IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

HUMANA INC. *et al.*, *Plaintiffs*, *v.* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 24-cv-1004-O

PLAINTIFFS' CONSOLIDATED REPLY IN SUPPORT OF THEIR EXPEDITED MOTION TO COMPLETE THE ADMINISTRATIVE RECORD AND OPPOSITION TO DEFENDANTS' MOTION TO STRIKE AMENDED COMPLAINT

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INTRODUCTION

CMS's opposition to the motion to complete the administrative record is wrong in two core respects. ***First,*** the agency has misconstrued its duty under the APA. It may not selectively limit the contents of the administrative record to the "issues" it believes relevant to the theories of illegality asserted in the complaint. Its obligation, instead, is to produce the "whole record" underlying the "final agency action" that is the object of the challenge (5 U.S.C. §§ 704, 706)—in this case, Humana's 2025 Star Ratings. ***Second,*** even if that were not so, the original complaint directly challenged the data and calculations underpinning Humana's 2025 Star Ratings. CMS does not deny that the amended complaint does so, requiring the agency to produce an AR comprising all of the data, analyses, and explanations that underlie Humana's 2025 Star Ratings. In all relevant respects, the original and amended complaints are identical.

Related, CMS's motion to strike the amended complaint is meritless and should be denied. The original complaint is a "pleading . . . to which a responsive pleading is required" within the meaning of Rule 15(a)(1)(B), and it therefore is one that may be amended once as a matter of course up to 21 days following a Rule 12 motion. The parties' negotiation of a joint scheduling motion does not alter that fact. The most that CMS's argument may support is a motion to amend the briefing schedule—but that is something that plaintiffs already have agreed will be required as to Count I of the complaint, given CMS's refusal to produce a complete AR. And if a different briefing schedule is all CMS wants, nothing prevents it from simply asking for one.

In all events, the motion to complete the AR should be granted, and CMS's motion to strike the amended complaint should be denied.

REPLY IN SUPPORT OF MOTION TO COMPLETE THE RECORD

A. CMS must produce the whole record, not just the portion it believes relevant to the issues raised

We begin with CMS's unusually narrow theory of its duty with respect to the AR. The ground rules should not be controversial: When a plaintiff challenges a reviewable agency action under the APA, the agency must produce the "whole record" (5 U.S.C. § 706) underlying the action being challenged—not just the portion of the record that the agency believes relevant to the plaintiff's claims in the case.

CMS disagrees. It believes (Opp. 8-10) that it may limit the AR solely to the "issues" raised in the complaint. It takes the position (Opp. 8) that the original complaint in this case challenged only a few specific "actions regarding Humana during the plan preview period" and did not include any challenge "to the calculation of the Star Ratings writ large." As CMS sees it (*id.*), it may therefore limit the AR solely to the communications and data exchanged by Humana and CMS during "plan preview periods," which is thus all that is "covered by the Administrative Record that CMS filed."

That is not how the APA works. The contents of the administrative record are determined by the identity of the final agency action that is the object of the lawsuit, not the issues raised in the complaint. The challenged agency action cannot be "[a] preliminary, procedural, or intermediate agency action or ruling," such as CMS's rejection of an objection during the plan preview period, because such interlocutory decisions are nonfinal and thus "not directly reviewable" under the act. 5 U.S.C. § 704. Just like interlocutory decisions of a district court that merge into a final judgment, such decisions become "subject to review [only] on the review of the final agency action." *Id.* But when a plaintiff challenges the substance of an intermediate decision underlying the final agency action, it

is the "final agency action" itself that is "subject to judicial review" under the APA (*id.*), and thus the "final agency action" as to which the whole record must be produced.

Practice bears this out. Suppose a regulated entity submitted a comment letter in a rulemaking, asserting that they agency has not disclosed the evidence or reasoning underlying its proposed action. Suppose further that the same entity later filed a lawsuit challenging the agency's final action, alleging that it was arbitrary and capricious on the same ground raised in the comment letter. In such a case, the plaintiff would be entitled to the entire AR underlying the final agency action—that is, it would be entitled to "all documents and materials directly or indirectly considered by agency" in the course of proposing and finalizing the rule. *Exxon Corp. v. DOE*, 91 F.R.D. 26, 33 (N.D. Tex. 1981) (Higginbotham, J.) (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-488 (1951)). The agency could not limit the AR solely to the plaintiff's comment letter and documents concerning the agency's consideration and rejection of the comment.

