HCCA 17th Annual Compliance Institute

Clinical Laboratories

Session PREAM11
Industry Immersion: Clinical Laboratories
Presented by:
Christopher P. Young, CHC
cpyoung@cox.net
www.Labcomply.com
Objectives For This Section

- Learn how to respond to government demands for refunds of laboratory overpayments and learn the ins and outs, and risks, of voluntary refunds and the appeals process as they pertain to laboratory claims.

- Discuss current and near future laboratory compliance issues and best practices for laboratory compliance officers.
Coding and Billing Still High Risk With Some Areas of Focus More Important

- Make sure that test ordering and claims processing are without error
  - Requires automated editing systems

- Toxicology and billing for pain management clinics is a high risk area in 2013

- Date of service where the 14 day rule for complex genetic tests is involved

- Molecular and genetic testing with the new codes and pricing scenarios

- Skilled Nursing Facilities (SNF) billing, ESRD testing and Hospice
Demands, Appeals and Voluntary Refunds

- Becomes important as auditing activity increases on both sides

- There are risks associated with each demand for a refund
  - Paying the refund without challenge could be seen as an admission of inaccurate billing
  - The 60 day refund time frame does not leave a lot of room for review and internal audit

- Your own audits may result in your laboratory making “voluntary refunds”
  - Risks associated with voluntary refunds include exposure to wider audits by contractors
  - Challenges of your auditing result especially when the refund is based on a sampling and not a 100% population review
  - Could expose your lab to prepayment reviews or even payment suspensions if seen as egregious
Errors vs Fraud

- Simply, errors are unintentional violations of Government or Medicare billing and/or coding rules and regulations.

- Fraud is intentional violations of Government or Medicare billing and coding rules and regulations.

- Both “errors” and “fraud” can result in improper payments.

- Improper payments was defined in the “Improper Payments Information Act of 2002” as:
  
  (A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and
  
  (B) includes any payment to an ineligible recipient, any payment for an ineligible service, any duplicate payment, payments for services not received, and any payment that does not account for credit for applicable discounts.
Errors vs Fraud

- Prevention of making improper payments is the duty of the payer
  - Usually accomplished by using computer edits to identify and deny improper claims
  - Educating providers and suppliers about billing errors and claims submittal problems

- Prevention of submitting claims that result in improper payments is the duty of the provider or supplier
  - Usually accomplished by using computer edits to prevent improper claims from being sent to the payer
  - Educating employees and clients about billing errors and claims submittal problems

- Improper payments can result in the appearance of fraud when there is no fraud
Denial Versus Return

• If a claim is not processable because there is missing information or the information provided is not valid, the claim is returned to the provider and the provider is afforded an opportunity to correct the claim and resubmit it.

• These claims effectively do not enter the Medicare system and are not adjudicated for medical necessity or any other problem; they are rejected before they ever get into the system.
  - These claims have not been “adjudicated” or “denied” so they are not subject to an appeal.
  - Once the corrected information is provided and the claim is resubmitted, it could be “denied” for some other reason.
Causes of Improper Payments

- Medically Unnecessary Services
  - Claims are placed into the medically unnecessary category when claim review staff identifies enough documentation to make an informed decision that the services billed were not medically necessary based on Medicare coverage policies or other medical necessity criteria.

- Insufficient documentation errors
  - An insufficient documentation error occurs when the provider does not submit sufficient documentation to determine whether the claim should have been paid
The overall goal of CMS’ claims review programs is to reduce payment errors by:

- “identifying and addressing billing errors concerning coverage and coding made by providers” and suppliers

- 10% of all Medicare fee for service claims payments are improper

- CMS employs various contractors to process and audit claims submitted by providers and suppliers
## Contractors and Responsibilities

