

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

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

Plaintiffs,

v.

SYLVIA M. BURWELL, Secretary,  
Department of Health and Human Services,

Defendant.

**Civil Action No. 10-01638 (CKK)**

**MEMORANDUM OPINION**

(July 7, 2014)

Plaintiffs are twenty-nine organizations that own or operate hospitals participating in the Medicare program. They have sued the Secretary of the Department of Health and Human Services (the “Secretary”), challenging certain regulatory actions taken by her in the course of administering Medicare’s reimbursement scheme.<sup>1</sup> Plaintiffs allege that as a result of the Secretary’s flawed promulgation and implementation of various payment regulations, they were deprived of more than \$350 million dollars in Medicare “outlier” payments for services provided during fiscal years ending 1998 through 2006. Presently before the Court is Plaintiffs’ [108] Motion for Leave to Further Amend and Supplement First Amended Complaint. Plaintiffs seek to add allegations and claims under 5 U.S.C. § 553 regarding the Secretary’s failure to disclose a 2003 Interim Final Rule. Upon a review of the parties’ submissions<sup>2</sup>, the applicable authorities,

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<sup>1</sup> Pursuant to Fed. R. Civ. P. 25(d), Sylvia Mathews Burwell has been automatically substituted for Kathleen Sebelius, whom the parties’ pleadings name as Defendant.

<sup>2</sup> Pls.’ Mot. for Leave to Further Amend and Supplement First Am. Compl., ECF No. [108] (“Pls.’ Mot.”); Pls.’ Mem. of P. & A. in Supp. of Pls.’ Mot. for Leave to Further Amend and Supplement First Am. Compl., ECF No. [108] (“Pls.’ Mem.”); Pls.’ Amendments and

and the record as a whole, the Court shall **GRANT IN PART** and **DENY IN PART** Plaintiffs' motion to amend the complaint. The Court denies Plaintiffs leave to amend their complaint to include claims that the Secretary's failure to disclose the Interim Final Rule and its contents violated 5 U.S.C. § 553. However, the Court grants Plaintiffs leave to amend their complaint to include factual allegations concerning the Interim Final Rule.

## **I. BACKGROUND**

The relevant statutory and regulatory background underlying Plaintiffs' claims and the lengthy procedural history of this litigation are set out in detail in the Court's prior opinions. *See Banner Health v. Sebelius*, 797 F. Supp. 2d 97 (D.D.C. 2011); *id.*, 905 F.Supp.2d 174 (D.D.C. 2012); *id.*, 945 F.Supp.2d 1 (D.D.C. 2013). Accordingly, the Court provides herein only a brief summary of the facts and history of this case, as relevant to the present motion.

Plaintiffs are twenty-nine organizations that own or operate hospitals participating in the Medicare program. Am. Compl., ECF No. [16], ¶ 22. On December 23, 2010, Plaintiffs filed their Amended Complaint, which remains the operative iteration of the Complaint in this action. *See* Am. Compl., ECF No. [16]. As this Court has previously observed, Plaintiffs' Amended Complaint is "sprawling"; it contains over two hundred paragraphs, spans fifty-nine pages, and appends two lengthy exhibits. Plaintiffs challenge the validity of a series of regulations establishing the methodology for calculating outlier payments (the "Outlier Payment Regulations"), 42 C.F.R. §§ 412.80-412.86, as well as the Secretary's annual promulgation of the

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Supplements to First Am. Compl., ECF No. [108-1] ("Pls.' Proposed Amendments"); Def.'s Mem. of P. & A. in Opp'n to Pls.' Mot. for Leave to Amend. Compl., ECF No. [109] ("Def.'s Opp'n"); Pls.' Reply to Def.'s Opp'n Regarding Leave to Amend the Compl., ECF No. [110] ("Pls.' Reply"); Pls.' Notice of Suppl. Auth., ECF No. [112] ("Pls.' Notice"); Def.'s Resp. to Pls.' Notice of Suppl. Auth., ECF No. [113] ("Def.'s Notice Resp.").

regulations through which she set the fixed loss threshold for the upcoming fiscal year, for fiscal years 1998 through 2006 (the “Fixed Loss Threshold Regulations”).<sup>3</sup>

In enacting a system for Medicare reimbursement, “Congress recognized that health-care providers would inevitably care for some patients whose hospitalization would be extraordinarily costly or lengthy” and devised a means to “insulate hospitals from bearing a disproportionate share of these atypical costs.” *Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1009 (D.C. Cir. 1999). Specifically, Congress authorized the Secretary to make supplemental “outlier” payments to eligible providers. *Id.* Outlier payments are governed by 42 U.S.C. § 1395ww(d)(5)(A). *See also* 42 C.F.R. §§ 412.80-412.86 (implementing regulations). Each fiscal year, the Secretary determines a fixed dollar amount that, when added to the DRG prospective payment – the standardized calculation for how much a hospital is paid for treating a particular case – serves as the cutoff point triggering eligibility for outlier payments. *See* 42 U.S.C. § 1395ww(d)(5)(A)(ii), (iv); 42 C.F.R. § 412.80(a)(2)-(3). This fixed dollar amount is known as the “fixed loss threshold.” If a hospital’s approximate costs actually incurred in treating a patient exceed the sum of the DRG prospective payment rate and the fixed loss threshold, then the hospital is

