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United States District Court, D.
South Carolina, Charleston Division.GOOSE CREEK PHYSICAL
MEDICINE, LLC, Plaintiff,

v.

XAVIER BECERRA, in his official capacity
as Secretary, United States Department of
Health and Human Services, Defendant.

No. 2:22-cv-03932-DCN

|
Filed 03/05/2024**ORDER**

DAVID C. NORTON UNITED STATES DISTRICT JUDGE

*1 The following matter is before the court on plaintiff Goose Creek Physical Medicine, LLC's ("GCPM") objections to the administrative record and motion to complete the administrative record. ECF No. 18. Also before the court is defendant Xavier Becerra's (the "Secretary" or "Secretary Becerra") motion for protective order. ECF No. 30. For the reasons set forth below, the court grants the motion to compel completion of the administrative record and grants the motion for protective order in response to GCPM's requests for admission.

I. BACKGROUND

Title XVIII of the Social Security Act, [42 U.S.C. § 1395 et seq.](#), commonly known as the Medicare Act, established a system of medically funded health insurance for elderly and disabled persons.¹ Under the Medicare Act, certain healthcare providers are eligible for reimbursement by the Department of Health and Human Services ("HHS") for services furnished to the Medicare beneficiaries. To promote the integrity of the Medicare program, the Secretary of HHS is authorized to enter into contracts with private entities to review claims for reimbursement submitted by providers; to determine whether Medicare payments should not be, or should not have been, made; and to recoup payments that

should not have been made. [See 42 U.S.C. § 1395ddd; 42 C.F.R. § 405.371\(a\)\(3\).](#)

There are a plethora of acronyms included within the amended complaint. The court clarifies the most salient and, in so doing, attempts to summarize the Medicare claim appeal process that precedes the filing of a complaint in federal court, before turning to the facts of the operative complaint.

There are several levels of agency review before judicial review of a Medicare denial. First, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS, administers the Medicare program and directs its contractors, who are responsible for the first two levels of administrative review of Medicare denials. Second, CMS contracts with Medicare Administrative Contractors ("MACs") to process and audit claims that have been submitted by Medicare providers in a specific geographic area of the country. MACs handle provider and supplier enrollment, as well as redeterminations, which form the first level of the Medicare claims appeal process. Third, until 2016, Zone Program Integrity Contractors ("ZPICs") audited the payment decisions made by MACs in a process referred to as a "post-payment review," which identified both overpayments and underpayments. In fiscal year 2016, CMS began transitioning from ZPICs to Unified Program Integrity Contractors ("UPICs"), which today perform similar duties to what ZPICs previously performed.

Fourth, CMS is mandated to enter into contracts with qualified independent contractors ("QICs") to conduct reconsiderations of redetermination decisions where the QICs are statutorily required to be independent of any MAC, ZPIC, or UPIC, as the QICs form the second level of the Medicare claims appeal process. The Office of Medicare Hearings and Appeals ("OMHA") is responsible for the third level of the Medicare claims appeal process—whereby a reconsideration decision by the QIC is reviewed by an OMHA adjudicator—and the appellant Medicare provider may request an administrative law judge ("ALJ") hearing. Where a party is dissatisfied with the ALJ's decision, that party may appeal the decision to the Medicare Appeals Council (the "Council"), and the Council is statutorily authorized to review the ALJ's decision. The Council is located within the Departmental Appeals Board ("DAB") within HHS and provides the fourth level of administrative review. The fifth level of appeal comes from judicial review in a federal district court.

*2 The CMS contractors evaluate overpayment to Medicare providers and suppliers through statistical sampling and extrapolation. CMS Ruling 86-1 was the first ruling that allowed a fiscal intermediary—such as a MAC, ZPIC, or QIC—to use sampling and extrapolation instead of claim-by-claim review. Chapter 8, Section 4, of the Medicare Program Integrity Manual (“MPIM”) provides detailed requirements for CMS contractors to follow in developing an audit plan and executing the sampling and extrapolation process. Under section 8.4.1.3 of the MPIM applicable during the statistical sampling and extrapolation at issue, the six mandatory steps are:

- (1) Selecting the provider or supplier;
- (2) Selecting the period to be reviewed;
- (3) Defining the universe, the sampling unit, and the sampling frame;
- (4) Designing the sampling plan and selecting the sample;
- (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable,
- (6) Estimating the overpayment.

Amend. Compl. ¶ 169. For purposes of extrapolation, the “target universe” of a provider’s Medicare claims consists of all claims submitted by the provider within the chosen time period, which typically covers all relevant claims or line items for the period under review.

Once the sampling unit is selected, certain limiting criteria are applied to the target universe, and the resulting set of sampling unit data is called the “sampling frame.” The contractor’s medical review staff thereafter audits each sampling unit to determine whether the claim was properly paid, overpaid, underpaid, or improperly denied payment. Upon completion of review of the sample claims, the contractor calculates the net average amount by which the provider was incorrectly paid for the sampled claims. In cases where the provider was initially overpaid, the net overpayment on the sample set is then projected to the target universe of that provider’s claims to form the extrapolated overpayment amount. This process requires the contractor to accurately assess underpayments as well as overpayments, including claims that were unpaid after adjudication (“zero-paid claims”)² to ensure the actual net overpayment is correctly calculated. Should a contractor seek to recover an overpayment from a provider, it shall

include information about the review and statistical sampling methodology that was followed in the overpayment demand letter.

GCPM is a South Carolina limited liability company and a former for-profit provider of physical medicine services, including chiropractic services, which was enrolled as a provider of services in the Medicare program.³ GCPM filed a complaint for judicial review against Secretary Becerra, in his official capacity as the Secretary of HHS. It alleges violations of law in the design and execution of the statistical sampling and the calculation of the alleged overpayment amount, plus interest, on claims GCPM submitted to Medicare. It also alleges improper accounting on payments made on the alleged overpayment. The relevant period is for dates of service between March 5, 2011, and November 30, 2013.

GCPM purportedly failed an audit performed by CMS’s designated ZPIC: NCI AdvanceMed (“AdvanceMed”). AdvanceMed opened an investigation into GCPM’s claims based on data analysis that GCPM’s top-billed code, other than for evaluation and management services, was for CPT⁴ 64450, a [nerve block](#) procedure. On October 14, 2014, AdvanceMed sent GCPM its Post-Payment Review Results and Overpayment Extrapolation Report (“OER”) containing the results of its completed audit. The report identified that AdvanceMed used a form of stratified statistical sampling to select 67 claims and 210 CPT line items from a total 2,979 sampling units. AdvanceMed explained that it initially identified an error rate of 89.5%; however, it voided sixteen zero-paid claim lines, “as they constitute no loss to the Medicare Trust Fund,” which ultimately increased the error rate to 94%. Amend. Compl. ¶ 207. AdvanceMed then extrapolated the 94% error rate across the total target universe to determine an overpayment amount of \$337,693.09. AdvanceMed purportedly sent GPCM an encrypted CD as well as the OER, but the information provided “did not contain the actual universe of claims on which the overpayment was determined.” *Id.* ¶ 210. On November 26, 2014, CMS’s designated MAC for South Carolina, Palmetto GBA, LLC (“Palmetto”), formally issued a demand for repayment in the amount of \$337,693.09.

