EXHIBIT 12

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April 11, 2019

By Email

Hugh Gilmore
Centers for Medicare & Medicaid Services
FOIA Office
Mailstop N2-20-16-7500
Security Blvd.
Baltimore, MD 21244
Hugh.Gilmore@cms.hhs.gov

Re: FOIA Requests 110920187047, 121420187009, 120720187005, and 022520197041

Dear Mr. Gilmore:

I am writing with regards to the FOIA requests noted above. As discussed in our prior correspondence,[1] these Requests cover documents related to the risk adjustment methodology that CMS describes in the proposed rule entitled "*Proposed Rule: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*" (the "Proposed Rule"). 38 Fed. Reg. 54982 (Nov. 1, 2018).

The above captioned FOIA requests were filed on November 9, 2018, December 4, 2018,[2] and December 13, 2018. Almost five months have now passed since we filed the first of

[1] *See* Letter from W. Sarraille to CMS FOIA Office (Nov. 9, 2018); Letter from W. Sarraille to CMS FOIA Office (Dec. 4, 2018); Letter from W. Sarraille to H. Gilmore (Dec. 4, 2018); Letter from W. Sarraille to CMS FOIA Office (Dec. 13, 2018); Letter from W. Sarraille to H. Gilmore (Dec. 18, 2018); Letter from W. Sarraille to H. Gilmore (Feb. 7, 2019); Email from W. Sarraille to H. Gilmore (Feb. 27, 2019); Letter from W. Sarraille to H. Gilmore (Mar. 1, 2019).

[2] CMS appears to have assigned two different control numbers to our December 4, 2018 FOIA request. CMS did not acknowledge receipt of our December 4, 2018 FOIA request for over 2 1/2 months after we submitted it. On February 26, 2019, following several rounds of phone calls to the CMS FOIA Office, we received an email from Mr. Jay Olin, Director, Division of FOIA Analysis – C, apologizing for CMS's delay in acknowledging receipt of the FOIA request. This email stated that CMS had assigned our December 4, 2018 FOIA request control number 120721087005. Later, on March 1, 2019, we received a letter from CMS via first class mail acknowledging receipt our December 4, 2018 FOIA request. This letter, which was dated February 26, 2018, stated that CMS had assigned

our FOIA requests regarding the Proposed Rule. During this time, the CMS FOIA Office has not produced any data or documents that are responsive to our requests—this despite the CMS FOIA Office acknowledging our "compelling need" for the documents we requested and granting our requests for expedited processing. Letter from H. Gilmore to W. Sarraille (Nov. 13, 2018) (granting expedited processing of Request No. 110920187047 based on our showing of "compelling need") (emphasis added); *see also* Letter from J. Olin to W. Sarraille (Feb. 26, 2019) (granting request for expedited processing of Request No. 022520197041).

As you may be aware, on March 6, 2019, the CMS program office made available a "limited data set" regarding the proposed risk adjustment methodology. While we understand that the CMS FOIA Office was likely not involved with the Agency's decision to release this limited data set or with decisions regarding its contents, we wanted to bring this development to your attention for two reasons.

First, CMS's limited data set is not sufficient to allow our client to meaningfully comment on the Proposed Rule. This is discussed in detail in a letter, which we recently submitted to Jonathan Smith, CMS Senior Technical Advisor, and Joanne Davis, CMS Senior Analyst, on this issue. A copy of this letter is attached. As explained in this letter, the limited data set does not include critical information that is necessary to understand the study that CMS conducted as part of its development of the proposed risk adjustment methodology. This missing information includes, among other things: (1) basic documentation underlying the methodology (*e.g.*, protocols, statistical analysis plans, etc.); (2) the criteria used to study the data files; (3) critical methodological steps taken during the study, including the programming used to run simulations, and the seed and algorithm used to generate random numbers; and (4) the results that CMS obtained for each simulation. Without this information, our client remains unable to reproduce CMS's study, and it is significantly limited in its ability to provide meaningful comments on the Proposed Rule.

Second, we wish to reiterate that the limited data set that CMS has released does not moot or in any way diminish the urgency of our receiving the data and document that were covered by our FOIA requests. These FOIA requests covered a wide range of data, documents, and other information regarding CMS's development of the proposed risk adjustment methodology, which are not included in the limited data that CMS has released. Without receiving these additional data and documents, our client's ability to comment on the Proposed Rule will be prejudiced for the reasons discussed in the attached letter and our prior correspondence.

It is noteworthy that CMS itself has acknowledged the importance of the information that we have requested to the ability to meaningfully comment on the proposed risk adjustment

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the request control number 022520197041. The letter further stated that CMS had granted our request for expedited processing of the request. Both tracking numbers are included in the caption to this letter.

