Session 115: Compliance Challenges for the Clinical Laboratory: 2010 and Beyond

HCCA’s 14th Annual Compliance Institute

Compliance Challenges

- Laboratories are unique in many ways
- Regulations and Medicare billing often have unique applications for the laboratory as opposed to other segments of health care
- Almost all providers of health care use laboratory services or interact with the laboratory
- Laboratories are often subject to rules and regulations that govern their business but over which they have little control
Panel

Paul Keoppel, Laboratory Compliance Officer,
Intermountain Healthcare Central Office, Salt Lake City,
Utah

Diana Voorhees, Principle/CEO of DV & Associated, Inc.,
Salt Lake City, Utah

Christine Anusbigian, Senior Manager Health Sciences,
Deloitte & Touche LLP, Detroit Michigan

Christopher Young, President, Laboratory Management
Support Services, Phoenix, Arizona

Laboratory Compliance Challenges: Recent Regulatory Activity Affecting Laboratories

Paul Keoppel, MBA, MT(ASCP)
Laboratory Compliance Officer
Intermountain Healthcare
Salt Lake City, Utah
paul.keoppel@imail.org
Healthcare Reform HR 3590

- Passed by congress on March 21, 2010 and signed into law on March 23, 2010
- This law has all current laboratory issues in it
  - Fee schedule reductions
  - Extension of grandfather of technical component
  - Complex diagnostic tests (date of service)
  - Extension of reasonable costs payment provisions for rural hospitals
  - Compliance program as a condition of doing business with the government

Health Care Reform Debate
Healthcare Reform HR 3590

- Fee schedule (clinical laboratory fee schedule) section 3401(l)
- For 2010 minus 1.9% (CPI-U of -1.4% plus -0.5%)
- For 2011 thru 2015 - CPI-U minus the productivity adjustment not allowing a negative adjustment (in place of the -0.5%), then -1.75% even if the fee schedule goes below 0.0
- 2016 and beyond – CPI-U minus the productivity adjustment, not allowing a negative adjustment
  - CPI-U and productivity adjustment are not accurately predictable at this time

Healthcare Reform HR 3590

- Extension of technical component grandfather until end of 2011 (section 3104)
  - Allows independent labs to bill for the technical component of surgical pathology testing on inpatients and outpatients for covered hospitals
  - Only applicable if similar arrangement existed prior to July 22, 1999
  - If audited, lab would have to be able to provide proof of previous qualifying arrangement
  - *Transmittal R1945CP (April 9, 2010) provides details*
Healthcare Reform HR 3590

- Extension of reasonable cost payment provisions for rural hospitals until July 1, 2011 (section 3122)
  - Transmittal R1940CP, Published April 2, 2010
- 2 year demonstration project for separate Part B payment for complex diagnostic tests where the specimen is collected during an inpatient hospital stay
  - This is the 14 day date of service correction
  - Certain genetic, molecular and chemosensitivity tests
  - Would set the rates for those tests
  - Would allow both hospital and independent labs to bill
  - Total Medicare allowance for the demo is $100 million
  - Report to congress not later than 2 years after demo concluded

Health Care Reform

- One constant theme throughout the discussions surrounding health care reform is how much money is lost because of fraud and abuse in the Medicare, Medicaid and other Federal programs
- Correcting this problem is one of the mechanisms the government believes will help to pay for reforming the health care system
- The enforcement escalation is ongoing and will be supported and funded by health care reform
Signatures on Lab Requisitions

- Difference between an order and a requisition
- CLIA regulation for test orders
- CMS documented order of intent for testing
- Signature is not required for tests reimbursed on the Clinical Laboratory Fee Schedule (CLFS)
- Signatures are required for procedures listed on the Physician Fee Schedule (Anatomic Pathology)
Signatures
Physician Fee Schedule

• “We believe that a written order, which may be a part of the medical record, and the requisition are two different types of documents, although a requisition that is signed may serve as an order.”

• “…a requisition is simply a paper mechanism for transmitting an order and more administrative in nature, it is less likely to be generated or handled by a physician. Thus, to require a physician’s signature on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS would be an added and unnecessary burden on physicians.”

• Federal Register Physicians Fee Schedule 25 Nov 2009, pg 61930

CERT audits
Comprehensive Error Rate Testing

• Valid Signatures
  • “In order to support physician intent, all medical documentation must be complete, including the specific tests to be ordered, legible, and authenticated by the ordering physician.”