*3 Four levels of administrative review have since followed, whereby GCPM challenged the validity of AdvanceMed’s sampling and extrapolation conducted during the audit. First, on January 9, 2015, GCPM timely submitted a request for redetermination to the MAC. On February 13, 2015, Palmetto issued a fully unfavorable redetermination decision

that confirmed the overpayment to be \$343,744.24, which included the original, alleged overpayment amount plus interest. Second, on April 13, 2015, GCPM timely submitted a request for reconsideration to the QIC in response to Palmetto's unfavorable redetermination. On June 12, 2015, the reviewing QIC, C2C Solutions, Inc. ("C2C"), issued an unfavorable reconsideration decision identified as Medicare Appeal Number 1-3125869890. As of August 5, 2015, GCPM had repaid Palmetto the entire alleged overpayment amount of \$355,844.92, which included the alleged overpayment amount plus interest.

Third, on August 5, 2015, GCPM timely filed a request for hearing by an ALJ with OMHA to appeal C2C's unfavorable reconsideration decision. Six years later, on December 9, 2021, ALJ Dean Yanohira of the Phoenix Field Office held a telephonic hearing and on January 18, 2021, ALJ Yanohira issued a partially favorable notice of decision (the "ALJ Decision"). The ALJ Decision found the statistical sampling and extrapolation of overpayment to be valid but ordered the overpayment amount to be recalculated in light of AdvanceMed's removal of sixteen zero-paid claim lines which had increased the error rate from 89.5% to 94%. Consequently, the ALJ Decision reduced the overpayment amount to \$280,018.10 and ordered a refund totaling \$60,775.79 be issued to GCPM. Fourth, on March 14, 2022, GCPM filed a Medicare Appeals Council Review Request with the Council requesting review of the ALJ Decision. GCPM specifically requested that the Council both "renew" the ALJ Decision requiring C2C to recalculate the overpayment amount and reverse the ALJ Decision regarding the validity of the sampling and extrapolation. Amend. Compl. ¶ 248.

Fifth, on June 21, 2022, GCPM electronically filed a letter with the Council which requested escalation to federal district court if the Council was unable to timely issue a decision. On June 30, 2022, after the Council failed to timely respond within the required five-day timeframe, GCPM electronically filed its final letter with the Council stating its intent to escalate the matter to federal court by August 26, 2022, in accordance with 42 C.F.R. § 405.1132(a). On August 25, 2022, the Council issued a Notice and Order of Medical Appeals Council Granting Request for Escalation. This lawsuit followed.

On August 19, 2022, GCPM filed the complaint in the United States District Court for the District of Columbia. ECF No. 1. On October 19, 2022, the court transferred the action to the

United States District Court for the District of South Carolina by consent of the parties.⁵ ECF No. 11. On March 24, 2023, GCPM filed an amended complaint, now the operative complaint, against the Secretary to allege multiple violations of GCPM's due process rights under the Fifth and Fourteenth Amendments to the United States Constitution, as well as violation of the Social Security Act, 42 U.S.C. § 1395 *et seq.*,⁶ and the APA, 5 U.S.C. §§ 551 *et seq.* ECF No. 24, Amend. Compl. On March 13, 2023, GCPM filed objections to the administrative record and moved to compel completion of the administrative record. ECF No. 18. On March 27, 2023, Secretary Becerra responded in opposition to that request, ECF No. 25, to which GCPM replied on April 3, 2023, ECF No. 26. On April 11, 2023, Secretary Becerra filed a motion for protective order in response to GCPM's first set of requests for admission. ECF No. 30. GCPM responded in opposition on April 20, 2023, ECF No. 31, to which Secretary Becerra replied on April 26, 2023, ECF No. 32. On February 15, 2024, the court held a hearing on these motions, ECF No. 42. As such, the motions have been fully briefed and are now ripe for review.

II. STANDARD

A. Motion to Compel Completion of Administrative Record

*4 The standards of review that govern the court's review of the MAC's final decision are set forth in the Medicare statute, 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq.* First, the Medicare statute provides that the MAC's factual findings must be upheld "if supported by substantial evidence." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Thus, the scope of review of the MAC's factual findings under this standard is quite limited. As the Supreme Court has explained, substantial evidence "does not mean a large or considerable amount of evidence, but rather 'such evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Pierce v. Underwood*, 487 U.S. 552, 565 (1988) (quoting *Consol. Edison Co. of N.Y. v. NLRB*, 305 U.S. 197, 229 (1938)). Moreover, the district court may not "reweigh conflicting evidence, make credibility determinations, or substitute [its] judgment for that of the [MAC]." *Johnson v. Barnhart*, 434 F.3d 650, 653 (4th Cir. 2005); see *Jarvis v. Berryhill*, 697 F. App'x 251, 252 (4th Cir. 2017) ("The duty to resolve conflicts in the evidence rests with the [agency], not with a reviewing court.").

Second, the APA authorizes judicial review of “final agency action[s] for which there is no other adequate remedy.” 5 U.S.C. § 704. A district court must set aside an agency decision that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Id.* § 706(2)(A). To determine whether an agency action is arbitrary or capricious, the court examines whether the agency considered relevant factors and whether the decision is the result of a clear error of agency judgment. [Ohio Valley Env’t Coal. v. Aracoma Coal Co.](#), 556 F.3d 177, 192 (4th Cir. 2009) (citing [Citizens to Pres. Overton Park, Inc. v. Volpe](#), 401 U.S. 402, 416 (1971), abrogated on other grounds by [Califano v. Sanders](#), 430 U.S. 99 (1977)). The court’s review of a final agency decision for clear error of judgment is limited to (1) asking whether the agency “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action” and (2) determining whether there exists a “rational connection between the facts found and the choice made.” [Armah-El-Aziz v. Zanotti](#), 2015 WL 4394576, at *6 (E.D. Va. July 16, 2015) (quoting [Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.](#), 463 U.S. 29, 43 (1983)). A court conducts such a review “based on the full administrative record” that was before the agency at the time of the decision. [Citizens to Pres. Overton Park](#), 401 U.S. at 416.

