Medicare Audits: A Survival Guide By Douglas M. Nadjari, Esq.

Good representation begins upon receipt of the demand for records, the arrival of which suggests that the physician or practice has likely been identified as an outlier or that data analysis has "flagged" some potentially ominous billing or coding pattern. While the U.S. Department of Health and Human Services, Office of Inspector General may undertake audits and investigations either on their own or in conjunction with a Justice Department task force, such inquiries are usually limited to investigations of criminal conduct.¹ Conversely, most Medicare audits are conducted by entities contracted to do so by CMS and there are four major types: (1) Medicare Administrative Contractor Audits ("MACs") that utilize data obtained from other contractors for the purpose of targeting improper payments; (2) Comprehensive Error Rate Testing Audits (CERTS) that perform statistical analyses to establish error rates and estimates of improper payment; (3) Zone Integrity Program Contractors (ZPIC'S) that both utilize data analysis and clinical records to identify potentially fraudulent conduct patterns and then refer those cases to the Office of Inspector General for further and more focused criminal investigation; and (4) Recovery Audit Contractors ("RACs") that based upon data analysis and chart reviews, identify circumstances where there is a "high probability that improper payments were made."²

Because ZPIC and RAC audits may result in either referrals for criminal investigation or extrapolated demands for repayment, it is important to identify the type of audit your client is facing so that risk may be fully assessed before determining how to proceed.

A. <u>Responding to a Record Request</u>

Demands for records made by RAC and ZPIC contractors are usually predicted upon a request for the provision of what the contractor will later assert is a statistically valid random sampling of the provider's claims (for a specific time period) and usually result in an extrapolated demand for repayment.³ When dealing with a RAC and ZPIC audit, all concerned should remain cognizant that that the contractors, are doing their level best to find patterns that support an extrapolated demand. Therefore, each record takes on, literally, exponential significance and it is important to make sure that complete copies of all requested records are provided.

When dealing with electronic records, one must determine if the printed copy the practice intends to provide contains the same data as the electronic record when viewed in its native form. If there are discrepancies between the electronic and hard copies, an IT consultant should be engaged to determine how a mirror image of the electronic record could be made, provided, and preserved. If the provision of a digital copy is not possible, an offer to permit access to the EMR (under supervision to assure HIPAA compliance) should be made and documented. This will blunt any claim that the practice failed to produce important records or that they were created after the fact.

B. Identifying Audit Issues

If the demand comes from a ZPIC contractor, it is likely that data analysis has already "flagged" potential fraud. If the demand is from a RAC auditor it is likely that a data analysis has already identified a "high probability that improper payments were made."⁴ Thus, if the audit period involves a relatively short

¹ In 2007, the Department of Health and Human Services and Department of Justice created the Health Care Fraud Prevention and Enforcement Action Team ("HEAT").

² See http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/

³ The American Tax Relief Act of 2012 replaced the three-year time frame for recovery efforts with a five year look-back period.

⁴ See http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map.

time frame, an assessment of the volume of claims for the codes at issue during that same period should be made. Likewise, when the audit focuses on a limited number of CPT codes, an examination of the records by an outside consulting clinician and/or a billing and coding expert should be undertaken to determine: (1) where the issues lie and (2) whether the pattern suggests a billing, coding or record keeping problem that requires immediate remedial attention to avoid future scrutiny or compliance problems. Consultants should be retained by counsel and pursuant to U.S. *v. Koval*, which clothes the findings and reports of consultants hired by counsel on behalf of the physician with the all of the protection of the attorney-client privilege.⁵ These reviews are preliminary and a more exhaustive analysis will be necessary after the demand for repayment is received.

C. Overview of Appeals Process

The demand itself is not the culmination of the process. If it is determined that a challenge should or must be mounted, the demand is little more than the beginning of a long appeals process. Indeed, there are four levels of appeal: (1) Redetermination by the CMS contractor that performed the audit, (2) Reconsideration by an independent contractor engaged by CMS for the purpose of conducting a "Qualified Independent Contractor "QIC" appeal; (3) Administrative Law Judge hearing; and (4) review by the Medicare Appeals Council. Upon the exhaustion of these administrative remedies, judicial review may be sought.⁶

D. The Initial Determination and Notice of the Right to Appeal

An initial determination should be forthcoming within thirty to fifty-five days of receipt of the records but there is little or no recourse for the contractor's failure to meet the time frames set forth by the controlling regulations. In pertinent part, 42 C.F.R. § 405.921(b) requires that the contractor provide written notice of: (i) the basis for any full or partial denial determination; (ii) information concerning the provider's right to a redetermination (or appeal); and (iii) all applicable claim adjustments reason and remark codes to explain the determination; the source of the remittance advice and identification of who may be contacted further information is required.

