Payor Audits: Preparing Your Lab

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Learning objectives

After this webinar, you will be able to:

- Describe the government audit process - from initial correspondence through the various stages of appeal and share speakers' experience with respect to commercial payor audits – what is similar and what is different from government audits. Explore recent case law regarding lab audits
- Discuss the lab's responsibilities with respect to the medical necessity of testing for which it is submitting claims
- Address the lab's duties with respect to the Reverse False Claims/60 Day Rule following an audit request
- Identify steps labs can take to prepare for audits prior to an audit being initiated

Today’s agenda

- Medicare Audit and Appeals Process
- Commercial Payor Audit and Appeals Process
- Medical Necessity
- Medicare Signature Requirements
- 60 Day Rule/Reverse False Claims
- New law affecting lab providers - EKRA

Medicare Audit and Appeals Process

- Medical Records Request
  - **Practice tip: Get counsel and/or consultant involved NOW**
- Notice of Payment Suspension and/or Pre-Payment Review
- Post payment review results and determination of Overpayment
- Overpayment Demand

Medicare Audit and Appeals Process

- Request for Redetermination
  - 120 days to file/30 days to avoid recoupment
  - Can submit new evidence
  - 60 days for MAC to issue decision
    - **Practice tip: Keep documents organized and label each page for easy reference**.
- Request for Reconsideration with QIC
  - 180 days to file/60 days to avoid recoupment
  - Last time (without good cause) to present new evidence
  - 60 days for QIC to issue decision

Medicare Audit and Appeals Process

- Request for ALJ Hearing
  - 60 days to file
  - No new evidence allowed without good cause
  - ALJ has 90 days to issue decision
  - Will issue an opinion with findings of facts and conclusions of law
  - Huge backlog

Medicare Audit and Appeals Process

- Medicare Appeals Council
  - 60 days to file
  - CMS can request this appeal also within 60 days, which the Council can decline
  - Council upon its own motion may elect to review the ALJ decision within 60 days
  - 90 days for Council to issue decision
- Federal District Court
  - 60 days to file

Commercial Payor Audit Process

- Determined by the individual payor
- Check online, provider manuals, provider contracts for process
- Usually starts with a Medical Records Request and/or overpayment demand
  - **Practice tip: Get counsel and/or consultant involved NOW**
- Can typically be resolved via settlement negotiations

Medical Necessity Documentation

- Definition of Medical Necessity: 42USC 1395y(a) “Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services –(1)(A) which, except for items and services described in succeeding subparagraphs , are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…”
- State definitions vary by state

- **Practice tip: Prepare physician education letter(s) or annual notice for all physician referrers**

Medical Necessity Documentation

- Upon request for review, it is the BILLING provider's responsibility to obtain supporting documentation from a referring physician's office or from an inpatient facility - CMS MPIM Ch. 3 Section 3.2.3.3
- Insufficient documentation errors
  - Incomplete progress notes (i.e. unsigned, undated, insufficient detail)
  - Unauthenticated medical records (i.e. no signature or invalid signature)
- *Groat v. Boston Heart Diagnostics*, Dist. DC:
  - Labs may rely on physician's determination of medical necessity, but labs still have a legal duty to certify that the claims submitted are medically necessary

Complying with Medicare Signature Requirements

- Medicare requires that services provided/ordered be authenticated by the author
  - Hand written, electronic or stamped signatures allowed
  - Exception
  - Orders for certain clinical diagnostic tests are not required to be signed BUT there must be documentation in the medical records of the order physician that establish that the physician intended the test to be ordered and medical records must be authenticated

- **<u>Practice tip:</u> Require physician signatures on all requisitions; review requisitions regularly to ensure compliance**

Complying with Medicare Signature Requirements

- Cannot add late signatures but can make sure of signature authentication process
  - If illegible, can submit a signature log or attestation statement
    - Signature logs can be created at any time
  - If signature is missing on the order, the order is disregarded during review of the claims
  - Attestations cannot be used for unsigned orders/requisitions
- If billing to Medicare, lab must obtain signed order (or authenticated progress notes) and documentation to support medical necessity for the ordered services
- Without signed order and without authenticated progress notes, the claim will be denied

60 Day Rule/Reverse False Claims

- 42 USC §1320a-7k
- 42 USC §422.326 – Medicare Advantage Contractors
- 42 CFR 401.301 – Providers
- May 23, 2014, CMS published Medicare Parts C & D Final Rule
- February 12, 2016, CMS published Medicare Parts A & B Final Rule
- No final rule for Medicaid yet, but statute still applies

