G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Pittsburgh Hospital Reviewing Pap Tests After Lawsuit

The Washington Hospital in Pittsburgh is reviewing at least 500 Pap smear slides analyzed in its laboratory following a lawsuit in which a woman alleged a pathologist misread her tests for five years before she was diagnosed with cervical cancer, according to a report by the *Pittsburgh Post-Gazette*.

In an e-mail to the newspaper, the hospital said it is taking the allegations seriously and is working to identify any patient safety concerns. "The hospital is also cooperating with independent agencies to evaluate the quality of pathology services, and preliminary results have not identified any widespread deficiencies in Pap smear interpretation. In the event that patient safety concerns are identified or verified, the hospital is prepared to follow up with individual patients and their physicians."

According to the newspaper report, groups investigating the allegations are the Pennsylvania Department of State, the Centers for Medicare and Medicaid Services, the Joint Commission, and the College of American Pathologists.

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Strategies for Assessing the Effectiveness Of Your Lab Compliance Program

Despite ongoing reports of clinical laboratories that have had enforcement actions brought against them as a result of a weak or faulty compliance program, many labs fail to routinely measure the effectiveness of the program they have in place.

The Health and Human Services Office of Inspector General (OIG) published a model compliance plan for the clinical laboratory industry on March 3, 1997, and updated the guidance on Aug. 24, 1998 (*https://oig.hhs.gov/authorities/docs/cpglab.pdf*). The model plan was intended to provide clear guidance to the lab industry on how to reduce the potential for fraud and abuse within their organizations.

The OIG identified seven critical elements of an effective compliance program (*see box on page 10*). This guidance has served as the basis for the majority of lab compliance programs, but over time, plans can lose their effectiveness if they are not measured, monitored, assessed, and adjusted as needed.

The keys to assessing compliance program effectiveness fall in three main areas—training and education, communication, and internal

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Pittsburgh Hospital Reviewing Pap Tests After Lawsuit, *from page 1*

The reviews were initiated after Jennifer Beiswenger, 30, of Canonsburg, Pa., filed a medical malpractice lawsuit Oct. 1 against the hospital, the hospital's pathology lab, and eight doctors, including her obstetrics and gynecological doctors, and Richard Pataki, the lab's medical director. Beiswenger was diagnosed with cervical cancer in May 2011, two months after giving birth. She responded well to treatment and was free of cancer by November 2011. She currently remains cancer free.

Beiswenger's attorney, Deborah Maliver, sent letters to various government and accrediting organizations letting them know what had happened. "It can't be random that her tests were misread for five straight years," said Maliver, a former physician now practicing law. "There's a potential for a health risk here."

According to the *Pittsburgh Post-Gazette*, the hospital reportedly has turned over 500 slides—a sampling of the thousands it reviews—from other women from the past five years to the pathology laboratory at Magee-Women's Hospital of University of Pittsburgh Medical Center for an outside review.

The hospital asked for review of its Pap smear slides because Beiswenger charged in her lawsuit that for at least five years, 2006 to 2010, Pataki misread her slides. According to the lawsuit, Pataki found the tests were normal while multiple pathology experts hired by Maliver concluded that the five years of tests showed a clear progression from precancerous cells to an invasive carcinoma.

According to the lawsuit, Pataki and his colleagues reviewed her slides on May 26, 2011, after learning that she had been diagnosed with cervical cancer and concluded that there were a number of multiple atypical glandular cells of undetermined significance. Such a finding "should have been a red flag for a biopsy or other additional testing," Mailver said. However, during that time Beiswenger never had additional testing that would have confirmed cervical cancer.

In 2006, Beiswenger was also tested for human papillomavirus, or HPV, which came back positive. That same year Pataki found her Pap smear showed "atypical squamous cells of uncertain significance." Those findings should have resulted in additional testing by her obstetrics and gynecological doctors when they were given the results, the lawsuit charges.

Millennium Laboratories Investigated by Grand Jury

A federal grand jury in Boston is investigating Millennium Laboratories of San Diego over allegations of health care fraud and intimidation of former employees.

According to a report by Reuters, five grand jury subpoenas seeking records on Millennium were reviewed by the news organization. Four witnesses who testified before the grand jury told Reuters they testified that Millennium was getting doctors to order unnecessary urine tests and charging excessive fees to Medicare and private insurers. Millennium has denied those accusations in lawsuits.