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methodology. In the Federal Register notice announcing the release of the limited data set, CMS explained to prospective commenters that CMS's "*ability to meaningfully evaluate and respond to comments [on the Proposed Rule] may depend on the extent to which commenters disclose any methodologies, statistical analyses, audit findings, and other factors underlying the comments*." 84 Fed. Reg. 8069, 8070 (Mar. 6, 2019) (emphasis added). To borrow from CMS's own language, stakeholders like our client cannot "meaningfully evaluate and respond" to CMS's proposed risk adjustment methodology because the Agency has not fully disclosed the "methodological, statistical analyses, audit findings, and other factors" underlying its proposals.

We urge the CMS FOIA Office to produce the documents and data that we have requested without further delay. The release of this information necessary for our client to comment on the Proposed Rule and for the Agency to comply with its obligations under the Administrative Procedure Act and the Data Quality Act.

Thank you for your consideration.

Sincerely,

/s/ William A. Sarraille
William A. Sarraille
Partner

Enclosure

cc: Hon. Seema Verma
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April 1, 2019

By Email

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Joanne Davis, Senior Analyst
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Re: Health Plan Management System Memorandum, *Release of Data Underlying the RADV Provisions in NPRM 4815-P* (Feb. 15, 2019)

Dear Mr. Smith and Ms. Davis:

We write further to our letter of February 25, 2019, in which we expressed several concerns regarding the announcement that the Centers for Medicare & Medicaid Services (CMS) would be releasing limited data in support of its proposal to eliminate the use of a Fee-For-Service (FFS) Adjuster when calculating final recovery amounts in risk adjustment data validation (RADV) audits. That letter followed several others asking that CMS release the full data and other information necessary to evaluate CMS' study.[1]

We have reviewed the data dictionary posted to CMS' website on March 1, 2019, and our consultants have obtained the corresponding data files. Unfortunately, many of the concerns expressed in our prior correspondence have been proven correct. To date, CMS has failed to make the disclosures required by both the Administrative Procedure Act (APA),[2] and the Data

[1] *See, e.g.*, Letter from W. Sarraille to J. Smith and J. Davis (Nov. 5, 2018); Letter from W. Sarraille to CMS FOIA Office (Nov. 9, 2018) (FOIA Request No. 110920187047); Letter from W. Sarraille to J. Smith and J. Davis (Nov. 27, 2018); Letter from W. Sarraille to H. Gilmore (Dec. 4, 2018); Letter from W. Sarraille to CMS FOIA Office (Dec. 4, 2018) (FOIA Request No. 120720187005).

[2] *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 263 (D.D.C. 2015); *see also Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008); *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007); *Chamber of Commerce of U.S. v. SEC*, 443 F.3d 890, 900 (D.C. Cir. 2006); *Time Warner Entm't Co. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001); *Am. Medical Ass'n v. Reno*, 57 F.3d 1129 (D.C. Cir. 1995); *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991); *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 530 (D.C. Cir. 1982).

Quality Act (DQA).[3] Because stakeholders remain unable to reproduce CMS' study, they are prejudiced and necessarily limited in their ability to provide meaningful comment. *See, e.g.*, Sean Creighton, et al., *CMS Methodology for Calculating Payment Errors May Result in Underpayments to Health Plans*, Avalere Health, 8 (Mar. 18, 2019) ("Avalere could not replicate in full CMS' study due to lack of availability of publicly-released data.").[4]

CMS has failed to meet the expectations that it has attempted to impose on stakeholders participating in the comment process. When it announced the availability of the new data files, CMS stated that its ability "to meaningfully evaluate and respond to comments may depend on the extent to which commenters disclose any methodologies, statistical analyses, audit findings, and other factors." 84 Fed. Reg. 8069, 8070 (Mar. 6, 2019). To borrow CMS' own language, stakeholders, like our client, cannot "meaningfully evaluate and respond" to CMS' proposals because the Agency has not fully disclosed the "methodologies, statistical analyses, audit findings, and other factors" underlying its proposals.

Below, we describe the information CMS has not disclosed in violation of the APA and the DQA. In general, the withheld information includes:

- Basic documentation (e.g., protocols, statistical analysis plans, etc.);
- The criteria used to create the study data files;
- Critical methodological steps taken during the study, including statistical tests used, the programming used to run simulations, and the seed and algorithm used to generate random numbers; and
- The results CMS obtained for each simulation.

We urge the Agency to avoid unnecessary litigation by fully disclosing the information requested and extending the deadline for comments to permit review of and meaningful comment on that information.