• Proper use of Protocols
  • Use of a standard written or implied protocol, rather than a patient specific physician's order.
Improper Protocol Examples

- White cells or bacteria discovered during a urine test will prompt the lab to run a urine culture without a specific order from the physician to perform the culture
- The lab receives an order for a CBC and automatically runs a CBC with differential although the differential was not specified in the physician's order

Source: Noridian Medicare Part A News Issue 2080

Medicare Billing Complexities

- Date of Service
- Specimen collection and travel
- CLIA categorization
- Screening services
- Automated panels
- Modifiers
- Medical necessity and ABNs – NCD and LCDs
- CCI edits
- Professional and technical billing
- Skilled Nursing Homes
- ESRD
- Bundling and unbundling of panels
- Blood products
- Part A versus Part B
- Referred testing
- MUE edits
Outreach Work
Hospital Based Laboratories

- Unique to the laboratory
- Specimen is collected at physician’s office or drawing station – lab never sees the patient
- Challenges include:
  - Pricing
  - Stark
  - Marketing compliance

Medicare Laboratory Fee Schedule

- Published annually – to include an increase based on CPI – often blocked by Congress
- Traditionally was published mid-November. This year’s was published on December 23, 2009 (CR 6657)– 1.9% decrease from 2008
- Laboratory is paid from 3 fee schedules
  - Clinical laboratory- glucose, cholesterol, CBC, etc.
  - Physicians Fee Schedule – Anatomic Pathology procedures – biopsies, etc.
  - OPPS – APC system for blood products
New G codes for Drug Screens

- G0430 and G0431 included in fee schedule without instructions on usage in conjunction with 80100 and 80101
- MLN Matters issued January 4, 2010, MM6657
- Explained use of G0430, but delays use of G0431 until they can figure out how to explain it

Mixed Signals?

Drug Screen Coding

- 80100 – Use for drug screens, multiple drug classes using chromatographic technique
- G0430 – Use for drug screens, multiple drug classes using rapid point of care testing, multiple results from one test cartridge (bill times 1 for non-waived labs. Waived labs use 80101QW until March 31st)
- 80101 – Use for drug screens, single drug class, each class- for drug screens run on instrumentation- (bill times the number of drug classes screened)
- G0431 – Same description as 80101 – waiting for enlightenment on how to use this code (Medicare Matters March 19th indicates this code is a direct replacement for Medicare use)
Technical Component Global Billing

- Topic is place of service and date of service for the interpretation (Professional Component) and Technical Component of Diagnostic Tests
- Would have eliminated global billing for the majority of anatomic pathology testing
- Rescinded on February 5, 2010 - a new CR will be issued.
- Transmittal 1873, CR 6375 issued December 11, 2009

Technical Component Grandfather

- CMS considers the technical component for hospital inpatient and outpatients
- Hospitals and pathologists that had an arrangement for the pathologist to bill globally before 1999 have been allowed to continue under the “grandfather” clause
- The clause is set by congress and must be renewed each year or it sunsets
- It was included in the health care reform bill this year – Expires December 31, 2010
ABN Modifier Change

- GA modifier was defined as “Waiver of Liability on File”
- GA redefined as “Waiver of Liability Statement Issued, as Required by Payer Policy”
  - “Medicare systems will now deny institutional claims submitted with modifier GA as a beneficiary liability (rather than subjecting them to possible medical review)”
- GX modifier added
  - GX defined as “Notice of Liability Issued, Voluntary Under Payer Policy”
  - Used for never covered services
- Transmittal 1840, CR 6563, October 29, 2009

Laboratory MUEs

- MUEs are problematic for the laboratory
  - High transaction volume
  - Many MUEs are still unpublished
  - Molecular, genetic and allergy testing are billed in multiples. MUEs are unknown
- Can add modifiers and resubmit claim
- Can appeal the denial with documentation of testing performed
MUE Billing Clarification

• Transmittal R652OTN
• MUEs are denied on a claim line level – entire line is denied if the MUE limit is exceeded
  • Allows for claim appeals
• Transmittal provides clarification for billing MUEs in excess of the MUE limit
• If the MUE is exceeded, use multiple lines and appropriate modifiers to bypass the edit
  • For labs these are 91 and 59 as applicable
• Make ABSOLUTELY certain the extra units of service are ordered, and, are medically necessary and appropriate

