the standardized amount.” R08:114. In connection with the change in the calculation of the rural floor adjustment, CMS also proposed a one-time change adjustment to standardize the amount, in effect neutralizing the 2007 rural floor adjustment. R08:161.

⁴ In the e-mail correspondence between plaintiffs’ consultant and CMS staff that was not included in the FY2007 record but was included in the FY 2008 record, CMS staff explained that the simulation model compared estimated payments resulting from the application of the next year’s wage data with the rural floor applied to estimated payments resulting from the application of the prior year’s wage data without the rural floor applied.

After the proposed rule was published, the plaintiffs submitted a request for additional information, including information about the proposed methodology, the proposed one-time adjustment and details about how the rural floor budget neutrality had been calculated in prior years. R08:699-705. CMS declined to provide additional information in a letter dated June 1, 2007, stating its belief that it had provided “more than sufficient explanation.” Plaintiffs then submitted comments on the proposed rule. R08:691-98. Specifically, plaintiffs (1) requested that CMS fully explain the basis and purpose for the proposed change and disclose known errors in the calculation of rural floor adjustment for prior years; (2) informed CMS that the proposed change in method was neither necessary nor sufficient to fix the data problem with CMS’s past calculations of the budget neutrality adjustment, and it may create other problems; and (3) requested that CMS correct the effects of known errors in the calculations for prior years and pay hospitals the additional sums due for cost reporting periods that are still subject to correction.

In August 2007, the Secretary published the final rule for 2008 and adopted the new methodology the agency had proposed. 72 Fed. Reg. 47130. While CMS acknowledged that additional information was requested, it did not provide the additional information in the final rule. CMS also noted a comment that the calculation of the rural floor budget neutrality adjustment for prior years was flawed because it created an “inappropriate duplicating effect” that was “permanently built into the standardized amount.” 72 Fed. Reg. at 47330. However, the agency responded that such alleged errors were beyond the scope of the final rule for 2008. Specifically, the agency stated that

“[e]ven if errors were made in prior fiscal years, we would not make an adjustment to make up for those errors when setting rates for FY 2008.” *Id.*

The one-time adjustment was also adopted in the final rule for 2008. In the appendix to the rule, CMS stated that the one-time adjustment was meant to “remove[] the effect of the budget neutrality adjustment applied in FY 2007 to the standardized amount for application of the rural floor. 72 Fed. Reg. at 47421. CMS did not explain why it only accounted for the previous year or the details of how the adjustment was calculated.

E. PRRB Appeal

Plaintiffs brought challenges to both the FY 2007 and 2008 Final Rules before the Provider Reimbursement Review Board (PRRB), the administrative body within HHS responsible for hearing provider payment claims pursuant to 42 U.S.C. §1395oo(a). All five hospitals appealed the final determination of the payment rates for 2007 but only two hospitals appealed the final payment rule for 2008. After the hospitals filed their initial appeal in 2007, they requested and the PRRB granted, expedited judicial review.

The PRRB initially denied the unopposed petitions and dismissed the appeals based on its conclusion that the Medicare regulations precluded judicial review. However, this court vacated the PRRB’s earlier decisions and remanded to the Secretary for reconsideration of the hospitals’ appeals. In September 2008, the Secretary remanded to the PRRB and the hospitals again filed a request for expedited judicial review, which again went unopposed by the Secretary. In October, the PRRB determined that expedited judicial review was appropriate pursuant to 42 U.S.C. § 1395oo(f)(1).

II. MOTION TO STRIKE

Initially, it is necessary to resolve defendant's motion to strike the partial administrative record filed by the plaintiff hospitals. When reviewing a decision under the Administrative Procedure Act (APA), "district courts generally are restricted to the administrative record that was before the agency." 5 U.S.C. § 706; *Commercial Drapery Contractors v. United States*, 133 F.3d 1, 7 (D.C. Cir. 1998); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). The court's review must "be based on the full administrative record that was before the [agency] at the time [it] made [its] decision." *Am. Bioscience v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001). In other words, to ensure fair review of an agency action, the court "should have before it neither more nor less information than did the agency when it made its decision." *Fund for Animals v. Williams*, 391 F.Supp.2d 191, 196 (D.D.C. 2005) (citing *IMS v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997)).