Observed Claim-Level Discrepancy Rates

As described in the Technical Appendix (TA), the first step in CMS' study involved a review of medical records associated with Medicare FFS claims subject to the Comprehensive Error Rate Testing (CERT) program. Through this review, CMS generated "claim-level"

[3] *See* 67 Fed. Reg. 8451, 8455 (Feb. 22, 2002) ("The reproducibility standard applicable to influential scientific, financial, or statistical information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted."); *see also* HHS, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public § II.E.V.D (Oct. 1, 2002).

[4] https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf

estimates of the discrepancy rate for each hierarchical condition category (HCC). These observations are the foundation for the rest of CMS' analysis. CMS has failed to disclose, however, the medical records (even under a Data Use Agreement and even with redactions) and has refused to answer several important questions regarding its review of those records.

CMS stated that it created a "subset" of 8,630 CERT claims with CY 2008 dates of service and described certain inclusion criteria. TA at 5-6. Unfortunately, those criteria are not sufficient to explain how the subset was created. CMS has not stated whether it combined data from multiple CERT audits to create its CY 2008 subset and, if so, how it accounted for the material changes in CERT process that occurred between audits. As reflected in the CERT reports on CMS' website, CY 2008 fell across two different CERT audits, and the requirements regarding medical record documentation, provider signatures, and other issues that bear on RADV results were significantly different for those two audits.

This risk of bias—which CMS has not addressed—is likely compounded by the fact that many CERT claims are characterized as errors because the CERT program received either "No Documentation" or "Insufficient Documentation" from the provider. The 2009 audit, for example, saw an increase in errors stemming from "Insufficient Documentation" due to the imposition of new documentation requirements. CMS has not stated whether it excluded those claims from its subset.

The "FINAL_CID_HCC_DISPOSITION" data table released on March 1, 2009, does not address a number of additional issues, including:

- No dates are provided for any of the 8,630 claims, which prevents stakeholders from identifying the CERT audits from which the claims were selected;
- No CERT findings are provided for any of the 8,630 claims, which prevents stakeholders from confirming whether CMS filtered its subset based on CERT error type, thereby biasing its selection of CERT claims;
- No provider information is given for any of the 8,630 claims, which prevents stakeholders from evaluating CMS' assertion that it limited its subset to claims that "originated from an acceptable risk adjustment provider type," TA at 6;
- RADV findings are presented as binary variables without identifying the type of discrepancy[5] or providing sufficient information to assess the nature of the findings or determine whether the results were "RADV-like," as CMS contends; and

[5] During the 2007 targeted RADV audits, for instance, CMS's reviewers classified each observed discrepancy as either missing documentation, invalid documentation (with nine distinct invalidity types), or a coding error.

- The "FFSQ and "Prev_FFSQ" fields are unexplained and may indicate that unspecified stratification or sampling techniques were used to create the subset.

CMS also has failed to answer several methodological questions regarding the CERT review. CMS has asserted that it followed "RADV coding guidelines" to perform the medical record review, *see* TA at 6, but it has not disclosed *who* performed the review, *what* those individuals' qualifications were, or *which* edition of RADV coding guidelines they applied. Because coding guidance, including RADV guidance, has changed, there is a risk that CMS has introduced bias by applying guidance from different time periods.

In addition, CMS has failed to answer questions about a prior study that was also based on CERT claims from CY 2008 (described in footnote 8 of the Executive Summary), which supported the use of a FFS Adjuster between 4.8% and 8.1%. We are concerned that the two studies reviewed the same CERT claims and medical records, and that CMS simply chose to re-analyze the same data in a different manner to generate a different result. Whatever the case may be, stakeholders cannot provide meaningful comment unless *all* of the studies that CMS conducted on this topic are fully disclosed.

Adjusted Claim-Level Discrepancy Rates

The Technical Appendix states that the CERT subset was too small of a sample to estimate discrepancy rates for all HCCs in the model. *See* TA at 8-9. It further states that CMS applied "a statistical test" to evaluate the significance of the results of its review of CERT claims and then adjusted the claim-level discrepancy rates for each HCC. However, because CMS has not identified the statistical test used or provided any further information regarding its methodology at this step, it is not clear to stakeholders how CMS:

- Determined that it would be appropriate to sort all HCCs in the V12 model into three buckets rather than a smaller or higher number of buckets;
- Defined the "high," "normal," and "low" buckets shown in Table 2b; or
- Calculated the "adjusted" discrepancy rate for each bucket.