<table>
<thead>
<tr>
<th>Type of Contractor</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affiliated Contractors (ACs) – Medicare claims processing</td>
<td>Process claims submitted by physicians, hospitals, and other health care providers/suppliers, and submit payment to those providers in accordance with Medicare rules and regulations. This includes identifying and correcting underpayments and overpayments.</td>
</tr>
<tr>
<td>carriers and Fiscal Intermediaries (FIs)</td>
<td></td>
</tr>
<tr>
<td>Medicare Administrative Contractors (MACs)</td>
<td></td>
</tr>
<tr>
<td>Program Safeguard Contractors (PSCs)/Zone Program</td>
<td>Identify cases of suspected fraud and take appropriate corrective actions.</td>
</tr>
<tr>
<td>Program Integrity Contractors (ZPICs)</td>
<td></td>
</tr>
<tr>
<td>Comprehensive Error Rate Testing (CERT) contractors – CERT</td>
<td>Collect documentation and perform reviews on a statistically-valid random sample of Medicare FFS claims to produce an annual error rate.</td>
</tr>
<tr>
<td>Documentation Contractor (CERT DC) and CERT Review Contractor (CERT RC)</td>
<td></td>
</tr>
<tr>
<td>Recovery Auditors</td>
<td>Identify and correct underpayments and overpayments, as part of the Recovery Audit Program.</td>
</tr>
</tbody>
</table>
Prepayment and Postpayment

<table>
<thead>
<tr>
<th>Prepayment Claim Review Programs</th>
<th>Postpayment Claim Review Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Correct Coding Initiatives (NCCI) Edits</td>
<td>Comprehensive Error Rate Testing (CERT) Program</td>
</tr>
<tr>
<td>Medically Unlikely Edits (MUEs)</td>
<td>Recovery Audit Program</td>
</tr>
<tr>
<td>AC/MAC Medical Review (MR)</td>
<td>AC/MAC Medical Review (MR)</td>
</tr>
</tbody>
</table>
AC/MAC Medical Review

- Tracks and monitors error rates produced by the CERT program, the Recovery Audit (RA), analysis of claims data and other information and sources
- Identifies suspected billing problem
- Targets Medical Review (MR) activities at the identified problem and reviews a sample of claims
- Verifies an error exists and classifies the error for severity as minor, moderate or significant
- Imposes corrective action appropriate for the severity of the problem
Corrective Actions

- Informs the provider of proper billing procedures
- Imposes a prepayment review process that may include MR of a sample of claims, or all claims, depending on severity which requires review BEFORE claims are paid
  - Results in delays in payment for the claims under MR
- Imposes postpayment review which involves an MR of a sample of claims without requesting all records from the provider
  - Sometimes none are requested
Review of Records

- Either prepayment or postpayment reviews may require providers or suppliers to provide medical records or other documentation in support of the claim.

- Providers should supply all documentation requested or provide a reason for not providing a document.

- Providers should supply the information within the time frame required or the claims will be denied.
Recovery Auditor Program (RA)

- In my experience, working with laboratories who are dealing with RA audits, the supporting documents for the audits and the interpretations made by the auditors often contain inaccuracies and inconsistencies in terms of the overpayment determination.

- Laboratories need to make a decision concerning RA audits and the information provided in those audits of whether they will appeal or not.

- In many cases, laboratories do not appeal because the cost of the appeal process often is financially not beneficial, in other words, it's cheaper to write them off then to appeal them, in the minds of the laboratory's administrators.

- There may be unintended consequences of taking this course of action and the laboratory should carefully consider how they respond to demands for overpayments by RAC contractors and other fraud subcontractors.
Zone Program Integrity Contractors (ZPIC) focus on performing integrity activities to prevent fraud, waste and abuse in Medicare.

- Very aggressive and specifically focus on fraud and abuse to report to the OIG.

- Already have experienced some problems with effectiveness of their audits and with conflicts of interest.

- Labs and hospitals have reported potentially abusive and irregular behavior by ZPICs.

- OIG has conducted two separate reviews of ZPICs since November of 2011.
ZPICs

- ZPICs are referred to as “the policeman of the Medicare contractor world”

- Authorized to conduct investigations, support law enforcement and conduct audits of Medicare Advantage plans

- Laboratories should take any contact from a ZPIC very seriously as they often lead to referral to the OIG for potential criminal investigations

- Contact by a ZPIC should set off bells and should invoke careful self reviews or audits of the activities cited by the ZPIC

- Some anecdotal reports by hospitals and laboratories indicating that ZPICs may overstep their authority

- CMS needs more effective oversight of ZPIC
**Potential Consequences**

- Generally speaking, the audits are conducted on a sample of claims representing a specific time frame.