MUE Billing Clarification

• MUE coding limits can be changed through various channels
  • Contractors can bring them to the attention of the NCCI contractor if providers question or seek changes
  • Claims appeals data may be reviewed to implement changes
• MUEs are coding denials and therefore not eligible for ABN use
• Beneficiaries cannot ever be billed because of MUE denials.
More Efficient And Effective Audits

• Based on MAC jurisdictions
• Same ZPIC contractor will look at all of the claims data for the same MAC contractor
• ZPICs will create and use “innovative data analysis methodologies” and “proactive data analysis”
• Expect more audits and claims denials

That’s a sure hit on that lab…….
Complete Blood Count (CBC)

- CPT book defines two separate and distinct tests as “CBC” or “Complete Blood Count”
- 85025: “Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and Platelet count) and automated differential WBC count”
- 85027: “Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and Platelet count)
- Physicians often order “CBC” and may expect to get a differential (historical experience)

29

Complete Blood Count (CBC)

- 2003 CPT the AMA changed descriptions for hematology tests
- CMS contractors and CERT auditors now consider an order for a CBC to mean 85027
- If the lab does an 85025 it could be subject to recoupment or possibly false claims
- If a physician wants a differential they must specifically indicate that preference on the order (e.g CBC and differential)
- Laboratories should change their requisitions to allow for both tests to be ordered
  - Default test for a CBC order is 85027 or call the doctor and document the call

30
RAC Audit – SNF Consolidated Billing

- Region D Recovery Audit Contractor (RAC) Healthdatainsights, Inc (HDI) has been sending refund demand letters to laboratories seeking refunds for duplicate billings related to Skilled Nursing Facility (SNF) patients
- Region D includes - Alaska, Arizona, California, Hawaii, Idaho, Kansas, Missouri, Montana, North Dakota, Nebraska, Nevada, Oregon, South Dakota, Utah, Washington, Wyoming, Guam, American Samoa, Northern Marianas

RAC Audit

- All laboratory services provided to a patient who is in a Part A stay in an SNF must be billed by the SNF
- Medicare pays the SNF, who is responsible to inform the laboratory of the patient’s status, as part of consolidated billing rules
- The laboratory bills the SNF
- Even if the services are provided outside of the SNF in a physician office
- The laboratory is responsible for the claim and must refund the program and then re-bill the SNF
- If successful, this audit could spread to other RACs
ZPICs

- Zone Program Integrity Contractors
- Replaces Program Safeguard Contractors (PSC)
- Ultimately will be responsible for ensuring the integrity of all Medicare related claims under Parts A, B, C, D and coordination of the Medicare-Medicaid (Medi-Medi) data matches
- Designed to simplify the fraud detection landscape and provide consistency

Medicaid Integrity Program

- The Deficit Reduction Act of 2005 (DRA)
- Funding - $560M over 5 Years
  - $255m for Medicaid Integrity Program
  - $180m for National Medi-Medi Expansion
  - $125m for OIG for Medicaid Fraud
- Staffing - 100 FTEs for CMS
- HR 3590 extends and supplements funding
Medicaid Integrity Program

• Medicaid Integrity Contractors (MICs)
  • Assigned by CMS regions and is scheduled for “reviews” in 2009 and beyond
• Three kinds of contractors
  • Review MIC – reviews provider claims and develops “target” lists
  • Audit MIC – audits provider claims and identifies overpayments
  • Educate MIC – educates providers on payment integrity & quality of care

Medicaid Integrity Program

• How it will work
  • CMS’ MICs conduct reviews and audits with the aid of the state Medicaid program
  • Audit results are reported to CMS then vetted with the state Medicaid program
  • State refunds to the federal government its share
  • State seeks refunds from providers
DISCUSSION & QUESTION AND ANSWERS
Molecular Diagnostics Update

- Diana W. Voorhees, M.A.
- CLS, MT, SH, CLCP
- Principal/CEO
- DV & Associates, Inc.
- dvassoc@aol.com

CPT Molecular Applications

- Molecular Diagnostics
  - Chemistry
- Infectious Agents
  - Microbiology
- HLA
  - Tissue Typing
- Molecular Cytogenetics
  - Chromosome Analysis, FISH
- Arrays
  - Surgical Pathology
Molecular Diagnostic Codes

- Six codes introduced in 1993
  - 83890, 83892, 83894, 83896, 83898, 83912
  - Expanded to 21 codes by 2007
    - No new codes in 2008 or 2009 or 2010
- CPT code series 83890 – 83914 used for analysis of nucleic acids