Relevant to the instant request, when conducting judicial review of agency action under the APA, “the court shall review the whole record or those parts of it cited by a party.” 5 U.S.C. § 706. The Supreme Court has made clear that this review must be based on the “full administrative record that was before the [agency] at the time [it] made [the] decision.” [Citizens to Pres. Overton Park](#), 401 U.S. at 420; see also [Camp v. Pitts](#), 411 U.S. 138, 142 (1973) (“[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.”). As explained by multiple courts, including district courts in the Fourth Circuit, “[t]he whole administrative record includes pertinent but unfavorable information, and an agency may not exclude information on the ground that it did not ‘rely’ on that information in its final decision.” [Outdoor Amusement Bus. Ass’n, Inc. v. Dep’t of Homeland Sec.](#), 2017 WL 3189446, at *7 (D. Md. July 27, 2017) (quoting [Tafas v. Dudas](#), 530 F. Supp. 2d 786, 793 (E.D. Va. 2008)). This means an agency must include all documents and materials “directly or indirectly” considered by the agency. See [Bar MK Ranches v. Yuetter](#), 994 F.2d 735, 739 (10th Cir. 1993) (stating “[t]he complete administrative record consists of all documents and materials directly or indirectly considered by the agency”);

[Thompson v. U.S. Dep’t of Lab.](#), 885 F.2d 551, 555 (9th Cir. 1989) (“The ‘whole’ administrative record ... consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency’s position.” (citations and quotation marks omitted)). As to pre-decisional deliberative materials, “absent a showing of bad faith or improper behavior, agency deliberations not part of the record are deemed immaterial.” [Oceana, Inc. v. Ross](#), 920 F.3d 855, 865 (D.C. Cir. 2019) (citations, alterations, and quotation marks omitted).

*5 “If an agency fails to produce a complete administrative record, a party may request supplementation⁷ of the record.” See [S.C. Coastal Conservation League v. U.S. Army Corps of Eng’rs](#), 611 F. Supp. 3d 136, 141 (D.S.C. 2020) (footnote added) (internal citations omitted). An agency is “entitled to a strong presumption of regularity that it properly designated the administrative record,” and therefore supplementation of the record is “the exception not the rule.” *Id.* (citations and quotation marks omitted). Nonetheless, a plaintiff can overcome this presumption if it:

- (1) identif[ies] reasonable, non-speculative grounds for the belief that the documents were considered by the agency and not included in the record, and
- (2) identif[ies] the materials allegedly omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are ‘likely’ to exist as a result of other documents that are included in the administrative record[.]

Id. at 141–42 (third alteration in original) (internal citations and quotation marks omitted). When a party is attempting to include documents considered by the agency, no showing of bad faith is required and a plaintiff must only present “clear evidence,” which means a “strong, substantial or prima facie showing that the record is incomplete.” *Id.* (quoting [Outdoor Amusement Bus. Ass’n](#), 2017 WL 3189446, at *18).

B. Motion for Protective Order

[Federal Rule of Civil Procedure 26\(b\)\(1\)](#) limits the scope of discovery to “any nonprivileged matter that is relevant to any

party's claim or defense.” “The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden and expense” by forbidding or limiting the scope of discovery. *Fed. R. Civ. P. 26(c)(1)*. “The standard for issuance of a protective order is high.” *Wellin v. Wellin*, 211 F. Supp. 3d 793, 800 (D.S.C. 2016) (quoting *Nix v. Holbrook*, 2015 WL 631155, at *2 (D.S.C. Feb. 13, 2015)), *order clarified*, 2017 WL 3620061 (D.S.C. Aug. 23, 2017). “The party moving for a protective order bears the burden of establishing good cause.” *Slager v. S. States Police Benevolent Ass'n, Inc.*, 2016 WL 4123700, at *2 (D.S.C. Aug. 3, 2016) (quoting *Webb v. Green Tree Servicing, LLC*, 283 F.R.D. 276, 278 (D. Md. 2012)). “Normally, in determining good cause, a court will balance the interest of a party in obtaining the information versus the interest of his opponent in keeping the information confidential or in not requiring its production.” *Id.* (quoting *UAI Tech., Inc. v. Valutech, Inc.*, 122 F.R.D. 188, 191 (M.D.N.C. 1988)). In other words, the court “must weigh the need for the information versus the harm in producing it.” *Id.* (quoting *A Helping Hand, LLC v. Balt. Cnty.*, 295 F. Supp. 2d 585, 592 (D. Md. 2003)). The district court is afforded broad discretion “to decide when a protective order is appropriate and what degree of protection is required.” *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984).

III. DISCUSSION

*6 The court first considers GCPM's motion to compel completion of the administrative record before turning to Secretary Becerra's motion for protective order.

A. Motion to Compel

At the outset, the court notes that the relevant issue it must decide is whether GCPM has met its burden to present “clear evidence” that the compiled administrative record is incomplete. See *S.C. Coastal Conservation League*, 611 F. Supp. 3d at 142. The court sets forth the parties’ respective arguments in turn.

First, GCPM alleges that the administrative record is missing documentation of the universe of records, which is necessary to replicate the statistical sampling and extrapolation. ECF No. 18 at 6. On June 30, 2015, counsel for GCPM sent a Freedom of Information Act (“FOIA”) request to CMS requesting specific documents related to GCPM and the request for records dated January 14, 2014. *Id.* That

FOIA request and the information produced in response are missing from the Administrative Record. *Id.* GCPM now moves to complete the Administrative Record with those files, including a spreadsheet, which AdvanceMed provided to GCPM in response to its FOIA request on May 11, 2016.⁸ *Id.* Specifically, AdvanceMed provided GCPM with a CD that contained the following statistical methodology documents: (1) Attachment A – Overpayment Extrapolation; (2) Attachment B – Universe; and (3) SSOE Memo. *Id.* These documents were the same documents listed as attachments to the OER. *Id.*

The case file and the administrative record before the ALJ—that the ALJ purportedly relied upon in his decision—are missing the “Attachment B – Universe.xlsx” file (the “Universe File”). *Id.* at 7. GCPM moves to complete the Administrative Record with this spreadsheet. *Id.* To further complicate matters, GCPM also contends that the missing Universe File is “not the actual, complete universe of claims.” *Id.* Specifically, the Universe File produced in the FOIA request included only fully and partially paid claim lines, meaning that all zero-paid claims had been removed. *Id.* at 7–8. Additionally, the Universe File only included the claim lines for the sampling frame, not all the claims from the review period from which the sampling frame had been created. *Id.* The file which includes all zero-paid claims and which includes all claims from the review period (the “Missing Universe File”) would correct these deficiencies. See *id.* at 7–9. GCPM avers that it consistently raised the Missing Universe File “at each appeal level” of agency review and states that it raised the issue in the initial report and at the ALJ hearing. *Id.* at 7–8 (citing AR Vol. 3, p. 9182, ln 23–25; AR Vol. 1 p.19).

