G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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Government Health Care Budgets Include Increased Funding to Fight Fraud

Mandatory funding to fight health care fraud in the administration's 2015 budget proposal is evidence that it remains a top priority among government agencies going forward, and compliance officers should understand that they are a focal point in defending their organizations as a result.

In contrast, the federal budget for 2015 proposes cuts of $7.9 billion for the lab industry over the next 10 years.

These kinds of budget cuts and the resulting belt tightening that will inevitably occur in all laboratories and hospitals create real challenges for laboratory compliance officers in many ways, including the risks associated with increased competition in the marketplace to grow business and increase revenues for the laboratory.

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CMS Ignores Uniform Billing Committee, Creating Compliance Risks for Hospital Labs

In spite of concerns expressed by members of the National Uniform Billing Committee (NUBC) in a Jan. 21 letter to the Centers for Medicare and Medicaid Services (CMS), the agency went forward with its plan to use type of bill (TOB) 14X to identify exceptions to new bundled payments for certain hospital laboratory claims.

Under new payment policies required by the Hospital Outpatient Prospective Payment System (HOPPS) final rule published in the *Federal Register* on Dec. 10, 2013, laboratory services will be bundled for payment under HOPPS with only a few exceptions. Hospitals scrambled to modify billing polices and systems to meet the new requirements. However, according to the NUBC letter, the CMS action related to the use of the TOB 14X for this purpose alters the official definition and purpose of an NUBC data element. Further, CMS did so without specifically requesting comments about the proposed change to the definition of TOB 14X, which is used for reporting "non-patient" laboratory services.

According to the NUBC, CMS cannot use the rulemaking process to arbitrarily change the definition of an NUBC data element. NUBC has a change request process that CMS did not follow. "CMS' failure to

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notify the NUBC of its intention to change our definition is extremely troublesome," stated the letter. The NUBC had to resort to threatening to file a Health Insurance Portability and Accountability Act complaint to get CMS's attention and get the issue corrected.

MLN Matters SE1412

CMS relented and issued an *MLN Matters* notice, SE1412, on March 5, changing the requirement to the use of a new Healthcare Common Procedure Coding System modifier to identify claims that should not be bundled under the new rules effective July 1. This *MM* notice is an important document and should be reviewed by all laboratory compliance officers as a guide for correctly implementing these new requirements and submitting proper claims. Hospitals must now begin working on preparing their billing systems to use the TOB approach and to use the new modifier, further increasing the cost of this change and the compliance risks associated with it.

Noncompliance Is Not an Option

Regardless of the process used to identify claims that should be bundled, the rule was effective Jan. 1 and CMS has made it clear that hospitals are responsible for billing correctly for outpatient lab services. There are limited exceptions to the bundling requirements for outpatient laboratory services. According to the new policy, outpatient laboratory tests, other than molecular pathology, will be bundled and paid to the hospital under the HOPPS payment system. Separate payment billed directly by the laboratory will be allowed in the following circumstances:

- Nonpatient specimens that are specimens received by the hospital and the patient is not present and the hospital does not collect the specimen;
- A hospital collects the specimen and furnishes only the outpatient labs on a given date of service; or
- A hospital conducts outpatient lab tests that are clinically unrelated to other hospital services furnished on the same day, for a different diagnosis and ordered by a different practitioner than the one who ordered the other hospital services.

In all of the above cases, except the first, the patients will still be outpatients of the hospital so the hospital lab will still have to bill them and cannot defer the billing to a reference laboratory in cases where the Medicare reimbursement is lower than the charge by the reference lab. Under the new requirements, the laboratory would bill the specimens in bullets two and three as outpatients on a TOB 13X but would add the new modifier to indicate the claims should not be bundled. Meantime, claims filed with dates of service between Jan. 1 and July 1 that should be separately payable under the exceptions listed above should be billed with a TOB 14X designation.

Lower Reimbursement, Added Cost

While the impact of the bundling rule change is yet to be determined, many laboratory experts believe hospitals and laboratories are going to experience lower reimbursements as a result of the rule change. If that is not enough, hospitals now will also bear the cost of dealing with CMS's interpretation error and the cost and compliance risks associated with having to develop two different processes for claims filed with dates of service between Jan. 1 and July 1 and then change that to use the new modifier for claims with dates of service after July 1.