Molecular Diagnostic Codes

- Codes are per procedure versus analyte/analysis
- Code each procedure in an analysis
- Not to be mingled with coding from cytogenetics section
Molecular Diagnostics

- Procedures related to nucleic acid testing
  - Isolation, extraction, purification
  - Enzyme digestion
  - Gel and capillary electrophoresis
  - Amplification
    - PCR Single, Multiplex, Signal
    - RT-PCR
  - Reverse transcriptase
  - Mutation scanning and identification
  - Sequencing
  - Interpretation

Coding Changes - 2010

- No description changes for 2010
- None for 2010
- New infectious agent code
- Two new culture typing codes
- Two new pathology codes
New CPT Codes - 2010

- 88387 Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (e.g., nucleic acid-based molecular studies);
  - each tissue preparation: (e.g., a single lymph)

New CPT Codes - 2010

- Do not report 88387 for tissue preparation for microbiologic cultures or flow cytometry studies
- Do not report 88387 in conjunction with 88388, 88329 – 88334
- Reimbursed under the MPFS
New CPT Codes - 2010

- +88388 Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (eg, nucleic acid-based molecular studies); in conjunction with a touch imprint intraoperative consultation, or frozen section, each tissue preparation: (eg a single lymph node) (List separately in addition to code for primary procedure)

New CPT Codes - 2010

- Use 88388 in conjunction with 88329 – 88334
- Reimbursed under the MPFS
Genetic Testing Code Modifiers

• Issues:
  ◦ Payers unable to identify services performed and determine appropriate payment
  ◦ Molecular diagnostic codes perceived as outdated
    • Microarrays
    • Complex NA extraction
    • High resolution separation

Genetic Testing Code Modifiers

• First Digit to Reflect Disease Type
• Second digit to identify a disease or gene
• Potential for 260 modifiers
  ◦ Currently 120 modifiers
  ◦ Hopefully last through decade
  ◦ Potential to use with HCPCS codes
  ◦ Scrutiny and adjustments expected
• Appendix I in CPT
  ◦ Cross-reference included in chemistry section
Genetic Testing Code Modifiers

- More Examples:
  - 4C  HLA-C
  - 5D  Huntington
  - 6A  Dystrophin (Duchenne/Becker muscular dystrophy)
  - 7C  Acid beta glucosidase (Grauber disease)
  - 8A  CTFR (Cystic fibrosis)
  - 9A  TPMT (thiopurine methyltransferase) patients on anti-metabolite therapy
  - 9Z  Dysmorphology NOS

Genetic Testing Code Modifiers

- Status – Late 2009
  - Certain providers may require
    - Recent notices of requirement
  - Medicare not requiring
    - Await Notice of Requirement
    - If utilize, should create no problem for claims processing (reimbursement) as no edits are in place (Hmmmm……….)
Reimbursement Factors

- Coding
  - CPT, HCPCS, ICD-9, Modifiers, DRGs, APCs, Certification, Revenue
- Billing Protocol
- Method of Reimbursement
  - Fee Schedule (National Limitations), MFS, RCC, UCR, RVS, Percent of Charge
- Payer Variances
  - Systems for edits, coverage policies

Correct Coding Initiative (CCI)

- Editing system that Medicare implemented in the late 1990s
- Detect potential coding errors prior to precipitating payment
- Only apply to Medicare Part B services
- External organization contracts with CMS
  - Establishing, monitoring, and effecting change in the CCI edit program
- Two types of edits
CCI Edit Impact

- Column 1/Column 2 Edits
  - All molecular diagnostics, cytogenetics, and array codes may not be reported with CPT 80500 or 80502 (clinical consults)
  - Molecular diagnostics codes not recognized with infectious agent DNA/RNA codes (caveat)
  - Array codes not recognized with molecular diagnostics codes for probes or ID
  - All edits allow use of modifier

CCI Edits

- Mutually Exclusive Edits
  - CPT 83890 with 83891 (both extraction)
  - CPT 83900 with 83908 (both amplification)
  - CPT 83904 with 83905 and 83906 (mutation ID)
  - CPT 83914 with 83904, 83905 or 83906 (mutation ID)
  - Array codes may not be reported together
  - All edits allow use of modifier
Array Codes

- CPT  Description
- 88384  Array-based evaluation of multiple molecular probes; 11 through 50 probes
- 88385  51 through 250 probes
- 88386  251 through 500 probes

