

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

_____)	
UNITEDHEALTHCARE INSURANCE)	
COMPANY, <i>et al.</i>,)	
)	
Plaintiffs,)	
)	
v.)	Civil Case No. 16-157 (RMC)
)	
ALEX M. AZAR II, in his official)	
capacity as Secretary of the)	
Department of Health and Human)	
Services, <i>et al.</i>,)	
)	
Defendants.)	
_____)	

**MEMORANDUM OPINION ON MOTION TO SUPPLEMENT THE
ADMINISTRATIVE RECORD**

The UnitedHealthCare Insurance Company challenges a formal rule issued by the Centers for Medicare and Medicaid Services (CMS). When CMS filed the administrative record, Plaintiffs protested the absence of two documents which had been released by CMS under the Freedom of Information Act in another matter. CMS contends that the two documents are not properly part of the administrative record for this rulemaking and that they are privileged by the deliberative process privilege. The Court concludes that the documents, as redacted upon release, are no longer privileged and should be made part of the record here.

I. BACKGROUND

Plaintiffs in this case are Medicare Advantage organizations in the UnitedHealth Group family of companies, the nation’s leading provider of Medicare Advantage health benefits plans (United). Under the Medicare Advantage program (MA), also known as Medicare Part C, private insurance companies provide Medicare insurance coverage to eligible individuals and are

reimbursed by CMS on a pre-set, per-member-per-month basis, pegged to a dollar value for health care attributed to each diagnostic code submitted by medical providers, and adjusted based on demographic data. CMS undertakes various efforts to review and audit these reimbursements to ensure their accuracy.

By law, CMS is to pay MA insurers at rates that ensure “actuarial equivalence” with what Medicare pays directly for similar health care to participants in traditional Medicare, also called “fee-for-service” or FFS Medicare, or Medicare Part A and Part B. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Codes covering all manner of diagnoses are used by Medicare and MA to identify the illnesses or conditions affecting the covered populations. Given the millions of participants in Medicare, it is only to be expected that some diagnostic codes will be reported in error for a patient who does not have that illness or condition; in addition, Medicare suffers from some rate of fraud whereby health care providers intentionally report erroneous diagnoses to increase their repayments. As a result of these two factors, it is inevitable that Medicare experiences an error rate—that is, a proportion of diagnosis codes that are unsupported in underlying medical charts—that can be actuarially calculated and/or predicted.

CMS sets the rates to be paid to MA insurers according to the amounts Medicare itself pays directly to providers for the same diagnoses, without regard to the Medicare error rate for unsupported diagnoses. In January 2014, CMS published a notice of proposed rulemaking to affect MA insurers. *See* 79 Fed. Reg. 1918-01 (Jan. 10, 2014). “The proposed rule also include[d] several provisions designed to improve payment accuracy.” *Id.* at 1918. After receiving comments, CMS published a Final Rule concerning MA overpayments. 79 Fed. Reg. 29844 (May 23, 2014) (2014 Overpayment Rule). The 2014 Overpayment Rule, challenged here, requires MA insurers to return to CMS payments that were based on incorrect diagnostic

codes once the insurer discovers, or through reasonable diligence should have discovered, the error in any individual patient's chart. *See id.* at 29923-24. Failure to do so exposes an insurer to a charge of having violated the False Claims Act, 31 U.S.C.A. § 3729, which can lead to treble damages, civil penalties, and debarment from federal contracts. Since a similar no-error standard is not applied by CMS in paying traditional Medicare providers, United alleges that MA insurers are not being reimbursed on an actuarially equivalent rate and that the 2014 Overpayment Rule must, perforce, be vacated.

CMS studied just such an issue in a separate 2012 rulemaking, which concerned an audit program to determine the diagnostic accuracy of medical charts for MA beneficiaries. In these "risk adjustment data validation," or RADV, audits, CMS reviews the medical records of a small sample of the patients covered by an MA insurance contract and then extrapolates the error rate of the sample to the entire population covered by that contract to determine whether the insurer had received an aggregate overpayment. As explained by CMS, "RADV audits determine whether the diagnosis codes submitted by MA organizations can be validated by supporting medical record documentation. . . . Diagnoses that cannot be validated contribute to a payment error rate." Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (Notice of Final Methodology), AR 005311. On December 20, 2010, CMS posted on its website a request for comments titled "Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits: Request for Comment." AR 005020. After receiving more than 500 comments, CMS determined that it needed to include a "Fee-for-Service Adjuster" (FFS Adjuster) in the RADV audit process: when an RADV audit results in a determination that an

