Challenges in Maintaining a Laboratory Compliance Program

Christopher P. Young, CHC
Writer, G2 Compliance Advisor
cpyoung@labcomply.com - 602-277-5365

Objectives

- Learn the latest developments in clinical laboratory compliance and billing issues and what you can do about them
- Maintaining compliance in a competitive environment
- Analyze legal developments including decisions of the DAB and federal courts, for their impact on clinical laboratory compliance

Compliance Programs

- The laboratory compliance guidance has not been updated since its publication on August 24, 1998
- The most out of date section is the section that lists laboratory billing risks
- This is not a problem if the laboratory regularly updates its compliance program regarding current risks the laboratory faces
- Lab compliance guidance is still used for reference for some things so compliance professionals need to know what it includes

Compliance Programs

- Laboratory compliance officers need to understand current issues and court cases not so much because they may have to defend their labs in court
- They often need to explain compliance issues to their internal administration to support decisions and recommendations
- In those labs that employ sales and marketing people, these folks often create some of the largest compliance problems for the laboratory

Current Laboratory Risks

- Medical necessity and insufficient documentation
- Orders for laboratory tests
- Pre and post claim reviews
- CMS release of provider utilization and payment data public use files - April 2014
- Data mining to detect potential fraudulent activity
- Providing laboratory test results to patients
- Improper use of Modifier 59

Current Laboratory Risks

- Drug testing billing and coding
- Protecting Access to Medicare Act of 2014
  - Changes to the clinical lab fee schedule
- Stark and Antikickback laws
- State laws
  - State false claims laws
  - State Stark and antikickback laws
  - Medicaid fraud control

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

7

Medical Necessity

- The OIG has stated in public venues that medical necessity will be an area of focus for government auditors
- Medical necessity is a subjective matter in some cases, so it will be critical that documentation to support claims is complete and accurate
- Orders and the source of key information like diagnosis codes and others that make a claim payable are among the most important documents related to a claim

Orders and intent

- One of the focus areas for Medicare billing is test orders
- In post payment audits, auditors often find tests that are billed without a specific order for the test in the patient's chart
- The laboratory may have what they believe is a clear order in the form of a requisition, however if this is not clearly reflected in the physicians medical record it is useless unless signed
- Several entries in a CERT audit report cite unsigned requisitions as a problem
  - Even this is not foolproof but it can be helpful

Orders and intent

- CERT audit report (Jan. 2014) – Insufficient documentation, medical necessity and services coded incorrectly are cited in the report
- Example 1 documentation: *Billed TSH, Potassium and CBC with differential for date of service 5/14/2013. Missing clinical documentation supporting plan/intent and medical necessity of billed labs. Submitted documentation includes includes an unauthenticated requisition and results. After MRS call received a copy of the results with notes written on it. These notes are not signed and no other documentation submitted.*

Orders and intent

- Example 2 medical necessity: *This line billed for Comprehensive metabolic panel for DOS 06/05/2013. Missing the treating physician's clinical documentation to support the medical necessity for the billed test. Submitted includes authenticated electronic order dated 06/05/2013; and lab results dated 06/05/2013. No response from MRS call. Documentation is insufficient to support this line billed per Medicare guidelines.*
- Example 3 incorrect code: *Billed is CPT 85025-Complete CBC with automated differential WBC Count. Submitted documentation supports physician's intent to order a CBC. Documentation supports code change to 85027-complete CBC automated. Received laboratory results and physician's progress note for 05/17/2013. Service incorrectly coded.*

Adequate documentation

- Documentation must be complete and in sufficient detail to allow verification of information
  - *Received laboratory reports and E-requisition. Requested additional documentation from ordering provider and received visit note dated 04/23/2013 that has a cut off signature at the bottom of the page. Insufficient documentation to support billed services.*
  - *Missing is the Physician's order/intent to order and medical necessity. Submitted are orders dated 9/14/11 and lab results. After MRS call received Duplicate lab results and a note "VitB12& Folate nl. Called Pleasant Manor NR gave Cara order for labs 4/15/13 @ 12:00pm. This is signed by unknown person with unknown title. No current physician lab orders, no progress note noting intent and R/N. Documentation is insufficient to support service billed.*

Related tests

- Transmittal R541PI – allows contractors to deny claims related to the claims or claim lines being reviewed
  - CMS approval required but approval is generic and not specific to a claim
  - Example: denial of an inpatient surgical claim for medical necessity could result in a denial of the surgeon's Part B services
  - Denial of a lipid panel because medical necessity not supported could result in denial of the venipuncture for that panel