New CCI Guidance

- CCI comments, Version 15.3:
  - “CPT codes 88384-88386 describe array-based evaluations of multiple molecular probes. Although CPT code 88384 is Carrier (A/B MAC processing practitioner service claims) priced, CPT codes 88385 and 88386 are payable from the Medicare Physician Fee Schedule and include significant physician work.
CCI, Continued

- If array-based evaluation of multiple molecular probes is performed by a laboratory scientist or technician rather than a physician, it should not be reported with global CPT 88385 or 88386 since these codes include physician work. Rather, it should be reported with 88385-TC or 88386-TC which includes the non-physician work including interpretation.”
- Significant change

Local Coverage Determinations

- Array codes
  - Example LCD:
    - A service or procedure on the “Local Non-Coverage Decisions” list is always denied on the basis that … it is ever medically reasonable and necessary. The … list of LCD exclusions contains procedures that, for example, are:
      - Experimental.
      - Not proven safe and effective.
      - Not approved by the Food and Drug Administration (FDA).
Coverage Issues

- KRAS Testing
  - FDA updated labels on Vectibix & Erbitux:
    - Use of above drugs not recommended for patients with tumors that have EGFR inhibitors to KRAS mutations in Codon 12 or 13
    - Colorectal cancer testing
    - $10K per month for therapy
    - Testing before treatment is noteworthy

New CCI Guidance

- Version 15.3 CCI Manual
- CPT 83912 “include the synthesis with interpretation and report of all molecular diagnostic testing........ respectively performed on a single date of service......should not be reported with separate units of service based on the number of specimens or tests on a single date of service.”
- MUE of “1”
“S” HCPCS Codes

- Temporary National Codes (Level II)
  - Identify drugs, supplies, and services for which no other national code exists
  - Used by private sector to help implement policies or programs or for claims processing
- Recognized by BCBSA and HIAA
- Used for Medicaid services
- Not recognized by Medicare

“S” Code Examples

- S3820 Complete BRCA1 and BRCA2 gene sequence analysis for susceptibility to breast and ovarian cancer
- S3823 Three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals
DISCUSSION & QUESTION AND ANSWERS

Pathology, Pricing and Other Issues

Christine Anusbigian, MBA, MT(ASCP), CHC
Senior Manager
Deloitte & Touche LLP
Detroit, Michigan
+1 313 396-5857
canusbigian@deloitte.com
Pathology Contracts

- From a Stark and anti-kickback perspective, it is typically the hospital that is in a position to influence the flow of business to the pathologists, rather than the pathologists making referrals to the hospital.
- The risk is if the hospital solicits or receives something of value – or if the pathologists offer to pay something of value – in exchange for access to the hospital’s Federal health care program business.
- Examples:
  - Hospital requires pathologists to pay more than fair market value (FMV) for services provided to the pathologist by the hospital
  - Hospital compensates pathologists less than FMV for goods or services provided to the hospital by the pathologists.

Pathology Contracts

- Types of contracts
  - Employee of hospital
  - Independent contractor
- Considerations
  - Will hospital bill for professional services or will the pathologist?
  - Will the pathologists be compensated for administrative duties?
    - Manage laboratory operations
    - Participate on various hospital committees
Pathology Contracts

Contracts must be:

– Current and signed by both parties to the contract
– At FMV
– Reviewed by legal counsel
– If pathologists are separately paid for administrative duties, any duties the pathologist will be compensated for should be documented within the contract and there should be documentation by the pathologist that these duties were performed (i.e., time logs)

Surgical/Cytopathology Exception

• Additional tests ordered by pathologists (e.g., additional testing related to surgical pathology)
• This exception applies to an independent laboratory’s pathologist or a hospital pathologist who furnishes a pathology service to a beneficiary who is not a hospital inpatient or outpatient, and where the treating physician/practitioner does not specifically request additional tests the pathologist may need to perform.
• The pathologist may perform such additional tests under the following circumstances:
  – These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
  – The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
  – The pathologist documents in his/her report why additional testing was done.
• See Medicare Benefit Policy Manual Chapter 15, section 80.6.5
Anti-markup

- Anti-markup rule:
  - Applies to physicians and physician practices billing for anatomic pathology professional and technical services.
  - Does not apply to hospitals or independent labs
  - 42 CFR § 414.50
  - If a physician or other supplier bills for the technical component (TC) or the professional component (PC) of a diagnostic test that was ordered by the same physician or supplier (or ordered by a party related to such physician or other supplier through common ownership or control) — and the diagnostic test was performed by a physician who does not “share a practice” with the physician or supplier billing for the service — then Medicare payment for the service will be subject to special payment limits (referred to by CMS as the “anti-markup payment limitation”).

