

# LABORATORY COMPLIANCE PROGRAMS: A REVIEW AND UPDATE

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# Objectives

- Understand today's the critical elements of a laboratory compliance program
- Determine if your laboratory has all of the current risk areas covered
- Decide if your laboratory compliance program needs to be reviewed and updated
- Discover if you are properly focusing your laboratory compliance resources
- Tips on how to select an outside reviewer for your laboratory program

# Compliance Program Elements

- What are the necessary (required) elements for any laboratory compliance program?
- What elements are most important for a program to be effective?
- What has changed for these elements since the 1998 OIG guidance?
- Has the Laboratory changed its policy to accommodate these changes?

# OIG Compliance Guidance

- Form the basis of a compliance program for different sectors of healthcare
- List specific areas of risk
- All contain the seven basic elements
  - All elements must be present if program is effective
- They reflect the government's perspective and expectation for a compliance program
- They are rooted in the U. S. Sentencing Commission's (USSC) guidelines for sentencing organizations

# OIG Compliance Guidance

- The specific guidance documents for laboratory compliance officers to be familiar with include:
  - Clinical laboratories (Aug, 1998)
  - Hospitals (Feb 1998)
  - Supplemental Compliance Guidance for Hospitals (January 2005)
  - Third Party Billing companies (Dec 1998)
  - Hospices (Oct 1999)

# Seven Elements

## OIG

- Establish standards and procedures
- Designate compliance officer and committee
- Effective training and education
- Effective communication (Hotline) and protect anonymity
- Respond to offenses and discipline offenders
- Audit and monitor
- Investigate and correct and non-employment of sanctioned individuals

## USSC

- Establish standards and procedures
- Assign high level personnel to oversee
- No delegation to person with propensity to engage in illegal activities
- Effectively communicate standards (training)
- Monitor and audit and have a reporting system
- Enforce standards through discipline
- Respond appropriately to offense and take steps to prevent further offenses

# Key Elements for Effectiveness

- Standards of conduct, policies & procedures for risk areas
  - Ensure employees know what to do
  - Ensure laboratory has recourse in the event a violation occurs
  - Basis for education and training and auditing and monitoring
- A strong, well trained compliance officer
  - Must be high level
  - Must have autonomy
  - Must have adequate resources

# Key Elements for Effectiveness

- Education and training of employees
  - Government believes this is key element
  - Untrained employees cannot detect and report problems
  - Must be provided to new employees and thereafter at least annually
  - Should be updated each year for changes in regulations and policies



# Key Elements for Effectiveness

- System of audits and monitors
  - Ensures policies are followed and problems are detected early
  - Government believes that an honest provider has no fear of examining themselves
- Evidence of corrective actions
  - Problems found, refunds and disciplinary action
- Reports to upper management and the Board of Directors

# Standards And Policies For Laboratory Risks Areas

- There should be a Code of Conduct and Ethics that:
  - Articulates a formal commitment to compliance by the governing body
  - Details the fundamental principles, values and framework for action for the organization
  - Brief, easily readable, available to all employees and be understandable by all employees
  - If the lab is part of a hospital or health system, Code may be from the larger entity

# Code of Conduct and Ethics

- All employees should be trained in the Code of Conduct and Ethics for your laboratory at the time of hire and retrained if and when there are changes
  - Must be understandable by all employees
- All employees should be required to sign a statement certifying that they have read and understood the Code
  - Should be maintained by the laboratory, usually as part of the personnel file

# Policy vs. Procedure

- A policy states the actions or set of principles adopted by the laboratory for a specific risk area
  - Usually brief and generalized
- A procedure establishes the correct method of meeting the requirements of the policy's stated actions or principles
  - Usually detailed, providing step by step instructions
  - Should be department or job specific

# Policies & Procedures

- Establish rules that help employees carry out their job in a manner that ensures compliance with laws and company standards
- Should be clearly written and relevant to day to day responsibilities
- Readily available to whomever needs them
- Re-evaluated on a regular basis
- Based on defined risk areas for the laboratory

# Laboratory Risk Areas

- What are the risks that a laboratory faces?
- How has the list changed since the OIG wrote the guidance for labs in 1998?
- What should labs be concerned about today?
- What should labs be concerned about in the coming year(s)?

# Laboratory Risk Areas

- The government identifies lab activities considered risk areas through:
  - Compliance Guidance documents
  - Fraud Alerts
  - Publications of new regulations
  - Advisory Opinions
  - Special Advisory Bulletins
  - Opinion letters
  - OIG annual Workplan
- Compliance programs need to focus on these identified risk areas

# Laboratory Risk Areas

- The laboratory should have policies and/or procedures for each identified risk area
- Include identified risk area policies in the education and training program
- Link them to the appropriate areas of the laboratory that can affect them
  - A specific risk may affect different departments of the laboratory differently
- Ensure the monitoring and audit plan includes all identified risk areas



# Laboratory Risk Areas from 1998 OIG Guidance

- If your laboratory compliance plan was written based on the 1998 guidance and has not been reviewed and updated, it may be out of date as far as risk areas are concerned
- Some of the underlying issues that existed at the time the guidance was written have been corrected through changes in regulation, CPT coding, Medicare computer billing edits, Fraud Alerts and Advisory Opinions

# Current Laboratory Risk Areas

- Billing and claim submission
- Financial relationships with referrals sources and other providers
- Kickbacks and incentives designed to induce referrals, including pricing and discounting
- Special clients like SNFs and Home Health
- Sales and marketing activities
- Compliance program specific requirements

# Billing and Claims Submission

- Review of claims is a primary government tool to find fraud and abuse
- Computer systems are used by payers to identify potential problems and/or providers
- Many seemingly unrelated activities affect laboratory billing and claims submission
- More laboratories use computers, the Internet and employees placed in client sites to enhance the test request process and other components of the billing process

# Billing - Old View

- The billing risks were viewed separately
  - Medical necessity of services
  - CPT Coding of services
  - ICD-9 coding/translating narratives
  - Coverage policies
  - ABN
  - Only bill for tests ordered and performed
  - Test ordered by authorized person
  - Standing orders
  - Ambiguous orders

# Billing - Old View

- Verbal orders and add-on orders
- Billing for calculations
- Billing for panels and profiles
- Custom panels
- Reflex testing
- Billing for referred tests

# Billing - Current View

- Medical necessity is the primary concern for LCOs in 2006 and forward
  - Labs should take a holistic view of medical necessity
  - Includes everything on the previous slides
- Main areas of concern going forward:
  - There must be a documented order for each test billed
  - Any ICD-9 codes or narrative diagnosis information must come from the treating physician

# Billing and Medical Necessity

- Billing:
  - Highest risk activity a laboratory has
  - Review of claims is one of the government best monitoring tools
- Medical necessity:
  - Medical necessity is an underlying principle of the Medicare program
  - Law permits Medicare to pay only for tests that are reasonable and necessary for the diagnosis and treatment of disease

# CPT Coding

- The amount of payment for a test is dependent on the CPT or HCPCS code
- The OIG's compliance guidance for clinical laboratories says that a technical person should make coding decisions
- Coding decisions should be made on the basis of methods, not reimbursement
- It is against the law to knowingly use the wrong CPT or HCPCS code for a test for the purpose of causing or increasing payment for a test



