**Medicare Red Tape Relief Project**

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: Physicians Advocacy Institute

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Statutory

Regulatory ✓

**Please describe the submitting organization’s interaction with the Medicare program:**

PAI is a not-for-profit advocacy organization focused on securing fair and transparent payment for physicians. PAI’s Board is comprised of CEOs/former CEOs of state medical associations from California, Connecticut, Georgia, Nebraska, New York, North Carolina, South Carolina, Tennessee and Texas and a Kentucky physician. A significant portion of the members of these and other states’ medical societies treat Medicare patients and submit claims to Medicare.

**Short Description**:

Recovery Audit Program – Medicare Audit Reform - The need for a statistically valid extrapolation process

**Summary:** The current approach to extrapolation employed by RACs is inconsistent and often statistically invalid. This often results in drastically overstated overpayment findings that can bankrupt a physician practice. The method of extrapolation is often a major issue in appeals, requiring the appealing physician to hire a statistician to challenge the RAC’s method of extrapolation. CMS should more rigorous, transparent and statistically valid standards and processes for extrapolation. Because this is a complicated topic, PAI offers the following background on extrapolation and the basis for its recommendations.

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Extrapolation is a statistical method that uses the results of an audit sample to calculate audit results for the universe of claims from which the sample was drawn. When RAC auditors use extrapolation to estimate the amount of overpayments made to physicians by the Medicare program, excessive amounts can be calculated unless the RACs use a statistically valid and representative sample and an appropriate extrapolation methodology. Although the Medicare Program Integrity Manual (“PIM”) contains general standards for extrapolation (PIM 8.4.2), they lack specificity. In addition, there are other issues with extrapolation that are not adequately addressed in the PIM, including precision and sample size. As a result, audits using extrapolation are often based on inappropriate samples and/or flawed methodologies, resulting in erroneous audit results and excessive overpayment demands.

Physicians appealing RAC audit findings frequently challenge the identification of the sample used in extrapolation and/or extrapolation methodologies and are often successful. Therefore, a more granular set of extrapolation requirements would likely minimize the conflict that results from these types of audits and reduce the burden on the currently backlogged appeals process.

It is particularly important that detailed standards are put in place because the current Recovery Audit Program Statement of Work encourages the RACs “to use extrapolation for some claim types when all requirements are met.” (Statement of Work for the Part A/B Medicare Fee for Service Recovery Audit Program – Regions 1 -4, November 30, 2016, p. 32).

**Related Statute/Regulation:**

Medicare Program Integrity Manual Chapters 1 and 8

**Proposed Solution:**

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|  |  | * Specific guidelines should be added to the PIM to standardize what tests can be done to ensure that the universe of claims is appropriate for creating a sample. This is important because if the claims universe is highly heterogeneous, it is not appropriate for extrapolation.
* The PIM should also be revised to provide more detail regarding the sample frame, which contains the units to be audited for the date range in question. For the most part, the sample frame should present a homogenous picture of the units and lack any issue that could bias the sample. To do this, zero paid claims and outliers should be excluded from the sample frame. In addition, stratification should be used to create more homogeneous subsets. Although the PIM generally discusses stratification, the language should be revised to require that the statistician provide the logic used to create the stratification.
* The PIM currently provides that the statistician can use any number of units for the audit, including the beneficiary, a date of service, the claim or the claim line. (PIM 8.4.3.2.2). However, the PIM does not contain any standards to determine which is the most appropriate unit. Unless this is obvious, CMS should require that statistical testing be conducted to ensure that the unit chosen reports low possible variability.
* To ensure that the randomization method is correct, the PIM should require that the statistician provide the sample frame or universe to the provider in the same rank order as was used to create the sample, along with the seed value, to allow the provider to replicate the random selection of data.
* Nowhere within the PIM is there a discussion of the distribution of the data for the most critical variable, which in most cases is the overpaid amount. The statistical theory on which extrapolation is based requires that the data be normally distributed and that the units be independent. Yet, the PIM does not discuss the importance of normally distributed data, and, as a result, it does not address which metrics to use when calculating the extrapolation. As such, the point estimates, sample error calculations, and precision calculations are often wrong and biased against the physician. In the majority of cases, the distribution will be heavily right-skewed because payments for provider services cannot be less than zero. As such, the distributions are always bounded on the left. The PIM should specify that when the data are non-normally distributed, the auditor must use the median to calculate the point estimate, sample error, and precision. If the data are normally distributed, then the use of the mean could be permitted.
* To ensure that the correct extrapolation formula is used for the type of audit, the PIM should be revised to require that the statistician use the ratio for extrapolation in attribute audits, which are audits examining whether claims in the sample should have been paid in full or not at all. The PIM should be revised to require that the statistician use the average for extrapolation in variable audits, which are audits examining claims in which some payment amount should be allowed, although at a lesser amount than originally paid.
* CMS recommends that the overpayment estimate be based on the lower bound of a one-sided 90% confidence interval, which is the same as the lower bound of a two-sided 80% confidence interval. This means that there is a 10% chance that the extrapolated estimate is too high. In general, most studies rely upon a two-sided 95% confidence interval and the government should be held to this standard. The PIM should be revised accordingly.
* Precision measures the relative distance between data points. Good precision is critical if an extrapolation is to accurately and fairly represent the results reported from a sample, but the PIM does not require any standards for precision. CMS should require RACs to use the same minimum precision standard of 2.5% at a 90% confidence interval as required by the Office of Management and Budget (OMB)[[1]](#footnote-1) for other government agencies.
* The PIM standards for sample size in 8.4.4.2 are nebulous and need to be revised to require a minimum sample size of 100, as is required by the OIG in the self-disclosure rules.
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1. *“[[Office of Management and Budget](http://www.whitehouse.gov/omb/%22%20%5Ct%20%22_blank)] [OMB](http://www.whitehouse.gov/omb/%22%20%5Ct%20%22_blank) [Circular A-123](http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-16.pdf%22%20%5Ct%20%22_blank), Appendix C*. [↑](#footnote-ref-1)