- Auditors may extrapolate over payment amounts based on the sample, resulting in larger refund determinations than may actually exist.

- If the laboratory agrees that the overpayments are justified and repays them, it must consider how to deal with similar cases that are outside of the timeframe used by the auditors.
  - In other words, the laboratory may find itself deciding on self-reporting additional refunds it suspects exist based on the findings of this particular audit.

- The results of these audits are reported to the Office of the Inspector General (OIG) and eventually could lead to other investigations.

- Prepayment review and medical review scrutiny is increasing.
Auditing And Being Audited

- One of the best defenses for coding and billing risks is an effective auditing plan focused on high risk areas
  - Routine auditing to catch problems
  - Defensive audits when demands for refunds are received

- Government auditors have not been very good so far and a fairly high percentage of refund demands are overturned if challenged with an appeal
  - Problem is many providers do not appeal
    - Cost of appeal outweighs refund amount
    - Fear of contractor retaliation
    - Unsure or coding and billing regulations
Appeals

- In addition to the case of a claim being denied by the contractor, a post-payment review by a CMS subcontractor like an RAC or ZPIC that includes a refund or repayment requirement may also be appealed using the same process.

- The same rules apply for both cases.

- We will review each level of appeal in some detail.
**Appeals**

- There are 5 levels to the appeals process
  - Redetermination
  - Reconsideration (QIC)
  - Administrative Law Judge Hearing (ALJ)
  - Appeals Council Review
  - Judicial Review in US District Court

- Beginning with the Administrative Law Judge Hearing, there is a minimum monetary amount that must remain in contention after the first two levels of appeal
Redetermination

- Performed by contractor staff not involved in the initial claim determination
- Must be filed within 120 days from the receipt of the initial determination (remittance advice (RA) issued to supplier)
- There is no minimum monetary threshold
- The initial determination will include information on how to file a request for redetermination
- Suppliers either follow the directions provided or use form CMS-20027
Redetermination

- A written request not using the CMS form must include
  - Beneficiary name
  - Medicare Health Insurance Claim (HIC) Number
  - Specific service or item for which a redetermination is being requested (HCPCS code)
  - Specific dates of service
  - Name and signature of the party or representative of the party filing the redetermination

- Attach supporting documentation

- Contractors will generally issue a decision within 60 days of receipt of the redetermination request
Reconsideration

- If you are dissatisfied with the redetermination you may file a request for a reconsideration

- Reconsideration’s are conducted by a Qualified Independent Contractor (QIC)

- This review may include a review of medical necessity issues by physicians or other health care professionals

- There is no minimum monetary threshold to request a reconsideration
Reconsideration

• A written reconsideration request must be filed within 180 days of the receipt of the redetermination

• The reconsideration request may be made on form CMS–20033

• If the form is not used, the written request must include all of the things necessary for a redetermination with the additional requirement of including the name of the contractor that made the redetermination
Reconsideration

• The appellant should clearly explain the reasons for disputing the redetermination decisions and include a copy of the remittance advice or other useful documentation to support their case.

• Avoid simply duplicating documentation used in the redetermination and/or include any evidence not previously provided along with a reason for submitting the evidence late.

• All parties involved so far in the process will receive the QIC decision generally within 60 days of the receipt of the request for reconsideration.

• The decision will include information on the next level of appeal and if the decision cannot be provided in the applicable time frame, the QIC will inform the appellant of their rights to escalate the case to the ALJ.
The Administrative Law Judge Hearing

- At least $130 must remain in controversy following the QIC decision

- Request the ALJ hearing within 60 days of the receipt of the reconsideration decision
  - Also send a copy of the request to all other parties involved in the QIC reconsideration

- ALJ hearings are generally held by video teleconference or by telephone

- The appellant may ask for an in person hearing if they have good cause
  - The ALJ decides if the in person hearing is needed
The Administrative Law Judge Hearing

- An appellant may request a decision by the ALJ without a hearing.

- CMS or its contractors may become a party to, or participate in, the ALJ hearing if they provide notice to the ALJ and the parties to the hearing.