MA insurer was paid based on unsupported diagnosis codes, the repayment the MA insurer owes to the government is adjusted downwards based on an estimated traditional Medicare payment error rate.¹ CMS explained the rationale for including an FFS Adjuster in auditing payments to MA insurers:

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

Notice of Final Methodology, AR 005314-15. This explanation reflected that an RADV audit determines a payment error rate based on actual medical records while the risk-adjustment model on which per-diagnosis rates are developed and paid is based on unaudited FFS claims. In 2012, CMS apparently intended to develop RADV-like audits of its own FFS claims data. As far as the record shows, that has not happened yet.

The fact that CMS considered and adopted the FFS Adjuster in the context of RADV audits forms the basis for the motion to augment the administrative record for the 2014 Overpayment Rule. United obtained two documents originally disclosed to a third party through a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, seeking records comprised of meeting materials in the files of certain named individuals, all but one of whom served as senior decisionmakers at CMS between the years 2011 and 2014 when the RADV audit methodology was under consideration. *See* Declaration of Daniel Meron (Meron Decl.) [Dkt. 44-1] ¶¶ 9-13; *see also* Joint Status Report ¶ 5(b), *Schulte v. HHS*, No. 14-cv-887 (D.D.C.

¹ *See* 42 U.S.C. § 1320a-7m(i)(5) (“The term ‘Medicare fee-for-service program’ means the original medicare [*sic*] fee-for-service program under Parts A and B of title XVIII of the Social Security Act (42 U.S.C. § 1395(c) *et seq.*)”). In traditional Medicare, CMS directly pays health care providers for services to Medicare beneficiaries.

Jan 15, 2016), ECF No. 30 (noting that the request included “meeting materials dated after January 1, 2012” of these decisionmakers).² The two FFS Adjuster Documents, a slideshow and a bullet-point-style briefing memorandum, describe the reasoning behind the FFS Adjuster for RADV audits. Neither document is included in the Administrative Record submitted by CMS for the 2014 Overpayment Rule.

United moves to add both documents to the administrative record. Mot. for Leave to File Suppl. to the Admin. Record (Mot.) [Dkt. 44]. Defendants opposed that motion, Mem. in Opp’n to Mot. for Leave to File a Suppl. to the Admin. Record (Opp’n) [Dkt. 45], to which Plaintiffs replied. Reply to Opp’n to Mot. for Leave to File Suppl. to the Admin. Record (Reply) [Dkt. 48]. Defendants also moved to file a surreply in opposition. Defs.’ Mot. for Leave to File a Surreply in Opp’n to Pls.’ Mot. to Suppl. the Admin. Record (Surreply Mot.) [Dkt. 54]; Proposed Surreply [Dkt. 54-1].

II. LEGAL STANDARD

The Administrative Procedure Act (APA) requires reviewing courts to “set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706 (2012). When reviewing an agency action under the APA, a court must “review the whole record or those parts of it cited by a party.” *Id.* Review “is to be based on the full administrative record that was before the [agency] at the time [it] made [its] decision.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99

² An investigative journalist, unaffiliated with this matter, submitted the original FOIA request in response to which the two documents at issue were released by CMS. A separate third party submitted a follow-on request for the same records, which were then circulated to, *inter alia*, United. See Meron Decl. ¶¶ 4-6.

(1977). The full administrative record “include[s] all documents and materials that the agency directly or indirectly considered,” *Animal Legal Def. Fund v. Vilsak*, 110 F. Supp. 3d 157, 159 (D.D.C. 2014), and a court “should have before it neither more nor less information than did the agency when it made its decision.” *Walter O. Boswell Mem’l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984).