CMS states that hospitals are not required to seek separate payment for laboratory services and may bill all lab services after Jan. 1 using TOB 13X and receive bundled

payments for all outpatient laboratory services. Further, hospitals are not required to reprocess any previously submitted claims.

Special Provisions for Sole Community Hospitals

Sole community hospitals with qualified laboratories are still eligible for the 62 percent payment under the Clinical Laboratory Fee Schedule (CLFS) for outpatient lab tests separately payable under exceptions 2 and 3 described previously in this article. The differential payment does not apply to nonpatient lab services billed with TOB 14X. These hospitals should carefully review the *MM* section addressing their special needs so they ensure proper claims submittals.

Avoid Compliance Problems

There is no indication that CMS has put any kind of effective system in place to detect improper claims or overpayments. If a hospital makes an error and designates a claim as separately payable when it is not, it is up to the hospital to detect and correct the claim. CMS goes to a lot of trouble to make it clear when a test is separately payable and when it is not, including using case study-type of examples to illustrate when and when not to bill separately. Further, the *MM* comments that "CMS will be reviewing claims data for CY 2014 for potential inappropriate unbundling of laboratory services under the new OPPS packaging policy. As stated in the OPPS final rule, CMS does not expect changes in practice patterns under the new policy. Hospitals may not establish new scheduling patterns in order to provide laboratory services on separate dates of service from other hospital services for the purpose of receiving separate payment under the CLFS."

This warning to providers is clear. Compliance officers should create policies and procedures to ensure compliance with the new requirements and communicate these changes throughout their hospitals to any department that has any responsibility for lab services. It would also be a good idea to audit claims to ensure correct claims submittal is occurring rather than wait for a post-payment audit by a government contractor to find them and result in a refund demand or worse. There are always risks associated with government audits where overpayments are detected. It is always a good idea for a laboratory to self-detect and repay any claims paid in error.

Takeaway: Regardless of government or contractor mistakes or errors, the laboratory is still responsible to make every effort to submit accurate claims for its services. G2

Eleventh-Hour Settlement Avoids Trial for Hospital Fraud Case

Halifax Hospital Medical Center and Halifax Staffing Inc. of Florida agreed to pay $85 million to settle a part of a whistleblower fraud case just before trial was scheduled to begin on March 3, thereby resolving allegations of violations of the False Claims Act by submitting claims to the Medicare program resulting from an allegedly illegal physician self-referral arrangement.

According to the Department of Justice (DOJ), Halifax agreed to a five-year corporate integrity agreement (CIA) with the Health and Human Services Office of Inspector General (OIG) that includes substantial internal compliance reforms including submitting its federal health care claims to an independent review for the period of the CIA. The IG, Daniel R. Levinson, says Halifax is also required to hire a legal reviewer to monitor its contracts and agreements with other providers and a compliance expert to assist the board in fulfilling its oversight obligations. "Both of these independent reviewers will submit regular reports to my agency," Levinson said.

The whistleblower in this case, Elin Baklid-Kunz, will receive $20.8 million of the settlement. The DOJ announcement says that the claims settled under this agreement are allegations only and there has been no determination of liability except as determined by the court in a Nov. 13, 2013, decision.

Halifax Still Not Out of the Woods

A report in the March 10 *Daytona Beach News Journal* says that the government settlement does not include another part of the suit involving allegations of unnecessary hospital admissions which is set for trial in July. That part of the case involves potential damages and penalties in excess of $240 million according to Marlan Wilbanks, an attorney for Baklid-Kunz. The government declined to intervene on those claims. The attorneys are also entitled to ask for fees and costs related to the case. Halifax has consistently denied the allegations brought by the whistleblower.

Takeaway: There are many reasons government prosecutors choose to intervene or not in a whistleblower case, but their absence does not lessen the validity of the case nor determine if it will proceed or not. G2

Ameritox vs. Millennium Laboratories Court Saga Continues

A motion filed by Ameritox Ltd. requesting sanctions against Millennium Laboratories (ML) for allegedly destroying e-mails, among other allegations, was denied in a Feb. 26 order by the U.S. District Court, Middle District of Florida.