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<sup>3</sup> *See* MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1998 RATES, 62 Fed. Reg. 45,966 (Aug. 29, 1997); MEDICARE PROGRAM; CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1999 RATES, 63 Fed. Reg. 40,954 (July 31, 1998); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2000 RATES, 64 Fed. Reg. 41,490 (July 30, 1999); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2001 RATES, 65 Fed. Reg. 47,054 (Aug. 1, 2000); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND RATES AND COSTS OF GRADUATE MEDICAL EDUCATION: FISCAL YEAR 2002 RATES, 66 Fed. Reg. 39,828 (Aug. 1, 2001); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2003 RATES, 67 Fed. Reg. 49,982 (Aug. 1, 2002); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2004 RATES, 68 Fed. Reg. 45,346 (Aug. 1, 2003); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2005 RATES, 69 Fed. Reg. 48,916 (Aug. 11, 2004); CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2006 RATES, 70 Fed. Reg. 47,278 (Aug. 12, 2005).

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

As noted, the Secretary “establish[es] the fixed [loss] thresholds beyond which hospitals will qualify for outlier payments” at the start of each fiscal year. *Cnty. of Los Angeles*, 192 F.3d at 1009. In each of the fiscal years at issue in this action, the Secretary set fixed loss thresholds at a level so that the anticipated total of outlier payments would equal 5.1% of the anticipated total of payments based on DRG prospective payment rates. Similarly, the amount of the outlier payment is “determined by the Secretary” and must “approximate the marginal cost of care” beyond the fixed loss threshold. 42 U.S.C. § 1395ww(d)(5)(A)(iii). During the time period relevant to this action, the implementing regulations generally provided for outlier payments equal to eighty percent of the difference between the hospital’s estimated operating and capital costs and the fixed loss threshold. *See* 42 C.F.R. § 412.84(k).

In this litigation, Plaintiffs claim that the Outlier Payment Regulations, in the form they existed prior to 2003,<sup>4</sup> contained “vulnerabilities” that made them “uniquely susceptible to manipulation” by unscrupulous hospitals. *Am. Compl.* ¶¶ 52-98, 138. According to Plaintiffs,

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<sup>4</sup> The Outlier Payment Regulations were first enacted in 1985 and have been revisited periodically over the years, most notably in 1988 and 2003. *See* MEDICARE PROGRAM; CHANGES TO IMPLEMENT THE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1989 RATES, 53 Fed. Reg. 38,476 (Sept. 30, 1988); MEDICARE PROGRAM; CHANGE IN METHODOLOGY FOR DETERMINING PAYMENT FOR EXTRAORDINARILY HIGH-COST CASES (COST OUTLIERS), 68 Fed. Reg. 34,494 (June 9, 2003). Plaintiffs’ allegations are directed principally towards the regulations in the form in which they were enacted in 1988. *See, e.g., Am. Compl.* ¶¶ 75-85, 98, 107-10.

these “vulnerabilities” in the Outlier Payment Regulations allowed unscrupulous hospitals to submit excessive reimbursement claims, “led to massive overpayments” to the wrong hospitals, prompted the Secretary to raise the fixed loss threshold at the beginning of each fiscal year as a misguided countermeasure, and ended with Plaintiffs being denied the outlier payments “to which they were entitled.” *Id.* ¶ 55.

Regarding the Fixed Loss Threshold Regulations, Plaintiffs contend that the Secretary, faced with an “aberrantly high” level of projected outlier payments caused by a flood of excessive reimbursement claims, made no attempt to diagnose the actual source of the problem but instead, as a misguided countermeasure, made “enormous, unprecedented and irrational increases” in the fixed loss threshold for the fiscal years at issue in this action, and did so without providing an adequate, reasoned explanation for the increases. *See id.* ¶¶ 14, 69, 112, 114, 119, 121, 125-26, 129-38, 147-48, 155-61. Plaintiffs contend that the Secretary’s failure to account for flaws in the Fixed Loss Threshold Regulations led to an irrational increase in the fixed loss thresholds for fiscal years 1998 through 2006, which allegedly had the ultimate effect of reducing the number of Plaintiffs’ cases that qualified for outlier payments and the amount of payments for those cases that did qualify. *Id.* ¶ 50.

Accordingly, Plaintiffs challenge the promulgation and implementation of the following agency actions: three sets of Outlier Payment Regulations promulgated in 1988, 1994, and 2003; and eleven sets of Fixed Loss Threshold Regulations for federal fiscal years 1997 through 2007. In addition, Plaintiffs challenge outlier payment determinations specific to each of the hospital Plaintiffs.