- The ALJ will generally issue a decision within 90 days of the receipt of the hearing request.
Appeals Council Review

- If one of the parties to the ALJ hearing is dissatisfied with the decision, they may request a review by the appeals Council
  - No minimum monetary threshold is required

- The request must be submitted in writing within 60 days of receiving the ALJ’s decision

- It must specify the issues and findings that are being contested

- Instructions for how to request the appeals Council review will be included with the ALJ decision

- Generally the Appeals Council review would issue a decision within 90 days
Judicial Review in US District Court

- The minimum monetary amount remaining in controversy must be at least $1,350

- The appellant must file the request for review within 60 days of the Appeal Counsel’s decision

- The Appeals Council decision will contain information about the procedures for requesting a judicial review
What Documentation Should You Submit?

• The best case for the laboratory is to win your appeal as early in the process as possible

• The best way to accomplish this is to provide complete information and documentation in the early parts of the appeal process

• Carefully review the documents associated with the denial or refund demand and make sure you provide all of the requested documents
  – Also make sure you understand why the claim was denied or the refund is required

• In any case where the documents requested are not available, explain why they are missing
+ Documentation

- If you know, or have an idea, that the documentation you are submitting may create a problem or misunderstanding by the auditor, explain the documentation
  - For instance, if the “order” includes a panel or profile that is customized and the explanation of the panel’s contents are included elsewhere, explain that and provide the necessary documentation to support the order which may be the signed physician acknowledgement
  - If there are inconsistencies in the documentation you send, explain that
Review of the Documentation

• Make sure that all of the documents you send are copied

• Make sure the submission is thoroughly reviewed by staff sufficiently knowledgeable about the claims submittal process in your lab

• Make sure the review includes the compliance officer

• Look for wrong documents, wrong dates of service, other inconsistencies with the request by the auditor as well as the issues involved in why the claims may be wrong

• Don’t get caught in simple problems like administrative errors which may irritate the requestor and give them a bad impression about your lab

• Use the same personnel throughout the appeal process to ensure efficient and effective responses
Follow-up and Tracking

- Keep a log or record of each refund request or audit conducted by government auditors
  - One reason is to make sure your lab isn’t subject to the same audit by some other government contractor

- Keep a library of the resources and laws and regulations involved in each audit
  - Try to determine any trends that may lead to an internal undiscovered trend or systemic problem

- Consider these audits and appeals as serious matters worth the commitment of appropriate resources to resolve them

- Use them as training tools and improvement tools for your laboratory systems and processes
Know What You Are Doing and/or Get Expert Help

- Develop auditing skills through education, conferences and self study
- Practice your skills by conducting mock audits or real audits of your own billing and coding
- Make sure you thoroughly understand the rules and regulations and the appeals process or hire an expert that does
- Read all government documentation that accompanies a demand for a refund carefully and critically, looking for errors and misquotes etc.
- Make certain you supply the appropriate documents requested and make note or comment on anything that is missing or cannot be provided
- Conduct your own review of the requested records and documents
Current Legislative And Regulatory Issues - Fee Schedule Issues

- Payment reductions for the clinical laboratory fee schedule

- 2013 clinical laboratory fee schedule (CLFS) was cut by 4.95% as of April 1, 2013
  - Includes the 2.95% cut that was effective January 1 as a result of the Affordable Care Act and left over legislation from previous years
  - The additional 2% comes from the “sequestration” cuts applied to all government agencies and became effective April 1, 2013

- There was a cut on the Medicare physician fee schedule specifically for the TC of CPT code 88305 of in excess of 50%

- Initial published in fees for molecular pathology codes appears to be reduced when compared to the stacked codes previously used
Current Legislative And Regulatory Issues - Fee Schedule Issues

- Transmittal R2675CP notifies providers of a change in the Travel allowances when billed either per mileage or per trip
  - CPT code P9603 per mileage basis and P9604 flat fee per trip basis

- Travel allowance is paid when medically necessary for a lab technician (phlebotomist) to draw a specimen from a nursing home or homebound patient
  - Travel allowance consists of two components, a mileage component and a payment of $0.45 for technician time and travel expense
  - Each year the travel allowance mileage rate is changed to reflect changes in gasoline and other automobile expenses
Current Legislative And Regulatory Issues - Fee Schedule Issues

- The per mileage basis payment is used when the travel is greater than 20 miles.