Just so here. CMS's nonfinal overrulings of Humana's objections during the plan preview period are not independently reviewable. 5 U.S.C. § 704. The object of the suit here is (and can only be) Humana's final 2025 Star Ratings. *See* Opening Mem. 7; FAC ¶¶ 109-116. No matter what precise errors plaintiffs may allege as to Humana's 2025 Star Ratings, the agency must produce the full administrative record.

CMS does not cite a single case holding otherwise. On the contrary, authoritative executive sources confirm plaintiffs' position. For instance, an Attorney General Bulletin confirms that, in undertaking judicial review of a final agency action, "a court evaluates the agency's *entire* administrative record," including "all documents and materials prepared, reviewed, or received by agency personnel and used by or available to the decisionmaker" "during the agency decision-making process." Joan Goldfrank, *Guidance*

to Client Agencies on Compiling the Administrative Record 7-8 (Feb. 2000), https://perma.cc/7GMU-A4E8 (emphasis added) (quoting 5 U.S.C. § 706). In compiling an AR in such a case, agencies must therefore include all documents and materials that "were available to the decision-making office at the time the decision was made." *Id.* at 8.

As another authoritative executive source explains, this includes the "analyses that support the final agency action" and "is not limited to documents and materials relevant only to the merits of the agency's decision, but also includes documents and materials logically connected to the process of making the decision or informing the decisionmaker." Leland E. Beck, Administrative Conference of the United States, *Agency Practices and Judicial Review of Administrative Records in Informal Rulemaking* 28-29 (May 14, 2013), https://perma.cc/4GZS-ZXVJ. At bottom, "[i]t is black-letter administrative law that in an Administrative Procedure Act case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." *The Record for Review*, 33 Fed. Prac. & Proc. Judicial Review § 8391 n.1 (2d ed.) (cleaned up) (quoting *Hearth, Patio & Barbecue Association v. EPA*, 11 F.4th 791, 802 (D.C. Cir. 2021)).

Again (Opening Mem. 5), the APA could not require less. To allow an agency to selectively curate the administrative record, limiting it to the "issues" (Opp. 8) it believes relevant to the plaintiffs' claims, would too easily permit evasion of meaningful judicial review. At the same time that the APA generally bars plaintiffs from introducing extra-record material, it requires the agency to include "*all* documents and materials directly or indirectly considered by agency." *Exxon*, 91 F.R.D. at 33 (emphasis added).

Here, CMS has conceded that "the Administrative Record that CMS filed" in this case "cover[s]" only "the results of [Humana's] administrative challenge during plan preview periods" and not the full range of documents and materials before CMS pertaining

to Humana's 2025 Star Ratings. Opp. 8 (cleaned up). That is an admission of incompleteness. Regardless of the "issues" raised in the complaint, CMS must produce the whole record concerning Humana's 2025 Star Ratings.

B. Plaintiffs' amendment of the complaint did not alter the relief requested or CMS's duty with respect to the administrative record

Even if, contrary to blackletter administrative law, CMS could selectively limit the contents of the administrative record based on the theories or issues in the complaint, plaintiffs still would be entitled to supplementation of the AR in this case.

CMS's position on this score (Opp. 5) is that "in amending their complaint, Plaintiffs changed the remedy they were requesting." That is simply wrong. As the attached redline shows (Ex. A), the prayer for relief is unchanged from the original complaint (Dkt. 1) to the amended complaint (Dkt. 21). In both versions, plaintiffs' first prayer is for an order of the Court that "[sets] aside and vacate[s] Humana's 2025 Star Ratings and remand[s] the matter to CMS for recalculation of Humana's 2025 Star Ratings without application of the unlawful practices and policies identified above." The second prayer, also unchanged, is for a declaration "that CMS's policy refusing to disclose all relevant data and information necessary to permit MAOs to validate the data and calculations underlying CMS's Star Ratings is arbitrary, capricious, and unlawful," which plaintiffs seek to help prevent the agency in future years from repeating its unlawful behavior.