E. Fight or Fold?

Upon receipt, a risk-benefit analysis must be undertaken to determine if payment should be made (before interest begins to accrue) or whether an appeal is advisable. If the demand is "out-sized," billing, coding and clinical experts should be consulted to determine whether additional records exist and were either overlooked or simply not considered. This may be particularly crucial when an adverse audit finding is based upon a finding that the procedure was not medically necessary. To be sure, a physician's clinical note is not a "stand alone" document and needs to be considered together with other clinical data to determine if there are sufficient indications exist.

F. <u>Recoupment & Rebuttal</u>

Because CMS may begin to recoup overpayments by offsetting the alleged overpayment debt against other, unrelated Medicare receivables, time is of the essence. Indeed, recoupment may begin within fifteen (15) days of receipt of a demand unless a formal rebuttal is submitted.⁷ While the rebuttal statement is not part of the audit process, and technically should address issues of financial hardship,

⁵ In *U.S. v. Koval*, 296 F.2d 918 (2d Cir. 1961). A law firm hired an accountant to assist in its representation of a client under investigation for tax fraud. While the district court judge held the accountant in contempt for refusing to testify when subpoenaed by the government, the Second Circuit vacated the contempt finding and held that because the accountant's expertise was needed to assist the attorneys that had retained him, the accountant's work-product, communications with counsel (and client) were all protected from disclosure by the attorney-client privilege.

⁶ http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedicareAppealsProcess.pdf

submission of a rebuttal will stop the government from offsetting the alleged debt against other claims while counsel perfects the initial appeal referred to as a "Redetermination."

G. The Contractor Appeals: Redetermination & Reconsideration

Technical Requirements of a Redetermination Request.

The first level of appeal is known as a Redetermination. While the regulations describe the proceeding as "...an independent review of an initial determination, nothing could be further from the truth."⁸ Indeed, the appeal is made to and decided by the same entity that made the initial determination and, as a result, significant victories are rare. The appeal must be submitted within 120 days from receipt of notice of the Initial Determination and include: the names of the beneficiaries, the Medicare claim numbers, the specific services at issue and the reason for the challenge. When the audit involves a larger sampling and the wholesale denial of claims, one may attach the Initial Determination containing all of the requisite data and incorporate the document by reference for purposes of meeting the statutes requirement to meet the regulation's requirements. Extensions may be sought, if request for a redetermination is not filed in timely fashion but interest may start to accrue and claims may be off-set or suspended. If the physician is represented by counsel, it is imperative that an Appointment of Representative Form be executed and included with the Redetermination request.⁹ Failure to include the executed form or submission of the appeal without all of the detail required by 42 C.F.R. § 944(b), may result in dismissal of the appeal and the accrual of interest. While a dismissal may be vacated upon a showing of good case, interest will continue to accrue during that hiatus and the loss may be significant.¹⁰

H. Time Limitations

Where a denial is based upon the contractor's finding that the treatment was not medically necessary, 42 U.S.C. § 1395pp, establishes a three year "look-back period"

I. <u>The Regulations</u> hold that the appellant should include any evidence that the party believes should be considered by the contractor, and we recommend including all evidentiary and procedural challenges as early as possible so that preclusion does not become an issue later in the game

J. <u>Clinical Records Expert</u>

The strongest and most direct challenge to a demand for over-payment rests upon good clinical recordkeeping that documents both the necessity of the service or goods at issue and, further, supports the code billed. Often, evidence of necessity or medical indications for a particular device or procedure may be found within progress notes not audited. Likewise, evidence of necessity may be found in consultation reports, operative reports, pathology reports and other data that was simply never audited.