*7 Second, GCPM claims that the Administrative Record is missing recalculation documentation, which is necessary to verify the recalculation of the overpayment amount. *Id.* at 9. Notably, after the partially favorable ALJ Decision, Palmetto sent GCPM a letter indicating that a refund of \$60,775.79 would issue, but the letter lacked any documentation explaining how Palmetto calculated the refund amount. *Id.* Upon GCPM's request, Palmetto sent GCPM's counsel a spreadsheet entitled “AdjustedOPAAfterALJ.xlsx.” (the “Adjusted OP File”) which purported to support Palmetto's recalculation of the overpayment amount. *Id.* at 9–10. GCPM moves to complete the Administrative Record with the Adjusted OP File. *Id.* at 10. However, GCPM also claims that the Adjusted OP File does not show the statistical analysis and related calculations that Palmetto used to reach the

\$60,775.79 (the “Adjusted OP File Calculations”). *Id.* Thus, GCPM further contends that the missing calculations deprives it of its right to independently verify this amount and therefore requests the court order Secretary Becerra to complete the Administrative Record with all documents regarding Palmetto's recalculation of the overpayment amount. *Id.* at 10–11.

Stated succinctly, GCPM requests that the court include in the administrative record three documents produced in response to its FOIA request to CMS, which it included as three exhibits in support of its motion: (1) June 30, 2015, FOIA Request; (2) the Universe File; and (3) the Adjusted OP File. ECF No. 18.⁹ GCPM also requests the court compel the Secretary to produce two files: (1) the Missing Universe File, and (2) the Adjusted OP File Calculations.¹⁰ ECF No. 18 at 2. GCPM is only seeking to include these five files into the administrative record, and the court assumes that the files' inclusion would complete the administrative record.

In response, Secretary Becerra emphasizes that GCPM's motion “reflects an inaccurate understanding of the nature of this civil action and of the principles that govern it” and requests that the court deny GCPM's request to supplement the Administrative Record. ECF No. 25 at 1–2. First, Secretary Becerra argues that GCPM's request “ignores the terms of the review applicable to this civil action for judicial review of a Medicare determination under 42 U.S.C. § 405(g);” meaning, the correct standard of review is set forth by the Medicare Act, not the APA. *Id.* at 2. That statute and the rules promulgated to enact it state, in relevant part, that the record at the ALJ level “consists of all materials that were before the ALJ,” and “[i]f the case is subsequently appealed beyond the ALJ level, ‘the complete record’ from the ALJ level gets forwarded to the next level for review.” *Id.* at 3–4 (quoting 42 C.F.R. § 405.1042(a)(4)). Thus, Secretary Becerra urges the court to find that upon the ALJ Decision's appeal, “[t]he record does not grow thereafter.” *Id.*

Second, Secretary Becerra emphasizes that construing GCPM's motion as brought pursuant to the APA does not change the conclusion that the request should be denied. *Id.* at 4–5. In essence, the Secretary explains that since the court is confined to the record considered by the agency at the time it reached its decision, courts ordinarily assume that the administrative record is complete and exclusive for purposes of judicial review. *Id.* Moreover, for the court to permit GCPM to supplement the existing administrative record, GCPM would need to show bad faith or improper behavior through

specific evidence. *Id.* at 6. Consequently, Secretary Becerra argues that the court's review must “be limited to assuring itself that there was substantial evidence in support of facts the ALJ found and that the ALJ's analysis comported with the applicable principles.” *Id.* In other words, GCPM's desire that the court reopen the Administrative Record to supplement it with materials “related to the effectuation of the ALJ's decision has no basis in the Medicare statute or regulations;” rather, any challenge to the effectuation must be presented to the agency through the appeal process. *Id.* at 8. Thus, Secretary Becerra urges the court to deny GCPM's request to complete the Administrative Record.

*8 In reply, GCPM argues that Secretary Becerra misstates the law and mischaracterizes the nature of its request. ECF No. 26 at 1–2. First, GCPM claims that the Secretary incorrectly contends that Section 405(g) prohibits supplementation of the Administration Record and that the Administrative Record is limited to what the ALJ relied upon. *Id.* at 2–5. Second, GCPM explains that the Secretary “mistakenly asserts that the APA only allows for supplementation of an Administrative Record by a showing of bad faith.” *Id.* at 5–6. Finally, GCPM contends that the Secretary “cherry-picks and misstates the law regarding the recalculation of an overpayment demand.” *Id.* at 7–8. The court examines the parties' arguments in turn.

1. Jurisdiction

First, the parties dispute which statute provides the applicable standard for the request to complete the Administrative Record. In general, a claim that is not first channeled through the agency may not be reviewed by a district court. *Ass'n of Cmty. Cancer Ctrs v. Azar*, 509 F. Supp. 3d 482, 491 (D. Md. 2020) (referencing § 405(h)); see also *Accident, Inj. & Rehab., PC v. Azar*, 943 F.3d 195, 200 (4th Cir. 2019) (noting that pursuant to § 405(g) an individual may obtain judicial review of a claim arising under the Medicare Act only after receipt of a “final decision” by the Secretary of HHS). The Fourth Circuit has noted “that the process that Congress has provided for obtaining Medicare reimbursement and administrative review of reimbursement decisions is comprehensive and specific ... which begins with the submission of a claim for reimbursement, continues through a detailed and multistep administrative process, and concludes with the provision for judicial review.” *Cumberland Cnty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 52–53 (4th Cir. 2016); see also *Heckler*

v. Ringer, 466 U.S. 602, 622 (1984) (noting that when a claim arises under the Medicare Act, a party may not use the APA or 28 U.S.C. § 1331 to bypass the review procedures set forth in the Medicare Act). First, the plaintiff must have “presented” the claim to the Secretary; this requirement is not waivable, because without presentment “there can be no ‘decision’ of any type,” which § 405(g) clearly requires. Mathews v. Eldridge, 424 U.S. 319, 328 (1976). The second element is the waivable “requirement that the administrative remedies prescribed by the Secretary be exhausted.”¹¹ Id. at 328.

*9 To be clear, the parties do not dispute that GCPM fully exhausted its administrative remedies as is required by sections 405(g) and (h) of the Medicare Act.¹² See 42 U.S.C. § 405(g), (h). Thus, the plain text of the statute demonstrates that GCPM is not subject to the jurisdictional bar in section 405(h). Having pled a colorable claim raising a federal question based on the APA and its application to a separate subchapter of title 42, GCPM has properly invoked this court's subject matter jurisdiction. The court next turns to GCPM's request that the court compel completion of the Administrative Record.