# CPT Coding

- Policies and procedures for CPT coding and review of existing codes or charge masters
  - How new codes are selected which includes a requirement for technical review
  - How coding reviews are done when methods are changed
  - How are coding issues addressed with reference laboratories
  - Frequency and procedures for code and charge master reviews
  - Auditing and monitoring for CPT codes used for billing

# CPT Coding Changes

- The 3 month grace period has been eliminated, codes must be ready for January 1 of the new year
- Date of service determines which code is used
- Laboratory billing systems now carry the burden of being able to bill with different codes for tests based on date of service

# CPT Coding Changes

- Electronic ordering systems and the Internet allow the laboratory to provide much more information and code lists to its clients
  - Must keep these lists current
  - Provide disclaimers so that if a list isn't current they have a recourse if a client gets in trouble for using a wrong code they got from the laboratory

# ICD-9 Coding

- ICD-9CM (International Classification of Disease, 9th Edition, Clinical Modification) codes are used to classify diseases and conditions, and describe signs, symptoms and medical circumstances.
  - ICD-9CM codes are used to indicate the medical necessity of a particular test.
  - It is against the law to knowingly use the wrong ICD-9CM code for the purpose of causing or increasing payment for a test.

# ICD-9 Coding

- Laboratories may contact an ordering practitioner to seek additional diagnosis information or ICD-9 codes
  - Must restrict the request to the specific information needed for privacy and confidentiality reasons
  - Must use care in making the request to avoid charges of “code steering”
- Laboratories may translate narrative coding information it receives
  - The narrative does not have to exactly match the description of the submitted ICD-9-CM.

# ICD-9 Coding

- The laboratory may NOT change an ICD-9 code it receives from an ordering practitioner even if the code is not a valid code, without first contacting the practitioner who submitted the code
  - Cannot add fourth and fifth digits
- Persons involved in translating narrative diagnosis information should have specific training and guidelines
  - Must be provided with the necessary resources and tools to do their job (e.g. current ICD-9 manual)

# ICD-9 Coding

- Policies and procedures for ICD-9 coding include:
  - Specific guidance for obtaining ICD-9 codes and how the associated documentation is maintained
  - If your laboratory accepts narrative diagnosis information, specific guidance on translating that information into codes and the necessary training and qualifications for the persons involved in that activity
  - Auditing and monitoring the ICD-9 processes described above

# ICD-9 Coding Changes

- All lab claims must have a “valid” ICD-9 code, not just tests with coverage policies
- No grace period, new codes must be in system by October 1 of each year
- Introduction of electronic ordering systems and placing employees in physician offices add new levels of complexity to the issue of obtaining and documenting the source of ICD-9 codes and code steering issues



# LMRPs and LCDs

- Medicare Carriers and Fiscal Intermediaries (FIs) published LMRPs (Local Medical Review Policies) for some laboratory tests
- Most LMRPs have been replaced with LCDs (Local Coverage Determinations)

# LCD Tests

- If a physician orders an LCD test, an ICD-9CM code that is included in the LCD must be given to the laboratory or the Medicare program will not pay for the test
- The Balanced Budget Act of 1997 made it illegal for physicians to order LCD tests and not supply diagnosis information

# National Coverage Determinations

- NCDs are national determinations and apply to all Medicare contactors and laboratories
- Laboratories should recognize the billing implications of the various aspects of these policies and account for them in policies and procedures and in audits and monitors of their billing and coding practices
- The Balanced Budget Act of 1997 made it illegal for physicians to order NCD tests and not supply diagnosis information

# NCDs and LCDs

- Electronic ordering systems allow the laboratory to do more effective up front detecting of invalid or unallowable codes with orders
- Adds risk that client will misuse or abuse the system or use it as a tool for selecting ICD-9 codes

# Advance Beneficiary Notices (ABNs)

- A laboratory cannot bill a Medicare beneficiary for a laboratory test unless it notifies the patient in writing, before the test is performed, that Medicare may not pay for the test
- This written notice is called an ABN.
- ABN provisions do not apply to statutorily excluded tests
- The laboratory must use one of the official government forms for ABNs
  - ABN-L or ABN-G

# Advance Beneficiary Notices (ABNs)

- The beneficiary can choose not have the test performed if they do not want to pay for it
- Laboratories cannot make all Medicare beneficiaries sign ABNs
- The ABN must contain the specific name of the test
- The ABN must give a specific reason the laboratory thinks payment for the test will be denied.
- The beneficiary should sign the ABN and be given a copy

# Advance Beneficiary Notices (ABNs)

- The laboratory should have specific policies and procedures for its employees who are directly involved in obtaining or reviewing ABNs
  - Phlebotomists and other patient service center employees
  - Billing

# ABNs, NCDs and LCDs

- Electronic ordering systems currently in use by laboratories can produce ABNs when they detect an incomplete order
  - CPT, NCD, LCD and ICD-9 code data bases must be current or ABNs may be collected when not necessary
  - The systems can provide ICD-9 code lists making the lab vulnerable to risks like code steering



# Requisitions

- Requisitions must be designed to ensure that ordering physicians can choose tests that are medically necessary for their patients
- Requisitions should contain reminders about Medicare rules of medical necessity and list the contents of panels and profiles
- Requisitions should provide a place for the physician to include diagnosis (ICD-9) codes

# Current Requisition Issues

- Introduction of electronic ordering systems and placing employees in physician offices add new levels of complexity for requisitions
  - When a requisition is received from a computer system that was entered by a laboratory employee there must be documentation of the original order
  - When the same requisition is received entered by the physician's employee it is the original order
  - The electronic system must provide the same kinds of warnings or information as a paper version

# Ambiguous Orders

- The laboratory cannot perform and bill for tests that are not specifically ordered
- When the orders for a test are not absolutely clear, the laboratory must contact the ordering physician to clarify the orders before performing and billing for the test.
- The laboratory cannot change a physician order without contacting the physician
- Electronic ordering systems tend to reduce this risk

# Tests Ordered and Performed

- The laboratory has a system in place to detect tests that are not performed due to a laboratory error and stop or credit the billing for these tests
  - The laboratory cannot bill for tests that are not performed
  - The laboratory cannot bill for tests that were performed in error if the error is the lab's

# Written and Verbal Orders

- All tests must have a written order on file
- Any verbal orders for tests including tests added on to a specimen already in the lab must be followed up by a request for a written order
- Proper documentation must be maintained for follow up written orders
  - If the original order was electronic, the new order must be filed in such a way the it can be located with the original

# Billing for Duplicate Services or QA testing

- It is against Medicare regulations to bill for calculated test results
  - Only tests actually performed may be billed
- It is against the law to bill for the same tests or services twice unless medically necessary
  - Use -91 modifier for this case
- It is against the law to bill for quality control or quality assurance tests or tests performed multiple times to check or verify the results

# Panels and Profiles

- It is not against the law for a laboratory to allow the use of panels, profiles and custom panels
- The laboratory must ensure that the ordering doctor knows what tests are included in a panel or profile and what CPT codes will be billed to the Medicare program
- The laboratory notifies doctors about panels and profiles through an annual written notice and the requisition

# Current View

- Improperly documented and updated custom profiles are still an area of concern for labs
  - Cause over-utilization of services
- Keep custom panels and profiles to a minimum
- Carefully monitor their use to insure only those who have signed agreements use them
- If using electronic orders, ensure that custom panels for one physician do not end up on the computer system of another physician