The relief requested in this case has thus been consistent—all along, plaintiffs have sought a vacatur of Humana's 2025 Star Ratings in light of the illegalities asserted, together with a declaration that CMS may not withhold the information necessary to permit MAOs to validate the data and calculations underlying the Star Ratings.

Plaintiffs have also consistently asserted that CMS's cut-point calculations are wrong, which even according to CMS's theory would require the agency to include in the AR all of the data, documents, and other materials needed to verify the agency's work. Both the original and amended complaints allege, in particular, that numerous "discrepancies" in the limited data disclosed "raise serious concern that the agenc[y's] methodologies and calculations were applied incorrectly," and that, "[c]ollectively, they leave little doubt that the cut points are inaccurate." FAC ¶ 88; Orig. Compl. ¶ 88. Plaintiffs thus allege "[u]pon information and belief" that Humana's contracts "would have received higher Star Ratings had the cut points been correctly calculated." FAC ¶ 112; Orig. Compl. ¶ 107.

More generally, both complaints allege that "the cut points for several measures moved abruptly and substantially upward, significantly depressing MAOs' Star Ratings" overall, and in ways that could not be explained by "broader, objective indications [of] MA plan quality." FAC ¶¶ 7-8; Orig. Compl. ¶¶ 7-8. But despite objecting to CMS about these "unexplained swings," MAOs were "denied an opportunity to determine why the measure-level cut points moved so suspiciously in the 2025 scores or to validate the accuracy of CMS's calculations." FAC ¶¶ 8-9; Orig. Compl. ¶¶ 8-9.

Against this background, the addition of ¶ 125 to the amended complaint merely summarized the prior allegations, adding nothing that was not already alleged in paragraphs 7-9, 83, and 107 of the original complaint. Paragraph 125 states in full:

> The substantial swings in the 2025 cut points relative to recent prior years introduces a plausible concern that the 2025 cut points are inaccurate. This may be because the data underlying the agency's calculations is flawed, or because its analysis is flawed. Either way, there are no independent, objective indications that MA plan quality has diminished in recent years as suggested by the decline in overall star ratings across the program, and the cut points are therefore arbitrary and capricious.

Insisting otherwise, CMS focuses (Opp. 7) on eight words appearing at the end of the new paragraph: "the cut points are therefore arbitrary and capricious." That also adds nothing new. The complaint all along has alleged *facts* showing arbitrariness, including that (1) CMS's data contains "discrepancies" leaving "little doubt that the cut points are inaccurate" (FAC ¶ 88; Orig. Compl. ¶ 88); and (2) the abrupt, substantial, and suspicious moves in the cut points cannot be explained by any "objective indications" of shifts in "plan quality." FAC ¶¶ 7-8; Orig. Compl. ¶¶ 7-8. It is on this basis that Count I, from the start, has entitled plaintiffs to an order "[setting] aside and vacat[ing] Humana's 2025 Star Ratings and remand[ing] the matter to CMS for recalculation of Humana's 2025 Star Ratings." Orig. Compl. 37.

In the end, CMS is just wrong to say (Opp. 9) that the original complaint did not "challenge to Humana's 2025 Star Ratings themselves" or the "policies and practices supporting them." It did exactly that, in plain terms. And it is beyond debate that when a regulated entity files a lawsuit seeking vacatur of an agency action under the APA, asserting that (1) the action is based upon bad data or analysis and (2) that the agency has not properly disclosed the data or analysis on which its decision was based, the agency must produce to the reviewing court an AR that contains all of the data and analysis on which it relied to reach its decision. Period.

C. A FOIA production is not an administrative record, and CMS's assertion of difficulty does not license it to withhold the AR

1. As a fallback, CMS notes that plaintiff Humana received documents on December 4, 2024, in response to a FOIA production request submitted to CMS, in which counsel for the plaintiffs requested the data and materials listed in ¶ 80 of the complaint. That is no help to CMS.

"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." *UnitedHealthcare Insurance Co. v. Azar*, 316 F. Supp. 3d 339, 349 (D.D.C. 2018) (quoting *Delaware Department of Natural Resources v. U.S. Army Corp of Engineers*, 722 F. Supp. 2d 535, 544 (D. Del. 2010)). "[T]he mere fact that a plaintiff possesses [an agency] document," whether it obtained the document through FOIA or by other means, "does not render it part of an administrative record." *Id.* And even now, CMS "maintain[s its] objection . . . to including [the FOIA production] in the Administrative Record." Opp. 11.

