SURVIVING MEDICARE AUDITS

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FORMALITIES

• Mark Cicka
• Health care attorney with the Hesse Martone law firm in St. Louis
• Specialize in representing health care clients in a wide variety of health care matters, including:
  • Transactions
  • Regulatory
  • Audits
  • HIPAA
  • Fraud and Abuse
  • Stark Law
  • Employment issues
• Hesse Martone also specializes in labor and employment issues from the management side.
INITIAL STAGES OF A MEDICARE AUDIT

• What is “Program Integrity”?  
  • “Fraud”.

• Walk through the initial stages of a Medicare audit, using real documents from a real case.

• Many types of Medicare audits, each of which has its own nuances.

• Focus on an audit conducted by a Zone Program Integrity Contractor (“ZPIC”).
WHAT IS A ZPIC?

- A commercial entity which has a contract with CMS to audit healthcare providers.
- CMS divides the country into different zones by region, and hires a ZPIC to review healthcare providers’ claims in that region.
- So in our case, the ZPIC is a company called AdvanceMed.
THE LABORATORY

- Independent clinical laboratory, CLIA certified.
- Received a letter from AdvanceMed.
- Document #1.
- The letter:
  - A “medical review”.
  - Determine whether the services were reasonable and necessary.
  - Also determine whether all other requirements for Medicare coverage were met.
- Keep in the back of your mind the “F” word – “fraud”.
• Protected health information asked for by the auditors.
• ZPICs perform health care operations as business associates of CMS with respect to the HIPAA Privacy Rule.
• Providing the requested documentation does not violate the minimum necessary provision of the HIPAA Privacy Rule and does not require beneficiary authorization.
• Means ok to give requested documentation without a business associates agreement or the consent of the beneficiaries.
THE AUDIT SAMPLE

- The “audit period”.
- ZPIC uses a computer-generated sample of claims to select for review from the universe of claims.
- Dates of service for the review were 12/23/14 – 6/20/15 – a six month period.
- Regulations prohibit a review of claims already paid if certain criteria are met.
  - Regulations are called the “reopening rules” found at 42 U.S.C. 405.980 (discussed later).
PROVIDER’S DUTY OF COOPERATION

- Requires provider to submit all information necessary to support claims for service.
- If certain records supporting the services rendered are at another facility, as the billing provider you are responsible for obtaining those records for review.
- 4th paragraph “as the billing provider, you are responsible for obtaining those records for review”.


REQUESTED RECORDS

- You must supply the following records for each beneficiary for services delivered during the audit period.
  - The itemized claim form
    - How many services provided
    - Dollar amount of each service
    - HCPC code for each service
    - Revenue code billed for each service
    - Place at which the service was performed
  - Consent for treatment, authorizing service
  - A copy of the beneficiary’s Medicare card
  - Advanced Beneficiary Notices completed during the requested time frame
  - Physician order/prescriptions for all services
  - Medical diagnosis/medical necessity for performing service
REQUESTED RECORDS cont.

- Clinical record documentation to support medical necessity of services performed
- History and physical
- Discharge summary
- Consultation reports and/or letters
- Physician/provider progress notes
- Laboratory result reports
- Radiology reports
- All other diagnostic test and/or diagnostic procedure reports
- Legends, keys, or acronym lists to assist with understanding documentation
- Operative/procedure reports, including pre and post procedure monitoring/flow charts
- Operative/procedure consent forms
- All medical findings and any other documentation to support the claims and services
TIMEFRAME TO SUBMIT DOCUMENTS

- Must be submitted within 30 days of the request.
- Don’t wait until the last minute for an extension.
- CMS approval for extensions.
- Submit the documents, then wait.
- If you are having a good day . . . .
- If you are not having a good day . . . .
POST-PAYMENT REVIEW RESULTS AND PROVIDER EDUCATION

- Post-payment review and provider education letter.
- Document #2.
- First time we see the “F” word.
THE OVERPAYMENT LETTER

- Laboratory has been overpaid by Medicare in the amount of $549,810.46.
- Not a demand letter.
- Wisconsin Physician Service is the Medicare Administrative Contractor (MAC).
- The MAC has authority to determine the amount due, repayment options and various ways to appeal this determination.
- Generally not appealable to a higher authority such as to the MAC, CMS, an administrative tribunal or a court.
• Why did AdvanceMed choose to review this laboratory?
  • AdvanceMed focused on drug screenings.
  • The laboratory was identified for qualitative drug screenings vs. assay tests.
• The laboratory was identified as the top biller for the G codes and Assay codes billed on the same date of service.
REOPENING OF CLAIMS

- 30 claims, 390 service lines and 28 beneficiaries.