# Reflex Tests

- Reflex testing is the automatic order of additional tests based on the results of an initial test
- Reflex testing is permitted as long as the laboratory informs the ordering doctor when a reflex will occur
  - Properly disclosed to any user
- The laboratory must allow the doctor to order the test without the reflex if they want

# Current View

- Reflex testing is still an area of risk
- All reflex tests must be specifically ordered
  - Should not be a default
- If using an electronic ordering system, system should flag the reflex test and warn of improper use
  - Should include directions on how to order non-reflex alternative

# Physician Acknowledgements

- Any physician who wants to create a **custom** panel, profile or reflex test should sign a physician acknowledgement
  - Only a physician who has signed the acknowledgement can use the panel
  - Remind the physician to use the panel only if all the tests are medically necessary
  - Renew physician acknowledgements annually
  - Include the billing consequences of the panel

# Standing Orders

- Standing orders are repeating orders for the same test for a set period of time
  - Must be in writing
  - Must have a start and end date
  - Must be renewed periodically and not less than annually
  - The ICD-9 code given with the original order covers the entire course of the standing order
- Issues don't change with an electronic ordering system except as described with requisitions

# Physician Notices

- The laboratory should send a notice to its customers once each year
  - These notices remind physicians about Medicare rules and regulations
  - These notices include summaries of laboratory test ordering policies, requisition use, CPT coding and ICD coding
- The laboratory should also advise its customers whenever there is a change in its policies regardless of the reason

# Current View

- There is no legal obligation to provide the notices
- Can be included in the laboratory's user guide or on its Internet site
- Laboratory should still advise clients of changes in its billing policies or changes in regulations that affect the lab's relationships with its clients

# Date of Service

- As of April 1, 2006, the Date of Service for a laboratory test is the date the sample was collected
  - If a specimen is collected over a span of more than 2 calendar days, use the date the collection ended
  - If a specimen is stored longer than 30 days, use the date it is retrieved from storage

# NCCI Edits

- Not mentioned in the OIG's original guidance
- Use of these edits is expanding
- Lab can override some edits through the use of the -59 modifier
- Should only use the modifier if it is justifiable
  - Difficult for labs to know if the physician orders do not indicate
  - Labs should not build the use of this modifier into its system as an automated process



# Documentation

- Electronic systems and requisition scanning are more common than previously
- Labs must insure that electronic records are complete and can be recovered before discarding hard copies
  - Quality control checks on scanned documents
  - Periodic audits to ensure files are intact
  - Periodic checks to make sure that old documents can be restored
  - Account for old records when changing computer systems

# Stark and Anti-kickback

- A laboratories financial relationships with clients is more of a risk today then when the original guidance was published
  - Stark rules have been finalized
  - Advisory opinions and fraud alerts
  - Government has started prosecuting cases
  - The Wall Street Journal story

# Relations With Referral Source

- Mandatory exclusion from Medicare if convicted for many of these
- Laws and regulations are very complex and not well understood by many LCOs and some attorneys
- Have many laboratory specific implications
  - First Stark law was specific to laboratories

# Basic Concept-Antikickback

- Provides criminal penalties for individuals or entities that **knowingly and willfully** offer, pay, solicit or receive remuneration in order to induce business reimbursed under Medicare and Medicaid
- Prohibited conduct includes inducing patient referrals or inducing the purchasing, leasing, ordering or arranging for any good, service or item paid under Medicare or Medicaid

# Basic Concept-Antikickback

- Remuneration as defined at 42CFR1003.101:
  - “... includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or other than fair market value.”

# Basic Concept-Antikickback

- Types of remuneration include kickbacks, bribes, direct or indirect rebates, and, overt or covert payments in cash or in kind
- Payment practices that will not trigger prosecution or exclusion under the statute are contained in regulations and are known as “safe harbors”

# Basic Concepts-Stark

- Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies

# Basic Concepts-Stark

- Prohibits the entity from filing claims with Medicare for those referred services unless an exception applies



# Basic Concepts-Stark

- Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind except the following are not considered remuneration:
  - Forgiveness of amounts owed for inaccurate or mistakenly performed tests or procedures or correction of minor billing errors

# Basic Concepts-Stark

- (Remuneration exceptions continued)
  - Furnishing items or supplies (not including surgical items, devices or supplies) used solely to collect, transport, process or store specimens for the entity furnishing them OR used solely to order or communicate the results of tests or procedures for the entity

# Basic Concepts-Stark

- (Remuneration exceptions continued)
  - Payments made by an insurer or self insured plan to a physician to satisfy a claim submitted on a fee for service basis, for furnishing health services to a covered individual
    - Not part of a contractual arrangement
    - Payment is on behalf of the individual
    - Payment is set in advance, at fair market value, does not consider value or volume of referrals

# Why Focus on Stark First?

- Stark is a civil statute so intent to violate it has no bearing
- Unintentional or technical violations can invoke the statute and a prosecution
- Stark requires compliance with antikickback and other federal and state laws

# Stark Analysis

- Three part inquiry
  - Is there a referral from a physician of a DHS?
  - Does the physician have a financial relationship with the DHS?
  - Does the financial relationship fit in an exception?
- If the answers are yes, yes and no, the statute has been violated

# Anti-kickback Analysis

- Is there any kind of remunerative relationship between the laboratory and the person or entity in a position to generate federal health care program business for the laboratory?
- If so, **could** one purpose of the remuneration be to induce or reward the referral of federal health care business

# Anti-kickback Analysis

- For AK purpose, neither a legitimate business purpose nor a FMV payment will legitimize a payment if there is an illegal purpose (i.e. inducing Federal health care business)
- Any remunerative relationship that may involve intent requires close scrutiny

# AK Aggravating Factors

- Does the remuneration have the potential to interfere with clinical decision making?
- Does it have the potential to increase costs to Federal programs or beneficiaries?
- Does it have the potential to cause overutilization or inappropriate utilization?
- Does it raise patient safety or quality of care concerns?



# Anti-kickback Analysis

- Does the remuneration arrangement fit “squarely” in an AK safe harbor?
  - Compliance with safe harbor is voluntary
  - Failure to comply does not mean the arrangement is illegal per se
  - Arrangements that do not fit in a safe harbor must be evaluated on a case by case basis

# Areas of Concern for Labs

- Lease and/or rental of space
- Lease and/or rental of equipment
- Placing employees in physician offices
- Provision of supplies
- Discounts

# Areas of Concern for Labs

- Payments for personal services
- Gifts and entertainment provided to physicians or referral sources
- Provision of education or CME
- Professional courtesy

# Lease or Rental of Space

- Written agreement, signed by parties, specifying the premises covered
- Term not less than one year
  - Stark-if termed earlier cannot enter a new agreement for the original term
- The rent is set in advance, is at FMV and does not take into account value or volume of referrals

# Lease or Rental of Space

- AK-if part time use-schedule must be specified
- Stark-space is reasonable for the intended purpose and is used exclusively by the lessor when being used by the lessor
  - May pay for common areas on a pro rata share of expenses

# Lease or Rental of Space

- Stark-the agreement would be commercially reasonable even if there are no referrals
- Stark-allows holdover month to month for up to six months as long as terms are the same