Because an agency is in the best position to know on what bases it made its decision, “[t]he record that an agency produces ‘is entitled to a strong presumption of regularity.’” *Univ. of Colo. Mem’l Hosp. v. Burwell*, 151 F. Supp. 3d 1, 12 (D.D.C. 2015) (quoting *Marcum v. Salazar*, 751 F. Supp. 2d 74, 78 (D.D.C. 2010)). However, supplementation of the record is appropriate where certain “unusual circumstances” exist. *Lee Mem’l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 47 (D.D.C. 2015). The United States Court of Appeals for the District of Columbia Circuit has found “at least three” circumstances in which such “unusual circumstances” might exist: “(1) the agency deliberately or negligently excluded documents that may have been adverse to its decision; (2) the district court needed to supplement the record with background information in order to determine whether the agency considered all of the relevant factors; or (3) the agency failed to explain administrative action so as to frustrate judicial review.” *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 55 (D.C. Cir. 2015) (quoting *American Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008)); see also *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010).

“[A movant] must do more than simply assert ‘that materials were relevant or before an agency when it made its decision.’” *Univ. of Colo. Mem’l Hosp.*, 151 F. Supp. 3d at 13 (quoting *Marcum*, 751 F. Supp. 2d at 78). Instead, the party “must identify reasonable, non-speculative grounds for its belief that the documents were considered by the agency and not

included in the record.” *Marcum*, 751 F. Supp. 2d at 78 (emphasis omitted) (quoting *Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng’rs*, 448 F. Supp. 2d 1, 6 (D.D.C. 2006)). The party “must identify the materials allegedly omitted with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are ‘likely’ to exist.” *Lee Mem’l Hosp.*, 109 F. Supp. 3d at 47. It must “introduce concrete evidence to prove that the specific documents allegedly missing from the record were before the actual decisionmaker involved in the challenged agency action.” *Id.*

“[A]n agency may exclude arguably relevant information that is not contained in the agency’s files but that may be available from third parties” and “generally may exclude material that reflects internal deliberations.” *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 197 (D.D.C. 2005); *see also Oceana, Inc. v. Ross*, 290 F. Supp. 3d 73, 82-83 (D.D.C. 2018) (“[M]aterials that fall within the scope of the deliberative process privilege are not part of the administrative record.”).

III. ANALYSIS

United asserts that the FFS Adjuster Documents meet the criteria for supplementation. It argues that these two documents, known to senior CMS decisionmakers, must have been considered at least indirectly by them in the course of developing the 2014 Overpayment Rule. Notably, the administrative record for the 2014 Overpayment Rule includes a plethora of material relating to the FFS Adjuster, including, *inter alia*, CMS’s December 2010 request for comments on its proposed payment-error calculation methodology for RADV audits; nearly 300 pages of comments it received on that proposal; and its February 2012 announcement of the final payment-error calculation methodology, in which it included the FFS Adjuster. United contends that “[i]t is simply not credible to suppose that in 2014 CMS reviewed the

public comments concerning the FFS Adjuster but not its own senior staff analysis of those comments. . . .” Mot. at 11.

CMS denies that the FFS Adjuster Documents were considered by any of its decisionmakers when promulgating the 2014 Overpayment Rule, and states further that, even if the documents had been considered, they are the product of internal deliberations and subject to the deliberative process privilege. *See Lee Mem’l Hosp.*, 109 F. Supp. 3d at 49 (noting that “materials reflecting an agency’s internal deliberations should not be part of an administrative record” because it could “discourage candid discussion within the agency”).

A party moving to include additional documents in the administrative record “must identify reasonable, non-speculative grounds for its belief that the documents were considered by the agency,” *Marcum*, 751 F. Supp. 2d at 78 (emphasis omitted) (quoting *Pac. Shores*, 448 F. Supp. 2d at 6; and “must identify the materials allegedly omitted with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are ‘likely’ to exist.” *Lee Mem’l Hosp.*, 109 F. Supp. 3d at 47. Here, by limiting its request to two documents, obtained through a FOIA request targeted towards senior decisionmakers in the relevant CMS office, United has met the “specificity” requirements to support its request. The questions are whether CMS decisionmakers could be said to have considered the documents, directly or indirectly, and whether, nonetheless, they are privileged and properly excluded from the administrative record.

CMS does not dispute that the Administrative Record for the 2014 Overpayment Rule includes the CMS original proposed RADV methodology, the public comments it received on that proposal, and its final decision that included an FFS Adjuster in RADV audits. The FFS Adjuster Documents at issue address important considerations involved in that final decision.

Nonetheless, CMS insists that these FFS Adjuster Documents were not considered, even indirectly, during promulgation of the 2014 Overpayment Rule, and argues that “[i]f the agency wanted the views of its senior staff as to issues involved in the earlier proceeding and their bearing on the later proceeding, it could have just asked them.” Opp’n at 10-11.