- Reopening rules:
  - A contractor may reopen and revise its initial determination or redetermination on its own motion:
    - Within one year from the date of the initial determination or redetermination for any reason;
    - Within four years from the date of the initial determination or redetermination for good cause as defined in 405.986;
    - At any time if there exists reliable evidence as defined in 405.902 that the initial determination was procured by fraud or similar fault as defined in 405.902.
• AdvanceMed within the timeframe set forth in the first subsection, i.e., “within one year from the date of the initial determination or redetermination.

• AdvanceMed took the position that its decision to reopen these claims for review were not subject to appeal.
“Program integrity” = “medical review of claim information and medical documentation focusing on addressing situations of potential fraud, waste and abuse”.

The Medicare Program Integrity Manual delineates the focus of medical review for benefit integrity purposes from other forms of medical review:

- The focus of medical review is to reduce the error rate through medical review and provider notification and feedback; whereas
- Medical review for benefit integrity purposes focuses on addressing situations of potential fraud, waste and abuse.

“The very nature of a ZPIC’s medical review function is to “investigate potential fraud on the part of suppliers and other entities who receive reimbursement under the Medicare program for services rendered to beneficiaries.”

“When the PSC and the ZPIC PI units receive an allegation of fraud, or identify a potentially fraudulent situation, they shall investigate to determine the facts and the magnitude of the alleged fraud. They shall also conduct a variety of reviews to determine the appropriateness of payments, even when there is no evidence of fraud.” [Medicare Program Integrity Manual, chapter 4 section 4.7].
THE MEDICAL REVIEW FINDINGS

- AdvanceMed provided with the overpayment letter a CD which contained a Claim Line Decision Spreadsheet list with details for each claim line reviewed.
- The spreadsheet contained a column titled “Decision”.
- The Decision column listed whether a claim was allowed, denied, down-coded or changed.
- Again, AdvanceMed conducted a review of 30 claims, 390 service lines and 28 beneficiaries’ medical records.
- **The review resulted in a 100% denial rate.**
General medical review findings:
- All beneficiaries in the sample were billed for the same laboratory studies and methodologies which included both qualitative and quantitative drug testing; and
- Also, all beneficiaries in the sample were billed for drug confirmation testing.

Of the 390 claim lines reviewed:
- 216 services (55%) were denied as not reasonable and necessary;
- 150 services (39%) were denied as related to non-covered services; and
- 24 services (6%) were denied as not rendered.
“Submitted laboratory reports for the billed date of service did not substantiate, G0431, Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter, was performed by the billing provider; recorded test results supported quantitative testing by the billing provider. Therefore, the billed laboratory study is denied.”
NOT REASONABLE/NECESSARY

- “No Medicare payment shall be made for items or services, which are not ‘reasonable and necessary’ for the diagnosis or treatment of illness or to improve the functioning of malformed body member.”
- The reasonable and necessary denials were related to qualitative and quantitative drug testing; none of the treating/referring provider records included the rationale for confirmation testing, supported confirmation testing as part of the plan of care, or supported the drug test results were used in management of the beneficiary’s specific medical problem.
To be considered reasonable and necessary, all diagnostic tests must be ordered by the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. Upon review of the documentation, it was determined that this requirement was not met.

- The diagnostic test was not used in the management of the beneficiary’s specific medical problem.
SERVICE RELATED TO NON-COVERED SERVICE

- Medicare payment may not be made for services related to other non-covered services. Upon review, it was noted that the billed service was related to a non-covered service.
- The denied services related to non-covered services consisted of lab testing methodologies (chromatography, column chromatography, mass spectrometry, tandem mass spectrometry) and drug confirmation.
EXTRAPOLATION

- $50,000 overpayment resulted in a $550,000 overpayment.
- The decision to extrapolate is predicated on the finding of a high or sustained level of payment error.
- The decision to extrapolate is not subject to appellate review.
WAIVER OF LIABILITY

- Social Security Act permits Medicare payments to be made to providers on services otherwise not covered:
  - If neither the beneficiary nor the provider knew, or could reasonably be expected to know, that the services were not covered.
- Providers are expected to be familiar with the coverage requirements/criteria of services billed.
- A Medicare provider is charged both with knowledge of the applicable regulations and with the understanding that Medicare would not provide reimbursement for services that are not demonstrably medically necessary and otherwise properly documented.
NOTICE OF SUSPENSION OF MEDICARE PAYMENTS

- Document #3.
- AdvanceMed has the authority, with the approval of CMS, pursuant to 42 C.F.R. 405.371(a)(1).
- The reason = reliable information that an overpayment exists or that the payments to be made may not be correct.
MECHANICS OF A MEDICARE PAYMENT SUSPENSION

- Payment suspension occurred on November 19, 2015 = before AdvanceMed even sent the letter to the laboratory.
- Suspension could last for 180 days.
- Suspension could be extended longer than 180 days.
- Prior notice of suspension not given because prior notice would place additional Medicare funds at risk and hinder AdvanceMed’s ability to recover any determined overpayment.
Laboratory submitted claims for payment to Medicare that included:
• Services not rendered; and
• Billing for services where non patient specific standing orders authorized by the referring providers were used for all patients.
RESPONDING TO PAYMENT SUSPENSION

- Laboratory has the right to submit a rebuttal statement in writing within 15 days addressing why the suspension should be removed.