Anti-markup (cont.)

....the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier’s net charge to the billing physician or other supplier. For purposes of this paragraph (a)(1) only, with respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC.
(ii) The billing physician or other supplier’s actual charge.
(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.....
Anti-markup (cont.)

• When the performing physician “shares a practice” with the billing physician or supplier, the anti-markup provisions do not apply.
• There are two ways of determining if the “sharing a practice” requirement is met:
  – the physician who supervises the TC or performs the PC furnishes at least 75 percent of professional services through the billing physician
  – the TC and PC are performed in the office of billing physician or supplier by a physician owner, employee, or independent contractor of the billing physician.

Medicare / Medicaid Laboratory Billing

Be aware of differences in billing requirements for Medicare and state Medicaid programs

  – State Medicaid requirements on billing are unique to each state.
  – Examples:
    • Some Medicaid programs specifically allow “handling charges” and Medicare does not
    • Some Medicaid programs do not allow venipuncture charges and Medicare does
    • Some Medicaid programs have provisions regarding how much a laboratory can charge Medicaid
    • Some states have “state Stark laws”
    • Some states do not have edits to bundle lab charges in accordance with their billing requirements, whereas Medicare has edits to bundle ATP tests.
    • Some Medicaid programs require a physician signature on the lab requisition
    • Some Medicaid programs require that the laboratory that performs the test should bill for the test. Medicare requires that the hospital bill for testing performed on hospital outpatients.
UB-04 versus CMS-1500 billing

• Laboratory tests are paid by Medicare Part B
• For patients that are not hospital inpatients:
  – Hospital labs bill on a UB-04 (inpatient, outpatient, non-patient), independent labs bill on a CMS-1500 claim form
  – Pathology professional charges are billed on a CMS-1500 claim form
  – For tests paid under the laboratory fee schedule, copayment and deductibles do not apply
Pricing of Laboratory Testing

- Hospital and independent laboratories may offer/sell laboratory testing to its clients (physicians and other health care entities) who then bill the patient or insurance company
  - Not allowed for Medicare except when one lab is billing another lab and within certain restrictions
- A key aspect to pricing analysis is that the laboratory should have knowledge that Medicare payments obtained are not subsidizing discounts to physicians or that a price given to physicians is not specifically linked to receiving federally reimbursed testing.

Pricing of Laboratory Testing

The OIG Compliance Program Guidance for Clinical Laboratories states:

“Policies should ensure that laboratories are not providing any inducements to gain a physician’s business, including charging physicians a price below fair market value for their non-Federal healthcare program tests. Laboratories that charge physicians a price below fair market value to induce them to refer their Federal healthcare program business may be risking anti-kickback enforcement and false claims actions.”

- Laboratories should be aware also of any state Medicaid requirements
Pricing of Laboratory Testing

Some questions to ask when evaluating pricing strategies:

• Is the pricing at or above the Medicare payment amounts?
• Are the charges at or above the charge to Medicaid or Medicare under comparable circumstances?
• Is pricing set at FMV?
• Is the pricing above cost (Average fully loaded cost/ incremental cost)?
• Is the pricing not linked to receiving Medicare or other Federally reimbursed testing?

• Is the discount to be provided to patients who meet the criteria specified in the organization’s indigent care policy?
• Is the discount related to a prompt pay discount?
• If testing is sold at a discount could the laboratory reasonably earn a profit on that testing, at that price, even if that were all the work it received (e.g., did not also receive Medicare, Medicaid, or other federally reimbursed testing from the same source?
• Responses of “no” to any of the above indicates there may be risk that pricing may violate the anti-kickback statute, Stark Law or other state laws/regulations.
End-Stage Renal Disease (ESRD) Laboratory Testing

- Hospital that perform laboratory testing for ESRD patients undergoing dialysis should be aware of the unique Medicare bundling and billing requirements.
- OIG performed audits as part of the 2009 OIG Work plan
- Certain testing is bundled into the ESRD composite rate and not separately billable.
- 50-50 rule for automated multichannel chemistry tests (AMCC)
- Use of CD, CE and CF modifiers