One assumes, of course, that senior staff of CMS *were* consulted before the 2014 Overpayment Rule was promulgated, at least in some fashion. *See id.* at 10 (acknowledging that “many of the same CMS staff members were involved in the creation of the RADV sampling methodology and the Overpayment Rule”). These staff members’ knowledge of the FFS Adjuster concept inevitably would have been informed by the recent work presenting the FFS Adjuster Documents to explain the identical issues to executive management, with which the 2014 Overpayment Rule arguably conflicts. There is no real dispute about the provenance of the FFS Adjuster Documents or that CMS chose to include in the Administrative Record the public comments that appear to have led to the agency’s analysis reflected in the FFS Adjuster Documents. These facts strongly suggest that CMS at least considered the FFS Adjuster Documents indirectly when promulgating the 2014 Overpayment Rule. *See Lee Mem’l Hosp.*, 109 F. Supp. 3d at 46 (noting an administrative record appropriately includes “all documents and materials directly or indirectly considered”).

In addition, a district court may need “to supplement the record with background information in order to determine whether the agency considered all of the relevant factors” *Dist. Hosp. Partners*, 786 F.3d at 55. The Court finds that this is the case here: either CMS naturally considered its recent analysis of the FFS Adjuster and omitted the documents in error or because they are adverse to its current position, or it failed to consider all of the relevant

factors in adopting the 2014 Overpayment Rule. In either event, the FFS Adjuster Documents properly supplement the Administrative Record of the 2014 Overpayment Rule.

CMS further protests that the FFS Adjuster Documents are internal deliberative, or “pre-decisional” documents, and are thus privileged and exempt from inclusion in the Administrative Record. *Oceana, Inc. v. Ross*, 290 F. Supp. 3d at 83. “Pre-decisional documents are those prepared in order to assist an agency decisionmaker in arriving at his decision rather than to support a decision already made. . . . Deliberative materials are those that reflect[] the give-and-take of the consultative process.” *Oceana, Inc. v. Pritzker*, 217 F. Supp. 3d 310, 317 (D.D.C. 2016) (quoting *Nat’l Ass’n of Home Builders v. Norton*, 309 F.3d 26, 39 (D.C. Cir. 2002)) (quotation marks omitted). Deliberative documents are usually excluded from an administrative record because they may “inaccurately reflect . . . the views of the agency, suggesting as an agency position that which is . . . only a personal position.” *Coastal States Gas Corp. v. U.S. Dep’t of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980).

The deliberative process privilege “allows the government to withhold documents and other materials that would reveal ‘advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.’” *In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997) (quoting *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 324 (D.D.C. 1966), *aff’d*, 384 F.2d 979 (D.C. Cir. 1967)). The D.C. Circuit has elaborated on the deliberative process privilege:

The deliberative process privilege is a qualified privilege and can be overcome by a sufficient showing of need. This need determination is to be made flexibly on a case-by-case, ad hoc basis . . . taking into account factors such as “the relevance of the evidence,” “the availability of other evidence,” “the seriousness of the litigation,” “the role of the government,” and the “possibility of future timidity by government employees.”

Id. at 737-38 (quoting *In re Subpoena Served Upon the Comptroller of the Currency*, 967 F.2d 630, 632 (D.C. Cir. 1992) (internal citation omitted)).

United argues that any “deliberative” nature of the FFS Adjuster Documents is now irrelevant for two reasons: (1) while the Documents may have been deliberative in the 2012 decision process that preceded adoption of the FFS Adjuster for RADV audits, they are not so related to the 2014 Overpayment Rule, as to which they were not deliberative; and (2) the release of the FFS Adjuster Documents by CMS in response to a press FOIA request, with some redactions for truly “deliberative” materials, indicates that the FFS Adjuster Documents are no longer shielded by any privilege.

As to the first argument, the fact that the deliberations in question related to a previous rulemaking does not preclude application of the privilege for deliberative materials. The deliberative process exemption protects documents that are “recommendatory in nature,” or “draft[s] of what will become a final document.” *Coastal States Gas Corp.*, 617 F.2d at 866. Moreover, the purpose of the deliberative process privilege—to “preserve the ‘open and frank discussion’ necessary for effective agency decisionmaking,” *Abteu v. U.S. Dep’t of Homeland Sec.*, 808 F.3d 895, 898 (D.C. Cir. 2015) (quoting *Dep’t of Interior v. Klamath Water Users Protective Ass’n*, 532 U.S. 1, 9 (2001))—could apply long after the deliberations in question.