In the motion, Ameritox alleges ML effectively destroyed evidence in the ongoing lawsuit by improperly redacting documents and destroying documents. ML denied the allegations. The hearing concerning the destruction of evidence was conducted Feb. 4 and the judge denied the motion in the Feb. 26 written order.

The motion requested the following sanctions: (1) an order finding that liability has been established on all of Ameritox's claims, (2) an adverse inference that the evidence Millennium destroyed would have contained information to prove Ameritox's claims, (3) the appointment of a special master, paid for by Millennium, to review the redacted documents, and (4) attorneys' fees and costs associated with investigating the missing evidence and bringing its motion, as well as any other relief deemed appropriate.

ML responded that Ameritox claims of misconduct are inaccurate and that Ameritox has not met its burden of proof that any sanctions are warranted. ML addresses each of the allegations with counter arguments of its own. The judge essentially agreed with ML, saying in the order that Ameritox failed "to adequately demonstrate that Millennium has wrongly withheld, lost, or destroyed evidence material to this litigation of such import that terminating sanctions or evidentiary presumption(s) are warranted." However, the court ordered ML to produce to Ameritox unredacted copies of e-mails related to certain aspects of the case.

In all, the judge comments that while the claim of alleged evidence destruction is not without some basis, on the whole, it is supported by suspicion and not proof.

The ongoing case, which has generated a large stack of motions and orders, will apparently continue. The latest documents were submitted to the case file on March 19 and the end to this case still seems to be somewhere in the future. G2 will continue to monitor and report on its progress until the final documents are filed and the final resolution is reached.

Takeaway: Stamina and resolve are required in health care lawsuits as many lawsuits continue for several years and involve a plethora of motions, responses, and other documents as part of the case file, all of which must be properly and timely filed. G2

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COMPLIANCE PERSPECTIVES

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Drugs-of-Abuse Testing: Noridian DL34754 Raises Critical Compliance, Legal Issues for Clinical Labs

Testing for drugs of abuse in clinical practice is a balancing act for the laboratory and health care practitioner. Testing too few or too many drugs or testing too frequently or not frequently enough may have significant financial and legal consequences. Choosing between test methods is also a balancing act, and some methods have demonstrable utility in clinical practice while others are better suited to performance by an independent clinical laboratory. The clinical laboratory's ability to achieve balance is related directly to its approach to and understanding of coverage determinations and applicable regulatory material on the need for testing. Failure to consider these issues may significantly impact the laboratory's financial and legal viability and expose it to health care audits and investigation for fraud and abuse, among other potential charges and legal actions.

MAC Attack (or Well-Coordinated Effort to Level the Playing Field?)

Recently released draft local coverage determinations (LCDs) by Medicare administrative contractors (MACs) Noridian Healthcare Services (NHS, formerly Noridian Administrative Services) and Palmetto GBA (J11) signal the federal government's intent to provide more structure to coverage decisions associated with drugs-of-abuse testing.[1] These draft LCDs seem coordinated and foretell additional system edits and provide guidance to audit and investigative personnel on where to look for trouble. Earlier LCDs for drugs-of-abuse testing lacked consistency and were almost devoid of helpful detail on medical necessity; they simply overlooked the importance of drugs-of-abuse testing in chronic pain management and circumvented testing frequency issues in chemical detoxification treatment.

The recent NHS and Palmetto draft LCDs derive from the collective Medicare audit experience, including findings associated with Zone Protection Integrity Contractor audits and recent U.S. Department of Justice prosecutions of clinical laboratories, laboratory management, and health care practitioners. This article is not intended to involve a detailed analysis of DL34754 but contains a discussion of a few important compliance and legal challenges associated with the policy. Readers should consider these issues in light of their laboratory's overall platform for drugs-of-abuse testing and seek clarification from a qualified health care attorney and industry compliance consultants. DL34754 is not part of a MAC attack to rid clinical laboratory from the health care system or to eliminate definitive testing following screening, but the policy does appear to hit the mark as the start of a well-coordinated effort by the MACs to level the playing field in clinical laboratory for drugs-of-abuse testing.