On March 23, 2012, Plaintiffs filed a motion to compel, requesting that the Court order the Secretary to file the “complete administrative record,” by supplementing the records she had

previously filed with various documents, including certain data files, identified by Plaintiffs and all other documents that were before the agency in connection with its rulemakings, and further order the Secretary to certify to the Court and Plaintiffs the completeness of the administrative record. *See* Pls.’ Renewed Mot. to Compel Def. to File the Complete Admin. Record and to Certify Same, ECF No. [60]. On May 16, 2013, the Court granted-in-part and denied-in-part Plaintiffs’ motion to compel, and ordered the Secretary to supplement the administrative record in this matter with several categories of materials. *See Banner Health*, 945 F.Supp.2d 1; Order (May 16, 2013), ECF No. [82]. Among the materials the Court ordered added to the administrative record was a February 2003 draft interim final rule (“Interim Final Rule”). As discussed at length in the Court’s prior Memorandum Opinion, the Interim Final Rule was “exchanged between HHS and [the Office of Management and Budget (“OMB”)]<sup>[5]</sup> pursuant to Executive Order 12866, which requires HHS to submit major rulemakings to OMB for review” and which “also requires that, after the regulation becomes final, OMB must make available to the public all documents exchanged between it and the agency during the interagency review.” *Banner Health*, 945 F.Supp.2d at 24 (citing 58 Fed. Reg. 51735, Exec. Order No. 12866 § 6(b)(4)(D)). Plaintiffs learned of the Interim Final Rule in February 2012 in response to a Freedom of Information Act request to OMB. Pls.’ Mem. at 1. The document itself is a “sixty-page Interim Final Rule sent, over the signature of then HHS Secretary, Tommy G. Thompson, to OMB for review and approval in early 2003.” *Banner Health*, 945 F.Supp.2d at 24.

The Court explained the significance of the Interim Final Rule as follows:

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<sup>5</sup> OMB is tasked with carrying out coordinated review of agency rulemaking to ensure that regulations are consistent with applicable law, the priorities of the President, and the principles set forth in Executive Order 12866. *See* 58 Fed. Reg. 51735, Exec. Order No. 12866 § 2(b).

[O]f the many agency actions challenged in this case is the Secretary's promulgation and application, in 2003, of invalid amended Outlier Payment Regulations and Fixed Loss Threshold Regulations. Plaintiffs argue that, in the Federal Register sections related to the rulemakings challenged in this case, the Secretary has variously stated that (a) there were no critical flaws in its Outlier Payment Regulations – and then, in 2003, that there were three fatal flaws, (b) that the agency had always used the best available data – and then, in 2003, that other data, which had previously been available and was better, should be used, and (c) that it would not make retroactive corrections to outlier payments – and then, in 2003, that retroactive corrections would be made. Plaintiffs further contend that in mid-2003, while the agency was in the process of reversing its position on each of these points, the Secretary should have taken the opportunity to lower the fixed loss threshold to correct for what the agency openly acknowledged had been the improper distribution of outlier funds to “turbo charging” hospitals, but instead, in June of 2003, promulgated amended regulations which left the threshold at its previous level, \$33,560. As explanation, [the Centers for Medicare and Medicaid Services (“CMS”)]<sup>[6]</sup> stated that “in light of the relatively small difference between the current threshold and our revised estimate, and the limited amount of time remaining in the fiscal year, we have concluded it is more appropriate to maintain the threshold at \$ 33,560.” A.R. at 4408 (68 Fed. Reg. at 34506).

Plaintiffs contend that the Interim Rule, which was approved by Secretary Thompson on February 6, 2003 and submitted for OMB's review on February 12, 2003, tells a different story. Specifically, Plaintiffs explain that the Interim Final Rule contains HHS's conclusion, with supporting facts and analysis, that the public interest required it, mid-year, to lower its FY 2003 fixed loss threshold from \$33,560 to \$20,760 – in other words, that the threshold was approximately 62% higher than it should have been. Upon the Court's own review of the document, HHS does appear to have proposed to OMB a reduction of the outlier threshold to \$20,760, to be effective as of the date of publication of the interim rule. Further, HHS acknowledged that the prior increase in the threshold was due to relatively few hospitals with extraordinary rates of increase in their charges, causing many truly high-cost cases not to qualify for outlier payments; HHS therefore proposed that the Interim Final Rule reducing the threshold be implemented without prior notice and comment procedures, so as not to extend the duration of these payment inequities.

Plaintiffs observe, however, that the Secretary's proposed rule, issued on February 28, 2003 – just over two weeks after HHS submitted the Interim Final Rule to OMB – makes no mention of the data and analysis stated in the Interim Final Rule. ... [See] [ ] A.R. at 4386-4395 (68 Fed. Reg. at 10420-10429).<sup>[7]</sup> Therefore, Plaintiffs argue, inclusion of the Interim Final Rule in the administrative record is necessary to show significant alternatives, facts, other

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<sup>6</sup> The Medicare program is administered by the Secretary through CMS.

<sup>7</sup> The proposed rule was issued by HHS for publication on February 28, 2003, and subsequently published on March 5, 2003. See A.R. at 4395 (68 Fed. Reg. at 10429).

data and analyses that HHS considered in the rulemaking process, but that were directly contrary to its published regulations which maintained the threshold at \$33,650. Plaintiffs also argue that this document goes to the heart of establishing the Secretary's promulgation of and continued application of invalid Fixed Loss Threshold Regulations as arbitrary and capricious, because it demonstrates that the agency knew that lowering the threshold would correct the problems engendered by its earlier regulations and believed it was obligated to do so immediately, but did not.