# Lease or Rental of Equipment

- In all cases the criteria are the same as space lease or rental except substitute equipment for space
- The Stark differences are also the same
- The primary Stark criteria that is significant
  - The space or equipment does not exceed what is reasonable for the purpose intended
  - The agreement is commercially reasonable in the absence of referrals

# Provision of Supplies

- The provision of free services and supplies for specimen collection, processing, transporting and storing is allowed
- Stark specifically prohibits provision of sterile or other gloves and other “fungible, general purpose supplies”
- Stark says the laboratory or physician should be ready to demonstrate that the supplies were furnished based on a community standard and describe the standard



# Discounts

- AK-the term “discount” does not include “A reduction in price applicable to one payor but not to Medicare or Medicaid”
- Stark-discount arrangements for laboratories are not directly discussed
  - Defers to either the FMV compensation exception or other laws and regulations

# Discounts-Stark and FMV

- Arrangement is in writing, signed, specifies covered services
- Specifies the timeframe and allows termination but only one similar arrangement per year
- Specifies compensation, set in advance, at FMV and doesn't reflect value or volume of referrals
- Would be commercially reasonable and further legitimate business purpose
- Does not violate AK or state laws

# Personal Services

- Set in writing, signed, specifies the services
  - AK-if part time specifies schedule
- Covers all of the services to be furnished
  - Stark-includes separate arrangements must be listed or incorporated by reference
- Stark-aggregate services do not exceed what is reasonable and necessary for legitimate business purposes

# Personal Services

- AK-one year term
- Stark-one year term and if terminated early cannot enter into the same or substantially the same agreement
- Compensation is set in advance, at FMV and does not reflect value or volume of referrals
- Does not violate any other Federal or state law

# Placing Free Phlebotomist

- AK-1994 Fraud Alert allows as long as the phlebotomist only performs lab related tasks and duties
- Stark-defers to the Fraud Alert saying that as long as the phlebotomist sticks to lab related tasks there is no benefit to the physician
- If the laboratory pays rent for the space the phlebotomist uses, the rental of space exception must be met

# Gifts and Entertainment

- AK-any free good or service may constitute remuneration if it is provided conditional on referral of health care services paid under Medicare or Medicaid
- Stark-considered remuneration but may be made to fit in the non-monetary compensation exception

# Non-Monetary Compensation

- Cannot exceed \$300.00 per individual physician per year AND
  - Does not take into account value or volume of referrals
  - Cannot be solicited by the physician
  - Does not violate AK of any Federal or state law
- Government expects DHS to monitor its non-monetary compensation
- Once \$300.00 is reach, cannot take referrals OR cannot file claims if any are made

# Professional Courtesy

- Stark has an exception for professional courtesy but the criteria requires that the arrangement does not violate AK
- The 1994 Fraud Alert prohibits free services for physicians, their family and their employees
- This exception is likely not applicable to laboratories



# Provision of Education

- AK-does not address this except generally as providing something of value to the referral source
  - If the education concerns non laboratory services or provides free CME, may be suspect
- Stark-has an exception for “compliance training”

# Compliance Training

- Means training regarding basic elements of compliance plans, requirements of Federal and state health care programs or Federal and state laws governing the conduct of the party being trained
- Does not include CME training

# Compliance Training

- Provided by an entity to a physician or office staff who practices in the entities local community of service area
- Must be held in the local community or service area
- Does not specifically address if a meal is served during the training if it can be excepted from the \$300.00 non-monetary compensation

# Special Clients or Services

- If you do business with clients that have special rules related to how billing should be done, these create a potential risk because
  - They are an exception for the laboratory's billing system and employees
  - They are usually low volume clients
  - They may be a focus area for government scrutiny

# Special Clients or Services

- Skilled Nursing Facilities (SNFs)
- Dialysis patients
- Home health companies
- Hospital laboratories
- Pathology services
- Miscellaneous lab specific compliance issues

# SNFs

- If the laboratory does business with nursing homes or SNFs it must insure it is properly billing for the services it provides
- Consolidated billing
  - For SNFs, the laboratory must insure it bills the SNF for any Part A services it provides
- Any discounts or special prices for the Part A services cannot be linked to the referral of Part B services in a case where the lab is billing directly for the Part B service

# SNFs

- If it provides services such as phlebotomy, it must account for the cost of such services in its pricing and/or discounting
- It must also insure its phlebotomists perform services for the laboratory only
- The laboratory should have a written agreement with its nursing home and SNF customers

# Dialysis (ESRD) Patients

- Special and complex billing rules that are constantly evolving
  - 50/50 rules for automated multi-channel chemistry (AMCC) tests and the use of the appropriate modifiers
  - Composite testing
- Focus for government because of the cost of providing services



# Home Health Companies

- High turnover of Home Health employees
- Special rules associated with insuring a patient is qualified for home health services according to Medicare
  - If patient not qualified, services like phlebotomy and travel fees may not be considered medically necessary

# Hospital Laboratories

- Who can bill for inpatient, outpatient and non-patient referred tests
  - The hospital must bill for inpatients and outpatients
  - Rules are still not clear for nonpatients
- 72 hour rule for outpatient test performed in hospital owned laboratories
- Rural and Critical Access Hospitals have special rules and allowances for billing, reimbursement and relationships with referrals sources

# Pathology Services

- Billed on the physician fee schedule
- Different rules than tests billed on the clinical laboratory fee schedule
  - Professional component, technical component and global billing
  - Co-pays for many services
- Different rules for referred services and consultations
- Reimbursement issues for molecular diagnostics and other new technology

# Pathology Services

- Pathologists may be contracted separate entities with different goals than the hospital or laboratory
  - Sometimes difficult to work with
- May have outside interests or business that creates risk for the hospital or laboratory

# Miscellaneous Risks

- There are other risks for laboratories that are not easily categorized that LCOs need to be cognizant of and monitor
- Indigent care and free or discounted services to patients without insurance
  - Should not do this at the request of an ordering physician without checking to insure patient needs the help
  - Monitor the frequency this occurs with clients

# Release of Test Results

- Policies should be established concerning the release of test results by phone, fax and other non-routine methods
- Employees should release test results only to the person who ordered the test
  - Never release test results to another physician or entity unless authorized by the ordering physician
  - Never release the results of a test to a patient unless authorized in writing by the ordering physician
- Some states have specific regulations

# Couriers

- The laboratory's couriers may not transport items except those related to the testing services offered by the laboratory
- Couriers cannot transport items for customers
- Couriers must follow all OSHA standards for the handling and transport of specimens

# Referral Tests

- The laboratory is responsible for all tests it refers to other laboratories
- A laboratory may bill for tests it refers if it meets the exceptions in the “70/30 rule”
- Hospitals must bill for their inpatients and outpatients
  - Rules regarding who must bill for nonpatient are unclear
- Laboratory should not change CPT codes supplied by a reference laboratory without contacting the reference laboratory



# Monitoring Utilization

- Laboratories must not induce physicians to order unnecessary tests through their marketing, education or any other activity
  - They must monitor the use of laboratory services by their clients
  - They must correct any situation where something they did caused an unnecessary increase in test utilization
  - Minimum requirement is to annually review top 30 CPT codes for unexplained increase in volume

# Current view

- This is not a law or regulation
- Laboratories have a responsibility to not cause unnecessary test to be ordered by something it does
  - Monitoring orders when requisitions are changed
  - Monitoring orders after a new test announcement is made