According to witnesses, the company's general counsel Martin Price showed a former employee in a body bag as part of a PowerPoint presentation during a national sales meeting in January during which Price described Millennium's success against its adversaries. One grand jury witness, former Millennium employee Jodie Strain, said grand jurors gasped when the body-bag image was projected onto a wall during her testimony Oct. 3. She said the toe tag identified the corpse as Ed Zicari, a former regional manager Millennium was suing. Zicari and Strain are currently pursuing suits against Millennium for wrongful termination and other claims.

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Howard Appel, Millennium's president, told Reuters that the company is cooperating fully with investigators and that it has done nothing wrong. Appel described Zicari and Strain as disgruntled former employees who were fired for cause, not for questioning company practices.

According to the Reuters report, grand jury witness said most of their testimony focused on the company's sales practices, which included aggressive pitches to pain clinics to order varieties of urine tests even when they were not needed, at up to $1,600 per test. Urine tests can show doctors whether their patients are taking extra pain drugs and whether they are taking their prescribed drugs.

The federal investigation is being led by Susan Winkler, former chief of the health care fraud unit for the U.S. attorney in Boston. Winkler reportedly signed the Millennium subpoenas and questioned the witnesses before the grand jury.

The urine drug testing industry has taken off as the number of pain drug prescriptions in the United States grew from 30 million to 180 million a year over the last two decades, raising demand for monitoring, Appel said. The burgeoning industry has spawned two previously disclosed prosecutions and scores of suits and countersuits by companies accusing each other of wrongdoing, Reuters noted.

In March, Calloway Laboratories of Woburn, Mass., paid $20 million to settle a Massachusetts state Medicaid case accusing it of paying kickbacks for unnecessary screening. Three Calloway officials were sentenced to four years' probation. And in 2010, Ameritox, based in Baltimore, paid $16.3 million to settle similar claims.

Lab Assistant Reaches Settlement With Quest Over Ban on Speaking Vietnamese

An Orange County, Calif., lab assistant who claimed that his boss banned him from speaking Vietnamese anytime on the job—even on breaks—has agreed to settle his employment discrimination lawsuit prior to a scheduled 2013 trial, according to *ocweekly.com*.

Hung Trinh filed a lawsuit against Quest Diagnostics in April, claiming he suffered "constant harassment" because of his Asian race by supervisor Estela Comba.

"Plaintiff believes that Ms. Comba had a problem with Vietnamese employees and specifically with him," the lawsuit stated. "Ms. Comba would prohibit him and the other six Vietnamese employees to speak Vietnamese even when they were not on company time. Ms. Comba even prohibited the seven Vietnamese employees from speaking their language at potluck parties."

According to the lawsuit, Trinh's complaints to the company's human resources department resulted in an even "higher level of hostility" that culminated in him being fired for an unexcused work absence on Nov. 1, 2011, even though he had actually worked a shift that day.

"[The company's] conduct amounts to an intolerable and discriminatory working condition, amounting to wrongful discharge," wrote Trinh lawyers Rex Sofonio and Maribe Ullrich, according to *ocweekly.com*.

In court documents, Quest Diagnostics officials denied any wrongdoing but on Nov. 20 filed a post-mediation, joint stipulation with Trinh to dismiss the matter before a jury could hear the case. Terms of the settlement were not disclosed.

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Lab Worker Claims Employer Violated Wage Laws

An employee of Med Fusion (Lewisville, Texas) filed a lawsuit against the company Nov. 7 in the Eastern District of Texas, Sherman Division, claiming he was fired for complaining about the company violating federal wage laws.

According a report in the *Southeast Texas Legal Journal*, Bradley Pruden was hired by Med Fusion for the position of field service specialist in March. Pruden claims that Med Fusion reduced his paycheck in June without prior notification. Pruden spoke to the human resources department and sent a written notice that he believed the defendant's action was contrary to law.

Pruden was successful at obtaining his missing wages. However, he stated that Med Fusion began to systematically retaliate against him for reporting his good-faith belief of being incorrectly paid under the Fair Labor Standards Act. Med Fusion is also accused of withholding a commission check from Pruden and creating a hostile work environment. Pruden was terminated on June 21, 2012, allegedly for his performance.

The lawsuit claims that Med Fusion violated the Fair Labor Standards Act, deliberately retaliated against Pruden, and wrongfully discharged him. Pruden is seeking an award of damages for mental anguish, emotional distress, lost wages, employee benefits, loss of wages capacity, attorneys' fees, exemplary damages, interest, and court costs.

