Office of Medicare Hearings and Appeals Statistical Sampling Initiative FREQUENTLY ASKED QUESTIONS

1.) What is statistical sampling?

Statistical sampling draws a random sample from a collection of claims and extrapolates (in other words, projects) the results of the sample to the entire "universe" of claims. OMHA statistical sampling is conducted using a trained and experienced statistical expert to develop the appropriate sampling methodology in accordance with Medicare guidance, and randomly select the sample units. Administrative Law Judges then review the sample units and make findings and decisions on them. The decisions on the sample units are then extrapolated to the universe of claims at issue.

2.) Which claims or appeals are eligible for statistical sampling?

To be eligible for OMHA statistical sampling:

- A request for hearing must appeal a Medicare Part A or Part B Qualified Independent Contractor (QIC) reconsideration decision.
- The appellant must be a single Medicare provider or supplier. (If multiple providers or suppliers with multiple National Provider Identifiers (NPIs) are owned by a single entity, the owning entity may serve as "a single provider or supplier" provided that the owning entity agrees to accept any payment that may be due from Medicare as a single payment, or agrees to make any payment that may be due to Medicare as a single payment).
- All jurisdictional requirements for a hearing before an Administrative Law Judge must be met for the request for hearing and all appealed claims.
- No hearing on the claim has been scheduled or conducted.
- The beneficiary must not have been found liable after the initial determination, or participated in the QIC reconsideration.
- There must be a minimum of 250 claims. Up to 10,000 claims can be accommodated in a single universe. All claims must fall into only one of the following categories:
 - A universe of claim appeals is limited to all pre-payment or all overpayment claims, but not a combination of both;
 - A universe of overpayment claim appeals is limited to all Recovery Auditor Contractor (RAC) claims or all non-RAC claims, but not a combination of both; or
 - A universe of RAC claims is limited to claims adjudicated by a single RAC. If the sample is spread among RACs, the benefits of joining the initiative are lost, as the appellant would have to attend multiple hearings.
- There cannot be an outstanding request for Settlement Conference Facilitation for the same claims.

3.) Who can initiate the use of statistical sampling?

Statistical sampling may be initiated in two ways: (1) request from an appellant with eligible appeals, or (2) consent from an appellant in response to an OMHA invitation.

4.) How can I request statistical sampling?

We encourage you to read this entire FAQ sheet before requesting statistical sampling. Please visit the statistical sampling page of the OMHA Website at www.hhs.gov/omha for the most up-to-date instructions, information requirements, and helpful templates for requesting statistical sampling, including a "Request for Statistical Sampling" form.

5.) Can I request a statistical sample of all of my pending appeals at OMHA?

Eligibility criteria may limit the pending appeals that can be sampled. Please see question 2, "Which claims or appeals are eligible for statistical sampling?" above.

6.) Can I request statistical sampling for claims from multiple providers or suppliers?

Only if the multiple providers or suppliers are owned by a single entity that agrees to the requirements for payment. Please see question 2, "Which claims or appeals are eligible for statistical sampling?" above. The payment requirements are necessary for CMS's effectuation process.

7.) Can I request a statistical sample of the Part B hospital claims that I would like to submit for Part A inpatient claims that continue to be denied?

No. For hospitals appealing denials of Part A inpatient hospital claims, the statistical sample can address the Part A claims only. OMHA adjudicators cannot consider claims that have not been submitted. Questions regarding how to address any available Part B billing options should be directed to CMS.

8.) Who is involved in the statistical sampling process?

OMHA will procure an independent statistical expert to assist the Administrative Law Judge(s) in carrying out the statistical sampling in accordance with Medicare guidance. In addition, CMS or CMS contractors may be involved in the hearing on the sample units, in accordance with 42 C.F.R. sections 405.1010 and 405.1012. An appellant may have its own statistical expert to assist in preparing for the hearing and evaluating the OMHA expert's methodology and sample selection process. If an appellant calls its expert as a witness, the expert will be subject to questioning by the Administrative Law Judge and CMS or any CMS contractor that has elected party status.

9.) What Medicare guidance applies to statistical sampling?

Medicare guidelines for conducting statistical sampling are found in Chapter 8 of the Medicare Program Integrity Manual (Internet-Only Manual Publ'n 100-08).

10.) What is the role of the OMHA Statistical Sampling "Coordinator"?

The OMHA Statistical Sampling Coordinator receives, tracks, and monitors all appellant requests for statistical sampling, as well as OMHA invitations to participate in the Statistical Sampling Initiative. The Coordinator serves as the central point of contact with an appellant in securing the initial consent for statistical sampling, and ensures sampling efforts are coordinated throughout OMHA.

11.) I Requested Statistical Sampling Initiative — what happens next?

The OMHA Statistical Sampling Coordinator will send an invitation letter containing information on the process. Appellants receive an updated universe of claims and a consent form. The appellant will have twenty (20) calendar days from receipt of the letter to consent to statistical sampling conducted at OMHA, and may request more time. OMHA does request that if an appellant is then not interested in using statistical sampling, that it sends a response so that the coordinator can close out the offer. If the appellant rejects three offers, OMHA will not send additional offers.