# Confidentiality

- All employees have a responsibility to maintain the confidentiality of medical information
- Medical information should never be discussed outside of the laboratory
- It should only be discussed with the ordering doctor or an authorized representative of the doctor
- Employees should verify the identity of the individual requesting such information

# Confidentiality

- Employees who communicate with patients, physicians or their office staff, insurance company representatives or government employees about any laboratory activity should only give information they know to be true and accurate
  - Employees should never give false information and should never guess the answer to any question
- In case of doubt, refer the person to a supervisor or the compliance officer

# Privacy and Security

- HIPAA regulations designed to protect the privacy and security of health information impose additional standards in this area
- Many states have state specific requirements for how confidential and private information is handled; compliance officers must understand and adhere to any laws or regulations specific to the state they are in or in any state where they do business

# CLIA and OSHA

- Laboratories must follow all CLIA regulations.
  - Failure to do so may result in a False Claims Act violation
  - Complying with CLIA is a component of the laboratory's participation agreement with Medicare.
- Laboratories must comply with all OSHA regulations

# Sales and Marketing Activity

- Sales and marketing employees must be properly trained
  - The sales and marketing representatives often are the point of contact for special requests and make offers on behalf of the laboratory
- Clear and non deceptive marketing of laboratory services includes ensuring that clients know the billing and testing consequences of services they order from the laboratory

# Sales and Marketing Activity

- Sales and marketing materials must be clear and non-deceptive
  - Properly represent the testing and services that are provided
- Sales proposals and presentations
  - Must be according to company policy with all approvals before offers are made
- Client education and specific instructions
  - Make certain clients know how to use services



# Sales and Marketing Activity

- Custom profiles
  - Making sure acknowledgements get signed and client understands risks
- Reflex testing
  - Make sure client understands risks, how to use the tests and how to order non reflex alternatives
- Special offerings
  - Ensuring that a client understands all aspects of any special offering like phlebotomists in their offices, computer placement, etc.

# Sales and Marketing Activity

- Primary department that provides gifts and entertainment to physician clients
  - Must follow all policies and procedures
  - Make certain all gifts and entertainment expenditures are recorded in a timely fashion
  - Make certain they are not “excessive”
  - Make certain they are not conditional on the referral of business

# Laboratory Compliance Officer (LCO)

- Compliance programs and the compliance profession are mature and expectations for compliance officers are greater
- Even the most experienced compliance professional needs help and resources
- Continuing education and self evaluation are essential components to staying effective as a compliance officer

# Level Of Authority

- The laboratory compliance officer position must have a high enough level of authority to be on equal ground with other management level laboratory administrative employees
- The LCO should be able to affect business decisions
- The LCO should understand and act as if she\he has autonomy
  - Freedom from external control or influence; independence

# Level Of Authority

- In the hospital or health system setting, the LCO should have direct access to the corporate compliance officer or corporate management
- In the independent laboratory setting, the LCO should have direct access to upper management, board members and/or owners
- This access should be reflected in the organizational chart
- The LCO should have access to a legal advisor

# Job Description

- Plan, implement and maintain an effective compliance program
- Ensure highest level of oversight knows about compliance program progress and any problems encountered
- Ensure program has proper resources committed
- Oversee the development of standards, policies and procedures for the risk areas for the laboratory

# Job Description

- Oversee the training and education program
- Install a monitoring and auditing plan
- Ensure any detected or reported violations of laws, regulations or policies are thoroughly and promptly investigated and corrective action is taken to prevent future problems
- Ensure that in any case where a refund or report is due, it is done in a timely fashion

# Laboratory Compliance Professionals Need To Know

- The OIG's Compliance Guidance for Clinical Laboratories, August 1998
  - Compliance guidance for other health care entities
- The Physician Self Referral Laws (Stark) and the associated regulations
- The Antikickback laws and regulations
- All Fraud Alerts related to laboratories
  - The 1994 fraud alert



# Laboratory Compliance Professionals Need To Know

- The Social Security Act
- False Claims Act and Qui Tam provisions contained therein
- Civil Monetary Penalties Laws (CMP) and regulations
- Laws that govern the actions of individuals and organizations in criminal investigations
  - Subpoenas and warrants
  - Obstruction of justice and witness tampering

# Laboratory Compliance Professionals Need To Know

- The basics of HIPAA as it relates to the privacy and security of medical information the laboratory has including:
  - Privacy regulations
  - Security of electronic data regulations

# Laboratory Compliance Professionals Need To Know

- The basics of legal protections of Attorney Client Privilege and Attorney Work Product Privilege
- The implications of Voluntary Disclosure
  - The risks and benefits of disclosure
  - When and how to disclose various kinds of discoveries
- The legal and ethical bounds by which attorneys operate
  - Understand what an attorney can and can't do under their codes of ethics

# Laboratory Compliance Professionals Need To Know

- CMS On-Line Manuals, Program Transmittals and Change Requests system
- CMS forms and instructions for those forms related to the submission of laboratory claims
  - Electronic standard transaction for X12N 837, current version
  - CMS 1500 & 1450 claims forms

# Laboratory Compliance Professionals Need To Know

- Be able to read and understand a Medicare Remittance Advice (RA)
- The basics of CPT coding including CMS's HCPCS system
  - Understand Charge Master reviews
- The basics of ICD-9 coding
- The basics of auditing and monitoring systems and processes
- CLIA and OSHA laws and regulations

# Laboratory Compliance Professionals Need To Do

- Subscribe to newsletters that specifically deal with general AND laboratory compliance
- Obtain books or manuals that contain general AND laboratory compliance information
- Attend seminars and programs about general AND laboratory compliance information
- Join professional associations that specifically focus on compliance
- Think of yourself as a compliance professional

# Other Documents

- Advisory Opinions for Laboratories
  - 05-08 lab providing free blood collection supplies and pays physician to draw blood
  - 04-16 lab providing employees and equipment and supplies for free to ESRD facilities to process specimens
  - 04-05 lab providing volunteer services for a charitable foundation for low income, uninsured patients

# Other Documents

- Advisory Opinions
  - 99-13 discounted lab and pathology services
- Fraud Alerts
  - 2/23/00 Rental of space from physicians
  - 12/19/94 5 Special Fraud Alerts includes the laboratory fraud alert mentioned earlier



# Other Documents

- Other Guidance
  - 4/26/00 Discount arrangements involving clinical labs
  - 9/22/99 Discount arrangements between clinical labs and SNFs
  - 10/2/97 Free services by labs
  - 8/4/97 Free prostate biopsy needles
  - 7/10/97 and 7/3/97 Provision of free goods and service, computers and fax machines

# Other Documents

- Compliance Guidance
  - 1/27/05 Supplemental Compliance Program Guidance for Hospitals
  - Has an excellent two sections devoted to Stark and Anti-kickback
  - While focused on hospitals, this information can be easily translated to clinical labs in many cases

# Evaluate Your Effectiveness

- Are compliance committee meetings attended by most or all of the members, most or all of the time?
- Do compliance committee members take their assignments seriously?
- Are your decisions often challenged by others on the management team?
- Are you included in most or all important issues that arise?
- Do you meet regularly with your Corporate Compliance Office, CEO or Board member?<sup>131</sup>

# Evaluate Your Effectiveness

- Do other management personnel insure their employees get to their compliance training?
- How many education programs focused on laboratory compliance have you attended this year?
- How long does it take you to respond to compliance questions?
- Has your compliance program been reviewed by an outside auditor within the last two years?