Aetna Agrees to Settlement Over Out-of-Network Payments

Aetna Inc. will pay up to $120 million to resolve multiple class actions by subscribers, providers, and state medical associations claiming the insurer improperly used flawed third-party databases to systematically and uniformly underpay out-of-network providers, under a proposed settlement filed in a federal court in New Jersey Dec. 7.

The proposed nationwide class action settlement filed in U.S. District Court for the District of New Jersey calls for Aetna to pay a guaranteed amount of $60 million into a general settlement fund and up to $60 million into a separate fund to be used to pay providers and subscribers who can document that the insurer underpaid specific claims for services and supplies.

The accord would resolve a number of class actions dating as far back as 2007 that were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation in 2009.

The complaints challenged Aetna's use of a database produced by Ingenix, a subsidiary of UnitedHealth Group Inc., to determine "usual and customary charges'' for medical services rendered by out-of-network providers.

The plaintiffs claimed Ingenix and Aetna intentionally manipulated data submitted to the Ingenix database to reduce reimbursements for out-of-network services, short-changing providers and forcing patients to pay an excessive portion of the cost of their medical care. The lawsuits also challenged other methods Aetna used to calculate out-of-network reimbursements and the insurer's alleged failure to disclose those methods.

The agreement defines two proposed settlement classes. The provider class includes anyone who was an out-of-network provider or out-of-network provider group at any time since June 3, 2003, and whose services to Aetna plan members were paid at less than the billed amount. The subscriber settlement class comprises individuals who were Aetna plan members at any time since March 1, 2001, whose claims for reimbursement for services from an out-of-network provider were paid at less than the amount billed by the provider.

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COMPLIANCE PERSPECTIVES

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Preparing for 2013: Molecular Pathology Codes Represent Dominant Path and Lab CPT Changes

The budgetary and policy climate will greatly impact laboratories in 2013. With the increased growth shift toward the adoption of accountable care organizations (ACOs), as well as bundled reimbursement strategies under this model, it is essential that labs understand correct coding and potential payment changes.

While the molecular coding issue has been addressed, pricing for codes is far from finalized. The Centers for Medicare and Medicaid Services (CMS) announced in its calendar year 2013 physician fee schedule (PFS) final ruling that it will place the new molecular pathology codes under the clinical laboratory fee schedule (CLFS). Part of this determination stemmed from the fact that approximately 80 percent of most molecular tests were interpreted by nonphysicians in 2010.[1] As the PFS payments are ordinarily for services requiring a physician to perform, and as the CLFS is in existence as an alternative fee schedule, it was chosen for the molecular tests fee schedule.

CMS will not publish the national payment amounts for these codes as reimbursement for CY2013 will be set by the gap-filling method. This isn't a well-used methodology as compared to "crosswalking" and has a history of issues among contractors, with a particular example of note involving HbA1c testing. With more than 100 molecular tests to be gap-filled, labs can expect a wide range in pricing. The payments for these codes will be published at a later date as Medicare contractors (MACs, carriers) complete the gap-filling methodology.

It is estimated the CLFS will be reduced by 4.95 percent. Should the sequestering issue be resolved before year-end, which represents 2 percent of this total, then the CLFS will only be reduced by 2.95 percent. Keep in mind that Part B lab spending represented only 1.6 percent of the total Medicare spending in 2011.

With one of the largest single additions to the CPT code set in 2012, the American Medical Association (AMA) continues in 2013 by adding additional codes in the Molecular Pathology section of the code book. In conjunction with the move to the new coding system for molecular pathology, the AMA deleted all of the "stacking codes" (83890-83914) for 2013. Expect to see increased editing by payers for the new codes. With this transition from stack codes to single codes, it makes possible tighter editing within their systems for diagnosis coverage decisions.

In addition, the array-based evaluation codes (88384-88386) have also been deleted. The molecular pathology Tier 1 and Tier 2 codes will be used exclusively for molecular diagnostic coding in 2013. Thirteen new codes have been added to Tier 1 and the base descriptor of the 81400-81408 code series (Tier 2 codes) has been revised to include 183 new analytes in this section, plus one additional code for unlisted molecular pathology procedures.

The AMA added a new subsection and heading, Multianalyte Assays with Algorithmic Analyses (MAAAs) in the category 1 introductory guidelines. These procedures utilize multiple results derived from assays of various types (including molecular pathology,

1. *American Medical Association*

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fluorescent in situ hybridization, and non-nucleic acid-based assays). In concert with the addition of this new subsection, the CPT code set also contains a new administrative code list (Appendix O). However, at least for 2013, CMS will not recognize these codes for payment purposes, but CMS did state in the CY2013 PFS final ruling that it would accept comments and revisit these codes for 2014.