DL34754

NHS is a MAC for jurisdiction E. On Jan. 7, 2014, NHS published DL34754 (titled "Drugs of Abuse Testing"). DL34754 contains significant new coverage guidance, and NHS recently extended the comment period for DL34754 from March 14, 2014, to May 2, 2014.

1. NHS DL34754 and Palmetto GBA DL34398.

DL34754 recognizes that drug testing is a clinical tool allowing practitioners to evaluate and monitor patient risk potentials for (1) overdose, drug-drug interaction, and toxicity in the emergency setting; (2) abstinence, new problems, and relapse in the substance abuse treatment setting; (3) developing drug abuse or misuse problems in the chronic opioid therapy setting; and (4) adherence to treatment plans involving the use of controlled medication. DL34754 fairly recognizes there is significant financial cost to the health care system when testing is not performed correctly or at all.

DL34754 is intended to minimize overpayments to those who order medically unnecessary drug testing. DL34754 covers drugs-of-abuse testing for Medicare patients; it does not cover neonatal testing for suspected prenatal drug exposure. Unlike past LCDs, DL34754 provides a detailed "overview of distinctions between qualitative, confirmation and quantitative drugs of abuse testing, and clearly indicates that coverage is dependent on proper documentation of clinical decision-making and test orders that are tailored to the individual patient's medical needs."

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DL34754 makes it very clear that drug testing is useful in the clinical setting (at the point of care) *because it may provide objective information to assist the provider in diagnosing and making treatment decisions*. DL34754 lists coverage indications for qualitative drug screening in the clinical setting and for quantitative and confirmation testing when used to definitively answer questions directly relevant to the individual patient's care situation. Wholesale retesting of qualitative screening results will not be covered and examples are provided.

DL34754 establishes basic parameters for test methods, test panels, and specimen type. NHS believes drugs-of-abuse testing "should only be ordered and performed on a patient/drug specific basis, within the parameters outlined in [DL34754] and documented in the patient record." This is not a new requirement. Earlier LCDs and the Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories both contain directives for individualized laboratory testing.[2] Clinical correlation between the individual patient record and the nature and the frequency of the testing ordered is a must for coverage. *The connection between the test order and clinical decisionmaking following test results must be reasonable and medically necessary to the ongoing care of the patient*.

Drug Test Panels

"No single drug panel is suitable for all clinical uses, and test options should be adapted to clinical needs through proper exercise of clinical decision-making."[3] Laboratory personnel should eliminate opportunities for health care practitioners to routinely order comprehensive drug panels without regard to the individual patient or clinical utility. For example, the routine testing of PCP, Ecstasy (MDMA, MDA, etc.), and barbiturates may present a coverage problem under DL34754. Of course, this does not mean that one should never test for these drugs, but the example offers insight into NHS's position. Test menus should consider the "demographics of drugs abused in a particular geographic area." Test forms should allow health care practitioners to identify the patient's current prescribed medication, document the results of any qualitative screening, and provide a fairly obvious connection between the drugs prescribed, the drugs to be tested, the test results, and the ongoing treatment plan. Test utilization monitoring is very important, and DL34754 is a natural extension and modernization of the OIG's guidance encouraging clinical laboratories to educate physicians about proper test ordering.

2. See First Coast Service Option's MAC-Part B LCD 30574 (2009 and 2010), available online through the CMS Medicare Coverage Database. See also the OIG Compliance Program Guidance for Clinical Laboratories, available online at *http://oig.hhs.gov/authorities/docs/cpglab.pdf*.
3. DL34754.

Laboratories must market drug test assays based on demonstrable clinical utility rather than reimbursement value. It is not reasonable to expect that any health plan cover and reimburse custom panel testing just because the drugs might potentially be abused or because broad test panels offer maximum legal protection to the health care practitioner against claims of inappropriate prescribing. Reasonable compliance efforts may offer some protection against a claim of specific intent to defraud a payer and may be useful in other forms of negotiation with payers. DL34754 is clear: Medicare intends to exclude "routine use" of test panels and may deny claims for reimbursement when documentation does not tie the drugs tested to the Medicare beneficiary's medical situation.