K. Local Coverage and National Coverage Determinations.

In making initial coverage decisions, Medicare contractors rely on National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"). The Secretary of the Department of Health and Human Services adopts NCDs to exclude certain items and services from coverage on a national level when it is determined that such items or services are simply not "reasonable and necessary." NCD's are binding on all Medicare contractors nationwide. When there is no applicable NCD, Medicare contractors rely on LCD's promulgated by local contractors to determine necessity and adjudicate claims. While the reasonableness of LCD's may be subject to challenge, the reasonableness of NCD's are not.¹¹ In preparing an appeal, careful consideration must be given to whether the LCD applied is outdated or otherwise subject to challenge. Likewise, due care should be taken to determine whether LCD's or

3

⁸ 42 C.F.R. § 405.948

⁹ https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf

¹⁰ 42 C.F.R. 942(b)

¹¹ 42 U.S.C.A. § 1395ff

NCD's have been misconstrued or misapplied. These arguments should be embodied in both your covering letter memorandum and within the analysis provided by your experts.

L. The Treating Physician Rule

In addition, audit findings may be challenged based upon the opinion of the treating physician who is likely the target of the audit. The "Treating Physician Rule" first arose in a context of a disability determination and holds that an Administrative Law Judge should give greater deference to the opinion of the treating physician than to those of non-treating physicians. The opinion of the treating physician is particularly important when challenging the applicability or reasonableness of a LCD.¹²

M. Challenging Credentials of Reviewers

Section 3.1.1.1 of the *Medicare Integrity Manual* requires that coverage determinations be made only by RNs, LPNs or physicians, unless the task can be delegated to another licensed health care professionals. Reviews of coding determinations, likewise, must be made by certified coders. Accordingly, upon receipt of disclosure of the identity and qualifications of the auditors, request for the disclosure of the identity and qualifications should be made. Likewise, if the matter is escalated to an ALJ hearing, we request formal discovery of such materials.

N. Challenging the Sampling and Extrapolation

While statutory or regulatory provision expressly authorizes the use of extrapolation in this setting, it is well-settled that "... sample adjudication represents a judicially approved procedure that can be reconciled with existing Medicare requirements for case-by-case considering..."¹³ Moreover, case law clearly holds that a presumption of validity attaches to the amount of an overpayment. Thus, the burden of proof with respect to a challenge to the statistical validity of an extrapolated demand rests squarely with the provider.¹⁴ However, the right to seek extrapolated repayments is not limit and 42 U.S.C. § 1395-ddd holds that a Medicare contractor may not use extrapolation to determine overpayment amounts absent a determination that there is a "sustained high level of payment error or documented educational intervention has failed to correct the payment error." Such determinations may be made by a variety of methods including a PROBE sample or data analysis and are not subject to administrative or judicial review.¹⁵ Indeed, in Gentiva Health Care Corp. v. Sebelius, 857 F.2d 1 (D.D.C. 2012), the court held that the responsibility for determining the existence of sustained high level of payment error or the failure of educational intervention may be delegated to contractors. Thus, the threshold for determining whether an extrapolated demand may be made rests with the contractor and is largely immune from review. The propriety of demand based upon a statistically valid random sampling is well-settled and the premise is not subject to challenge.

However, efforts should be undertaken to obtain sufficient data to determine whether a reliable sampling was drawn and likewise, whether a reliable program was chosen (and properly employed) to draw the sampling. Indeed, *The Medicare Program Integrity Manual* requires contractors to maintain documentation "of the sampling process" and as well as "complete documentation of the sampling methodology that was followed." Further, it requires contractors to maintain and "identify the source of the random numbers used to select the individual sampling units."¹⁶ Upon receipt of an extrapolated demand for repayment, we generally serve a litigation hold notice upon the contractor. Thereafter, with the assistance of a statistician, we will request disclosure of all relevant documentation on hold notice and request all documentation pertaining to the choice of sampling methodology. While we leave the challenge to the validity of the sampling to our statistical experts, we posit our Reconsideration (and

¹² *Klementowski v. Secretary, Dept. of Health and Human Services*, 801 F. Supp. 1022 (W.D.N.Y.1992).

¹³ Chaves County Home Health Servs. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991.