60 Day Rule/Reverse False Claims

- Part A & Part B Rules:
  - 6 year look back
- **Practice tip: review your document retention policies to ensure compliance (Scanned or electronic records are sufficient)**
  - Counted from identification of overpayment
  - Provider may rely on good faith and reasonable interpretation of the statute
- **Practice tip: Create overpayment policy and create written guidelines/policies for internal investigations (process, timing and reporting expectations)**

60 Day Rule/Reverse False Claims

- "IDENTIFY" Providers have an obligation to exercise reasonable diligence through timely, good faith investigation of credible information.
  - Includes proactive compliance activities conducted by qualified individuals in good faith
  - Credible information determination is fact specific
  - The amount of the refund must be quantified
  - 60 day clock begins running after reasonable diligence period (max of 6 months absent extraordinary circumstances)

60 Day Rule/Reverse False Claims

- Refund processes:
  - MAC voluntary refund process
  - Claims adjustments
  - Credit balances
  - Voluntary offset
  - OIG Self Disclosure Protocol
  - CMS Self-Referral Disclosure Protocol
- **Practice tip: Check state law requirements re refunds of patient cost-share amounts**

60 Day Rule/Reverse False Claims

- No minimum threshold; preamble states: “After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim.”
- CMS will refer to OIG for appropriate action and suspend repayment obligation until resolved – the OIG has the authority under the Civil Monetary Penalty Law to address non-criminal violations of the AKS

60 Day Rule/Reverse False Claims

- Tolling
  - use of SRDP and OIG SDP toll the period of time to identify and return an overpayment
  - disclosures to DOJ or MFCU do NOT toll time to identify and return overpayment
- Get legal counsel involved early to establish attorney-client privilege and maintain confidentiality as long as possible
- Entire process should be documented; correct the problem; identify and review policies/procedures involved in the action; identified and review potentially relevant documents; prepare a summary report

EKRA

- Eliminating Kickbacks in Recovery Act (EKRA)
- Passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Section 8122 of the SUPPORT Act)
- Effective 10/24/2018
- Impacts recovery homes, clinical treatment facilities, and laboratories

What is EKRA?

- Intended to address America's opioid epidemic
- Attempt to expand prohibited conduct that would be an AKS violation if a government payor were involved to any services paid for by ANY payor
- Applies to ALL payors, not just federal payors (i.e., Medicare and Medicaid)
- No legislative history because added to SUPPORT Act so late

Prohibited Conduct

Whoever knowingly and willfully:

- Solicits or receives any remuneration directly or indirectly for referring a patient or patronage to a recovery home, clinical treatment facility or lab; or
- Pays or offers any remuneration directly or indirectly
  - To induce a referral of an individual to a recovery home, clinical treatment facility, or lab; or
  - In exchange for an individual using the services of that recovery home, clinical treatment facility, or lab

shall be fined not more than $200k/offense, imprisoned not more than 10 years, or both, ***for each occurrence***

Definition of Laboratory

- “[A] facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” 42 U.S.C. 263a
- Applies to both clinical AND anatomic pathology labs
- **Important: Not limited to substance abuse/toxicology testing**

Preemption

- EKRA does not apply to conduct:
  - prohibited under AKS
  - prohibited by state laws on the same subject matter

EKRA Exceptions

1. Discount obtained by provider of services or other entity if reduction is properly disclosed and reflected in costs claimed by provider
2. Payment by employer to W-2 or 1099 for employment, if the payment is not determined by or does not vary by:
   - # of individuals referred to a particular recovery home, clinical treatment facility or lab;
   - # of tests of procedures performed; or
   - Amount billed to or received from payor
3. Discount in price of drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program
4. Payment made by a principal to an agent for services rendered under a personal services and management contract that meets AKS requirements (*Adopts AKS Personal Services and Management Contracts Safe Harbor*)

EKRA Exceptions (con't.)

5. Waiver or discount of any coinsurance or copayment by a payor if
   - Waiver or discount is not routinely provided; and
   - Waiver or discount is provided in good faith.
6. Remuneration described in 1128B(b)(3)(I) of the Social Security Act (*Adopts AKS FQHC Safe Harbor*)
7. Remuneration made pursuant to an alternative payment model or payment arrangement used by a State, health insurance issuer, or group health plan if HHS has determined such arrangement is necessary for care coordinate or value-based care.
8. Any other payment, remuneration, discount or reduction determined by the AG in consultation with HHS.

Considerations

- Convert all 1099 sales reps to W-2
- Pay all sales reps a flat rate?
  - Many lab providers are exploring alternatives to traditional commission-based structures
  - ACLA advocating for clarification on government expectations
- MH continues to monitor

Questions?

The information in this presentation is provided for educational purposes only and is not legal advice. It is intended to highlight laws you are likely to encounter, but is not a comprehensive review. If you have questions or concerns about a particular instance or whether a law applies, you should consider contacting your attorney.

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