CMS also failed to disclose whether it considered alternative statistical methods to evaluate variance in the observed discrepancy rates or any information about such alternatives. Given that CMS' "adjustment" of the actual results from the CERT review is a critical step in its analysis, this lack of transparency fundamentally limits stakeholders' ability to comment.

In addition, at least some HCCs were assigned to the "normal" bucket by default, but CMS has not specified the criteria used. The Technical Appendix suggests that a threshold of 28 observations was used because CMS found that to be the minimum number of observations needed to generate a reliable estimate of the discrepancy rate for a given HCC. *See* TA at 8 &

n.4. However, at least some HCCs were assigned to the "low" and "high" buckets based on fewer than 28 observations, which indicates that CMS did not actually rely on the threshold identified in the Technical Appendix in some circumstances.

Further, CMS' bucketing decisions appear to have been inconsistent. CMS reported twelve and sixteen observations for HCC 5 and HCC 155, and both were assigned to the "high" bucket. CMS also reported twelve and sixteen observations for HCC 112 and HCC 52, but these HCCs were assigned to the "normal" bucket, despite observed discrepancy rates of 50% and 43.8%. CMS should disclose the methods and criteria used for these unexplained decisions.

Beneficiary-Level Discrepancy Rates

After adjusting the results of the CERT review, CMS engaged in a thought experiment to convert the adjusted discrepancy rates for each HCC to an estimate of the "beneficiary-level" discrepancy rate for that HCC. *See* TA at 9-11. This experiment exponentially reduced the adjusted discrepancy rate for each HCC by the average number of claims per beneficiary. CMS has not disclosed any work papers or analysis supporting this approach.

CMS also has not disclosed the data and information necessary to reproduce CMS' claim count calculations. We understand from CMS' website that the ten "FFS" datasets released on March 1, 2019 were, in conjunction with the "HCC" file, the source of CMS' calculation of average claim counts. However, only some of the averages set out in Table 2b can be precisely replicated using these files. Others cannot be replicated exactly. Given the *exponential* impact that these figures have on CMS' study, the lack of reproducibility is concerning. It also underscores why the disclosure of a few data tables is insufficient under the APA and DQA. In order for its study to be reproducible, CMS must be transparent about the software and code used to generate the average claim counts from these data tables.

The FFS files also raise substantial new questions. They contain just 12 fields, which provide only minimal information about each claim. Further, they use a de-identified beneficiary identifier, so there is no means to tie the FFS files back to other Limited Data Set (LDS) files. This prevents stakeholders from assessing whether CMS inflated the average claim counts by including claims that would not be eligible for risk adjustment in the MA program. CMS' data dictionary states that the "RAS_DGNS_IND" should indicate whether the diagnosis maps to an HCC, but some of the diagnoses identified as "R" do not actually map to an HCC. Further, that field does not specify whether the claim is from an eligible provider. Although the data dictionary suggests that the "PRVDR_TYPE_CD" field would contain this information, it does not. The only values populating that field are 01, 02, 10, and 20. Three of those values are not

defined, which suggests that the data in the FFS files were modified in some undisclosed way after being pulled from the National Medicare Utilization Database (NMUD).[6]

Finally, the lack of meaningful data regarding the claims used to create the averages set forth in Table 2b prevents stakeholders from evaluating CMS' decision to include extreme outliers when calculating average claim counts. For example: CMS appears to have included a beneficiary with *625 claims* in its calculation of the average for HCC 1. That value is *more than thirty standard deviations* higher than the mean (which was 11.4). Because such outliers clearly distort the mean, CMS should have considered alternatives that did not rely on simple averages. CMS has not disclosed any documents or information reflecting consideration of this issue, alternatives, or analysis regarding the impact of high outliers.

Estimated Payment Impact

The last step in CMS' study consisted of simulating the impact of the beneficiary-level discrepancy rates on MA risk scores. *See* TA at 13-16. Several categories of critical information regarding CMS' simulations remain undisclosed.

Uncorrected Dataset and Original Risk Factors

CMS states that it created a "proxy" for the actual HCC model using "the uncorrected dataset," that generated an estimate of "the original [risk] factors" used to make MA payments. TA at 13. No information regarding that proxy has been disclosed; CMS has not disclosed the estimates of the original risk factors it created, explained why it was necessary to create this proxy, instead of relying on the actual HCC models, or identified any alternatives considered.

We understand that the dataset used to create CMS' proxy for the HCC model has been produced as "FFS04_05_PROFILEPAYMENTS." However, the Agency has not released the code used to create its proxy. As a result, stakeholders can attempt to create their own "proxies," but they will not be able to reproduce the proxy used by CMS or be able to assess the accuracy of the baseline that CMS created.