# Training and Education

- Effective compliance training and education is a requisite for an effective compliance program
- If compliance training is included with other training, it must be distinctly identified and recognized by employees
- The company must commit sufficient resources to ensure an effective training program

# Training and Education

- Use qualified trainers who know the subject
  - This means someone who is familiar with laboratory specific issue and problems
- Annually re-evaluate the training program to ensure it is current and relevant for laboratory issues
- Make sure that laboratory specific risk areas are covered in the training program
  - Particularly if the lab is in a hospital or health system and uses their program for training

# Training & Education Programs

- A training and education program should include a basic training package that all employees receive at hire
  - If basic training is provided at the hospital or health system level make sure there is one at the laboratory level
- Special training for “high risk” employees or departments (e.g. billing, marketing, managers)
  - Again, make certain it is lab specific

# Training & Education Programs

- A training & education program may use different methods to accomplish its goals but the information should be consistent
  - Videos, purchased or internally produced
  - Computer based, Internet, Intranet or CD ROM
  - Paper based
- All methods should be monitored for effectiveness



# Tips For Training

- If using generic purchased electronic or video based training systems, supplement them with a component that is specific to your laboratory
- Any training that is not face to face should include an opportunity to ask questions AND a testing tool to assess effectiveness of the training
  - Inform the employee that the test will be administered and they will have to score a certain amount to pass

# Assessing Effectiveness

- Administer tests at the close of training and analyze testing results
- Exit surveys for trained employees
- Follow up testing of a random selection of employees from a testing event
- Track the number of times that the root cause of a compliance problem was because of a lack of effective training

# System of Audits and Monitors

- All laboratories should have an annual audit plan designed around covering all of the risk areas that a laboratory faces
- Includes both monitors and audits
- Everything in the audit and monitoring plan flows from the risks the laboratory faces and the associated policies and procedures

# System of Audits and Monitors

- Many think of auditing and monitoring as auditing and monitoring the billing and coding system only
- The lab faces other risks that need to be addressed
- It is also necessary to audit and assess the status and effectiveness of the compliance program itself

# Monitors

- Monitors are overseen, conducted by and corrective action determined and taken by employees of the laboratory
  - Usually the department director, manager or supervisor
- Monitors make up the internal auditing process for the compliance program

# Monitors

- Monitors should be simple but focused
- Should be part of the routine scheduled work
  - Often already being done but not thought of as a monitor for compliance
- The compliance committee should help each other develop monitors for their respective areas of responsibility
- There should be regular reports of monitors to the compliance committee
- The reports should be simple and straight forward

# Monitors

- Monitors are focused around the individual policies and procedures for the items on the risk list
  - Hence, there will be many more monitors than audits
- Highest risk areas or processes should take priority if limited resources are available
  - Compliance committee should help make this determination and allocate resources like computer system priorities or personnel

# Example Monitors For Laboratory Billing/Coding

- Monthly review of RAs for denials
- Monthly review of ABN use
- Monthly review of ICD-9 codes received from ordering physicians
- Monthly review of ICD-9 translations
- Review of accuracy of data entry
- Review a sample of requisitions check for ambiguous orders, verbal orders, etc.
- Review standing orders at draw stations or other sites



# Example Monitors - Laboratory Referral Sources

- Monitors Anti-kickback and Stark
  - Review of new client set up documents
  - Review of proposals and offers by sales representatives
  - Review of employees or equipment placed in physician offices
  - Periodic review of contracts, leases and agreements to ensure appropriate and not expired
  - Review of new panels and profiles
  - Review of supplies given to clients
  - Review expense reports for gift and entertainment expenses

# Example Monitors For Compliance Program

- Program administration
  - Review records of new hires for training requirements, check against sanctions etc
  - Review hotline calls and follow up
  - Check records for retention policy
  - Compliance committee attendance and participation
  - Reporting requirements to upper level management

# Monitor Tips

- Create a worksheet for the monitor to allow for the least amount of writing possible
  - Use checklists or items to circle
- Ensure that the importance of the monitors are clear to employees who record
- If the monitor is to be compared periodically, take that into account when designing the worksheet for it

# Monitor Tips

- Keep reports simple and informal
  - Use the worksheet if possible
- Perform monitors only with the frequency needed for the error rate in the system being monitored
- Adjust the monitor schedule periodically as error rates change or problems arise

# Auditing

- The auditing part of the plan should be conducted by an objective third party who has experience with lab compliance risk areas
  - Can be from another area of the organization or from an outside entity
- Laboratory risk areas can be divided up into three major categories for audit purposes
  - Billing and coding
  - Anti-kickback and Stark
  - Compliance Program Administration

# Annual Audit Plan

- The annual audit plan consists of three audits corresponding to the categories previously identified
  - May be conducted all at once or as separate audits
  - Depends on resources, costs, current problem areas and other factors
- Use a risk list or the table of contents of the compliance manual and department manuals
- Place each item into one of the three categories

# Annual Audit Plan

- If the annual plan is carried out in three separate audits, the individual audits should be conducted at 3 or 4 month intervals
  - Allows time to analyze, report and correct problem
- If the plan is carried out in a single audit certain efficiencies in sample selection and reporting can be applied
  - One basic sample can yield several sub-samples
  - Multiple subjects can be covered in interviews
  - Report narrative can be combined for some reportables

# Annual Audit Plan

- Billing and coding in March or April
  - Can detect problems with CPT and ICD-9 code updates earlier
- Anti-kickback and Stark in June or July
- Program Administration in October or November
  - Can form the basis of an annual report to the Board or owner
- The laboratory should plan for a year end summary of the effectiveness of the audit plan and make adjustments to it as needed



# Selecting An Outside Auditor

- Create a written description of the audit(s) you want performed
  - State the purpose or type of audit requested
- Include enough detail to insure the end result will meet the needs of the compliance program written policies for auditing
- Include a list of the “reportables” for the audit
  - List the specific issues to be addressed in the audit report

# Selecting An Outside Auditor

- Create a request for proposal that includes:
  - The audit description and reportables
  - A requirement that the person(s) actually conducting the audit have a background in the clinical laboratory, preferably management level
  - Include a requirement to furnish professional history or experience of the individuals that will be conducting the audit or analyzing the data
  - Include a requirement that the auditor have at least some experience auditing laboratories as opposed to other kinds of health care facilities

# Selecting An Outside Auditor

- Include a requirement that any software used for sample selection and data analysis be identified
  - If something like Excel is used, ask for specifics of the source for the tools employed
- Include a requirement for a draft report for review and a final report after the draft is discussed with the auditor
- Include a requirement for a written agreement for the specifics and the cost of the audit

# Selecting An Outside Auditor

- Using an outside auditor does not relieve the LCO from responsibility for the audit
- The LCO must insure that everything in the audit report is accounted for in some way
  - Corrective action
  - Challenge the auditor's conclusion and amend or correct the report where appropriate
  - Follow up on any items left open or reportables not included in the report
- Do not sign off on the audit until satisfied

# Selecting An Outside Auditor

- The audit report or supporting documentation may be reviewed by a government auditor if an overpayment is discovered and made
- The laboratory is ultimately responsible for anything in the audit report once it has accepted it