*Id.* at 25-26 (internal citations to the parties' pleadings omitted).

In view of the foregoing, the Court found that Plaintiffs had "made a sufficient showing that 'unusual circumstances' warrant supplementation of the administrative record – namely, that 'the agency deliberately or negligently excluded documents that may have been adverse to its decision.'" *Id.* at 26 (citing *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010)). On July 30, 2013, the Court denied the Secretary's motion for reconsideration of the decision to require inclusion of the Interim Final Rule in the administrative record. *See* Order (July 30, 2013), ECF No. [96]. The Secretary filed the administrative record in this action on July 31, 2013.

After the Court resolved issues relating to the completeness of the administrative record, this case moved to the scheduling of summary judgment briefing. Subsequently, however, the Secretary sought leave to file an additional motion to dismiss for lack of subject matter jurisdiction. *See* Def.'s Mot. for Leave to File Mot. to Dismiss for Lack of Subject Matter Jurisdiction, ECF No. [99]. The Court granted the Secretary's request, but ordered that the Secretary file this motion "simultaneously with, and in the alternative to, Defendant's cross-motion for summary judgment." Order (Aug. 13, 2013), ECF No. [102] at 1. The Court set a deadline of October 25, 2013 for the parties' initial summary judgment briefs and directed the parties to file a joint status report by October 4, 2013 "(a) outlining in bullet-point format the arguments the parties intend to raise in support of or in opposition to summary judgment; and (b)



indicating the extent to which there is a need to expand the page limits placed on memoranda of points and authorities by the Local Rules of this Court.” *Id.* at 4. In this subsequently filed Joint Status Report<sup>8</sup>, Plaintiffs indicated, for the first time, their intention to file a Motion for Leave to Further Amend and Supplement the First Amended Complaint in light of the addition of the Interim Final Rule to the administrative record. *See* Joint Status Report and Mot. to Reset Briefing Schedule, ECF No. [107]. In light of this request, the Court delayed the scheduled summary judgment briefing pending resolution of Plaintiffs’ motion to amend. *See* Minute Order (Oct. 22, 2013). Plaintiffs subsequently filed their Motion for Leave to Further Amend and Supplement First Amended Complaint. Defendant filed an Opposition, and Plaintiffs filed a Reply. Accordingly, the motion is now ripe for review.

## **II. LEGAL STANDARD**

Under the Federal Rules of Civil Procedure, a party may amend its pleadings once as a matter of course within a prescribed time period. *See* Fed. R. Civ. P. 15(a)(1). Where, as here, a party seeks to amend its pleadings outside that time period, it may do so only with the opposing party’s written consent or the district court’s leave. *See* Fed. R. Civ. P. 15(a)(2). The decision whether to grant leave to amend a complaint is entrusted to the sound discretion of the district court, but leave “should be freely given unless there is a good reason, such as futility, to the contrary.” *Willoughby v. Potomac Elec. Power Co.*, 100 F.3d 999, 1003 (D.C. Cir. 1996), *cert. denied*, 520 U.S. 1197 (1997). As the Supreme Court has observed:

If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure

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<sup>8</sup> In light of the lapse of appropriations for the Department of Justice from October 1, 2013 through October 16, 2013, the deadline for this joint status report was subsequently extended to October 21, 2013. *See* Minute Order (Oct. 18, 2013).

deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should, as the rules require, be “freely given.”

*Foman v. Davis*, 371 U.S. 178, 182 (1962). “[A] district court has discretion to deny a motion to amend on grounds of futility where the proposed pleading would not survive a motion to dismiss.” *Nat’l Wrestling Coaches Ass’n v. Dep’t of Educ.*, 366 F.3d 930, 945 (D.C. Cir. 2004), *cert. denied*, 545 U.S. 1104 (2005). Review for futility is practically “identical to review of a Rule 12(b)(6) dismissal based on the allegations in the amended complaint.” *In re Interbank Funding Corp. Secs. Litig.*, 629 F.3d 213, 215-16 (D.C. Cir. 2010) (quotation marks omitted). Because leave to amend should be liberally granted, the party opposing amendment bears the burden of coming forward with a colorable basis for denying leave to amend. *Abdullah v. Washington*, 530 F.Supp.2d 112, 115 (D.D.C. 2008).<sup>9</sup>

### III. DISCUSSION

Plaintiffs’ proposed motion to amend consists of two components. First, Plaintiffs seek to add claims under 5 U.S.C. § 553 that “the Secretary did not allow for meaningful public comment when she failed to disclose data, analysis and conclusions which had been set forth in the Interim Final Rule, and were adverse to the determinations the Secretary later proposed and