The rationale for this limitation derives from the court's functional role in the administrative process. As the Court of Appeals for the D.C. Circuit has explained:

[J]udicial reliance on an agency's stated rationale and findings is central to a harmonious relationship between agency and court, one which recognizes that the agency and not the court is the principal decision maker. Were courts cavalierly to supplement the record, they would be tempted to second-guess agency decisions in the belief that they were better informed than the administrators empowered by Congress and appointed by the President. The accepted deference of court to agency would be turned on its head: the so-called administrative state would be replaced with one run by judges lacking the expertise and resources necessary to discharge the function they had arrogated unto themselves.

San Luis Obispo Mothers for Peace v. NRC, 751 F.2d 1287, 1325-26 (D.C. Cir. 1986), *rev'd en banc on other grounds*, 789 F.2d 26 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 923 (1986).

In order to ensure that the administrative record contains “neither more nor less” information than was before the agency, “courts in this circuit have directed agencies to collect those materials that were compiled by the agency that were before the agency at the time the decision was made.” *Fund for Animals*, 391 F. Supp. 2d at 196 (citing *James Madison Ltd v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996)). Specifically, the record must contain all documents that the agency “directly or indirectly considered.” *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993); *Amfac Resorts v. Dep’t of Interior*, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (Lamberth, J.); *Alaska Excursion Cruises v. United States*, 603 F. Supp. 541, 550 (D.D.C. 1984); *see also Pers. Watercraft Indus. Ass’n v. Department of Commerce*, 48 F.3d 540, 546 n.4 (D.C. Cir. 1995) (noting that a complete administrative record contains all materials “pertaining to the [challenged] regulation”).

Courts are not permitted to supplement the record unless a party can demonstrate “unusual circumstances justifying a departure from [the] general rule.” *Tex. Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685, 698 (D.C. Cir. 1991). Absent clear evidence to the contrary, an agency is entitled to a presumption that it properly designated the administrative record. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99, 105 (1977); *see also Calloway v. Harvey*, 590 F. Supp. 2d 29, 37 (D.D.C. 2008); *Pac Shores Subdiv., Cal. Water Dist. v. U.S. Army Corps of Eng’rs*, 448 F.Supp.2d 1, 6 (D.D.C. 2006); *Amfac Resorts*, 143 F.Supp.2d at 12 (noting the “standard presumption” that the agency presented the administrative record properly).

However, the rule limiting judicial review to the administrative record is subject to “certain narrow exceptions.” *Amfac Resorts*, 143 F. Supp. 2d at 11. In this Circuit, eight separate exceptions are well established, especially when in addition to the “substantive soundness of the agency’s decision is under scrutiny,” the procedural validity “also remains in serious question.” *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989). Specifically, supplementation is appropriate:

1. when agency action is not adequately explained in the record before the court;
2. when the agency failed to consider factors which are relevant to its final decision;
3. when an agency considered evidence which it failed to include in the record;
4. when a case is so complex that a court needs more evidence to enable it to understand the issues clearly;
5. in cases where evidence arising after the agency action shows whether the decision was correct or not;
6. in cases where agencies are sued for a failure to take action;
7. in cases arising under the National Environmental Policy Act; and
8. in cases where relief is at issue, especially at the preliminary injunction stage.

Id. See also *Lake Pilots Ass’n v. U.S. Coast Guard*, 257 F.Supp.2d 148, 165 (D.D.C. 2003).

In the first two circumstances, “the record itself will reveal whether non-record review is merited.” Specifically, it will be apparent from the face of the record whether the agency action is adequately explained in the record or whether the agency considered all of the relevant factors. However, for the remaining exceptions to the general rule, “the completeness of the record and the good faith behind it can only be grasped by looking beyond the record itself.” *Amfac*, 143 F. Supp. 2d at 12. Thus, the plaintiff must make a

“strong showing” that the record is incomplete. *Overton Park*, 401 U.S. at 420 (requiring a “strong showing” before extra-record inquiry will be permitted).