- The flat fee rate is used when the trip is less than 20 miles.

- Contractors have the discretion to establish a local policy to pay based on a flat fee basis only.
  - According to the Transmittal this is because there is a audit evidence that some laboratories abuse the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary.

- Laboratories that bill travel fees should make sure that they carefully document the mileage phlebotomists travel to ensure billing is properly documented.
Claims Denials for Invalid PECOS Records

- Full Implementation of the edits on ordering/referring providers in Medicare Part B
  - MedLearn Matters SE1305
  - Effective May 1, 2013

- ACA Section 6405 required eligible providers who order or refer items or services for Medicare beneficiaries be enrolled in the Medicare program

- Edits will determine if the ordering/referring provider has a current Medicare enrollment record with a valid NPI and if they are eligible to order or refer tests
  - Must have a current Provider Enrollment, Chain, and Ownership System (PECOS)
Claims Denials for Invalid PECOS Records

- According to the MedLearn Matters article, Phase 1, which provided an informational message to alert billing providers and suppliers (including laboratories) of the lack of a current record, began October 5, 2009.

- Claims were not denied but the following “informational messages” were included:
  - N264 Missing/incomplete/invalid ordering provider name
  - N265 Missing/incomplete/invalid ordering provider primary identifier

- When Phase 2 is implemented, these claims will be denied.
Claims Denials for Invalid PECOS Records

- The Claims Adjustment Reason Code (CARC) used will be 16 “Claim/Service lacks information which is needed for adjudication”

- This will be accompanied by one of the above Remittance Advice Remark Codes ((RARC) N264 or N265

- Some of the things that will trigger these denials are:
  - Misspelled names
  - Improperly completed claims (see SE1305)
  - NPI is an entity NPI and not an individual provider NPI

- Requires an appeal if denied
Current Legislative And Regulatory Issues

- Medicare Audit Improvement Act of 2013 reintroduced on March 19th, 2013

- Addresses problems in the Recovery Audit Contractors program (currently the Recovery Audit program)
  - Creates a “hard cap” on Additional Document requests (ADRs) by auditors
  - Mixed reactions to the Bill with many saying it does not go far enough in reducing the administrative burden
  - Supporters say the Bill is needed and provides a balance between detecting fraudulent claims and reducing the administrative burden

- The appeals process would be changed to include compensation for providers who win their appeals
Other Miscellaneous Regulatory Related Issues for Laboratories

- Electronic Health Records (EHRs) may introduce inaccuracies in the patient charts
  - Things like pull down menus and limited choices can cause problems in post payment audits
  - Automatic text based on limited dictation

- State laws may preempt Federal anti-kickback protections for donations of EHR software and hardware
  - Laboratories must now watch state laws
  - States issuing laws with various restrictions or limits include New York, New Jersey, Pennsylvania, Tennessee, Missouri, Washington and West Virginia

- Many include laboratory specific opinions or interpretations of laws
Other Miscellaneous Regulatory Related Issues for Laboratories

- HR 8 “American Taxpayer Relief Act of 2012” extended the provisions governing recoupment by Medicare of overpayments from 3 years to 5 years
  - CMS must make other changes to make this change in Medicare administration
  - Providers who identify overpayments now must carefully consider their investigative and remedial plans

- Old and previously defeated proposals once again raise their ugly heads
  - Co-payments for beneficiaries on laboratory claims
  - Competitive bidding for laboratory services
Other Miscellaneous Regulatory Related Issues for Laboratories

- Reductions in laboratory reimbursements may affect the lab’s ability to maintain effective compliance programs
- Exposes the laboratory to greater risks from becoming the target of a government audit

- The introduction of ACOs and other new types of provider entities create new compliance challenges as labs search for ways to create value in this new environment
- Can create new anti-kickback and Stark Self Referral law potential violations
- Payment incentives for physicians can lead to labs providing too much help in meeting the requirements when a lab test component is involved
Compliance Perspective

- When revenue gets tight, competition gets ruthless and cost cutting occurs
  - Labs may cut compliance budgets
  - Take bigger risks in the marketplace as competition gets fierce