2. Complete the Administrative Record

The Supreme Court has clarified that “a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide ... including, where necessary, the authority to develop an evidentiary record.” Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 23–24 (2000).¹³

*10 Secretary Becerra argues that the Medicare Act, 42 U.S.C. § 405(g), restricts the court to the existing administrative record that was presented to the ALJ and that exceptions under the APA do not apply because § 405(g) comprehensively governs the contents of the Administrative Record. ECF No. 25 at 2–3. Moreover, the Secretary argues that even if the APA were to apply, there is a heightened standard that allows the district court to supplement the administrative record only in limited circumstances. Id. at 5–6. Those limited circumstances purportedly do not exist in this case. Id. at 5–9. While GCPM notes that the general rule holds that judicial review of agency actions is confined to a review of the record that was before the agency at the time it made its

decision (the “record rule”), there are exceptions to the record rule which allow the court to complete the administrative record. ECF No. 18 at 3. GCPM argues that those exceptions apply to this case. See id. The court considers the parties’ arguments in turn.

As a general matter, “claims brought under the APA are adjudicated without a trial or discovery, on the basis of an existing administrative record.” Mayor & City Council of Balt. v. Trump, 429 F. Supp. 3d 128, 137 (D. Md. 2019) (quoting Audubon Naturalist Soc’y of the Cent. Atl. States, Inc. v. U.S. Dep’t of Transp., 524 F. Supp. 2d 642, 660 (D. Md. 2007)). This “reflects the recognition that further judicial inquiry into ‘executive motivation’ represents ‘a substantial intrusion’ into the workings of another branch of Government and should normally be avoided.” Dep’t of Com. v. New York, 139 S. Ct. 2551, 2573 (2019) (citation omitted).

“Section 706 of the APA commands the reviewing court to review the ‘whole record or those parts of it cited by a party.’” Tafas, 530 F. Supp. 2d at 793 (quoting 5 U.S.C. § 706). “The record is incomplete if it fails to provide a court with all of the documents, memoranda, and other evidence that was considered directly or indirectly by the agency.” Id. at 795. “If an agency fails to produce a complete administrative record, a party may request supplementation of the record.” See S.C. Coastal Conservation League, 611 F. Supp. 3d at 141 (internal citations omitted). The Fourth Circuit succinctly stated the foundation of this principle when it noted that “[i]f judicial review were to be tethered to these abbreviated documents, it would almost inevitably become[] a meaningless gesture and would be reduced to a game of blind man's bluff.” Appalachian Power Co. v. EPA, 477 F.2d 495, 507 (4th Cir. 1973), overruled on other grounds by Union Elec. Co. v. EPA, 427 U.S. 246 (1976) (internal quotation marks omitted).

Consequently, “although review is based on a limited record, ‘there may be circumstances to justify expanding the record or permitting discovery.’” Fort Sumter Tours, Inc. v. Babbitt, 66 F.3d 1324, 1336 (4th Cir. 1995) (quoting Pub. Power Council v. Johnson, 674 F.2d 791, 793 (9th Cir. 1982)). As such, completion of the administrative record in an APA case is appropriate only in very limited circumstances, such as:

- (i) if it appears that the agency relied on documents or materials not included in the record or if the agency deliberately or negligently excluded documents that may have been adverse to its decision;

- (ii) if background information is needed to determine whether the agency considered all the relevant factors, or to permit explanation or clarification of technical terms or subject matter; or
- (iii) if the agency so failed to explain administrative action that it frustrates judicial review.

Brandon v. Nat'l Credit Union Ass'n, 115 F. Supp. 3d 678, 684 (E.D. Va. 2015) (citing City of Dania Beach v. FAA, 628 F.3d 581, 590 (D.C. Cir. 2010)); see also Tafas, 530 F. Supp. 2d at 793–95 (collecting cases).¹⁴ Courts must apply the “presumption of regularity”—i.e., the presumption that public officers have properly discharged their official duties—absent clear evidence that those duties were improperly discharged. See United States v. Chem. Found., 272 U.S. 1, 14–15 (1926). Applying that concept to judicial review of agency action, “there is a presumption that the agency properly designated the administrative record, and plaintiffs must show clear evidence to the contrary to obtain discovery.” Tafas, 530 F. Supp. 2d at 795; see also Sanitary Bd. of City of Charleston v. Wheeler, 918 F.3d 324, 334 (4th Cir. 2019) (explaining there is a strong presumption that the agency properly designated the full and accurate record).

*11 Nevertheless, the record is not comprised of only those documents that the agency has compiled and submitted as the administrative record. Clinch Coal. v. U.S. Forest Serv., 597 F. Supp. 3d 916, 921 (W.D. Va. 2022). “In other words, the agency ‘may not unilaterally determine what constitutes’ the record, otherwise there would be no need for a presumption.” Id. (quoting Bar MK Ranches v. Yuetter, 994 F.2d 735, 739–40 (9th Cir. 1989)). A party seeking to “complete” the record may overcome that presumption with “clear evidence” that the documents it seeks to add were considered by agency decisionmakers. S.C. Coastal Conservation League, 431 F. Supp. 3d at 723. To make this showing, a party must provide “reasonable, non-speculative grounds for the belief” that documents actually considered by the agency were omitted and identify the pertinent materials “with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are likely to exist.” Id.; see also Tafas, 530 F. Supp. 2d at 795 (explaining that clear evidence may be demonstrated by a strong, substantial, or prima facie showing that the record is incomplete).

GCPM argues that the first exception applies in this case: namely, the agency has considered or relied on documents, yet the agency failed to include certain documents in its

administrative record. ECF No. 18 at 3. GCPM explains that “the Fourth Circuit has ‘focused on whether evidence was known to the administrator when it rendered its decision, not whether it was part of the administrative record.’” Id. at 4 (quoting Helton v. AT & T, Inc., 709 F.3d 343, 352 (4th Cir. 2013)). Thus, because GCPM argues the agency relied on the Universe File, the Missing Universe File, the Adjusted OP File, and the Adjusted OP File Calculations in reaching its decision, those documents should be part of the Administrative Record, GCPM claims that it has demonstrated clear evidence that the record is incomplete. See id. at 4–11; ECF No. 26 at 6.

In response, Secretary Becerra emphasizes that the court's review of the Secretary's final decision is to be based solely on the administrative record before the decisionmaker—here, the ALJ—and the Secretary's findings of fact, if supported by substantial evidence, shall be conclusive. ECF No. 25 at 3. Thus, the Secretary claims that the complete Administrative Record is that which the ALJ considered, and there is “no suggestion that there were materials before the ALJ at the time he reached his decision that subsequently failed to make their way into the Administrative Record.” Id. at 3–4, 6. In reply, GCPM argues that case law supports the interpretation “that the administrative record is anything the agency—not just the ALJ—relied upon, directly or indirectly.” ECF No. 26 at 4 (first citing Chestnut v. Jaddou, 2022 WL 4096607, at *3 (D.S.C. Sept. 7, 2022); and then citing Exxon Corp. v. Dep't of Energy, 91 F.R.D. 26, 33 (N.D. Tex. 1981)). Consequently, the Universe File, the Missing Universe File, the Adjusted OP File, and the Adjusted OP File Calculations should have been included in the Administrative Record since AdvanceMed and Palmetto acted on behalf of the agency and relied on them. See id.; 5 U.S.C. § 706; see also Appalachian Power Co., 477 F.2d at 507 (noting that the APA requires courts to review and agency's decision based on the whole record).