End-Stage Renal Disease (ESRD) Laboratory Testing

- Certain tests are considered medically necessary and billable every three months (aluminum and ferritin).
- Composite rate tests performed in excess of specified frequencies or not included in the composite rate payment are to be billed separately, provided that medical necessity is documented.
- Hospitals based facilities bill for the ESRD testing on the dialysis claim (bill type 721)
- Many other commercial and Medicaid payors have similar requirements
- See Medicare publications 100-2 Chapter 11 and 100-4 Chapter 8.
Laboratory Compliance Investigations

- Nichols Institute – 40 million criminal fine and a $262 million fine to resolve False Claims Act allegations. Pleaded guilty of misbranding of one of its products, a test called Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay. Laboratories use the test to measure parathyroid hormone (PTH) levels in patients. The tests provided elevated results that lead to unnecessary medical treatments for patients who were thought to have high levels of PTH.
- Others related to:
  - Paying physicians for referrals/kickbacks
  - Unbundling
  - California Medi-Cal investigating pricing of tests charged the state Medicaid program up to six times more for tests compared to other clients over the past 15 years

• This presentation contains general information only and Deloitte* is not, by means of this presentation, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This presentation is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor.
• Deloitte shall not be responsible for any loss sustained by any person who relies on this presentation
  - As used in this document “Deloitte” means Deloitte & Touche LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries.
DISCUSSION
&
QUESTION
AND
ANSWERS

Electronic Health Records (EHRs) And The Laboratory

Christopher P. Young, CHC
President
Laboratory Management Support Services
www.labcomply.com
Health Care Reform

- As part of reform effort, government is pushing the move to electronic records
- Providing monetary incentives and eventually penalties for physicians, hospitals and others to move towards EHRs
- Standard transactions (HIPAA) for electronic claims attachments for laboratory claims (NPRM September 2005)
- LOINC (Logical Observation Identifiers Names and Codes) will be required at some point

E-Prescribing and EHR

- The government believes:
  - Industry wide adoption of e-prescribing and EHRs will improve quality of care, reduce errors and improve efficiencies thereby saving money
  - Physicians have been slow to adopt to electronic methods with cost cited as the main obstacle
  - Secondarily, physicians and others expressed concerns that donating computers and software would create liability under current Federal law
MMA 2003

- The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA 2003) mandated the creation of a Safe Harbor to the anti-kickback law and an exception under the Stark law to allow hospitals and others to “donate” hardware, software and training to physicians specifically for electronic prescribing (e-prescribing) of drugs and the creation and maintenance of electronic health records (EHR).

Applicability to Laboratories

- Do not apply to laboratories unless laboratories go beyond the previously described allowed uses for computers or software placed by them.

- If the laboratory system goes beyond what is allowed already, all of the criteria of the new safe harbor and exception must be met.

- Existing systems likely do not meet all of the criteria as they are and would require substantial changes.
There have been significant issues concerning CLIA regulation and electronic health records (EHRs) implementation because certain aspects of HIPAA and the HITECH Act are perceived to conflict.

CLIA issued a clarification in the form of an 18 page revision to its Appendix C Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

The CMS guidance addresses four categories in the manual:

- The electronic transmission of lab results to the “authorized” individual and others designated by the authorized person to receive the information
- Inclusion of data from EHRs under existing retention requirements
- Additional considerations labs need to take into account when using health information technology in the exchange of lab data
- Managing corrected reports for an EHR
CLIA and EHRs

- CLIA is perceived as prohibiting the release of test results to patients
- CLIA leaves this to state law which determines who is “authorized” to receive lab results and a physician can instruct the lab to release results to patients
- Lab results must be saved and retrieved in the same “identical” format as originally reported
- CLIA requires that all the required elements be present but does not specify the format

CLIA and EHRs

- CLIA requires both a paper and electronic copy of results
- CLIA does not specify the method of storing test results
- Managing corrected reports in the electronic environment only requires the lab to notify the 1st entity receiving the results
- The lab must get the result to the “authorized” person to meet its CLIA requirements
CLIA and EHRs

- This is a brief overview of these issues and revisions, they are a little more complex
- All laboratories should obtain the revised interpretative guidelines and review them in sufficient detail to insure they are in compliance
- These went into effect March 1, 2010
Background

- Labs have been allowed, within certain limits, to place free computers, printers, fax machines and/or load software onto a physician’s computer system since the early 1990s.
- Allowed by the publication of a 1994 Fraud Alert concerning lab services.
- The Fraud Alert said the following:
  - The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute: Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.