The Secretary makes two arguments in her motion to strike. First, she argues that the “Partial Administrative Record” submitted by the plaintiffs is duplicative and redundant and the admission of extra-record evidence would serve no purpose. Second, and more substantively, the defendant argues that the partial administrative record submitted by the plaintiffs contains two documents that the agency has not included in the FY 2007 administrative record and should therefore be stricken. Specifically, the Secretary argues that the e-mail from Mr. Giovanis and the letter submitted by Mr. Giovanis should not be contained in the record. However, in regard to the formal comments submitted by Mr. Giovanis, the plaintiffs contend that Mr. Giovanis did, in fact, follow proper procedures and call a CMS employee who works within the agency’s Division of Acute Care as required by the proposed rule, arranged for delivery with her, met her at the security desk of the office and delivered the letter after she executed the delivery receipt. Further, the plaintiffs contend that at no time did the employee indicate she was not authorized to accept delivery of the comment letter.

While the Secretary concedes that Mr. Giovanis’ e-mail was received during the time frame of when the agency was eliciting comments for the FY 2007 rule, the e-mail exchange was included only in the FY 2008 rulemaking record. Specifically, the Secretary states that “the omission of the e-mail from the FY 2007 rulemaking record implicitly suggests a determination on the part of agency staff that whatever interest there might be in addressing the question raised in this e-mail, that interest was insufficient to warrant consideration in the FY 2007 rulemaking process.” Def. Motion to Strike at 7.

The Court agrees with the Secretary that plaintiffs have been unable to show if and how CMS considered the e-mail exchange in the context of the FY 2007 rulemaking. Simply because CMS received the e-mails from Plaintiff's consultant, it is not sufficient to show that the exchange was, or even should have been, considered during the FY 2007 rulemaking period. The e-mail was not submitted as a formal comment but, rather, was a question posed to the agency employee, to which the agency failed to respond. Therefore, the e-mail exchange was properly excluded from the FY 2007 administrative record.

While the Court concludes that the e-mail exchange was properly excluded from the administrative record, the Court finds that the formal comment submitted by plaintiffs was improperly excluded from the FY 2007 rulemaking record. In the CMS proposed rule instructions for submitting comments via hand delivery, the instructions told commenters: "If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members." While it is clear Mr. Giovannis did not call the telephone number listed, the purpose of calling the number was to schedule arrival with "one of" CMS's staff members prior to dropping off the comment. This is precisely what Giovanis did. The comment was properly addressed and hand-delivered to the address given in the notice. Further, Giovanis called a staff member responsible for PPS payment policies and arranged for his arrival. Giovanis also submitted the two additional copies of the comment letter, as required by the instructions. The Secretary asserts that the comments must be excluded because Mr. Giovanis failed to call the exact number as listed in the Federal Register. However, Mr. Giovanis called a staff member and in any event, the

government argument fails because the agency accepted the comments in fact, as indicated on the time-stamped acceptance of the comments. By honoring the scheduled arrival of Giovanis and accepting the comments, the government indicated that Giovanis's submission was acceptable.

Further, the plain language of the Federal Register request informs prospective commenters that calling the specific telephone number listed is not required. The instructions state to "please call" in advance. The use of the word "please" evinces the agency's intent to make the instruction recommended, rather than mandatory. *See Webster's Ninth New Collegiate Dictionary* 903 (1990) (defining "please" as "used as a function word to express politeness or emphasis in a request"). If the agency intended to make this provision mandatory, it would have stated as such. For example, in directing commenters that there is only one address to submit comments via overnight or express mail, the agency stated that "[y]ou may send written comments . . . to the following address ONLY" R07:2 (emphasis in original).

The Secretary contends that even though the letter has "a supposed acknowledgement of receipt by a CMS employee, that signature is insignificant . . . to authenticate the letter" because the letter can not be found in CMS files. This argument must fail. If taken to its logical conclusion, whenever the government misplaces a file, it could claim that it simply never existed. This result would be absurd. Therefore, the Court concludes that the e-mail exchange between Mr. Giovanis and CMS staff members was properly excluded from the FY 2007 rulemaking record. However, the formal comments submitted by Mr. Giovanis were improperly excluded from the FY 2007 rulemaking record. *See Public Citizen v. Heckler*, 653 F.Supp. 1129, 1237 (D.D.C. 1986)

(providing that supplementation of the record may be necessary when an agency excludes information adverse to its position from the administrative record).