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<sup>9</sup> Plaintiffs argue that the Court should also apply Rule 15(d), under which “the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented.” Fed. R. Civ. P. 15(d). Plaintiffs argue Rule 15(d) is applicable here because they are seeking to add allegations concerning when they became aware of the Interim Final Rule, an event that occurred in February 2012, after the filing of the First Amended Complaint. Pls.’ Mem. at 2-3. Defendant, by contrast, argues Plaintiffs’ motion only implicates Rule 15(a) and that Rule 15(d) does not apply here “because the proposed amendments pertain to events before the filing of the action.” Def.’s Opp’n at 3 n.1. The Court need not resolve this dispute because, as both parties concede, “[c]ourts resolve Rule 15(d) motions under the same standard as they resolve motions to amend under Rule 15(a).” *Tereschuk v. Bureau of Prisons*, 851 F.Supp.2d 157, 162 n. 6 (D.D.C. 2012). *See also Wildearth Guardians v. Kempthorne*, 592 F.Supp.2d 18, 23 (D.D.C. 2008). Accordingly, whether considered under Rule 15(a) or Rule 15(d), the same standard governs Plaintiffs’ requests.

finalized in her subsequent published rulemakings relating to the Outlier Payment Regulations and the [Fixed Loss Threshold] Regulations in 2003 through 2007.” Pls.’ Proposed Amendments at 1. Second, Plaintiffs seek to add factual allegations relating to when they became aware of the Interim Final Rule. Pls.’ Mem. at 2. For the reasons discussed below, the Court concludes that the former proposed amendment is improper while the latter is appropriate.

#### **A. Proposed Additional Claims Under 5 U.S.C. § 553**

Defendant argues that Plaintiffs’ motion should be denied because the proposed additional claims under 5 U.S.C. § 553 are futile as contrary to D.C. Circuit precedent. Def.’s Opp’n at 8. The Court agrees that Plaintiffs’ claims are not appropriate under § 553, and for this reason, leave to amend the complaint to add these additional claims is denied.

In their proposed Amended Complaint, Plaintiffs state that by failing to disclose data, analysis, and conclusions which had been set forth in the Interim Final Rule which were adverse to the determinations the Secretary later proposed and finalized in her subsequent published rulemakings relating to the Outlier Payment Regulations and the [Fixed Loss Threshold] Regulations in 2003 through 2007, the Secretary violated 5 U.S.C. § 553 by preventing meaningful public comment on these rulemakings. Pls.’ Proposed Amendments at 1. The D.C. Circuit has long adhered to the principle that “[i]t is not consonant with the purpose of a rule-making procedure to promulgate rules on the basis of inadequate data, or on data that, [to a] critical degree, is known only to the agency.” *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375, 393 (D.C. Cir. 1973). Therefore, “an agency’s failure to disclose *critical* material, on which it relies, deprives commenters of a right under § 553 ‘to participate in rulemaking.’” *Allina*

*Health Svcs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) (quoting *Air Transp. Ass’n of Am. v. F.A.A.*, 169 F.3d 1, 7 (D.C. Cir. 1999)).<sup>10</sup>

The D.C. Circuit’s most recent comprehensive discussion of this doctrine came in *American Radio Relay League, Inc. v. Federal Communication Commission*, 524 F.3d 227 (D.C. Cir. 2008), where the panel concluded that the FCC “failed to satisfy the notice and comment requirements of [§ 553] by redacting studies on which it relied in promulgating the rule . . . .” In that case, the FCC placed five technical studies on which it had relied in promulgating the rule at issue into the rulemaking record, but only in redacted form. *Id.* at 237. The court found that these redactions violated § 553 and ordered the FCC, on remand, to “make available the unredacted ‘technical studies and data that it has employed in reaching [its] decisions.’” *Id.* at 240 (quoting *Conn. Light & Power Co. v. Nuclear Regulatory Comm’n*, 673 F.2d 525, 530 (D.C. Cir. 1982)). On this point, the panel found:

The Commission has chosen to rely on the data in those studies and to place the redacted studies in the rulemaking record. Individual pages relied upon by the

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<sup>10</sup> As Defendant notes, there is considerable debate as to whether this doctrine conflicts with the Supreme Court’s decision in *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519 (1978), which limited a court’s power to order additional procedures in rulemaking beyond those imposed by the Administrative Procedures Act. *See Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 245 (Kavanaugh, J., dissenting); *Allina Health Svcs.*, 746 F.3d at 1110 (noting “the possible tension between *Vermont Yankee* and our critical material doctrine”). *See also* Jack M. Beermann & Gary Lawson, *Reprocessing Vermont Yankee*, 75 GEO. WASH. L. REV. 856, 892 (2007); Richard L. Pierce, *Waiting for Vermont Yankee III, IV, and V?*, 75 GEO. WASH. L. REV. 902, 916 (2007). Yet to the extent Defendant argues that this debate renders Plaintiffs’ proposed claims futile, her argument must be rejected. The *Portland Cement* doctrine remains the prevailing law of this Circuit, and this Court is bound to follow it. Nevertheless, in light of this tension, the Court is reluctant to read the doctrine more broadly than the D.C. Circuit has in past cases. Indeed, even while upholding its continued application, the D.C. Circuit has emphasized the narrowness of this doctrine, perhaps out of a concern that a broader doctrine would more clearly run afoul of *Vermont Yankee*. *See Am. Radio Relay League, Inc.*, 524 F.3d at 239 (“The narrowness of our holding under section 553 of the APA is manifest.”); *Allina Health Svcs.*, 746 F.3d at 1110 (“Perhaps because of the possible tension between *Vermont Yankee* and our critical material doctrine, we have more carefully examined whether a failure to disclose such material actually harmed a petitioner.”).