New definitions for inversion, loss of heterozygosity, and uniparental disomy have been added to the introduction of the Molecular Pathology section. In addition to the molecular pathology changes, additional code changes in the Pathology and Laboratory section occurred: 10 codes have been revised and 18 additional codes have been added to the Immunology, Tissue Typing, Microbiology, and Chemistry sections.

With the deletion of the 83912-26 code by the AMA for CY2013, CMS introduced a new G-code to replace 83912-26. G0452-26 will be used by pathologists when an interpretation of a molecular pathology test is performed. **Importantly, however, nonphysician practitioners (e.g., Ph.D. scientists etc.) are not eligible to report this code for Medicare services; only physicians may bill this code**. G0452 must be billed with modifier 26 since it was placed in a category of code that CMS considers interpretation services of clinical laboratory tests.

CMS designated the G0452 code as an interim code and stated that it will be monitoring the use of the code, likely for accuracy and volume. Since CMS only allowed one unit of service per Medicare beneficiary per date of service for the 83912-26 code regardless of the number of molecular tests interpreted in that patient case, the G0452 code will likely follow that requirement as well. Right now it is uncertain how the commercial payers will address this interpretation code, but most expect they will likely accept the G0452-26 code as a replacement for 83912-26.

The following is a list of the new, deleted, and revised codes for 2013 in the Pathology and Laboratory Medicine section.

MOLECULAR BIOLOGY	
NEW CODES	**CODE DESCRIPTION**
G0452	Molecular pathology procedure; physician interpretation and report
81201	Gene analysis (adenomatous polyposis coli), full gene sequence
81202	Gene analysis (adenomatous polyposis coli), known familial variants
81203	Gene analysis (adenomatous polyposis coli), duplication/deletion variants
81235	Gene analysis (epidermal growth factor receptor), common variants
81252	Gene analysis (gap junction protein, beta 2, 26kDa; connexin 26), full gene sequence
81253	Gene analysis (gap junction protein, beta 2, 26kDa; connexin 26), known familial variants
81254	Gene analysis (gap junction protein, beta 6, 30kDa, connexin 30), common variants
81321	Gene analysis (phosphatase and tensin homolog), full sequence analysis
81322	Gene analysis (phosphatase and tensin homolog), known familial variant
81323	Gene analysis (phosphatase and tensin homolog), duplication/deletion variant
81324	Gene analysis (peripheral myelin protein 22), duplication/deletion analysis
81325	Gene analysis (peripheral myelin protein 22), full sequence analysis
81326	Gene analysis (peripheral myelin protein 22), known familial variant
81479	Unlisted molecular pathology procedure

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CHEMISTRY	
NEW CODES	**CODE DESCRIPTION**
82777	Galectin-3 level
IMMUNOLOGY	
NEW CODES	**CODE DESCRIPTION**
86152	Cell enumeration using immunologic selection and identification in fluid specimen
86153	Cell enumeration using immunologic selection and identification in fluid specimen; physician interpretation and report, when required
86711	Analysis for antibody to John Cunningham virus
TISSUE TYPING	
NEW CODES	**CODE DESCRIPTION**
86828	Assessment of antibody to human leukocyte antigens (HLA) for the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens
86829	Assessment of antibody to human leukocyte antigens (HLA) for the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens
86830	Assessment of antibody to human leukocyte antigens (HLA) with antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I
86831	Assessment of antibody to human leukocyte antigens (HLA) with antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II
86832	Assessment of antibody to human leukocyte antigens (HLA) with high definition qualitative panel for identification of antibody specificities, HLA Class I
86833	Assessment of antibody to human leukocyte antigens (HLA) with high definition qualitative panel for identification of antibody specificities, HLA Class II
86834	Assessment of antibody to human leukocyte antigens (HLA), HLA Class I
86835	Assessment of antibody to human leukocyte antigens (HLA) with solid phase assays, HLA Class II
MICROBIOLOGY	
NEW CODES	**CODE DESCRIPTION**
87631	Detection test for respiratory virus, multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets
87632	Detection test for respiratory virus, multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 6-11 targets
87633	Detection test for respiratory virus, multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets
87910	Analysis test for cytomegalovirus
87912	Analysis test for hepatitis B virus
SURGICAL PATHOLOGY	
NEW CODES	**CODE DESCRIPTION**
88375	Microscopic imaging using an endoscope, interpretation and report, real-time or referred
MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA)	
NEW CODES	**CODE DESCRIPTION**
81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score