# Corrective Action

- Corrective action includes:
  - Reviews and investigations to determine the seriousness of a problem
  - Correcting the problem and ensuring that it will not happen again
  - Reporting or disclosure to government agents when appropriate
  - Refunds to government or other payers as soon as possible when appropriate
  - Discipline of employees involved in a problem
  - Ensuring that appropriate high level persons at the company are properly informed

# When a Problem Is Discovered

- Take control of the situation
- Suspend all activity including any investigations or document reviews
- Conduct a preliminary review to determine the exact nature and seriousness of the problem
  - Interview all persons involved in the problem
  - Review all documents gathered so far
- If in a hospital or health system lab, notify the corporate compliance officer

# When a Problem Is Discovered

- If initial review does not provide enough information to determine a course of action perform additional investigations or interviews
- If these additional investigations must be conducted by persons other than the LCO
  - Give specific instructions
  - Limit persons involved
  - Monitor for timeliness
- If there are additional interviews needed, these should be done by the LCO



# Serious Or Not That Is The Question

- The seriousness of the problem is key to determining the correct course of action
- Optional courses of action:
  - Is a refund alone appropriate?
  - Is a self disclosure necessary?
  - Can a corrective action and go forward approach be taken without reporting the problem to a government agency?

# Serious Or Not That Is The Question

- How was the problem identified?
- How long has the company been aware of the problem?
- What has the company done so far?
- Are there internal documents suggesting knowledge of the problem at high levels of management?
- Was legal counsel sought to clarify the problem?

# Serious Or Not That Is The Question

- Did a company employee contact a government payer about the problem?
- Has the problem occurred in the past?
- Is there an overpayment of government funds involved?
- Are there other parties involved in any way in the problem like partners or clients?

# When Refunding is Appropriate

- Problem is identified internally
- Time problem exists is relatively short (6 months)
- Amount of money involved is not great
- The problem is the result of an inadvertent error or a misinterpretation of a manual instruction or Carrier bulletin or notice
- Risk of refunding
  - May be viewed by the Carrier as more serious
  - Will get reported to the OIG

# What About Carrier Error?

- Make sure your evidence is correct
- The laboratory must refund
- Initiate contact with the Carrier to explain the problem and your data or information
  - Offer to meet with them or send the information
- If you cannot make progress with the Carrier, contact the CMS regional office for your jurisdiction
  - If refunds are necessary, keep the money, in escrow until the matter can be resolved

# Refunding Money to the Contractor

- Don't let too much time go by before making the refund
  - 30 to 60 days is best
- Don't just send a check, there is a form and a protocol for refunding
- It is best to contact the contractor and let them know you are refunding
- Follow the instructions given by the contractor
- Keep documentation of the refund, including any attachments

# When Self Disclosure is Appropriate

- Discovered internally or by an external communication/investigation or audit
- Investigation reveals
  - Deliberate ignorance of truth or falsity
  - Reckless disregard of truth or falsity
  - Outright criminal conduct
  - Deliberate violations of company policies or procedures designed to prevent the problem
- Knowledge of problem but failure to correct

# Self Disclosure

- As soon as a problem takes on the appearance of something more serious than a refund to the contractor, stop all activity and contact legal counsel
- Insure the company leadership is aware the problem exists
- Counsel will decide what action to take and how to proceed



# Correct and Go Forward

- There is no overpayment involved
  - If lab has been underpaid
  - If lab has used the wrong CPT code but there was no overpayment as a result
- The problem did not result in abuse or over-utilization of services
- No patients were harmed either medically or financially

# Disciplinary Actions

- The government believes that disciplinary actions for employees who violate compliance policies and procedures or laws and regulations is an essential component of an **effective** compliance program
- Any investigation should include a clear understanding of who was involved and at what level

# Disciplinary Actions and the LCO

- For every credible problem reported, there must be some consideration of accountability and disciplinary action
  - The LCO must insure it is considered
  - Must insure it is fair (e.g. includes culpable managers if necessary)
  - Must insure there is no retribution against reporting employees
  - Must insure it is documented
  - May include everything from retraining to termination

# Non Retaliation Policy

- Nearly all significant prosecutions of health care providers are the result of whistleblower suits
- Non retaliation is essential to encouraging employees to report problems, particularly if a company officer is the problem
- This policy must be explained to employees carefully
  - Not a free pass for policy violators
  - Applicable to employees who come forward in a timely manner and report problems

# Report To Leadership

- Make sure that the CEO, Board member or owner are aware that the problem exists and what is being done about it early in the investigation
  - As soon as the LCO has information
  - Don't assume they don't need to know unless you find something significant
  - Let them decide how much they want to know and when
- Make sure they are aware of the corrective actions taken and why

# Reports To The Board, CEO or Owner

- How often should reports be made?
- Who should make the reports?
- What form should the reports be in?
  - Written, verbal or some combination
- What should the report include?

# Reports To The Board, CEO or Owner

- The problems in large corporations have made the government aware of the need to ensure that the very top most officers in a company can be held accountable
  - Reports to the Board of Directors from the CO and the compliance committee are considered a key element of an effective compliance program

# Reports To The Board, CEO or Owner

- Reports should be at least annual
- May be made to a subcommittee of the Board (auditing committee is most common)
- If there is a Board, the LCO should have a designated Board member they can talk to if they have a problem that can't be reported any other way
- LCOs in a health system or hospital may not report directly to the Board but report to the corporate compliance officer instead



# Reports To The Board, CEO or Owner

- The reports should be written even if a verbal presentation is made
- The report is confidential and should be so marked and handled
  - Don't let a temporary assistant do the copying, etc.
- Strictly control the number and distribution of copies

# Reports To The Board, CEO or Owner

- Reports should be written/presented by the LCO and should be in general terms, with specifics available on request or as attachments
- Reports should include at a minimum:
  - Current status of the compliance program
  - A listing and summary of significant compliance events
  - A report of all Hotline calls
  - Results of audits since the last report
  - Any significant changes to the compliance program since the last report
- Report recipient(s) should have an opportunity to question the LCO about any item in the report

# Reports To The Board, CEO or Owner

- It is the ethical duty of the LCO to be open and forthcoming in the report
  - If the recipients don't know a problem exists they can't correct it
  - If the LCO is not receiving the resources needed to be effective, that must be reported
- The recipients will be held accountable for problems whether they knew about them or not

# What's Coming

- The LCO must prepare for what is coming in regulation and reimbursement changes to be effective
- Allows for planning and avoids unnecessary potential risks
- It is important the the LCO remain in tune with the current trends in regulation and government views on lab related issues
  - Attending conferences and participating in audio-conferences are good practices for LCOs

# Chaos or Change at CMS?

- Medicare Modernization Act of 2003 (MMA) has imposed many changes and projects on CMS
- CMS is still implementing regulations going back to HIPAA (1996) and BBA of 1997
- Issuing and rescinding of transmittals and change requests are but one symptom
- Inability to answer queries and respond to the provider community is another

# Too Mention a Few ....

- CMS has a section of its webpage specifically devoted to various demonstration projects
- <http://www.cms.hhs.gov/researchers/demos/>
- MMA alone has 14 active demonstrations plus 5 other “projects”
  - Laboratory competitive bidding demonstration is among these
  - Some of the projects don’t even start until 2010