12.) I received an OMHA invitation to participate in the Statistical Sampling Initiative — what happens next?

An OMHA invitation to participate in the Statistical Sampling Initiative is an invitation to use the statistical sampling process to adjudicate a group of appeals. The appellant decides whether to utilize the process. The appeals may be decided more quickly using statistical sampling because it is a more efficient means to adjudicate appeals, but rejecting the offer will not affect the adjudication of the individual claims. The invitation to participate in the Initiative, forwarded by the Coordinator, will provide information on the process, a consent form, and a tentative universe of claims. The appellant will have twenty (20) calendar days from receipt of the letter to consent to statistical sampling conducted at OMHA, and may request more time. OMHA does request that if an appellant is not interested in using statistical sampling, that it respond in the negative so that the coordinator can close out the offer. If the appellant rejects three offers, OMHA will not send additional offers.

13.) If I consent to the use of statistical sampling what should I expect?

To proceed with statistical sampling, OMHA will request consent from the appellant in writing. Because of the costs and amount of time and effort that will be invested in the statistical sampling process, this consent is required to proceed with the process. After the written consent is obtained, a prehearing conference will be scheduled. The prehearing conference will be conducted by an Administrative Law Judge for the purpose of confirming the consent, establishing the universe from which the sample will be drawn, and agreeing to other matters to facilitate the hearing. This Administrative Law Judge will serve as the lead judge. The process for selecting judges is outlined in question 14 below.

A prehearing conference order will then be issued in accordance with 42 C.F.R. section 405.1040. The appellant may object to the order within ten (10) calendar days of receipt. If there is no objection, the order will become binding.

14.) How will my statistical sampling appeal be assigned?

After the prehearing conference order becomes binding, OMHA will combine the universe of appeals under a single appeal number. Appeals will be assigned in accordance with random assignment principles to a lead Administrative Law Judge. Administrative Law Judges from the same field office will be assigned as follows:

• If the universe size is 250 to 749 claims, a cadre of 2 additional Administrative Law Judges will be assigned. Each Administrative Law Judge will hear and decide one third of the statistical sample claims

• If the universe size is 750 claims or greater, a cadre of 3 to 4 additional ALJs will be assigned. Each Administrative Law Judge will hear and decide one quarter to one fifth of the statistical sample claims.

15.) Can I withdraw my consent to use statistical sampling?

Consent may be withdrawn up to the point when the prehearing conference order becomes binding in accordance with 42 C.F.R. section 405.1040. At that point, the appellant has affirmatively consented to the statistical sampling in writing and confirmed the consent at a proceeding before an Administrative Law Judge. the consent will have been documented in the prehearing conference order and the appellant will have had an opportunity to object to the prehearing conference order.

16.) What happens if I do withdraw my consent or object to the pre-hearing conference order?

If you withdraw your consent for statistical sampling before the pre-hearing conference order becomes binding, the appeals will be returned to the standard Administrative Law Judge hearing process. If your objection to the pre-hearing conference order is on a different matter, the Administrative Law Judge will consider your objection and attempt to resolve it; however, if the Administrative Law Judge does not believe the matter can be resolved or concludes that resolving the matter would require a violation of law or policy, the statistical sampling effort will not proceed and the appeals will be returned to the standard Administrative Law Judge hearing process.

17.) How is a statistical sample of appealed claims effectuated by Medicare?

The Medicare Program Integrity Manual (MPIM) states that, due to the uncertainty inherent in the sample design, in most situations the lower limit of a one-sided 90 percent confidence interval shall be used to determine the amount of overpayment recovery because this conservative method works to the financial advantage of the provider or supplier. In the context of the OMHA statistical sampling initiative, where statistical sampling may be used to determine the amount of an extrapolated overpayment on a universe of post-payment denials, or the amount of payment due to a provider or supplier for a universe of prepayment denials, it is possible that the upper bound of the confidence interval will be most financially advantageous to the provider or supplier. Consequently, OMHA instructions to the statistical expert will state that the statistician should generally base his/her decision on either the upper or lower bound of a one-sided 90 percent confidence interval—whichever is most

financially advantageous to the provider/supplier. The amount due may not exceed the amount that would be reimbursed if all claims in the universe were deemed payable.

The statistician will detail his/her effectuation instructions in his or her responses to the interrogatories propounded by the lead Administrative Law Judge. The Administrative Qualified Independent Contractor will instruct the Medicare Administrative Contractors to effectuate the claims at issue in accordance with the statistician's effectuation instructions, which will be stated explicitly in the decision order.

18.) How can I get more information on OMHA statistical sampling?

More information and the most current instructions, information requirements, and helpful templates for requesting statistical sampling are available on the Statistical Sampling Initiative page of the OMHA Website at www.hhs.gov/omha.