Given that "judicial review of an agency decision is typically limited to the administrative record" (*Kappos v. Hyatt*, 566 U.S. 431, 438 (2012)), it is thus hard to see how the FOIA production makes any difference here. That is especially so because the FOIA production, even if taken into the AR, would comprise only a portion of the "documents and materials directly or indirectly considered by agency" in the course of calculating Humana's 2025 Star Ratings. *Exxon*, 91 F.R.D. at 33.

2. Finally, CMS asserts that the AR underlying Humana's 2025 Star Ratings is "breathtaking" in scope, comprising 600 million lines of data that could not be produced on any schedule (Opp. 12)—or at least that it "could take years to redact" it (Def. App. ¶ 5). That is unpersuasive for several reasons.

To begin, the Goldstein Declaration, which is attached as an exhibit to CMS's opposition, states that "[t]here are over six hundred million (600,000,000) records (lines of data) that have [protected personal health information] that were included *in the calculation of the 2025 Star Ratings*." Def. App. ¶ 5 (emphasis added). That is a red herring. Our position is not that CMS must produce the data underlying the calculation of *all* 2025 Star Ratings for *each* of the thousands of MA contracts throughout the country. Our

position, instead, is that CMS must produce the data and analyses used to derive (1) the 2025 cut points and (2) Humana's measure-level scores, which together were used to produce *Humana's* 2025 Star Ratings. It is flat wrong to say that producing a proper and complete AR in this case would require anything close to the dramatic volume of data that CMS cites in its brief. CMS's counsel baldly asserts otherwise (Opp. 12), but the Goldstein Declaration notably does not.

Moreover, the agency's FOIA production demonstrates that the agency is capable of producing a properly redacted AR in a timely manner. The FOIA production was made in just 30 days' time, without a peep concerning impossibility or undue burden. And it demonstrates that the data used to derive the 2025 cut points is far more limited than the data used to calculate all 2025 Star Ratings across the entire MA industry.

In any event, there is no "it's too much work" exception to producing an AR in APA cases. It is not uncommon for agencies to receive and process millions of comments in rulemakings, or for other agencies to crunch millions of lines of data in their underlying analyses. Agencies have thus developed sophisticated and detailed recordkeeping protocols for storing, processing, and producing the materials used in their work, whether production is required by FOIA or the APA. *See generally* Beck, *supra*.

The agency's obligation remains the same in all events. As a baseline, "an agency must make available to the public, in a form that allows for meaningful comment, the data the agency used to develop its proposed rule." *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 315 (D.D.C. 2016) (cleaned up). This general commitment to agency transparency allows the regulated public "to point out where that information is erroneous or where the agency may be drawing improper conclusions from it" (*id.* (cleaned up)), as Humana and other MAOs often have done during the plan preview periods (Am. Comp. ¶¶ 83-89). And

when an entity files suit under the APA alleging a failure to meet that obligation and challenging the accuracy of the agency's data and calculations, the agency assuredly must make those data and calculations available in the administrative record, without which meaningful judicial review would not be possible. The motion to complete the record accordingly should be granted.

OPPOSITION TO MOTION TO STRIKE

At the same time that CMS filed its opposition to our motion to complete the record, it filed a related motion to strike the amended complaint. *See* Dkt. 26. That motion is meritless and should be denied.

A. Rule 15 entitles a party to amend its "pleading" once as a matter of course "no later than . . . 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12," as long as "the pleading is one to which a responsive pleading is required." Fed. R. Civ. P. 15(a)(1). The phrase "pleading . . . to which a responsive pleading is required" is a complaint, counterclaim, or crossclaim, because a defendant "must" serve an answer to a such a pleading. Fed. R. Civ. P. 12(a). A pleading to which "a response is not allowed" (Fed. R. Civ. P. 15(f)(2)), in contrast, is an answer, because a reply to an answer is generally not permitted unless ordered by the court. Fed. R. Civ. P. 15(a)(1)(C).