- AdvanceMed will determine whether the suspension should be removed or should remain in effect within 15 days of receipt of the complete rebuttal statement.

- AdvanceMed would then notify the laboratory in writing of its determination to continue or remove the suspension, and provide specific findings on the conditions upon which the suspension may be continued or removed.

- The determination is not appealable.
IF THE SUSPENSION IS CONTINUED

- If the suspension is continued, AdvanceMed will review additional evidence during the suspension period to determine whether the claims are payable and/or whether an overpayment exists.
- Claims will continue to be processed during the suspension period, and the laboratory would be notified about bill/claim determinations, including appeal rights regarding any bills/claims that are denied.
- Payment suspension applies to both claims in process and future claims.
- However, suspension of Medicare funds would continue while the rebuttal statement is being reviewed.
IF AN OVERPAYMENT IS DETERMINED

- If an overpayment is determined and it is determined that a recoupment of payments should be put in effect, the laboratory would receive a separate written notice of the intention to recoup and the reasons therefore, and will be given an opportunity for rebuttal.

- When the payment suspension has been removed, suspended payments first will be applied to reduce or eliminate any overpayments, and then to reduce any other obligation to CMS.
The laboratory was also placed on prepayment review.
THE LABORATORY’S
REBUTTAL STATEMENT

DOCUMENT #4

The ZPIC Improperly Derived an Error Calculation for the 216 Claims Which were Denied as Not Reasonable and Necessary

- Laboratory met all of the requirements of the local coverage determination (LCD).

- LCD was internally inconsistent with respect to the reasonableness and necessity of confirmation testing, and therefore could not be utilized by the ZPIC to determine that an overpayment was due.

- The LCD relied on by the ZPIC to perform its error calculation was materially changed during the timeframe of the ZPIC’s sample selection, rendering the calculation useless.

- The standing order used by the laboratory for the patients in the ZPIC’s sample selection complied with applicable regulations and guidance.

- Out of abundance of caution, the laboratory established a policy and procedure regarding standing orders.
The ZPIC Improperly Derived an Error Calculation for the 24 Services Which were Denied as Not Rendered

The laboratory sent in to the ZPIC medical records demonstrating that the laboratory tests were performed.
Sampling Methods were Not Statistically Valid
We believe it imperative to state that the laboratory is, and always has been, a responsible provider of healthcare items and services with a deep commitment to operating in compliance with applicable rules and regulations. The laboratory is in the process of, or has already effectuated, the following measures to ensure its compliance with applicable rules and regulations:
CEASED SUBMITTING CLAIMS TO MEDICARE PROGRAM

Upon receipt and careful analysis of the Education Letter, the laboratory has ceased submitting claims to the Medicare program. The purpose of the cessation was to ensure that all claims submitted by the laboratory prospectively are in compliance with the guidance provided in the Education Letter, as well as the applicable rules and regulations of Medicare.
The laboratory has also established a policy regarding medical necessity. The laboratory will send the policy regarding medical necessity to its physicians and distributors, and will also post the policy on its website and provider portal.
The laboratory has also established a policy and procedure regarding standing orders. The laboratory will send the policy and procedure regarding standing orders to its physicians and distributors, and will also post the policy on its website and provider portal.
The laboratory recognizes that all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

The laboratory also recognizes that tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. The laboratory will therefore perform clinical records sampling of its providers in order to ensure that the laboratory and its providers are meeting the Medicare program's requirements related to medical necessity and documentation. However, such monitoring and auditing will not cause the laboratory to be ineligible for the waiver of liability provisions of the application regulations.
ADDITIONAL EVIDENCE OF EFFECTIVE COMPLIANCE

- The laboratory has retained the services of a clinical compliance consultant, which provides further evidence of laboratory’s commitment to effective compliance with the Medicare program requirements.

- Lastly, the laboratory has identified claims submission errors which were the fault of its billing provider, a third-party entity. My laboratory will return funds for those errors to the Medicare program and seek restitution from its billing provider.
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