Specimen Type

DL34754 states urine is the preferred specimen and may be the "best source for broad qualitative drugs of abuse testing because blood is relatively insensitive for common drugs such as psychotropic agents, opioids, and stimulants." DL34754 also acknowledges potential "clinical value in the limited use of other specimen types, such as saliva and serum, so long as clinical rationale therefore is clearly stated." Stakeholders should work together to understand when urine is an appropriate specimen for drugs-of-abuse testing and when other specimen types may produce test results with higher clinical utility. Presently, there is no way to differentiate urine from other specimen types in claims (the Current Procedural Terminology allows for any specimen except breath or as otherwise indicated in the code descriptor). Thus, payers may seek documentation to ensure a valid claim.

DL34754 is clear: Medicare intends to exclude "routine use" of test panels and may deny claims for reimbursement when documentation does not tie the drugs tested to the Medicare beneficiary's medical situation.

DL34754 preserves the long-standing Medicare decision to exclude from coverage "the testing of two different specimen types from the same patient on the same date of service." More than payment is at stake for violations of these coverage limitations, and attempts to circumvent specimen type boundaries to increase test orders may be viewed as fraud. Clinical laboratories should explore this area carefully with legal counsel.

Specimen Validity Testing

DL34754 excludes specimen validity testing (SVT) from coverage because Medicare views it as a quality control measure. This is a matter of heated debate in the clinical laboratory community. Palmetto GBA's DL34398 contains the same exclusion. NHS believes various aspects of specimen validity can be determined at the point of care and should not be left to the independent laboratory as part of confirmation or other definitive testing. This can be understood when a urine sample lacks a normal temperature just after collection or is off-color, suggesting possible adulteration or dilution. SVT is probably *not* an issue for other specimen types, such as saliva and serum, because the health care provider in effect performs an observed collection. Urine specimen collection, however, may not be observed, allowing patients the opportunity to adulterate, substitute, or tamper with their urine sample.

Clinical laboratories argue that SVT is more than a quality control measure for urine drug testing. Clinical laboratories are in the best position to offer comments on SVT to NHS and should support submissions with validated clinical studies. Clinical laboratories would do well to recognize that NHS appears to believe that SVT is a quality control measure used to determine *whether* a urine specimen should be tested. In other words, if a specimen is not valid, it should not be tested, and test results based on invalid samples should not be billed because they are not medically necessary. Why not simply report to the provider that the specimen was "invalid" and not tested?

Homework

Clinical laboratories must be familiar with coverage decisions that impact the jurisdictions within which they operate. Clinical laboratories should also review state

professional licensing board guidelines and rules governing health care practitioners who operate in the substance abuse treatment and pain management communities,[4] and use these materials to support provider education on the frequency and nature of drugs-of-abuse testing in these patient populations.

Clinical laboratories should attempt to reconcile any differences between testing frequencies and specific test panel requirements using coverage decisions and state regulatory materials. The reconciliation process should examine the potential for legal liability for both over- and underutilization of clinical laboratory services. Clinical laboratories may also want to:

1. Identify professional organization and society materials, such as consensus documents, guidelines, and position statements, about the role of drugs-of-abuse testing in clinical settings.
2. Review the OIG Compliance Program Guidance for Clinical Laboratories.
3. Review testing policies and protocols with laboratory and medical provider staff. This step can help minimize the potential for whistleblower efforts and misunderstandings about the need for and scope of drugs-of-abuse testing. Review periodically to ensure any compliance program remains current with the changing clinical and regulatory landscape.
4. Engage payer representatives, state licensing board officials, and law enforcement representatives in dialogue about the resources supporting their published position.
5. Keep a due diligence file that supports all of the laboratory's compliance efforts to submit only medically necessary and reasonable claims for reimbursement.

Summary

While imperfect, DL34754 represents progress in the battle for balance in drugs-of-abuse testing.