Commission reveal that the unredacted portions are likely to contain evidence that could call into question the Commission's decision to promulgate the rule. Under the circumstances, the 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.

*Id.* at 239. The focal point of this analysis was the Commission's *reliance* on materials that were undisclosed, or that were disclosed only in part with redactions. Importantly, *American Radio Relay League* distinguished cases where the agency did not rely on the undisclosed materials, such as *EchoStar Satellite LLC v. Federal Communications Commission*, 457 F.3d 31, 40 (D.C. Cir. 2006), in which "the non-disclosed staff analysis represented 'merely . . . cogitations upon the evidence' that was part of the rulemaking record." *Am. Radio Relay League, Inc.*, 524 F.3d at 238. "By contrast, the challenged orders" in *American Radio Relay*, "were, according to the Commission, a central source of data for its critical determinations." *Id.* Moreover, the court concluded that its conclusions were "not inconsistent with the view that 'the *Portland Cement* doctrine should be limited to *studies on which the agency actually relies* to support its final rule.'" *Id.* at 240 (quoting 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 437 (4th ed. 2002)) (emphasis added in original). *See also* 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 584 (5th ed. 2010) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators. Thus, the *Portland Cement* doctrine should be limited to studies on which the agency actually relies to support its final rule.")

Here, according to Plaintiffs' proposed Amended Complaint, the relevant undisclosed material at the time of the rulemakings is the "data, analysis and conclusions which had been set forth in the Interim Final Rule [which] were adverse to the determinations the Secretary later proposed and finalized in her subsequent published rulemakings." Pls.' Proposed Amendments

at 1. The parties disagree in their present briefing as to whether the Secretary “relied” on this material in the challenged rulemakings, such that her failure to disclose these materials runs afoul of § 553 under the *Portland Cement* doctrine. Compare Pls.’ Reply at 1-2 with Def.’s Opp’n at 8. As support for the proposition that the Secretary relied on the Interim Final Rule and the supporting materials, Plaintiffs look to this Court’s decision to include the Interim Final Rule in the administrative record. Pls.’ Mem. at 3; Pls.’ Reply at 2. Plaintiffs cite the Court’s statement that “there can be little doubt that the Interim Final Rule reflects views adverse to those finally adopted by the Secretary and that the Secretary considered – and indeed proposed to OMB – the Interim Final Rule as an alternative in its path to promulgation of the 2003 amended Outlier Payment Regulations now challenged by Plaintiffs.” Pls.’ Mem. at 3 (quoting *Banner Health*, 945 F.Supp.2d at 27). Yet such language does not show that the Secretary *relied* on these materials. In fact, it shows the opposite – that the Secretary in all likelihood discounted these materials in issuing the Proposed Rule.

Plaintiffs attempt to bring this case within the ambit of *American Radio Relay League* by arguing in their Reply brief that the 2003 Proposed Rule reflects portions of the Interim Final Rule favorable to the agency, but excludes unfavorable portions, just as the FCC included favorable portions of studies in *American Relay* while redacting unfavorable portions. Pls.’ Reply at 1-2. Yet Plaintiffs’ prior briefing in this case, and the Court’s conclusions based on this briefing contradict this newfound argument. As noted in the Court’s prior Memorandum Opinion, Plaintiffs themselves have previously pointed out the sharp disconnect between the Interim Final Rule and the Proposed Rule. Indeed, the Court’s previous Memorandum Opinion includes the following language: “Plaintiffs observe, however, that the Secretary’s proposed rule, issued on February 28, 2003 – just over two weeks after HHS submitted the Interim Final Rule to

OMB – makes no mention of the data and analysis stated in the Interim Final Rule.” *Banner Health*, 945 F.Supp.2d at 25 (emphasis added). Plaintiffs’ instant attempt to argue a contrary position – that the Secretary cherry-picked data and analysis that was utilized in the Interim Final Rule – is unpersuasive.<sup>11</sup> Indeed, the position asserted in Plaintiffs’ Reply brief is similarly undercut by Plaintiffs’ proposed Amended Complaint. This proposed filing likewise contends that the Secretary did *not* rely on the Interim Final Rule and its supporting materials, and further undermines application of the *Portland Cement* doctrine here. On this point, Plaintiffs state:

In the published Proposed Rule, the Secretary made no mention of the IFR and did not include much of the data, methodological changes and analysis that the Secretary had included in the IFR relating to the agency’s conclusion that the fixed-loss outlier threshold should be recalculated and set immediately at \$20,760 (plus the additional payments referenced above in paragraph 198.5.b). Among other things, the Proposed Rule failed to mention the Secretary’s analysis quantifying the impact of hospitals identified as having “taken advantage of two vulnerabilities” in the Secretary’s regulations, the agency’s obligation to recalculate the fixed loss threshold, methodological changes the Secretary used for the recalculation, and the agency’s findings regarding the public interest. All of these topics were discussed in the IFR.