The court grants the request to complete the Administrative Record to make the record whole. The court finds that GCPM has, first, identified reasonable, non-speculative grounds that documents that were considered by the agency were not included in the administrative record and, second, properly identified the specific excluded records. GCPM requests that the court include its FOIA request and the resulting Universe and Adjusted OP Files in the administrative record and that the court compel the Secretary to produce the Missing Universe File and the Adjusted OP File Calculations. Moreover, GCPM has provided clear evidence that AdvanceMed and/or Palmetto acted on behalf of the

agency and relied on the Universe, the Missing Universe, the Adjusted OP File, and the Adjusted OP File Calculations, which are not currently included in the administrative record before the court.¹⁵ “To exclude these documents and any similar documents that have yet to be disclosed would, in effect, create an inaccurate record for the court’s ultimate review.” *S.C. Coastal Conservation League*, 431 F. Supp. 3d at 723. As such, the court orders that the Secretary produce the Missing Universe File and the Adjusted OP File Calculations within forty-five (45) days. The court also orders that the FOIA Request, the Universe File, and the Adjusted OP File be included in the administrative record such that the administrative record is completed within forty-five (45) days.

B. Motion for Protective Order

*12 The analysis of the motion for protective order has significant overlap with the motion to complete the administrative record. That is because each motion tends to request that the administrative record be expanded either through the inclusion of documents received from FOIA requests or through admissions. In any event, the court will start by setting forth the parties’ arguments as to this motion. The court next will examine whether the district court may permit discovery in [section 405\(g\)](#) and APA cases, and, if doing so is within the court’s authority, the court will determine under what circumstances such discovery should be permitted. Thereafter, the court will analyze whether those circumstances exist in this case.

Secretary Becerra filed a motion for protective order in response to GCPM’s first set of requests for admission.¹⁶ ECF No. 30. The Secretary essentially argues that under [42 U.S.C. § 405\(g\)](#), “a court’s review is based solely upon the Administrative Record filed by the Secretary and the pleadings of the parties.” *Id.* at 1. In other words, “there is no discovery” in these types of cases. *Id.* Since the Administrative Record is “a closed administrative record,” “neither party may put any additional evidence before the district court.” *Id.* at 3 (citing *Mathews*, 423 U.S. at 270). Consequently, Secretary Becerra urges the court to grant his protective order. *Id.* at 4.

In response, GCPM sets forth four reasons why the court should deny the Secretary’s motion. ECF No. 31 at 1. First, GCPM emphasizes that this court has previously ordered that discovery is allowed in this case. *Id.* at 1–2. Second, Secretary Becerra fails to address that other courts have allowed for

discovery where the parties sought judicial review of a final agency action pursuant to [42 U.S.C. § 405\(g\)](#) and the APA. *Id.* at 1, 3–6. Third, the Secretary “mischaracterizes the utility of requests for admission in general and disregards that the requests for admission at issue here ... are appropriately limited and focused on relevant issues.” *Id.* at 1–2, 6–8. Fourth, GCPM highlights that Secretary Becerra’s initial opposition brief to GCPM’s requests for admission as a whole is the incorrect procedural response; rather the Secretary should have objected to a specific request, admitted, denied, provided a detailed explanation why the matter can be neither admitted nor denied, or provided a good faith qualified admission which admits some aspects but denies or gives a qualified answer to the rest.¹⁷ *Id.* at 2, 8–9.

In reply, Secretary Becerra again emphasizes that “[t]his civil action poses no singular circumstance that could justify a departure from the statutory language that prescribes how such a case is conducted;” and, as such, “there is no basis for discovery.” ECF No. 32 at 1. Moreover, the Secretary contends that GCPM’s contention that the district court has the authority to develop an evidentiary record impermissibly expands the scope that the quoted phrase was intended to cover—“[n]othing in that brief phrase ... suggests that the ordinary review of individual agency decisions under [42 U.S.C. § 405\(g\)](#) is free to incorporate discovery at will.” *Id.* at 2–3. Thereafter, Secretary Becerra goes through each of the cases that GCPM cites and explains that those cases are distinguishable from the instant case. *Id.* In essence, the Secretary agrees that a district court may, in certain limited circumstances, permit discovery; however, the Secretary emphatically notes that those special circumstances are not present in this case. *Id.* at 4–5. As such, he requests that the court find GCPM’s discovery requests to be unauthorized and unwarranted and therefore should be quashed. *Id.*

*13 The motion for protective order specifies that GCPM served them by electronic mail on April 3, 2023, and notes that GCPM “seeks ‘admissions’ from the Secretary as to various alleged legal obligations, ‘fail[ures]’ to satisfy obligations, ‘[in]sufficien[cies],’ etc.” ECF No. 30 at 1, 4 (alterations in original). The response in opposition notes that the requests “are appropriately limited and focused on relevant, technical issues.” ECF No. 31 at 7. The parties did not file the requests with the court until after the hearing.

The focal point of judicial review under the APA is the administrative record already in existence and not a new record made by the reviewing court. *Fla. Power & Light Co.*

v. Lorion, 470 U.S. 729, 743 (1985) (quoting Camp, 411 U.S. at 142). It is inappropriate for courts reviewing appeals of agency decisions to consider arguments not raised before the administrative agency. Pleasant Valley Hosp. Inc. v. Shalala, 32 F.3d 67, 70 (4th Cir. 1994); see also United States v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952) (“Simple fairness ... requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice.”). As such, broad ranging discovery aimed at matters beyond those included in the administrative record is inappropriate. See Harvard Pilgrim Health Care of New England v. Thompson, 318 F. Supp. 2d 1, 8–9 (D.R.I. 2004); Exxon Corp., 91 F.R.D. at 33 (finding that matters not considered by the agency are outside the record evaluated by the district court, legally irrelevant, and not discoverable under Fed. R. Civ. P. 26).