III. SUMMARY JUDGMENT STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(c), a court must grant summary judgment when the evidence in the record demonstrates that there are no disputed issues of material fact and that the moving party is entitled to judgment on the undisputed facts as a matter of law. Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine issue of material fact exists if the evidence, when viewed in a light most favorable to the non-moving party, “is such that a reasonable jury could return a verdict for the non-moving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The burden is on the movant to make the initial showing of the absence of a genuine issue of material fact in dispute. *Celotex*, 477 U.S. at 323. The moving party is then entitled to summary judgment if the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's claim, and on which that party will bear the burden of proof at trial. *Id.* at 322. At the summary judgment stage, a judge may not make credibility determinations, as that is the function of a jury. *George v. Leavitt*, 407 F.3d 405, 413 (D.C. Cir.2005).

However, judicial review of final agency decisions under 42 U.S.C. § 1395 is conducted pursuant to the APA, 5 U.S.C. §§ 701-06. Therefore, the “standard set forth in Rule 56(c) does not apply.” Rather, “summary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.” *Hi Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 13, 28 (D.D.C. 2008) (citing *Richards v. INS*, 554 F.2d

1173, 1177 & n. 28 (D.C. Cir.1977), cited in *Bloch v. Powell*, 227 F.Supp.2d 25, 31 (D.D.C. 2002), *aff'd*, 348 F.3d 1060 (D.C. Cir. 2003)). In other words, “the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.” *Baystate Medical Center v. Leavitt*, 545 F. Supp. 2d 20, 34 (D.D.C. 2008) (citing *Occidental Eng’g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)).

IV. DISCUSSION

Plaintiff hospitals present three challenges to CMS’s rulemaking for FY 2007 and FY 2008: (1) whether the Secretary’s interpretation of § 4410, the statutory provision requiring the calculation of a budget-neutral rural floor adjustment exceeded her statutory authority; (2) whether the Secretary acted arbitrarily and capriciously by failing to give adequate notice of data used in the calculation of the rural floor adjustment; and (3) whether the Secretary acted arbitrarily and capriciously by failing to respond to significant comments concerning the calculation of the rural floor adjustment.

a. The Secretary Did Not Exceed Her Statutory Authority Because the Secretary’s Interpretation Is Reasonable

In order to determine if the CMS exceeded its statutory authority in violation of 5 U.S.C. § 706(2)(C), the Court must engage in the two-step inquiry required by *Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). When “Congress has directly spoken to the precise question at issue . . . , that is the end of the matter.” *Chevron*, 467 U.S. at 842-43.. When addressing this first step, the Court should employ the traditional tools of statutory interpretation, including the text of the statute, legislative history, the structure of the statute and its purpose. *Shays v. FEC*, 414 F.3d 76, 105 (D.C. Cir. 2005). However, if the Court determines that the statute is “silent or ambiguous with respect to

the specific issue, [the Court] will uphold the Secretary's interpretation so long as it is based on a permissible construction of the statute." *Anna Jaques Hospital v. Sebelius*, 583 F.3d 1, 4 (D.C. Cir. 2009). Under this second step, if Congress has explicitly delegated authority to the agency to supplement the statutory framework through appropriate regulations, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation" made by the agency. *Chevron*, 467 U.S. at 844. Finally, "in framing the scope of review, the court takes special note of the tremendous complexity of the Medicare statute. That complexity adds to the deference which is due to the Secretary's decision." *St. Michael's Medical Center v. Sebelius*, 648 F.Supp.2d 18, 26 (D.D.C. 2009) (quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994)).

For example, in *Universal Health Services v. Sullivan*, 770 F. Supp. 704 (D.D.C. 1991), aff'd, 978 F.2d 745 (table) (D.C. Cir. 1992), a hospital brought a challenge to regulations that allowed the Secretary to treat certain rural hospitals as urban hospitals for purposes of determining average standardized amounts and area wage indexes. The Secretary established principles for determining which rural hospitals qualified under the provision. Hospitals that were excluded challenged the Secretary's methodology. The court held that the Secretary's "promulgation of a proximity requirement in the regulation did not exceed his statutory authority nor did it contravene congressional intent." *Id.* at 716. The Court reasoned that Congress expressly gave the Secretary the authority to determine the standards to use and so long as the Secretary's standards were consistent with the statute, the Secretary did not exceed his authority. The court found the fact that "Congress has amended relevant provisions of the Act subsequent to the enactment of the

[regulation in question] and has not acted to overrule that requirement” to be relevant in its inquiry. *Id.* at 717. Specifically, the court stated that “where Congress has reenacted the statute without pertinent change . . . failing to revise or repeal the agency’s interpretation is persuasive evidence that the interpretation is the one intended by Congress.” *Id.* (citing *NLRB v. Bell Aerospace Co. Div. of Textron Inc.*, 416 U.S. 267, 275 (1974)).