Balance is achieved when drugs-of-abuse testing is targeted to the individual patient and test results are well-documented and properly used in the clinical setting to support ongoing treatment decisions, such as the continued use of opioids for pain management. Balance also means an awareness of which test methods are acceptable for the clinical setting. Some test methods enable the health care provider to make basic and timely treatment decisions, such as whether to provide the patient with a controlled substance prescription at that visit or whether to refer the patient to a facility for detoxification. Other test methods are more appropriate for the independent clinical laboratory setting because they require more sophistication in instrumentation or testing processes. DL34754 makes these points. Achieving balance here is no easy task, but it is part of creating a sustainable path forward.

Clinical laboratories should seek the input of qualified health law counsel and compliance consultants to address concerns with DL34754. Expect more LCDs and related billing and coding articles this year on drugs-of-abuse testing. Stay current. Clinical laboratories will benefit from new coverage policies, as they will help level the playing field for all stakeholders and, most importantly, the patients who need clinical laboratory services as part of a quality health care package.

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4. Several states, including Georgia, Kentucky, and Tennessee, have pain clinic registration acts accompanied by requirements for drug testing policies and testing frequencies. Some state professional licensing boards have recently broadened practice guidelines and rules for substance abuse treatment (office-based treatment of opioid addiction) and chronic pain management to include specific directives regarding the use of drug testing in clinical practice.

Government Health Care Budgets Include Increased Funding to Fight Fraud, *from page 1*

The laboratory market is not likely to expand through the addition of new physicians and hospitals, so the primary way to grow the business is by taking business away from other laboratories. These kinds of activities generate big compliance risks and can lead to sales and marketing departments taking compliance risks they may not usually take. In other areas, such as billing and coding of services, it can be tempting to increase revenue by taking risks through upcoding or creative applications of billing and coding that may normally be considered too risky for an organization.

Areas of Government Focus

Understanding where the government will focus its compliance efforts informs the compliance officer where they should focus their compliance efforts. Reducing improper payments is a top priority for government agencies, and new initiatives based on data mining techniques and predictive modeling through innovative computer technology are the vehicles the government believes will get the results they need to generate savings for the Medicare and Medicaid programs.

According to budget documents, investments in program integrity efforts will yield $13.5 billion in gross savings. The government proposes to increase funding for the Health Care Fraud and Abuse Control (HCFAC) and Medicaid Integrity programs by $438 million. The budget proposal says that all new HCFAC funding be mandatory starting in 2016 in addition to the base discretionary funding. Fraud prevention through the Fraud Prevention System, which focuses on reducing improper payment by preventing them from being made in the first place, will also be a priority.

New funding for the Health and Human Services Office of Inspector General will be used to support the activities of the Health Care Fraud Prevention and Enforcement Action Team among other initiatives. The budget also proposes $100 million for the Office of Medicare Hearings and Appeals, an increase of $18 million over 2014, in an attempt to address the critical backlog of appeals cases. Part of the money is intended to ensure the quality and accuracy of decisions in appeals cases, which often set precedents for future claims filing decisions and can influence new regulations or shed light on other kinds of fraud.

Another area of focus is the Medicaid program. CMS supports state fraud prevention efforts through providing technical assistance with reviews and audits, identification of overpayments, educational activities, and timely access to claims data and encounter information.

Laboratory Compliance Officers Must Respond

Identifying risks for their laboratories and devising cost-effective ways to address those risks and prevent improper payments is where laboratory compliance officers earn their compensation. During times of fiscal restraint it is more important than ever for compliance officers to find ways to accomplish their tasks with the resources at hand.

One of the more critical areas for compliance effectiveness is the ability of the compliance officer to maintain current knowledge of laws and regulations and government areas of focus for their segment of the industry. It is important that limited resources are directed at the correct risk areas and time and resources are not spent on lower-risk areas that are not likely to be an issue. Consider the impact of overlooking or missing a compliance issue that results in the laboratory having to spend resources investigating and then refunding potential overpayments in the thousands or millions of dollars.

Effective Auditing, Monitoring Program Is Best Defense

Effective auditing and monitoring is the best way to identify areas that pose the greatest risk to the laboratory and to prevent potential compliance disasters. Finding

the time and resources to operate an effective auditing program is the challenge for the compliance officer. The only way to really be effective is to tear a page out of the government's book and employ innovative technology and computer skills to the auditing and monitoring program. It may be time to add an information technology expert to the compliance team to facilitate the review and auditing processes. Compliance officers can increase their auditing effectiveness many fold through the effective use of technology and data mining techniques.