Original MA Risk Scores

CMS took its estimates of the original risk factors and applied them to the "MA Sample" to obtain estimates of the original risk scores. TA at 13. CMS has not disclosed the values it obtained at this step of its analysis or otherwise provided the information necessary to recreate the steps that CMS took.

[6] Similarly, because the FFS files contain records corresponding to more than 1.5 billion and more than 33 million beneficiaries, we question whether the FFS files actually represent the 5% sample for 2004-2005, as claimed in CMS's data dictionary. The volume suggests that the data may have been pulled from the 100% sample.

Although CMS has disclosed the "MA Sample" files, the "SAMPTB_Y13_ELIG1M" and "SAMPTB_Y13_FULL1M" tables leave important questions unanswered. For instance, both files contain exactly 1,000,000 records that allegedly correspond to "one randomly-sampled beneficiary" taken from the 2011 overpayment run. CMS has not disclosed why it selected one million records for its samples, why it used 2011 data for this analysis, or why it is using data from the overpayment run. CMS also did not explain the basis for its decision to use a model consisting of an equal split of beneficiaries who are and are not eligible for inclusion under current RADV rules. *See* TA at 5.

In addition, the six inclusion criteria described by CMS for the MA sample appear to be inaccurate. According to the data dictionary, neither file should contain any beneficiaries with end-stage renal disease (ERSD) or hospice status. But both files, in fact, contain such beneficiaries. The data dictionary also does not specify whether beneficiaries included in the SAMPTB_Y13_FULL1M file should have at least one diagnosis that maps to HCCs. More than 60% of the beneficiaries included in SAMPTB_Y13_FULL1M do not have any HCCs, resulting in an average risk score for sampled beneficiaries of less than one. CMS has not disclosed any analysis evaluating whether the samples it created were representative of the MA population, whether it is appropriate to rely on this sampling methodology, or any alternatives considered.

Corrected Datasets

The Technical Appendix states that CMS used a "random number generator" to apply the beneficiary-level discrepancy rates to the "FFS04_-PROFILESPAYMENTS" data set, which yielded "50 independent corrected FFS data files." TA at 15. Those files, the programing used to generate them, and the random seed and randomization algorithm used all should have been produced. This information is critical to offering meaningful comment.

CMS' failure to disclose the random seed and randomization algorithm is not appropriate under its own policies.[7] The Medicare Payment Integrity Model states that the random seed and randomization algorithm constitute critical information that must be available to permit meaningful analysis. CMS' manual states that contractors must "document all steps taken in the random selection process ***exactly as done*** to ensure that the necessary information is available for anyone attempting to replicate the sample selection." CMS, Medicare Program Integrity Manual, Chap. 8, Section 8.4.4.2, *Random Number Selection* (June 28, 2011) (emphasis added). The Provider Self-Disclosure Protocol similarly instructs that the "source of random numbers used" is part of the "minimum" information that must be included to enable replication. HHS-OIG, *OIG's Provider Self-Disclosure Protocol*, 8 (Apr. 17, 2013). CMS has failed to provide the methodological information that it insists others maintain when performing similar analyses.

[7] This critique applies equally to CMS's failure to disclose the random seed and algorithm used to create the MA Sample files discussed above.

Corrected Risk Factors

CMS has not adequately disclosed how each "corrected FFS data file" was used to develop corrected risk scores. TA at 15. The Technical Appendix indicates that a set of new coefficients was taken from each file, and each set of coefficients was applied to "the original FFS data set, normalizing a new set of relative factors to one." TA at 13. The results from these analyses should have been disclosed, but were not. The same is true of the programming used by CMS. As a result, CMS' normalization method remains undisclosed.

Payment Impact

The final step in each of the 50 simulations was to apply the corrected and normalized risk coefficients to the MA sample to determine payment impact. *See* TA at 13, 15. CMS disclosed only a summary of these results. *Id.* at 16. The actual results of each simulation, and the code used, were not disclosed.

* * *

As described above, we believe that CMS has failed to disclose the data and information required by the APA, the DQA, and its own policies. We urge the Agency to make a full and open disclosure that fulfills its legal obligations. We note, however, that additional disclosures must be made in time for stakeholders to meaningfully incorporate the data and information into their comments. Thus, in the event that CMS makes the disclosures required by law, the Agency should provide another extension of the comment period sufficient to permit full analysis of that information.

Thank you for your consideration.

Sincerely,

William A. Sarraille
Sean C. Griffin
SIDLEY AUSTIN LLP

Cc: Hon. Seema Verma
Janice Hoffman, Esq.
Jennifer Shapiro