Pls.’ Proposed Amendments at 2. Consequently, despite their present briefing to the contrary, Plaintiffs’ proposed amendments and their previous statements in this case show that they are not alleging that the Secretary relied on these materials and failed to disclose them. Rather, they appear to contend that she improperly considered and then did not rely on these materials, and

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<sup>11</sup> Plaintiffs’ prior briefing includes additional language revealing the disconnect between the Interim Final Rule and the Proposed Final Rule. *See* Pls.’ Mem. of P. & A. in Supp. of Renewed Motion to Compel Def. to File the Complete Admin. Record and to Certify Same, ECF No. [60] at 16 (“In stark contrast, HHS’s published rulemaking . . . conspicuously lacks the foregoing data, other facts, analysis.”); *id.* at 17 (noting that exclusion of the Interim Final Rule “would only serve to conceal significant alternatives, facts, other data and analyses that HHS considered in the rulemaking process, but that were contrary to its published regulations.”); *id.* at 18 (arguing that “the data and other facts used, and analysis undertaken, by HHS in reaching its conclusions in the Interim Final Rule” “bear upon options that HHS considered, but did not disclose or address in the Federal Register, when the agency was revising the Outlier Payment Regulations.”)

that the contrary conclusions and information contained in the Interim Final Rule *undercut* the alternative conclusions set forth in the Proposed Rule. This is not the sort of undisclosed basis for a rule that triggers the *Portland Cement* doctrine. See 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 583-84 (5th ed. 2010). (“[A]ccess to the data that putatively *supports* a proposed rule is critical to the right to comment on the rule and, hence, is part of the notice required by § 553(b).”) (emphasis added). Instead these allegations more properly go to the question of whether the Secretary’s actions, taken in apparent disregard of contrary data and analysis, were arbitrary and capricious, and thus substantively invalid. *Id.* at 584-85 (noting that it is consistent with *Portland Cement* for “[a] reviewing court [to] require an agency to add to the rulemaking record documents in the agency’s possession that contradict the predicates for a rule . . . and then use those documents to support a holding that the rule is arbitrary and capricious.”). For this reason, this Court’s decision to include the Interim Final Rule in the administrative record – for purposes of assessing the substantive validity of the Secretary’s regulations – does not establish that the Secretary relied on these undisclosed materials. Compliance with § 553 is an issue distinct from the completeness of the administrative record.

Accordingly, because the Court concludes that Plaintiffs’ have failed to assert proper claims under 5 U.S.C. § 553 based on non-disclosure of the Interim Final Rule and the underlying data and analysis, Plaintiffs’ proposed amendment to add these claims is denied as futile.<sup>12</sup>

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<sup>12</sup> In light of the Court’s conclusion that Plaintiffs’ proposed § 553 claims fall outside of D.C. Circuit precedent, the Court does not reach the Secretary’s alternative argument for futility – that the Court lacks subject matter jurisdiction over the § 553 claims because they were not properly presented in administrative proceedings. See Def.’s Opp’n at 6-8. While the Supreme Court has held that a court should address jurisdictional questions such as Article III standing prior to addressing any question on the merits, see *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 101 (1998), that doctrine is inapplicable here, where Defendant’s jurisdictional argument is



## B. Proposed Additional Factual Allegations

Although the Court concludes that Plaintiffs' proposed additional claims are futile, this does not doom the entirety of Plaintiffs' motion. Defendant's futility arguments go only to the additional claims asserted by Plaintiffs and not to the additional factual allegations raised in the proposed Amended Complaint. Indeed, in making her futility argument, Defendant nowhere contends that these allegations themselves are futile as additional factual background for Plaintiffs' existing claims. Def.'s Opp'n at 6-8. Accordingly, in the absence of a futility argument, the Court looks to whether there are other reasons – such as prejudicial delay – to deny leave to add these additional allegations. For the reasons discussed below, the Court finds Plaintiffs' delay in seeking leave to add these allegations, although lengthy, was not prejudicial or in bad faith. Therefore, the Court permits Plaintiffs to add these additional allegations as support for their existing claims.

“Only limited circumstances justify a district court's refusal to grant [ ] leave to amend: undue delay, bad faith on the part of the moving party, or undue prejudice to the opposing party.” *Sinclair v. Kleindienst*, 645 F.2d 1080, 1085 (D.C. Cir. 1981). Moreover, “[t]o warrant denial of leave to amend, any delay in seeking leave must be accompanied by a showing of bad faith or prejudice.” *Council on American-Islamic Relations Action Network, Inc. v. Gaubatz*, 891