¹⁴ See *Kinston Medical Specialists, P.A. v. Cigna Government Services*, 2011 WL 6960267, (2011) and CMS Ruling 86-1

¹⁵. 42 USC§ 1395ddd

¹⁶ Medicare Integrity Manual Sections 3.10.4.2, 3.10.4.4 and 3.10.4.3

before the Administrative Law Judge) that the failure to save and/or provide pivotal data requested – data necessary to test its validity, is a violation o due process ands renders the extrapolated portion of the demand a nullity.¹⁷ Alternatively, when a significant number of claims can be challenged on the merits, the extrapolated calculation can be significantly diminished.

O. Reports and Affidavits

The report or affidavit of: (1) billing and coding consultants (together with a claim by claim analysis of your experts' findings), (2) clinical experts and, (3) if appropriate statistical experts should be submitted with the other available evidence. Creating a complete record at the earliest possible date will make it easier to perfect subsequent appeals, avoiding troublesome deadlines and the accrual of interest.

P. Beyond the Redetermination

Little or no relief is usually obtained at the Redetermination level and, while a second level appeal, known as a Reconsideration is available, the review is cursory and the best chance of success will be found at the Administrative Law Judge hearing before a provider can seek review from an Administrative Law Judge, a request for reconsideration must be filed and adjudicated by a qualified independent contractor designated by CMS. The reconsideration requires a "full and early presentation of evidence" and the failure to present all available evidence may result in preclusion of evidence at the ALJ hearing. The reconsideration must be issued within sixty days of receipt of the request and, a decision must be issued within sixty days of receipt. If the qualified independent contractor, however, fails to issue a Reconsideration within the time allotted, the physician may seek to escalate the appeal directly to the Administrative Law Judge level.¹⁸

In recent days, the appeal process has been brought to a grinding halt. Facing a backlog of over 350,000 appeals from payment demands issued by recovery audit contractors, CMS announced that the Office of Hearings and Appeals will simply not act on new requests for appeal hearings filed by hospitals, physicians and other providers. CMS blames the federal sequester and an unprecedented increase in appeal requests. It expects that the suspension of hearing rights will last about two years and no appeals filed after April 1, 2013 will be assigned to Administrative Law Judges.

As a result, litigants are left in limbo wondering whether they no have a right but no true remedy. 42 C.F.R. § 405.1104 and 42 C.F.R. § 405.1016 hold that an appellant who files a timely request for hearing before an Administrative Law Judge ("ALJ") may request escalation of the matter to the Medicare Appeals Counsel if the ALJ does not issue a decision, order of dismissal or remands the matter to the QIC within ninety (90) days of filing and, in view of the administrative crisis at the Office of Hearings and Appeals, we have recently sought escalation.

Conclusions

1. Identify the type of audit confronting your client so that you may determine whether it is a civil demand for repayment or whether it suggests the potential for criminal investigation and liability.

2. Determine who will be responsible for locating and copying the requested records and, further, determine that a true copy has been provided even if the practice must do so in an electronic format.

3. Analyze the demand carefully to determine whether it is just billing, coding, recordkeeping or clinical issues that require immediate remedial attention or suggest that further compliance activities are appropriate.

4. Retain appropriate consultants pursuant to U.S. v. Koval to review a sampling of the audited claims.

5. Upon receipt of the initial determination, re-enlist your consultants to determine whether additional records or evidence should be provided and, whether appropriate standards have been applied.

5

 ¹⁷ See *Pruchniewski v. Leavitt*, 2006 WL 2331071 (MD Fla. 2006), where the court suggested, in *dicta*, that in certain circumstances, the failure to save or provide pivotal data may render the extrapolation demand invalid.
¹⁸ 42 C.F.R.§ 405.940- 958

6. Make appropriate requests for the preservation and disclosure of records at each level of appeal.

7. Make sure that all available evidence is presented at the earliest possible moment and, without exception, before a decision upon the Level II Reconsideration.

8. Have counsel engage a statistical expert to assist you in requesting the necessary information to determine whether the sampling and the extrapolation are vulnerable and subject to challenge.

9. As a prophylactic measure, providers should be aware CMS publishes utilization data each year that enables providers to compare themselves to the billing and coding habits of their peers. Periodically, utilization data should be reviewed and test audits should be conducted by counsel's consultant to determine whether the practice remains in compliance, thereby reducing the risk of further audits.

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