DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-116

In the case of	**Claim for**
Global Home Care, Inc. (Appellant)	Hospital Insurance Benefits (Part A)
**** (Beneficiaries)	**** (HIC Numbers)
National Government Services (Contractor)	**** (ALJ Appeal Number)

The Medicare Appeals Council received the above-captioned case on an October 18, 2010, referral from the Centers for Medicare and Medicaid Services (CMS) regarding a partially favorable ALJ decision dated August 20, 2010.[1] *See* 42 C.F.R. § 405.1110. In its referral, CMS contests the ALJ's determination that the statistical sample used to calculate Medicare's overpayment to the appellant was invalid. The CMS memorandum is hereby entered into the record as exhibit (Exh.) MAC-1.

The Council may decide on its own motion to review a decision issued by an ALJ. When, as here, CMS or its contractor did not participate in the appeal before the ALJ, the Council will review the ALJ action only if: (1) there is an error of law material to the outcome of the case, or (2) there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's action to those exceptions raised by CMS. 42 C.F.R. § 405.1110(c)(2). In its referral memorandum, CMS indicated that it was referring the case for review due to the first criterion (error of law). As set forth below, the Council declines to review the ALJ's decision in the context of the CMS

[1] In addition, the Council has received the appellant's request for review, also dated October 18, 2010, which seeks Council review of the ALJ's individual coverage determinations. The Council will issue a separate decision addressing the issues raised in the request for review.

referral memorandum, inasmuch as no error of law is shown in the ALJ setting aside the extrapolation of an overpayment when CMS or its contractors have not produced documentation necessary to recreate the sampling frame.

BACKGROUND

The instant case arises from the Program Safeguard Contractor (PSC)'s determination that, based on a post-payment audit utilizing statistical sampling and extrapolation, the appellant had received $7,192,821.00, in Medicare overpayments for home health services furnished to various beneficiaries on October 1, 2000, through July 31, 2005. *See, e.g.,* Claim File 1 at Exh. 4.

On appeal, the ALJ determined that the administrative record did not contain sufficient documentation to support the contractor's use of statistical sampling and extrapolation in this case. Dec. at 63. Having set aside the statistical sample and extrapolation, the ALJ then considered whether Medicare coverage was reasonable and necessary for each of the 90 claims appealed, which arose from 84 individual beneficiaries. *Id.* at 64-103. The ALJ granted full Medicare coverage for six of the claims at issue, allowed partial coverage for one claim, and denied coverage for each of the 83 remaining claims. *Id.* The ALJ also determined that the appellant was not "without fault" for the remaining overpayment and thus, was not entitled to a waiver of its liability based on section 1870 of the Social Security Act. *Id.* at 103-05.

In its referral to the Council, CMS limits its exceptions to "only the ALJ's determination that the sampling methodology and extrapolation are statistically invalid." Exh. MAC-1. In this context, CMS also takes issue with what it perceives as the ALJ shifting the burden of proof from the appellant to the contractor to prove the validity of the statistical sampling methodology used and the ALJ not providing adequate notice of the specific issues to be decided at the hearing. *Id.* CMS, in essence, contends that the ALJ should not have invalidated the statistical sample on the basis that the documentation was not present in the record and should have instead requested that the PSC participate in the hearing and provide the appropriate documentation. *Id.*

As noted above, the appellant also filed a request for review of the ALJ's partially favorable decision as it pertained to the 84 claims denied full Medicare coverage. The appellant's October

18, 2010, request for review, including its 84 individual requests for review pertaining to one claim each, is entered into the record as exhibit MAC-2. The request for review does not reference or otherwise contain any suggestion that it was prepared in response to the CMS referral. Exh. MAC-2. In fact, both the appellant's request for review and the CMS referral are dated October 18, 2010. Exhs. MAC-1, MAC-2.

The appellant also submitted a supplementary brief, dated November 29, 2010, which both elaborates on the issues set forth in its initial request for review, and responds to the CMS referral memorandum. The brief is entered into the record as exhibit MAC-3.

Before the Council, the appellant asserts that the home health services at issue were reasonable and necessary, and thus, should be covered by Medicare. Exh. MAC-2. The appellant also repeats several contentions regarding its interactions with the contractors that were already raised before, and considered by, the ALJ: the case should be dismissed as a result of the contractor's failure of due care; post-payment review guidelines were ignored; the contractor violated reopening rules; an inexcusable delay occurred in transmitting the results of the post-payment audit; and the contractor illegally recouped the provider's reimbursement. *Id.;* MAC-3. In response to the CMS referral, the appellant asserts that the record supports the ALJ's decision to invalidate the use of statistical sampling and extrapolation in this case because the contractor did not properly document its sampling methodology. Exh. MAC-3. The appellant also asserts that, aside from the ALJ's notice of hearing, the contractors had actual notice that statistical sampling was at issue in this case because it mailed copies of its request for hearing, brief before the ALJ, and a copy of its expert report to the Qualified Independent Contractor (QIC). *Id.* The appellant further asserts that the ALJ did not improperly shift the burden of proof to the contractor; instead, it explained that it presented evidence to rebut the presumption that the sample was valid and the contractors chose not to defend their finding. *Id.* at 11.