- Compliance officers must meet this challenge
  - Find ways to reap revenue benefits from compliance program activities like auditing
  - Closely monitor “deals” to find ways to make them work while remaining compliant
  - Requires compliance officers to step up and be true experts in rules and regulations
CLIA Proficiency Testing Violations

- The CLIA proficiency testing standards for laboratories performing nonwaived testing are included in Subpart H and I (493.801 through 493.959)

- The standards are very detailed and presented by the various specialties and subspecialties for laboratories performing moderate and high complexity testing

- Most laboratories have specific policy and procedure for handling and testing proficiency test samples to ensure it does not violate the CLIA rules and regulations

- The consequences of violating these rules can be severe and can result in the lab having its certification revoked for one or more specialties or subspecialties
493.801 Enrollment and Testing of Samples

- Each laboratory must enroll in an approved program for each specialty or subspecialty in which it is certified.

- Testing requirements are included in 493.801(b) “Testing of proficiency testing samples” (1-4):
  - PT samples must be tested with the regular test workload and by the personnel who routinely test patient samples.
  - Samples must be tested the same number of times as patient samples.
  - The laboratory may not discuss proficiency test results with any other laboratory before the reporting date for the PT including other testing sites or locations owned by the same laboratory.
  - The laboratory may not refer its PT samples to another laboratory for testing or reporting.
  - The laboratory must report to CMS if it receives a PT sample from another lab for testing.
CLIA Proficiency Testing Violations

- Late 2011/Early 2012 Lab Receives PT Samples From CAP
  - PT errors from ‘mistaken referral’ of PT samples to other labs
  - CLIA says:
    - Labs must not send PT samples to another lab
    - Adverse actions based on improper PT referrals
  - Lab self reports to CAP
  - Lab later fully accredited

- CMS notifies lab of impending actions (loss of CLIA license, etc.)

- Lab advocates appealed to CMS & Congress: this was an error!
CLIA Proficiency Testing Violations & CMS’ Proposed Rule

- Congress enacts “Taking Essential Steps for Testing (TEST) Act”
  - Intended to give CMS ‘more flexibility’ in sanctioning labs
  - CMS nonetheless sends notice to lab:
    - Revocation of lab’s CLIA license
    - Loss of Medicare, other reimbursement
- Settlement on 1/16/13:
  - $268,000 fine ($450,000+ in legal fees)
  - Must replace medical director
  - Must provide additional training to lab staff
  - Media release: “We are grateful to CMS for its willingness to work toward a resolution”
CLIA Proficiency Testing Violations & CMS’ Proposed Rule

Was There a Catch-22 to This?

- CLIA says:
  - “….the laboratory must test the (PT) samples in the same manner as patient specimens…”
- What if the lab’s protocols require reflexive or confirmatory testing?

- CMS, in its Proposed Rule: “…we believe it would be appropriate......to allow for imposition of alternative sanctions when there is a single instance of PT referral related to reflex or confirmatory testing....Alternative sanctions may include [CMP’s], directed plan of correction, temporary suspension of Medicare or Medicaid payments...”
CLIA Proficiency Testing Violations & CMS’ Proposed Rule

- “Repeat referrals, even if related to reflex or confirmatory testing, would be considered ‘intentional’ and may be subject to sanctions…”

- “A PT referral is a prohibited act and will always involve consequences.”

CMS’ Proposed Rule:

- #1. Add statement to § 493.801(b) to explicitly note that the requirement to treat PT samples in the same manner as patient samples does not mean that it is acceptable to refer to another lab even if that is [SOP]
CLIA Proficiency Testing Violations & CMS’ Proposed Rule

- CMS’ Proposed Rule:
  - #2. Adopt “narrow exception” in CMS’ interpretation of what an “intentional referral” is:
    - Referral to another lab was limited to reflexive or confirmatory testing
    - Referral was done per existing written SOP’s for patient specimens
    - “…then we would consider the referral to be improper and subject to alternative sanctions…but not intentional…”
  
  - 2nd referral event could be lethal to your lab!
Questions and Discussion

- We can discuss the information I or Diana provided during the presentation today or any other laboratory related questions you may have.

- If participants would like to add comment or share their experience don’t be shy, networking among participants is one of the real benefits of the HCCA conference.

- Thank you for inviting me.