The applicable statutory provision here is found in the Balanced Budget Act of 1997 § 4410, which states that the “Secretary . . . shall adjust the area wage index . . . in a manner which assures that the aggregate payments made under [the PPS] in a fiscal year for the operating costs of inpatient hospital services are not greater or less than those which would have been made in the year if this section did not apply.” However, the statute does not specifically direct the Secretary how to accomplish this task. Consequently, through Congress’s silence, it has delegated these decisions to the Secretary. *See Methodist Hosp. v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994). Under the statute, the Secretary has the discretion to apply the rural floor adjustment, so long as the agency accomplishes the goal set forth in the statute, namely that the costs of services are “not greater or less than those which would have been made” had the section not applied.

Having concluded that the statute does not specifically address the precise question at issue, the Court must consider whether the Secretary’s interpretation of the rural floor adjustment is reasonable and, if so, must defer to that interpretation. The Secretary asserts her interpretation of the statute is permissible. Specifically, the Secretary argues:

The statute does not say ‘if this section had never been enacted’ or ‘if this section had never been applied in the current or in prior years.’ Because the section addresses a calculation that is performed every year, the only plausible reading of the phrase ‘if this section did not apply’ is that it refers to the application of subsection (a) in the year in question. Moreover, even if the statutory language were deemed ambiguous, plaintiffs offer no justification that would compel the Court to substitute their interpretation for that of the Secretary.

Reply Memo. in Support of Def.’s Cross-Mot. for Summ. J. The Court finds it reasonable to interpret the provision to require that aggregate payments in the fiscal year not be greater or less than those that would have been made in the fiscal year without such adjustment. *See* 55 Fed. Reg. at 36075. Therefore, the statute “clearly contemplates looking to the year in which the new relative weights and wage index will be effective, rather than to the prior year, when establishing budget neutrality.” *Id.*

Nothing in the language of the statute requires the Secretary to recalculate the budget neutrality factors for prior years. The statute only requires the Secretary to ensure budget neutrality in the “fiscal year” for which the adjustment is applicable. The Court agrees with the Secretary that her conclusion in the FY 2008 Final Rule that past errors would not be revisited constitutes a reasonable rejection of plaintiff’s assertions. *See Southeast Alabama Medical Center v. Sebelius*, 572 F.3d 912, 920 (D.C. Cir. 2009).

Further, the fact that the Secretary has interpreted the rural floor provision in a similar manner since 1998 without disapproval from Congress is persuasive evidence that the methodology is not contrary to congressional intent. *See Universal Health Services*, 770 F. Supp. at 717. *But see Southeast Alabama Medical Center*, 572 F.3d at 920 (including postage costs as a “wage-related” cost is not reasonable even though it was consistent with past practice).

Plaintiffs suggest that because the Secretary chose to alter her methodology in FY 2008, it is some sort of concession that the earlier calculations were incorrect. However, it is well established that an agency may depart from prior policy provided the departure is explicitly and rationally explained. *Atchison, Topeka & Santa Fe Railway Co. v. Wichita Board of Trade*, 412 U.S. 800, 808 (1973) (plurality opinion). As the Supreme Court explained in *Chevron*:

An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis. Moreover, the fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.

Chevron, 467 U.S. at 863-64. See *Smiley v. Citibank (South Dakota) N.A.*, 517 U.S. 735, 742 (“ . . . [the] whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency.”) See also *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm*, 463 U.S. 29, 42 (1983) (“[T]here is no more reason to presume that changing circumstances require the rescission of prior action, instead of a revision in or even the extension of current regulation”). Given the Secretary’s interpretation of the relevant statute is reasonable, she is entitled to deference because it is based on a permissible construction of the statute text.

b. The Secretary Violated the APA’s Procedural Requirements With Respect to the FY 2007 Rulemaking But Not With Respect to FY 2008 Rulemaking