# Too Mention a Few ....

- Ongoing maintenance and updates to Medicare coverage policies (NCDs)
- Ongoing updates and maintenance of the Internet Only Manuals
- Quality initiatives and pay for performance projects
- Medicare contracting reform
  - Medicare Administrative Contractors (MAC)

# What Does This Mean for Labs?

- CMS may be slow to respond to problems and questions from the health care community
- May rush to meet deadlines and implement poorly written regulations
  - Make changes after implementation
- May have to delay or implement regulations in stages or phases



# What Does This Mean for Labs?

- These issues make it hard for laboratories to plan properly for regulatory changes
  - May affect budgeting and other operational functions
- Associations and advocacy groups have a difficult time organizing responses and lobbying efforts

# What Should Labs Do?

- Labs need to devote some specific time and expertise to tracking and monitoring regulatory activity
  - More than just signing onto listserves and receiving information
  - Must review and analyze the information and make decisions about where to focus resources

# What Should Labs Do?

- Labs must be actively involved with associations and advocacy groups that are working with government to implement these various laws and regulations
- Support advocacy and lobbying efforts with cash and human resources
  - Encourage employees to write letters when an important issue arises
  - Pay association dues and newsletter subscriptions

# Changes in 2006

- CR 3835 Effective 4-3-06 concerns a redefined Type of Bill (TOB) to be used on hospital laboratory claims for non-patient services
  - TOB 14X used for nonpatients only to differentiate outpatients from nonpatients for payment issues for CAH and Maryland waiver hospitals
  - Will be required of all hospitals

# Duplicate Claims Edits

- CR 3946 is one more in a series of CRs that deal with referred laboratory services
  - The CMS system did not have a Common Working File (CWF) edit to detect duplicate claims filed in different jurisdictions
  - Previous edits did not check all claims, only those with -90 modifiers
  - Effective January 1, 2006 the edit will be expanded to include a larger universe of claims

# All ICD-9 Codes on Claims

- CR 4097 is the first phase of CMS' effort to meet the Negotiated Rulemaking requirement to use up to eight ICD-9 codes to adjudicate laboratory claims
  - HIPAA format claims allow submittal of up to 8 but claim system uses only first four
  - This is “first phase” and requires only the analysis and design part

# All ICD-9 Codes on Claims

- Future CRs will provide additional information and specifics
- Effective date for contractors to be able to process all 8 codes is October 1, 2006
  - Would be applicable for paper claims up to the number of codes allowed on an electronic claim

# No Surrogate UPINs

- CR 4177 concerns the elimination of using the surrogate UPIN OTH000 on Medicare claims
- Effective April 3, 2006 any claim with the UPIN OTH000 will be returned as unprocessable
- Check your physician data base to insure this UPIN is not assigned to any physicians



# National Provider Identification (NPI)

- All providers will have to obtain an NPI before May 23, 2007
- See the CMS NPI webpage at <http://www.cms.hhs.gov/providers/npi/>
- Providers should apply sooner rather than later
- May apply on the web or mail in a paper application
- An organization may apply for many other providers en masse

# NPI Implementation

- Implementation timetable
  - May 23, 2005 to January 2, 2006; do not use your NPI on claims
  - January 3, 2006 to October 1, 2006; may include NPI on claims but must also include an existing provider ID
  - October 22, 2006 to May 22, 2007; may submit with either an NPI or an existing provider ID
  - May 23, 2007 and beyond; only an NPI

# Contracting Reform

- Medicare Administrative Contractors (MACs) will replace the Carrier and Fiscal Intermediary system
- MACs will do both Parts A & B
- By 2011 there will be only 15 MACs for general Medicare claims processing
- For information see
- <http://www.cms.hhs.gov/medicarerereform/contractingreform/>

# Electronic Claims Attachments

- CMS published a proposed rule in the Federal Register on September 23, 2005 that describes the process and code sets that will be used for electronic claims attachments
- The most significant piece of this rule for laboratories is the establishment of the LOINC code set for laboratory attachments including test results

# Electronic Claims Attachments

- The effective date would be some time after the final rule is published
  - Will depend on how many comments are received and how many credible problems are exposed
- Information on the LOINC code set can be found at <http://www.regenstrief.org/loinc/>

# Medically Unbelievable Edits

- MUEs are caps on the number of units of services (UOS) allowed on a patient on the same date of service
- Based on the following:
  - Anatomic consideration
  - CPT code descriptors and instructions
  - Medical reasonableness
- Being refined by a contractor named Correct Coding Solutions LLC

# Medically Unbelievable Edits

- Originally published by CMS as a Change Request then rescinded
- An actual list of the edits was never officially published
- The file as it exists today includes edits for more than 1250 HCPCS codes including pathology codes paid on the Medicare Physician Fee Schedule

# Medically Unbelievable Edits

- Purpose of the edits is to prevent overpayments resulting from errors or misunderstandings of coding rules
- Edits UOS are set so that most appropriately coded services would be paid
- There will be no modifiers to bypass the edits
- CMS has not yet decided if it will allow appeals of individual claims



# Medically Unbelievable Edits

- Some examples of MUE UOS from the laboratory section of the edits
  - 82784 Gammaglobulin; IgA, IgD, IgG, IgM, each - MUE UOS = 1
  - 88302 through 88309 allow 2 UOS for each code
  - Molecular codes 83890 through 83912 allow 1 UOS for each code

# Medically Unbelievable Edits

- 88312 and 88313 - Special stains group I and II - 4 UOS each code
- Immunohistochemical codes 88342 through 88347 - 4 UOS for each code
- CMS has distributed the file to CAP, CLMA, AMA and other associations for review and comment
  - Due by March 20th
  - Effective date for MUEs is July 1, 2006

# OIG 2006 Workplan

- Lab services during inpatient stays that are “unallowable”
- Excessive or unnecessary laboratory services in nursing homes
- Consolidated billing in SNFs during 2001, 2002 and 2003
- Laboratory proficiency testing
- Separately billable laboratory tests for ESRD patients

# OIG 2006 Workplan

- Medicare pricing of laboratory services
  - OIG believes that Medicare pays “significantly higher prices” than other payers for “certain laboratory tests”
  - Will compare the current lab fee schedule to fee schedules of other government and private payers

# OIG 2006 Workplan

- Physician Pathology Services
  - Pathology services performed in a physician's office
  - Focus on relationships between physicians and outside pathology companies
  - Key may be the place of service code on a claim
  - Review of a physician who is purchasing technical component services but performing and billing the professional component may drag the reference lab or pathologist into the review

# Cytology Proficiency Testing

- House gives verbal approval to a bill (HR 4568) to suspend cytology proficiency testing for one year or longer until the program is fixed
- Sent to Senate and then to committee on January 27, 2006
- Would require four changes to the cytology proficiency testing

# Cytology Proficiency Testing

- Reflect the collaborative decision making process actually used in laboratories
- Revise grading and scoring criteria to reflect current practice guidelines
- Test no more than once every 2 years
- Make other revisions to standards to bring them in alignment with current lab operations and practices

# Laboratory Competitive Bidding

- There has been no activity since the presentation by Research Triangle, Linda Lebovic from CMS and Donna MacMillan from the Technical Expert Panel
- The metropolitan areas have not yet been selected
- The last modification or update to the website is 9/14/05  
<http://www.cms.hhs.gov/center/clinical.asp>



# QUESTIONS AND ANSWERS