However, the inverse should be equally true, meaning the court may permit discovery of documents which form the administrative record, particularly where the party objecting has consistently raised the same objection throughout the administrative review process. See, e.g., Harmon v. Apfel, 211 F.3d 1172, 1177 (9th Cir. 2000) (“[J]udicial review in cases under the Social Security Act is limited to a review of the administrative record [under § 405(g)]”); Hummel v. Heckler, 736 F.2d 91, 95 (3d Cir. 1984) (“Section 405(g) permits consideration of additional evidence on a showing of good cause for the failure to incorporate such evidence into the [agency] record.”); Yale-New Haven Hosp., Inc. v. Thompson, 198 F. Supp. 2d 183, 185 (D. Conn. 2002) (“[T]he scope of this Court's review is limited to the pleadings and transcripts from the administrative proceedings, including all evidence considered by the Administrative Law Judge”), aff'd sub nom. Yale-New Haven Hosp. v. Leavitt, 470 F.3d 71 (2d Cir. 2006); cf. Freitag v. Sec'y of Health & Hum. Res., 2001 WL 267635, at *2–3 (D. Or. Feb. 12, 2001) (explaining that judicial review of the agency does not permit expanding the administrative record, though § 405(g) does not explicitly preclude discovery in federal court). As the court noted above, supra n.7, it is important that the court distinguish between new evidence sought to be included in the record (“supplementing the record”), and existing evidence initially omitted from the administrative record (“completing the record”), as the former has specific statutory mechanisms which govern the circumstances requiring remand. See Arriva Med. LLC v. Sec'y of U.S. Dep't of Health & Hum. Servs., 2020 WL 5032978, at *2–5 (S.D. Fla. Aug. 25, 2020), report and recommendation adopted, 2020 WL 5757084

(S.D. Fla. Sept. 28, 2020) (explaining the difference between completing the administrative record and supplementing the administrative record where the latter involves providing materials not considered by the agency, but which are required for the court to conduct a substantial inquiry). Reviewing courts are to determine whether an agency's action was arbitrary or capricious considering the information the agency confronted, which requires a completed administrative record. See Citizens to Pres. Overton Park, 401 U.S. at 420. As such, the determination on the motion for protective order is impacted by whether those requests seek to complete versus supplement the administrative record.

*14 Given that GCPM only seeks to compel inclusion of the five identified files—the Universe File, the Missing Universe File, the FOIA Request, the Adjusted OP File, and the Adjusted OP File Calculation—into the administrative record, the court assumes that the files’ inclusion will complete the administrative record. Consequently, GCPM's discovery requests for the inclusion of files, documents, and admissions beyond those five files serve to supplement, rather than complete the administrative record.¹⁸

“Supplementing the administrative record” means that a party seeks to include new evidence in the record, which requires the court and the parties to follow a specific statutory mechanism which governs the circumstances requiring remand to the agency. See Vega v. Comm'r of Soc. Sec., 265 F.3d 1214, 1218 (11th Cir. 2001) (“42 U.S.C. § 405(g) permits courts to remand a case to the [agency] for consideration of newly discovered evidence.”); Goodrich v. Heckler, 628 F. Supp. 187, 189–90 (D. Conn. 1986) (“The only evidence not presented to the ALJ which the court may consider is material evidence which was not previously presented for which good cause is shown as to why [the] same was not so presented.”). If a party seeks to incorporate new evidence into the administrative record, a specific procedure must be followed:

[A] remand is appropriate only where three criteria have been met: (1) there is new, non-cumulative evidence; (2) the evidence is material, that is, relevant and probative so there is a reasonable possibility that it would change the administrative result; and (3) there is good cause for the

failure to submit the evidence at the administrative level.

[Yale-New Haven Hosp.](#), 198 F. Supp. 2d at 185. GCPM has not made arguments in its response in opposition that support supplementation of the administrative record through requests for admission. See ECF No. 31. Nor does the court infer that the three criteria have been met which would permit supplementation of the administrative record. See [Yale-New Haven Hosp.](#), 198 F. Supp. 2d at 185. Based on the evidence and arguments before the court, the court grants the Secretary's motion for protective order.

IV. CONCLUSION

For the reasons set forth above, the court **GRANTS** the motion to compel completion of the administrative record and **GRANTS** the motion for protective order.

AND IT IS SO ORDERED.

All Citations

Slip Copy, 2024 WL 942918

Footnotes

- 1 The court notes that the remaining facts included in this section are drawn from the amended complaint, unless otherwise specified, and therefore the court omits citations throughout. See ECF No. 24, Amend. Compl.
- 2 Zero-paid claims, which are claims that were unpaid after adjudication, are distinguishable from unpaid claims, which are claims that have been submitted for payment but have not yet been adjudicated or processed for payment determination.
- 3 As of September 2017, GCPM's clinic ceased operations. However, GCPM's limited liability company remains in existence and is in good standing with the state of South Carolina.
- 4 The current procedural terminology ("CPT") codes offer doctors and health care professionals a uniform language for coding medical services and procedures.
- 5 The parties agreed to transfer the case from the District Court for the District of Columbia to the District of South Carolina upon the parties' consent that venue is proper in GCPM's judicial district. ECF No. 10-1 (citing 42 U.S.C. § 405(g)). As such, the appropriate venue is the district in which the plaintiff resides or has his principal place of business. Id. GCPM's principal place of business is in the District of South Carolina and therefore the District of South Carolina is the appropriate venue for this action. Id. When a transfer is made from an improper venue to a proper one, the district court receiving the case must apply the law of the state in which it is held rather than the law of the transferor district court. 28 U.S.C. § 1406(a); [Myelle v. Am. Cyanamid Co.](#), 57 F.3d 411, 413 (4th Cir. 1995). As such, the court applies the law of this district and of the Fourth Circuit.
- 6 GCPM stipulates that this court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) as applied to Medicare appeals by 42 U.S.C. § 1395ff, which authorizes judicial review of a final agency decision of the Secretary.
- 7 As far as this court can discern, the Fourth Circuit and District Courts within that circuit have not defined the difference between "supplementing the administrative record" and "completing the administrative record." However, this court finds the distinction, and respective definitions, important for the pending motions and

therefore provides the definitions. “Supplementing the administrative record” means that a party seeks to include new evidence in the record, which requires the court, and the parties, to follow a specific statutory mechanism which governs the circumstances requiring remand to the agency. See [Vega v. Comm’r of Soc. Sec.](#), 265 F.3d 1214, 1218 (11th Cir. 2001) (“42 U.S.C. § 405(g) permits courts to remand a case to the [agency] for consideration of newly discovered evidence.”). In contrast, “completing the administrative record” means including existing evidence initially omitted from the administrative record to make that record whole, which does not require the court to apply the same rigorous test. See [Arriva Med. LLC v. Sec’y of U.S. Dep’t of Health & Hum. Servs.](#), 2020 WL 5032978, at *2–5 (S.D. Fla. Aug. 25, 2020), [report and recommendation adopted](#), 2020 WL 5757084 (S.D. Fla. Sept. 28, 2020). Courts in this circuit have interchangeably used the terms “supplement” and “complete” when confronted with facts analogous to this case. See, e.g., [S.C. Coastal Conservation League](#), 611 F. Supp. 3d at 141. Using this court’s above definitions, the undersigned emphasizes that GCPM requests that this court “complete” the administrative record and not “supplement” it in the instant motion to compel.