Courts reviewing agency actions under 5 U.S.C. § 706 must “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). In

assessing agency action against this standard, the Court need not find that the agency's decision is "the only reasonable one, or even that it is the result [the Court] would have reached had the question arisen in the first instance in judicial proceedings." *Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 422 (1983). The Court is also not entitled to substitute its judgment for that of the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). When reviewing the record, the Court considers "whether the agency has considered the relevant factors and articulated a rational connection between the facts found and the choice made." *Jifry v. FAA*, 370 F.3d 1174, 1180 (D.C.Cir.2004); *see also Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Therefore, if the "agency's reasons and policy choices . . . conform to certain minimal standards of rationality . . . the rule is reasonable and must be upheld." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 521 (D.C. Cir. 1983). Or in other words, an agency's rule will be found arbitrary and capricious "if the agency has 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 difference in view of the product of agency expertise." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

i. The Secretary Gave Adequate Notice of Data Used in Both 2007 and 2008

The court does not find the Secretary's notice of data used in FY 2007 and FY 2008 to be arbitrary and capricious. The APA requires an agency engaged in informal rulemaking to publish a notice of proposed rule-making in the Federal Register that includes the terms or substance of the proposed rule in order to allow members of the

public to “communicate information, concerns, and criticisms to the agency during the rule-making process.” *Conn. Light and Power Co. v. NRC*, 673 F.2d 525, 530 (D.C. Cir. 1982). The statute itself provides that an agency must include “either the terms of substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3). If the notice fails to give the public adequate information on which to base their comments, the interested parties will be unable to participate meaningfully in this vital exchange between the agency and the public. “To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport.” *Conn. Light and Power Co.*, 673 F.2d at 530.

Under APA notice and comment requirements, “[a]mong the information that must be revealed for public evaluation are the technical studies and data upon which the agency relies [in its rulemaking].” *American Radio Relay League v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (citing *Chamber of Commerce v. SEC*, 443 F.3d 890, 899 (D.C. Cir. 2006)). The purpose of enforcing the APA’s notice and comment requirements ensures that an agency does not fail to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary so that a genuine interchange occurs . . .” *American Radio Relay League*, 524 F.3d at 236-37.

Here, the FY 2007 Proposed Rule indicated that CMS had “include[d] the effects of the [the rural floor] in [its] calculation of the proposed wage update budget neutrality factor.” 71 Fed. Reg. at 24149. That factor was calculated by using data from prior years to simulate payments and compare aggregate payments using the following year. The agency also noted that this was the “same methodology” that was used in prior years. The

Court agrees with the Secretary that this description satisfies the APA's notice requirement because it adequately explains the nature of the calculations. In fact, plaintiffs were able to inquire further about the calculations which are the basis of this complaint because CMS provided notice of how to obtain the data used in the Proposed Rule. 71 Red. Reg. at 24137-39 (describing available data and procedure for obtaining data sets).

Plaintiffs rely heavily on *American Radio Relay League v. FCC*, 524 F.3d 227 (D.C. Cir. 2008). In *American Radio Relay League*, the D.C. Circuit held that the FCC violated the APA's notice requirements because it redacted portions of five scientific studies consisting of empirical data, on which the FCC relied on its proposed rules regulating radio frequencies. *Id.* at 236-37. The court held that by failing to disclose the redacted portions of the studies, the agency was in essence, "cherry-pick[ing]" studies on which it had chose to rely in part. The court concluded that the plaintiffs had met their burden "to demonstrate prejudice by showing that it has something useful to say regarding the unredacted studies that may allow it to mount a credible challenge if given the opportunity to comment." *Id.* at 237-38 (citation omitted). Of particular importance, the court found that some of the redacted portions of the studies dealt directly with "new information" that appeared to contain information in tension with the agency's conclusions." *Id.* at 238. Specifically, the redacted portions of the studies had the potential of revealing "the limitations of [the agency's] own data and that its conclusions may reveal methodology or illuminate strengths and weaknesses of certain data or the study as a whole." *Id.*

Unlike *American Radio Relay League*, there is no allegation here that CMS failed to disclose technical studies on which the agency was basing policy decisions. To the contrary, the agency had been employing the methodology for years prior. Plaintiffs contend that the Secretary's failure to disclose data used to calculate the rural budget adjustment left them "in the dark as to how the Secretary performed the rural floor adjustment calculations." Mot. for Summ. J. at 30. However, the Secretary disclosed how interested parties could obtain this data in the Federal Register. Therefore, the plaintiff hospitals have failed to meet their burden "to demonstrate prejudice by showing that [they] have something useful to say" regarding the data relied upon by CMS, unavailable to them, that may allow them to "mount a credible challenge" if given the opportunity to comment. *American Radio Relay League*, 524 F.3d at 237-38 (citing *Chamber of Commerce v. SEC*, 443 F.3d at 905).