United protests that “even if the document is predecisional at the time it is prepared, it can lose that status if it is adopted, formally or informally, as the agency position on an issue” *Coastal States Gas Corp.*, 617 F.2d at 866. United emphasizes that CMS, in fact, adopted the FFS Adjuster for RADV audits. CMS disagrees and contends that “[t]he only relevant principles that CMS actually adopted were set out in its *announcement* of the RADV sampling methodology.” Opp’n at 10 (emphasis added). Nonetheless, the Secretary agrees that

CMS “stud[ied] this problem” of dueling statistics between medical records and FFS claims and did adopt an FFS Adjuster. Opp’n at 5. CMS distinguishes its FFS Adjuster from an “agency position” because the “Secretary said nothing at all about what he expected the value of this FFS Adjuster to be” when it was announced. *Id.* To the contrary, CMS explained that “if the payment error rate calculated by the RADV audits was smaller than the adjustment factor that resulted from his study [*i.e.*, the FFS Adjuster], then nothing would be recouped on the audited contract.” *Id.* Wordsmithing aside, this sounds very much like an “agency position” to agree to use the FFS Adjuster in RADV audits.

This debate need not be resolved, however, because the Court finds that the deliberative process privilege no longer applies to the FFS Adjuster Documents (except as redacted upon release by CMS). The deliberative process is not absolute; it can be waived. *See In re Sealed Case*, 121 F.3d at 740 (“[I]f we find that waiver has occurred, we need not proceed further.”). Such waiver is limited to “the document or information specifically released, and not [] related materials.” *Id.* at 741. In *In re Sealed Case*, the D.C. Circuit held that the White House had “waived its claims of [deliberative process and executive] privilege in regard to the specific documents that it voluntarily revealed to third parties outside the White House.” *Id.* at 741-42.

The agency contends, with good reason, that the mere fact that a document has been released under FOIA does not require its inclusion in an administrative record. The Court agrees that the questions at issue and the deliberations that give rise to the privilege in question may be completely separate from a FOIA analysis. *See, e.g., State of Del. Dept. of Nat. Resources & Env’l Control v. U.S. Army Corps of Eng’rs*, 722 F. Supp. 2d 535, 544 (D. Del. 2010) (“A FOIA production request is an entirely discrete legal concept that bears no relation to

the administrative record compiled for a court's review under the APA.”). The same analysis would apply to a document obtained outside the FOIA process: the mere fact that a plaintiff possesses such a document does not render it part of an administrative record.

The D.C. Circuit has already decided that public disclosure of deliberative materials does not necessarily mandate inclusion in the administrative record. *See Kansas State Network, Inc. v. FCC*, 720 F.2d 185, 191-92 (D.C. Cir. 1983) (in action seeking review of FCC's denial of application for tax certificate, refusing to consider a transcript of public deliberations regarding the application); *Deukmejian v. Nuclear Regulatory Comm'n*, 751 F.2d 1287, 1323-29 (D.C. Cir. 1984) (denying motion to supplement administrative record and the record on appeal with transcripts of Commission's deliberations and finding it unnecessary to reach the question as to whether public disclosure of those transcripts was required under the Sunshine Act, 5 U.S.C. § 552b), *vacated in part on other grounds, San Luis Obispo Mothers for Peace v. U.S. Nuclear Regulatory Comm'n*, 760 F.2d 1320 (D.C. Cir. 1985). This conclusion is not surprising because only materials considered directly or indirectly in rulemaking should be part of the record on review.

On the other hand, a document that was privileged as part of the deliberative process can lose its privilege when revealed outside the agency. *In re Sealed Case*, 121 F.3d at 741-42 (holding that the White House “waived its claims of privilege in regard to the specific documents that it voluntarily revealed to third parties outside the White House”). That is what happened here. CMS waived any deliberative process privilege in the FFS Adjuster Documents to the extent that information was not redacted when it released them to the public. Thus, the privilege does not prevent the FFS Adjuster Documents from being made part of the administrative record.