Related tests

- Comment section from CERT audit report:
  - *Services related to non-covered services are not covered under Medicare. Billed laboratory test(s) not medically necessary for lack of the verification of treating physician's order(s), and lack of signed progress notes for medical necessity/reason for ordering specified test(s); therefore, associated venipuncture service denied as not reasonable and necessary*

Medical review program

- Includes pre and post-payment reviews and audits
- Prepayment includes:
  - National Correct Coding Initiatives (NCCI)
  - Medically Unlikely Edits (MUEs), and
  - Medical reviews by Medicare contractors like Medicare Administrative Contractors (MACs) and Zone Program Integrity Contractors (ZPICs)
- Postpayment includes
  - Comprehensive Error Rate Testing (CERT)
  - Recovery Auditors (RACs)
  - Medical reviews by MACs and other contractors

16

Claims Review Programs

- 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 through the Fraud Prevention System (FPS)
    - Prevent improper payments to avoid the "pay and chase" system
- Develop and deploy sophisticated data gathering and analysis tools like predictive modeling and comprehensive billing reports designed to detect providers exhibiting a pattern of claims submittal that suggests it is submitting improper claims or committing fraud
- Allows contractors to avoid paying claims with a high likelihood of being incorrect or fraudulent

Fraud Prevention System

- Authorized by the Small Business Jobs Act of 2010 (SBJA)
  - Began gathering data in June 2011
  - Includes predictive modeling program
- Uses advanced analytics in real time claims processing to detect bad claims before paying
- In 2013 FPS saved the government $210.7 million with a $5 to $1 return on investment
  - Next report due in June 2015
- Detects all kinds of payment and provider errors or fraud
- Represents a comprehensive and coordinated program
  - Currently focused on MACs and ZPICs but will expand

HCFAC

- Health Care Fraud and Abuse Control program and Healthcare Fraud Prevention Partnership
- The government has joined with private insurance companies, state agencies and trade associations to prevent fraud on a national scale
- Shifts pay and chase to detect and prevent
- According to CMS in Fiscal Year (FY) 2014 the government recovered $3.3 billion as a result of these programs

Using Data to Detect and Prevent

- Share information and best practices between government agencies and private payers to detect fraud and abuse
- Uses and is continually improving complex data analysis and predictive analytics
- The FPS is used on all claims almost real time to detect patterns of aberrant or suspicious claims submissions
- The information provides leads for CMS and other investigative or audit programs to make them more effective

Corrective actions

- Informs the provider of proper billing procedures
- Imposes a prepayment review process that may include medical review (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

Transparency

- Transparent and accountable healthcare system
- Medicare Provider Utilization and Payment Data: Physician and Other Supplier (Includes labs)
- Data is from CMS's National Claims History Standard Analytic Files for 2012 – Public Use Files (PUF)
- Includes information on utilization, payment and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) and place of service
- Data is provided in a tab delimited format or in 14 different Excel spreadsheets

Provider utilization and payment data

- CMS expects that the information will be useful to beneficiaries in helping select hospitals, physicians, labs and other suppliers
- CMS also believes the data will be useful in ferreting out fraud and abuse
- Others are concerned about how the public might interpret, or misinterpret, the data
- There are also concerns about the potential for lawsuits and whistleblowers as more and more people pick through the data

Lab Specific Data

- National and State HCPCS Aggregate
- Includes approximately 600 lab HCPCS codes
- Provides volume, payment and charge information
- Physician and other supplier alphabetic spreadsheets
- Lists laboratories by name
- Download Last Name "L" for LabCorp or "Q" for Quest information to benchmark against the largest labs
- Includes separate states for national labs and volume by HCPCS code, payment and charge information

Comparative Billing Report (CBR)

- Immunohistochemistry and special stains released August 2014 through a contractor eGlobalTech and Palmetto GBA
  - Report designation is CBR201407
- Sent to 5,000 individual labs that meet certain coding criteria and were identified as having different billing patterns when compared to their peers
- Developed as an educational tool and includes an example of what the report looks like
- Any provider receiving a CBR should thoroughly review the information that accompanies the report and immediately review their claims data
- Other providers should review the example report

RAC Status

- Congressional mandates to lessen the burden on providers, increase transparency and improve oversight efforts
- Add limits to additional documentation requests
- Delay auditor contingency payments until the second level of appeal is exhausted
- Increase opportunities for providers to take advantage of discussion periods
- Changes to be implemented as new contracts are awarded