Further, the plaintiff hospitals present a commonsense conundrum. While they assert the Secretary failed to give adequate information and data to calculate the rural floor adjustment, their own consultant was able to calculate the floor budget using the Secretary's data. According to the plaintiffs, their consultant identified what he perceived to be a fault in CMS's calculations and identified the potential flaw to the agency. The plaintiffs' actions in themselves presents evidence that the Secretary gave adequate notice in both FY 2007 and FY 2008. Otherwise, the plaintiffs would have been unable to comment in the first place.

ii. The Secretary Failed to Adequately Respond to Comments submitted in FY 2007 Rulemaking Process

The purpose of the rulemaking process is to ensure that an agency examines "relevant data and articulate[s] 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. The duty to respond to comments on a proposed rule is based within the agency’s duties under the APA to provide a statement of the basis and purpose of rule itself. *Alabama Power Co. v. Costle*, 636 F.2d 323, 384 (D.C. Cir. 1979) (“[T]he duty to respond to significant comments finds a statutory basis in required notice and comment procedures, for the ‘opportunity to comment is meaningless unless the agency responds to significant points raised by the public.’”) (quoting *Home Box Office v. FCC*, 567 F.2d 9, 35-36 9D.C. Cir. 1977)); *see also Independent U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 853 (D.C. Cir. 1987) (Secretary’s statement of basis and purpose fails to give an adequate account of how the [regulation] serves [the statute’s] objectives and why alternative measures were rejected in light of them.”); *Rodway v. U.S. Dep’t of Agriculture*, 514 F.2d 809, 817 (D.C. Cir. 1975) (APA’s required statement of basis and purpose meant to require agencies to “respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how that resolution led the agency to the ultimate rule”).

The Secretary claims that “there is no indication in the rulemaking record that any public comments regarding [the rural floor’ adjustment were properly submitted.” As a result of this assertion, the Secretary claims “[t]here were therefore no comments to which the Secretary could have responded on this issue in the FY 2007 Final Rule.” Having already concluded that the Secretary improperly omitted the formal written comment submitted by Mr. Giovanis, it is clear this argument lacks merit. The Secretary received comments, pursuant to the agency’s instructions in the Federal Register, on June 9, 2006, several days before the deadline for comments to be submitted pursuant to 71

Fed. Reg. 23996. The Final Rule did not acknowledge Mr. Giovanis' comment. Therefore, while the Secretary did address plaintiffs' formal comments in FY 2008, CMS failed to address plaintiffs' comments from 2007 in any way.

iii. The Secretary Adequately Responded to Comments submitted in FY 2008 Rulemaking Process

In regard to the FY 2008 rulemaking process, plaintiffs contend that the Secretary failed to adequately respond to comments about the rural floor adjustment. However, "an agency is free to change its mind so long as it supplies 'a reasoned analysis.'" *Nat'l Cable & Telecomms. Ass'n v. FCC*, 567 F.3d 659, 667 (D.C. Cir. 2009) (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 57). Explanation of a change in policy is not subject to a heightened standard of review by the Court. *Anna Jaques Hospital*, 583 F.3d at 6. The agency directly responded to the comments submitted regarding the rural floor adjustment by directly changing the methodology of the way the adjustment is calculated. The FY 2008 Proposed Rule describes CMS's proposed new methodology in Section III.G.4. 72 Fed. Reg. at 24787-88. Specifically, the agency noted that some ambiguity exists regarding whether the rural floor adjustment should be applied to only hospitals to which the adjustment did not apply or to all hospitals. *Id.* at 24787. The FY 2008 Proposed Rule then explains CMS's assessment that "a uniform budget neutrality factor . . . applied to all hospitals' wage indices" would be in compliance with the statute. *Id.* at 24788. As described by the Secretary in her cross-motion for summary judgment:

CMS noted that this approach differed from that of previous years . . . but because the wage index would ultimately be multiplied by the labor-related share of the standardized amount to obtain final rates in any case, the result would be substantially the same There would be a slight difference in the distribution of the adjustment due to the fact that the labor-related share for hospitals with wage indexes greater than 1.0 is 69.7%, a higher percentage than the 62% labor-related share that currently

applies to hospitals with wage indexes lower than 1.0. Finally, CMS explained that it would calculate the adjustment by comparing simulated [PPS] payments using FY 2006 discharge data and FY 2008 wage indexes without the rural floor to simulated payments “using the same data with a rural floor.