Physician Self Referral (Stark)

- The Stark rule definition of “remuneration” makes an exception for the placement of free computers.
- (ii) the provision of items, devices, or supplies that are used solely to—
  - (I) collect, transport, process, or store specimens for the entity furnishing the item, device, or supply, or
  - (II) to order or communicate the results of tests or procedures for such entity.
Exclusively and Solely

- The use of these two words in the definitions in the rules allowed labs to place computers in physician offices for free because, the presumption was that they did not provide anything the physician would normally have to pay for themselves as long as they were used “exclusively” or “solely” for ordering or reporting the results of laboratory tests.

- No other kind of provider was allowed to place computers or provide software to physician offices for free.

Computers Are a Key Element In Laboratory Sales Programs
Placing Computers/Software

- There are many different ways that a laboratory can provide electronic access to order tests and receive results.
- Third party companies that have turnkey systems that can be adapted to many different laboratory computer and physician office systems.
- The laboratory’s LIS may have the capability to interface with desktop computers or the physician office system.
- The Internet can provide the platform for allowing access.

Who Pays For The Interface?

- Everybody understands that the computer system is free but when it comes to interfacing with the physician office system, the cost can be significant.
- The laboratory can pay for the Interface as long as it is working with the interface vendor directly.
- In the case of an Internet connection or portal, can the laboratory pay for the Internet charges?
- If the laboratory pays, it must take steps to insure that the Interface is used solely for lab purposes just like the computer system.
Lab Order Systems vs. EHR Interfaces

- Laboratory ordering systems generally are stand alone systems that use laboratory software or protocols to accomplish their tasks.
- Results are often image or other formats that are easily transmitted and printed in the physician office.
- In some cases, Internet access is provided for secure lookup and ordering by the physician.
- There may be interfaces to the physician computer system but generally this is for the purpose of transferring patient demographics to avoid duplicate data entry.

Lab Order Systems vs. EHR Interfaces

- Placing test results in the physician’s EHR is a much more complicated matter.
- The interface requirements to accomplish this are extremely costly and because of the variety of systems in the physician market often must be customized for each office.
- There is little standardization related to test directories and nomenclature among laboratories which requires that each laboratory would have to develop its own interface for a physician.
HIT Government View

- The government view includes issues of state licensing laws relate to the release of test results and who can order tests.

- There is a white paper on the subject titled HIT Policy Committee Information Exchange Workgroup: Electronic Exchange of Laboratory Information: Statement of Joy L. Pritts, JD (Oct 2009).

- It is important as we move forward to monitor government activity and views because whether or not the laboratory initiates the EHR system, it will have to be aware of issues that affect it.

- [Link](http://healthit.hhs.gov/portal/server.pt)

Issues That May Affect Laboratories

- Government reimbursement programs will provide incentives to both donors and recipients to adopt electronic technologies.

- Standards such as the interoperability standard and the standards related to “necessary technology” and use restricted to what is used predominantly or solely for EHR or e-prescribing are not currently part of laboratory computers placed in physician offices.

- Generally they are restricted from these purposes.
Issues That May Affect Laboratories

- Laboratories cannot place hardware under these regulations, only software
- Physician offices have limited space for the placement of computer equipment in their offices
- May have to choose between stand alone laboratory system and hospital or physician group E-prescribing/EHR system that also allows ordering of lab tests
- May change the market dynamic that currently exists that confers a benefit to larger independent labs

Preparing For The Future

This trash bin was spotted outside a physician office

When asked, the physician responded, “the hospital wants to give me a better computer but I can’t take it if I already have one....”
Issues That May Affect Laboratories

- Physician office or other recipient’s (nursing home, dialysis facility, etc.) personnel would have to be trained to use two different systems if there is a separate stand alone lab system
- Duplication of data entry or transfer of information between systems will be required if separate systems are allowed to exist
  - Use of donor personnel to facilitate this is prohibited

Issues That May Affect Laboratories

- Once widespread adoption of electronic health technology occurs, hospital based laboratories may have market advantages over separate independent laboratories
- May also affect the way managed care plans contract if physician offices have hospital based electronic record systems that include laboratory test records
- Existing laboratory computer systems do not meet the criteria of these rules but changing them to meet these criteria would mean that all of the criteria would have to be met
QUESTION AND ANSWERS
OR ???