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premised on a lack of statutory, rather than constitutional, jurisdiction. “*Steel Co.* requires that we prioritize the jurisdictional issue only when the existence of *Article III* jurisdiction is in doubt; that decision ‘explicitly recognized the propriety of addressing the merits where doing so made it possible to avoid a doubtful issue of *statutory* jurisdiction.’” *Chalabi v. Hashemite Kingdom of Jordan*, 543 F.3d 725, 728 (D.C. Cir. 2008) (quoting *Kramer v. Gates*, 481 F.3d 788, 791 (D.C. Cir. 2007)). Here, Defendant does not raise an issue of *Article III* jurisdiction in arguing for futility. Rather, the Secretary argues that this Court lacks *statutory* subject matter jurisdiction to rule on claims that may not have been properly channeled through the “expedited judicial review” process of 42 U.S.C. § 1395oo(f)(1), which allows for judicial review in the absence of prior exhaustion before the Medicare Provider Reimbursement Review Board. Def.'s Opp'n at 6-7. Accordingly, the Court may rule on alternative bases for futility without addressing Defendant's statutory jurisdiction argument.

F.Supp.2d 13, 33 (D.D.C. 2012) (citing *Caribbean Broad. Sys., Ltd. v. Cable & Wireless P.L.C.*, 148 F.3d 1080, 1084 (D.C. Cir. 1998)). Defendant, as the party opposing amendment, bears the burden of establishing bad faith or prejudice. *City of New York v. Group Health, Inc.*, 649 F.3d 151, 157 (2d Cir. 2011); *Abdullah*, 530 F.Supp.2d at 115.

Here, the Court finds that Defendant has not met her burden of showing that Plaintiffs' delay in adding these additional allegations is accompanied by bad faith or prejudice. Certainly, Defendant is correct that Plaintiffs have known about the Interim Final Rule since February 2012 and could have moved to add these additional factual allegations to support her claims far sooner. Def.'s Opp'n at 4. But Defendant points to no prejudice from the failure to add these allegations earlier. *See Estate of Gaither ex rel. Gaither v. Dist. of Columbia*, 272 F.R.D. 248, 252 (D.D.C. 2011) ("the mere passage of time does not preclude amendment – the delay must result in some prejudice to the judicial system or the opposing party."). Indeed, the Secretary's entire prejudice argument addresses the harm from allowing Plaintiffs to add new claims – rather than new factual allegations to existing claims – at this stage of the litigation. Def.'s Opp'n at 5-6. Yet the Court has already rejected the proposed additional claims as futile. In the absence of a new claim, Defendant does not provide any reason to believe that she would be prejudiced by allowing the addition of new factual allegations concerning the Interim Final Rule to Plaintiffs' existing claims. Nor can the Court discern any, as leave to add clarifying factual allegations to existing claims is typically freely given. *See Council on American-Islamic Relations Action Network, Inc.*, 793 F.Supp.2d at 324 ("Plaintiffs' factual allegations merely fine-tune the basis for the relief Plaintiffs seek in this action. Factual allegations of this kind, which clarify but do not reshape the action, are rarely a bad thing."). *See also Harrison v. Rubin*, 174 F.3d 249, 253 (D.C. Cir. 1999) (stating that technical corrections and clarifications of legal theories without a

showing of prejudice are not sufficient grounds for denying a motion). Here, these allegations merely explain the discovery and content of the Interim Final Rule, and provide additional basis for Plaintiffs' arguments that certain actions taken by the Secretary were substantively invalid. Pls.' Proposed Amendments at 1-2.

The Court is also unpersuaded by Defendant's accusations that Plaintiffs have acted in bad faith. Def.'s Opp'n at 5. Defendant contends that "[t]he most likely explanation for the plaintiffs' motion is that after seeing which of their claims survived the Court's July 2011 and November 2012 rulings and which did not, and then seeing which of their multifarious challenges to the administrative records succeeded and which did not, the plaintiffs decided to shift their bets in hopes of improving their overall chances in this litigation." *Id.* Again, this accusation goes mainly to Plaintiffs' proposal to add new claims, rather than new factual allegations to existing claims. Accordingly, it does not provide a basis to reject these supplemental allegations.

Therefore, although it denies Plaintiffs leave to add new claims pursuant to 5 U.S.C. § 553, the Court will grant Plaintiffs leave to add factual allegations concerning the Interim Final Rule. Accordingly, Plaintiffs may amend their complaint to include the allegations contained in sub-paragraphs 198.5(a)-(e) of their Proposed Amendments.<sup>13</sup> See Pls.' Proposed Amendments at 1-2. These allegations, though arguably untimely, are not accompanied by bad faith or prejudice.

#### IV. CONCLUSION

For all of the reasons stated herein, the Court **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' [108] Motion for Leave to Further Amend and Supplement First Amended

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<sup>13</sup> Plaintiffs may not add the heading paragraph 198.5, which contains the proposed claims under 5 U.S.C. § 553. Pls.' Proposed Amendments at 1.

Complaint. The Court denies Plaintiffs leave to amend their complaint to include claims that the Secretary's failure to disclose the Interim Final Rule and its contents violated 5 U.S.C. § 553. However, the Court grants Plaintiffs leave to amend their complaint to include factual allegations concerning the Interim Final Rule. An appropriate Order accompanies this Memorandum Opinion.

Date: July 7, 2014

/s/  
**COLLEEN KOLLAR-KOTELLY**  
United States District Judge