Cross-Mot. for Summ. J. at 27 (paraphrasing 72 Fed. Reg. 24792). The Court finds this description an adequate response to comments concerning the revised rural floor adjustment methodology.

As stated in *Universal Health Services*, “although a better method may exist by which to reclassify hospitals – or, more to the point, a method may exist which does not deny reclassification to [plaintiff] – the law requires only that the Secretary’s guideline be reasonable as applied over the entire population of hospitals.” *Universal Health Services*, 770 F.Supp at 718. Similar to *Universal Health Services*, while methods exist that would benefit plaintiffs, this alone does not render the Secretary’s methodology unreasonable. “The Court will not strike down this otherwise reasonable guideline because it, unfortunately, disadvantages one provider of services.” *Id.*

c. Even Though the Secretary Failed to Adequately Respond to Comments Submitted During FY 2007 Rulemaking, This Failure is Harmless Because the Error is Now Moot

While generally the proper remedy for the Court is to remand the case to the Secretary for further proceedings consistent with the Court’s opinion, in this case any injury done by the Secretary’s failure to respond to FY 2007 comments is harmless. Even though the Secretary failed to adequately consider plaintiffs’ comments during the FY 2007 rulemaking period, the plaintiffs’ challenge is moot because the Secretary already reversed the FY 2007 adjustment in the FY 2008 final rule. In the FY 2008 Final Rule, a one-time adjustment of 1.002214 reversed the effect of the FY 2007 adjustment. 72 Fed.

Reg. at 47241 (indicating that the one-time adjustment “removed the effect of the budget neutrality adjustment applied in FY 2007 to the standardized amount for application of the rural floor”). Since this element of relief for any procedural error from FY 2007 has already been corrected by the agency, the plaintiffs’ claim with respect to this relief is now moot. *See McBryde v. Committee to Review Circuit Council Conduct*, 264 F.3d 52, 55 (D.C. Cir. 2001) (“[I]f events outrun the controversy such that the court can grant no meaningful relief, the case must be dismissed as moot”). “This requirement applies independently to each form of relief sought . . . and ‘subsists through all stages of federal judicial proceedings.’” *Id.* (citing *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990)).

This Circuit has made clear that setting aside a final rule is not required when the error found by the court is a procedural violation. *See Penobscot Indian Nation v. U.S. Department of Housing & Urban Dev.*, 539 F. Supp. 2d 40, 54 (D.D.C. 2008) (citing *Advocates for Highway & Auto Safety v. FMCSA*, 429 F.3d 1136, 1151 (D.C. Cir. 2005)). While “unsupported agency action normally warrants vacatur, *Ill. Pub. Telecomm. Ass’n v. FCC*, 123 F.3d 693, 693 (D.C.Cir.1997), the court is not without discretion. ‘The decision whether to vacate depends on the seriousness of the order’s deficiency . . . and the disruptive consequences of an interim change that may itself be changed.’” *Advocates for Highway and Auto Safety*, 429 F.3d at 1151 (citing *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm’n*, 988 F.2d 146, 150-51 (D.C. Cir.1993) (internal quotations omitted)).

Thus, even if plaintiffs are correct that the FY 2007 calculation failed to comply with the statutory provision, the alleged flaw was reversed in FY 2008 and has no further

impact on PPS rates. Plaintiffs' argument that this one-time adjustment is insufficient goes back to their assertion that the Secretary's interpretation of the rural floor adjustment in prior years was unreasonable, which the Court has already held was permissible.

V. Conclusion

Accordingly, for the reasons stated, the Court GRANTS in part and DENIES in part defendant's motion to strike. Additionally, for the reasons stated, the Court GRANTS the defendant's cross-motion for summary judgment. Accordingly, the plaintiffs' motion for summary judgment is DENIED. An appropriate Order accompanies this Memorandum Opinion.

/s/ Royce C. Lamberth

December 21, 2009