RAC Status

- RAC contracts are in process of being renewed
- Most RAC contract awards are disputed causing extended delays in getting new contracts and contractors in place
- CGI Federal lawsuit over contract changes further delayed contract awards, possibly until 2016
- Delays cause a pause in auditing activity
- During this down period providers should focus on Medicare Administrative Contractors (MACs) and other CMS auditors

Tools and Tips for Billing

- Review the CMS's transparency, data mining and data analysis efforts
- Develop an internal system that includes an information technology component to monitor and react to CMS's advances and improvements
- Use the information in the various data releases, OIG reports and other documents to benchmark and provide direction and focus for auditing program

Tools and Tips for Billing

- Other documents and reports useful to labs
- *Questionable Billing for Medicare Part B Clinical Laboratory Services* (OEI-03-11-00730, August 2014)
- *Report to Congress Fraud Prevention System Second Implementation Year,* June 2014
- Review and revise, if necessary, policies and procedures for accepting orders for tests, documentation of information received from referring physicians and responding to government inquiries
- Carefully review any materials from a government contractor or any demand for records

Protecting Access to Medicare

- Protecting Access to Medicare Act of 2014 (PAMA)
- Reforms the Medicare fee schedule for clinical laboratories so that the fees the government pays are in alignment with private sector market rates
- The schedule for implementation requires appointment of an expert outside advisory panel by July 1
- The collection of test volumes and private payer market rates begin January 1, 2016
- Significant penalties for laboratories who don't report accurate data or exclude any data

Modifier 59 – X {EPSU}

- CMS has long considered the 59 modifier a source of claims fraud and abuse
- The modifier can be used to circumvent correct coding edits including medically unlikely edits
- Beginning this year the new modifiers are available for use but the 59 modifier may still be used where it was used before
  - Do not use both 59 and and an X modifier on the same claim line
- CMS will issue more instructions at a later date for the use of specific X modifiers

X {EPSU} Modifiers

- When using X modifiers make certain the documentation will support its use for the purpose identified by the modifier description
  - XE is used for separate encounters
  - XS is used for separate structures
  - XP is used for separate practitioner
  - XU Unusual non-overlapping service
- UnitedHealthcare stated that it will recognize the X modifiers on commercial claims for laboratory services beginning February 15 in a Networking Bulletin

Providing Test Results to Patients

- Applies to labs that are "covered entities" under HIPAA
- Pre-empts state laws unless state law is "more stringent" where more stringent means greater rights to access
- No limits on how far back the lab must go if they still have the records
- Must provide the result in a form or format acceptable to both parties
- The lab is not required to take extraordinary measures to accommodate patient requests

Test Results to Patients

- Labs are responsible to take reasonable steps to verify the identity of the person and their authority to receive the results
- There are limits on how much a lab can charge for the service
- Laboratories will need to set up appropriate policy and procedure for verifying the identity of the person requesting results and their authorization to receive them as well as other aspects of the rule
- It is essential that laboratories train the employees who will handle these requests because of the potential risks of patients misinterpreting their rights under this rule

Stark and Antikickback

- Are a focus area for the government for all sectors of health care including laboratory
- Continuing updates to the regulations make the rules complex and difficult to interpret should a problem arise
  - Seek the advise of knowledgeable legal advisor if you think your laboratory has a Stark or Antikickback problem
- There have been several recent cases that specifically involve laboratories
- Also, laboratory services have been the subject of recent Advisory Opinions

Stark/Anti-kickback Concerns For Labs

- Lease and/or rental of space or equipment
- Placing employees in physician offices
- Provision of free supplies or computers, printers and interfaces
- Discounts or forgiving copays or free managed care testing
- Payments for personal services such as consulting or medical review
- Gifts and entertainment provided to physicians or referral sources
- Provision of education or CME
- Professional courtesy

State Issues

- State Medicaid programs are becoming more aggressive when it comes to claims denials and pursuing billing fraud and abuse
- Medicaid expansion has increased Medicaid enrollment by millions as a result of the Affordable Care Act
- Medicaid Integrity Auditors (MIC) are improving and the government continues to fund the program
- Many states have their own versions of Stark and antikickback laws
  - 28 state have applied for OIG review of their programs

Coming Up !

Stay tuned for Robert Mazer's exciting and insightful presentation

Compliance Issues Affecting Laboratories