The initial pleading in this case was (obviously) a complaint—meaning that it was a "pleading . . . to which a responsive pleading is required" under Rule 15(a)(1)(B). Rule 12(a)(2) makes this clear: "The United States, a United States agency, or a United States officer or employee sued only in an official capacity must serve an answer to a complaint, counterclaim, or crossclaim within 60 days after service on the United States attorney." Plaintiffs' initial pleading thus may be amended once as of right under Rule 15(a)(1).

In taking the contrary position, CMS does not deny that the complaint in this case falls within the meaning of Rule 15(a)(1)(B). Instead, it observes (Mot. 2[1]) that plaintiffs "waive[d] the requirement that Defendants file an answer to the complaint" in the joint motion to establish an expedited summary judgment briefing schedule.

Plaintiffs' waiver of CMS's Rule 12(a)(2) duty to file an answer to the initial complaint—which plaintiffs agreed to as a courtesy to the agency—indicates only that they were waiving enforcement of the Rule. That waiver did not magically transform the *complaint* (a pleading "to which a responsive pleading is required") into an *answer* (a pleading to which "a response is not allowed"). Nor did either party, in negotiating the contents of the joint motion, convey the remotest hint that plaintiffs were forfeiting their right to amend their complaint as of right under Rule 15(a)(1). CMS's sophistic reading of the joint motion—which the parties negotiated cooperatively and with an eye to eschewing unnecessary filings—is not defensible.

B. Even if the Court were to credit CMS's stingy interpretation of the joint scheduling motion, the appropriate course would be to construe this opposition as a motion for leave to file the amended complaint and to grant leave. This is plaintiffs' first amendment of the complaint, made before the parties have joined issue on the merits. For the most part, the amendment adds allegations that CMS improperly sub-delegated its regulatory authority to nongovernmental entities. A similar claim was found meritorious in *United-Healthcare Benefits of Texas v. CMS*, 2024 WL 4870771, at *7-*9 (E.D. Tex. Nov. 22, 2024). Plaintiffs here did not uncover the factual basis for the claim until CMS produced the partial AR on November 21, after which they promptly amended the complaint.

[1] CMS's motion has two pages labeled with a "1." We cite, therefore, to the page number in the ECF header at the top of each page.

The amendment is in no way prejudicial to CMS. In arguing otherwise, CMS says (Mot. 5) that "the amended complaint adds an entirely new count" and "changes one of the remedies they seek." True, the amended complaint adds a new count, but there have been no merits briefs filed in the case, so it is hard to see how that could be prejudicial, especially given that CMS has already briefed a similar sub-delegation claim in *UnitedHealthcare*.[2] And it is wrong to say that the amended complaint changes the nature of the relief requested—again, the prayers for relief in the original and amended complaints are identical. *See* Ex. A.

Either way, the only theory of prejudice that CMS offers (*id.*) is that it was denied "an opportunity to renegotiate the briefing schedule and related issues concerning the administrative record." That is no prejudice at all. To start, plaintiffs would not have waited to file their motion to complete the AR to negotiate a motion for leave to file the amended complaint. As for the briefing schedule, there is nothing to stop CMS from seeking a modification of the schedule any time it likes. *See* AR Opening Mem. 9 n.2. But as undersigned counsel made clear to counsel for CMS during the meet-and-confer concerning this motion, if CMS's objection is to the schedule, plaintiffs would prefer to engage on that topic directly, rather than wasting party and judicial resources on a meritless motion to strike the amended complaint, which counsel for CMS conceded is nothing more than a "symbolic" gesture to express the agency's displeasure with plaintiffs' motion to complete the AR.

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[2] It bears noting that the plaintiffs in *UnitedHealthcare* did not amend their complaint after the limited AR revealed the sub-delegation problem. Curiously, CMS did not complain then about any prejudice from introduction of the new claim. It is inexplicable that it would complain here simply because Humana has taken the extra, cautionary step of amending its complaint before making the argument in its summary judgment motion.

CONCLUSION

The Court should order CMS to amend the administrative record by December 27, 2024, with all documents, data, analyses, communications, and other materials that CMS considered or had before it in its determination of the 2025 Star Ratings for plaintiff Humana. It should deny the motion to strike the amended complaint.

Dated: December 10, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

Undersigned counsel certifies that a true and correct copy of this document was served via CM/ECF on all counsel of record pursuant to the Federal Rules of Civil Procedure on December 10, 2024.

/s/ *Michael B. Kimberly*