DISCUSSION

As noted above, CMS asserts in its referral memorandum that the ALJ erred in invalidating the statistical sample used to calculate Medicare's overpayment to the appellant. Exh. MAC-1. After considering the record in this case, the Council finds

that the ALJ did not err in the context of the CMS referral memorandum. 42 C.F.R. § 405.1110(c)(2).

The regulations state that the administrative record at all levels should include all of the evidence considered by the contractor in making its initial overpayment determination. 42 C.F.R. §§ 405.948, 405.968(a), 405.1042(a)(2) (each adjudicator reviews the evidence and findings upon which the initial determination was based). In this case, the ALJ was not able to review the evidence and findings supporting the PSC's use of statistical sampling and extrapolation because such documentation simply was not present in the record.

As noted by CMS, the Medicare Program Integrity Manual (MPIM) requires that when a contractor seeks to recover an overpayment it must "include in the overpayment demand letter information about the review and statistical sampling methodology that was followed." Exh. MAC-1 at 7 (citing MPIM, Pub. 100-08, Ch. 3 at § 3.10.7.1). *In addition, the contractor shall maintain complete documentation of the sampling methodology that was followed*. An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the form of the frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in your record of how the sampling was done. A record shall be kept of the random numbers actually used in the sample and how they were selected. *Sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged. The contractor shall keep a copy of the frame.* MPIM, §§ 3.10.4.4 and 3.10.4.4.1, *see also* § 3.10.7.1.

The record in this case does not contain complete documentation to support the use of statistical sampling and extrapolation to calculate Medicare's overpayment to the appellant. The sampling frame cannot be recreated from the documentation present. Without this basic documentation, a provider does not have the information and data necessary to mount a due process challenge to the statistical validity of the sample, as is its right under CMS Ruling 86-1.

Further, despite CMS' assertions to the contrary, the contractors had adequate notice that statistical sampling and extrapolation were at issue in the present case, and have

already been given the opportunity to supply the missing documentation. The case was originally before the ALJ as ALJ appeal number 1-408263964. On June 16, 2009, the ALJ remanded the case to the QIC pursuant to 42 C.F.R. § 405.1034(a) in an attempt to develop the record, because the claim files forwarded by the QIC "did not provide any of the documentation relative to the overpayment, or the extrapolation." ALJ Master File, Exh. 6 at 3. As the ALJ explained, "[a]ll of the documentation relative to the overpayment and the extrapolation are material to resolving the issues on appeal, and without them, the [ALJ] cannot issue a proper decision, or even determine if this case is properly before her." *Id.*

In response, the QIC returned the case to the ALJ with a cover letter dated July 23, 2009. *Id.* at 99. In that letter, the QIC's counsel indicated that he believed the ALJ had erred in remanding the case for additional documentation and stated that "the QIC does not determine the amount in controversy or effectuate the decisions, but merely determines if the services can be paid under the applicable Medicare regulations and then directs the affiliated contractor to effectuate the decision as rendered…*.To the best of our knowledge, all documentation that First Coast Service Options used in rendering their decision was included in the case files sent to your honor*." *Id.*

The ALJ's remand order did not request that the QIC provide her with a precise calculation of the amount in controversy as the QIC discussed in response. Thus, the QIC's response did not address the actual basis for the ALJ's remand: the administrative record did not contain any documentation to support the contractor's use of statistical sampling or extrapolation in calculating the overpayment at issue. The agency referral does not assert that the contractor can now provide the missing data, or explain how the ALJ erred as a matter of law when remand to the QIC failed to produce the missing evidence.

Moreover, the record reflects that the ALJ provided notice as required by the regulations at 42 C.F.R. § 405.1020(c) to the affiliated contractor that rendered the initial determination (National Government Services) and the QIC (First Coast Service Options) with notice of the scheduled hearing.[2] ALJ Master File,

[2] CMS has since clarified that notice to the QIC alone provides adequate notice to CMS and its contractors of the pending hearing, and that it is not necessary to also send notice to other contractors. 74 Fed. Reg. 65296,

Exh. 8 at 3. The record does not contain any evidence to suggest that either contractor responded to the notice of hearing or otherwise indicated that it would like to participate in the hearing. The content of the notice of hearing was also sufficient to put CMS on notice that the overpayment was at issue, which includes any challenges to the statistical sampling the appellant might raise.

For these reasons, the Council finds that CMS' objections to the ALJ's action do not present an error of law material to the outcome of the claims at issue. The Council therefore has decided not to review the ALJ's decision in the context of the CMS referral memorandum.

However, as the Council has received a separate request for review from the appellant, the Council will consider the remaining portions of the ALJ's decision, including 84 of the individual coverage determinations arising from sample claims, when it issues an action addressing the request for review.

The Council retains the record in ALJ appeal number 1-469916242, pending its resolution of the issues present in the appellant's request for review.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: January 11, 2011

65322 (Dec. 9, 2009). The CMS suggestion that the ALJ should have sent notice directly to the PSC also has no foundation in the regulations.