- 8 GCPM initially filed objections to the administrative record and requested to supplement the administrative record. See ECF No. 18 at 1. On November 13, 2023, the court directed the parties to either consent to having the court construe their filings to reflect the appropriate motion affiliated the substantive matter at issue or to withdraw and refile their requests. On November 14, 2023, counsel for GCPM requested that the court update the docket to reflect ECF No. 18 as a motion to compel. As such, the court construes the filing as a motion to compel completion of the administrative record.
- 9 These exhibits were sent separately via flashdrive. ECF No. 18.
- 10 Based on the briefs and the parties’ arguments presented at the hearing, GCPM requests the inclusion of both the Universe File and the Missing Universe File despite potential redundancy, because of the possibility that the government is unable to locate the Missing Universe File. See ECF Nos. 18; 26; 42. The dispute underlying this case started on October 17, 2013, and spans more than a decade. See Amend. Compl. ¶ 202. Given this lengthy process, counsel for GCPM indicated at the hearing that the omission of these files from the administrative record might be a consequence of the appeals process’s complexity and the many actors involved in claim review. See ECF No. 42. Presumably, GCPM requests the inclusion of the incomplete Universe File to ensure the record is as complete as possible if the government cannot locate the Missing Universe File. See [id.](#)
- 11 Most district courts within the Fourth Circuit, and the Fourth Circuit itself, have not reached the merits of the instant question because those courts found that the parties’ failed to establish that the federal court had jurisdiction. In other words, those courts found that the court lacked jurisdiction because the parties failed to exhaust administrative remedies. See, e.g., [Cumberland Cnty. Hosp. Sys., Inc. v. Burwell](#), 816 F.3d 48, 55–57 (4th Cir. 2016) (acknowledging that the Medicare reimbursement claims process is heavily backlogged and delayed but noting that, “despite the legitimacy of the Hospital System’s frustration,” the district court correctly dismissed the claim for failure to exhaust); [N.C. Ins. Guar. Ass’n v. Becerra](#), 55 F.4th 428, 435–36 (4th Cir. 2022) (concluding the jurisdictional bar of § 405(h) controls the plaintiff’s claim because it can use the appeals process for Medicare demands of repayment and therefore the district court properly dismissed the complaint for failure to exhaust administrative remedies). Those cases which incorporate consideration of both the APA and the Medicare Act, consider completion of the administrative record, and which have found that the petitioner exhausted administrative remedies come from outside of the Fourth Circuit. See, e.g., [Harvard Pilgrim Health Care of New England v. Thompson](#), 318 F. Supp. 2d 1, 8–12 (D.R.I. 2004); [Arriva Med. LLC](#), 2020 WL 5757084, at *2–3.
- 12 At the hearing, the court confirmed with the parties that Secretary Becerra contends that GCPM’s challenge to AdvanceMed’s recalculation of the overpayment, which he describes as “the effectuation of the ALJ’s decision,” has not exhausted the applicable administrative remedies. See ECF Nos. 25 at 8–9; 42. The

Secretary emphasizes that “[u]nder the governing Medicare regulation, a Medicare administrative contractor’s effectuation of an ALJ decision is ‘a new initial determination.’” *Id.* (quoting 42 C.F.R. § 405.1046(a)(3)). Thus, the Secretary concludes that “any challenge to the effectuation must be presented to the agency through the appeal process.” *Id.* GCPM replies that the Secretary’s interpretation is not clearly applicable because it reaches its conclusion by “cit[ing] to an unpublished, out-of-circuit decision.” ECF No. 26 at 7 (referencing the Secretary’s citation to [Pinnacle Peak Neurology, LLC v. Noridian Healthcare Sols., LLC](#), 773 F. App’x 910 (9th Cir. 2019)). GCPM instead points the court to a published out-of-circuit decision that reaches the opposite conclusion—namely, that effectuation of final agency decisions are reviewable under § 405(g) as continuous aspects of the initial, properly exhausted administrative decision. *Id.* (citing [D&G Holdings, L.L.C. v. Becerra](#), 22 F.4th 470, 471–72 (5th Cir. 2022)). The court finds the latter interpretation more persuasive, adopts the reasoning in [D&G Holdings](#), and thereby concludes that GCPM did not need to take another decade to exhaust administrative remedies to request that the Adjusted OP File be included in the administrative record because the “effectuations” of final agency decisions are reviewable under § 405(g) as continuous aspects of the initial, properly exhausted administrative decision. *See* [D&G Holdings](#), 22 F.4th at 471–72, 474–77.

- 13 Supplementation of the record used to be explicitly addressed in 42 U.S.C. § 1395ff. If the court determined that the record was “incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemented record.” *Id.* However, that provision was removed from the statute in 2000, Consolidated Appropriations Act, 2001, Pub. L. No. 106–554, § 521, 114 Stat. 2763A, 534, and 42 U.S.C. § 1395ff is now silent regarding the procedures and consequences of supplementing the administrative record once the matter has reached federal court. Thus, the court looks to § 405(g), which governs the court’s review in this matter, as well as decisions from other courts which have considered the same issue. *See* 42 U.S.C. § 405(g).
- 14 The court notes that there is not a clear consensus as to what factors are sufficient for the court to allow a party to supplement the administrative record. Compare [Brandon](#), 115 F. Supp. 3d at 684 (listing three circumstances where a court may permit the administrative record to be supplemented) with [Piedmont Env’t Council v. U.S. Dep’t of Transp.](#), 159 F. Supp. 2d 260, 270 (W.D. Va. 2001) (identifying four scenarios where courts have allowed the record to be supplemented, which include the first two scenarios described in [Tafas](#)), *aff’d in part, remanded in part*, 58 F. App’x 20 (4th Cir. 2003). Since the court finds that the first exception applies in this case, it need not opine as to whether there are three or four factors, since both tests include the first factor as a clear exception to the general rule that a court may not supplement the administrative record. This court notes that the first factor of both tests requires that the agency complete the administrative record, rather than supplement it.
- 15 The court permits the parties to include the FOIA Request documentation to the administrative record because it explains how GCPM received the Universe File and Adjusted OP File. If the Secretary objects to the FOIA request’s inclusion, the court alternatively compels the Secretary to produce the Universe File and Adjusted OP File in addition to the Missing Universe File and the Adjusted OP File Calculations.
- 16 Secretary Becerra initially filed a response in opposition to GCPM’s first set of requests for admission. *See* ECF No. 30 at 1. On November 13, 2023, the court directed the parties to either consent to having the court construe their filings to reflect the appropriate motion affiliated the substantive matter at issue or to withdraw and refile their requests. On November 21, 2023, counsel for Secretary Becerra requested that the court update the docket to reflect ECF No. 30 as a motion for protective order. As such, the court construes the filing as a motion for protective order.

- 17 The court notes that, in the time since GCPM filed its response in opposition brief, the court and the parties have construed the Secretary's initial response in opposition as a motion for protective order and therefore this fourth objection no longer applies.
- 18 If, in fact, GCPM wishes to open discovery, it may file a motion requesting as much.

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