Educating the Executives

The phrase "compliance responsibility and commitment must start at the upper most levels of management if the compliance program is going to be truly effective" cannot be repeated enough. Compliance officers must make certain that those responsible for the laboratory understand their role in making the compliance program effective. That role includes demonstrating their commitment to compliance and providing a role model for all employees to follow. They cannot be effective role models unless they are educated in compliance. Seeing to their education and constant awareness of the importance of compliance is one of the compliance officers' most important tasks. Included in that task is a responsibility compliance officers must impose on themselves to be real compliance experts that the management team can rely on to be good stewards of the resources given to operate the program.

Compliance Must Support Vision, Goals of Lab

Compliance officers must support the overall goals and vision of the laboratory by finding ways to make certain that the goals can be accomplished without violating laws, regulations, or company policy and without compromising ethics. This requires the compliance officer to always think in terms of what can be done and how it can be done as opposed to what cannot be done.

Takeaway: In times of fiscal restrictions and budget issues, compliance officers must find ways to accomplish their tasks and responsibilities of protecting the laboratory from compliance disasters while operating within the budget restraints imposed on the laboratory by outside forces. G2

OIG Joins Medicaid Whistleblower Kickback Lawsuit Involving Tenet Healthcare

A program that directed pregnant illegal immigrants to hospitals owned by Tenet Healthcare Corp. and Health Management Associates (HMA) for delivery services in exchange for kickbacks paid to obstetrics clinics primarily serving undocumented Hispanic women is the subject of a whistleblower lawsuit filed in the middle district of Georgia.

The lawsuit alleges that four hospitals owned by Tenet in Georgia and South Carolina and one HMA hospital in Monroe, Ga., owned by HMA paid kickbacks to the clinics, known as Hispanic Medical Management (HMM) d/b/a Clinica de la Mama, disguised as payment for services provided by the clinics, like translation and other services. The scheme allegedly dates back to March 2000 and involved millions of dollars in improper claims. This article is compiled from a variety of sources reporting on the case as well a Feb. 19 Department of Justice announcement and a Securities and Exchange Commission (SEC) submittal made by Tenet in 2013. Clinica de la Mama is also named in the lawsuit.

Medicaid covers emergency medical assistance services, which includes childbirth services to undocumented aliens; the baby is then eligible for newborn Medicaid

coverage. Atlanta attorney Marlan Wilbanks, who represents the whistleblower in this case, said that while Medicaid is not famous for being a generous payer, delivering babies is one exception if the volume is high enough.

The hospitals involved are Tenet hospitals Atlanta Medical Center, North Fulton Regional Hospital, Spalding Regional Hospital, and Hilton Head Hospital in South Carolina, and one HMA facility, Walton Regional Medical Center (since renamed Clearview Regional Medical Center), in Monroe, Ga.

The whistleblower, Ralph Williams, was the chief financial officer at the HMA hospital from April to October 2009. In the course of his duties he discovered a contract with Clinica de la Mama for translation services but could not find evidence that any services were provided. After further investigation, Williams was told by the hospital CEO that the contract was really for referral of pregnant patients, according to statements made by Williams to a local TV news station.

SEC Filing Notes the Pending Lawsuit

Tenet reported the government investigation concerning HMM in its 2013 Form 10-K SEC submission. In the form, Tenet indicates that a May 12 subpoena from the Office of Inspector General requested documents from January 2004 through May 2012 related to its relationship with HMM. The documents say that Tenet has contracts with HMM for translation, marketing, management, and Medicaid eligibility services. Tenet says it submitted a motion to dismiss on Nov. 8, 2013, that is still pending.

The document goes on to say that the potential outcome of the lawsuit, which alleges violations of the anti-kickback statute, could include reimbursing related government program payments received during the subject period, assessing civil monetary penalties including treble damages, excluding individuals or subsidiaries from participation in federal health care programs, or seeking criminal sanctions against current or former employees of the hospital subsidiary companies or the hospital companies themselves.

Tenet has not admitted to any illegal acts and no liability has been attached to the allegations discussed in this article.

This case could turn out to be significant, rivaling some of the cases against pharmaceutical companies. It is unique in the fact that the federal government has intervened in a Medicaid qui tam action, which is rare. It also demonstrates that a potentially improper activity in a health care entity that has, arguably, an effective compliance program can continue for an extensive period before someone within the organization asks about it. Finally, Tenet emerged from a five-year corporate integrity agreement in September 2011.

Takeaway: Whistleblowers are the government's best source to find problems within an organization that are not obvious by reviewing claims or by other traditional means to detect compliance problems.

Compliance Corner

How often should a laboratory conduct compliance audits of its billing and coding?

The answer depends on many factors and will vary from provider to provider. The frequency of audits and reviews of billing and coding is a function of risk, size of the laboratory and complexity of its service offering, complexity of its client portfolio, how often critical changes occur in the laboratory's billing and coding procedures, and the resources available to the compliance officer to conduct the audits and analyze the data. Audits of all facets of a laboratory claim submittal and the associated policies and procedures should be done at least annually. If the laboratory is very large, the audits may have to be split up and performed piecemeal over the course of a year in order to make sure every area is audited at least annually. High-risk or problematic areas may need more frequent audits to ensure accurate claims submittals are occurring.

News-At-A-Glance

ANOTHER PHYSICIAN ADMITS ACCEPTING BRIBES FROM BLS: Biodiagnostic Laboratory Services (BLS) paid $1,800 a month to 60-year-old Dr. Charles Goldberg in exchange for referrals of lab tests as part of a sham lease agreement at his Montclair, N.J., medical practice, according to a Feb. 26 Department of Justice (DOJ) announcement. So far, 23 people, including 12 physicians, have admitted to participating in the bribery scheme organized by BLS. According to the DOJ, the scheme resulted in more than $100 million in payments to BLS from government and private payers. Goldberg faces a potential $250,000 fine and a maximum five years in prison when he is sentenced on a date yet to be determined, in addition to $58,000 already forfeited representing the amount of the bribes he received.

NORIDIAN REDETERMINATION REQUEST UPDATE: In a notice posted on March 5, Noridian Healthcare Solutions reminds providers requesting redeterminations about submission of documentation. The update reminds providers that the requests must be in writing, either in a letter or on the Centers for Medicare and Medicaid Services (CMS) Form 20027, and include what the appeal concerns and the reason providers are appealing. Redetermination requests must include the beneficiary name, Medicare claim number, the specific services and dates for which the redetermination is being requested, and the name and signature of the requesting party at a minimum. Providers should send only one form or letter per denial. Documentation to support the request must be included or attached, meaning that all applicable documentation related to the claim or line item being appealed. If the request involves an Advance Beneficiary Notice, include the signed notice. The update also includes a list of resources available to providers to assist with the process. CMS has previously reported extremely long delays of appeals at the administrative law judge level of the appeals process, so it is to a provider's advantage to try to resolve problems at the redetermination level of the process. Even though the notice is published by Noridian, understanding how to facilitate the redetermination process by submitting all necessary documentation should help any provider regardless of the Medicare Administrative Contractor involved.

LATEST CCI EDITS UPDATE: The Centers for Medicare and Medicaid Services (CMS) updates the Correct Coding Initiative (CCI) edit files every quarter during the year. The latest batch of CCI edits was announced in a Feb. 28 transmittal (R2892CP, change request 8558) with an effective date of July 1 and an implementation date of July 7. This is version 20.2 and, as usual, will include all previous versions and updates since Jan. 1, 1996. In the case of an error in the CCI files that causes improper denials, providers will have to bring them to the attention of their Medicare contractors, who are instructed not to make corrections on their own. Providers can obtain more information about the edits on the CMS Web site at *http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index*.html. The Web site includes a link to the CCI coding policy manual published annually and a link to the Medically Unlikely Edits (MUE) files. The MUE file is also updated quarterly. Unfortunately, the specific changes to the edit files are not yet available, but providers should monitor the Web site and their contractor's Web site for the specific information so they can update their billing system edits to avoid unnecessary claims denials.

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