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MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA)	
NEW CODES	**CODE DESCRIPTION**
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score
81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adoponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reported as a risk score
81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score
81599	Unlisted multianalyte assay procedure with algorithmic analysis
REVISED CODE DESCRIPTORS (Items underlined represent revised verbiage, strikethrough represents deleted verbiage)	
REVISED CODES	**CODE DESCRIPTION**
82009	~~Acetone or other ketone~~ bodies~~~~Ketone body(s) (eg, acetone, acetoacetic acid, ~~serum~~ beta-hydroxybutyrate); qualitative
87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, reverse transcription and amplified probe technique
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, reverse transcription and amplified probe technique
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, reverse transcription and quantification
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, reverse transcription and amplified probe technique
87536	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, reverse transcription and quantification
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, reverse transcription and amplified probe technique
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, reverse transcription and quantification
81401	FGFR3 (fibroblast growth factor receptor 3) (eg, achondroplasia, hypochondroplasia), common variants (eg, 1138G>A, 1138G>C, 1620C>A, 1620C>G) HTT (huntingtin) (eg, Huntington disease), evaluation to detect abnormal (eg, Huntington disease), evaluation to detect abnormal expanded alleles) expanded

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REVISED CODES	CODE DESCRIPTION
81402	Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD])
81403	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma), gene analysis, variant(s) in exon ~~23~~ (eg, codon 61)
DELETED CODES	**CODE DESCRIPTION**
83890	Molecule isolate
83891	Molecule isolate nucleic
83892	Molecular diagnostics
83893	Molecule dot/slot/blot
83894	Molecule gel electrophor
83896	Molecular diagnostics
83897	Molecule nucleic transfer
83898	Molecule nucleic ampli each
83900	Molecule nucleic ampli 2 seq
83901	Molecule nucleic ampli addon
83902	Molecular diagnostics
83903	Molecule mutation scan
83904	Molecule mutation identify
83905	Molecule mutation identify
83906	Molecule mutation identify
83907	Lyse cells for nucleic ext
83908	Nucleic acid signal ampli
83909	Nucleic acid high resolute
83912	Genetic examination
83914	Mutation ident ola/sbce/aspe
88385	Eval molecul probes 51-250
88386	Eval molecul probes 251-500
CPT codes © American Medical Association	

Laboratories should begin with the coding crosswalks for the old stacking code assignments to the new molecular pathology codes. Precise assignment of the codes should be followed with an update to the chargemaster for these new codes. The chargemaster is the data file that contains the laboratory pricing and coding information used to populate service claims. Outdated information in the file can cause a claim to be rejected and quickly affect cash flow.

While there are still many uncertainties regarding the CMS contractor pricing, there are even more where the private payers are concerned. With the volume of ACO growth, the management of cost will be imperative. Strategies to recoup lost revenue due to pricing reductions should be carefully explored and accessed for profitability margins to ensure the continued fiscal viability of the lab.

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Strategies for Assessing Effectiveness, *from page 1*

monitoring and auditing—according to Marguerite Busch, vice president and chief compliance officer for PAML and PAML Ventures in Spokane, Wash. Busch discussed strategies for measuring effectiveness during this year's G2 Intelligence Lab Institute, held Oct. 10-12 in Arlington, Va.

Training and Education

Effective training and education should include new employee orientation, annual general/core compliance training, annual special topics training, periodic education on high-risk topics for high-risk departments, and just-in-time training if processes, regulations, and forms change, says Busch, who notes that "documentation of all training is critical." Training for new employees should cover standards of conduct, location of policies and procedures, how to report compliance concerns (four-step process discussed below), and an overview of regulations governing fraud and abuse, waste, and false claims. New marketing representatives should also have additional, in-depth orientation as soon as possible after hire to include review of the company's sales compliance policies, contracting process with sources of referrals including approvals for all contract proposals, and gifts and entertainment policies.

Seven Elements of an Effective Compliance Program

1. Written policies, procedures, and standards of conduct
2. Compliance officer and compliance committee
3. Effective training and education
4. Effective lines of communication
5. Disciplinary guidelines for enforcing standards
6. Internal monitoring and auditing
7. Prompt response to offenses and corrective action plans

Source: HHS OIG

General/core compliance training should cover an overview of the code of conduct, any new or changed compliance policies, any new regulatory compliance issues, an emphasis on how to report compliance concerns, and a test or survey to assess comprehension. Special training for high-risk areas might apply to billing staff, phlebotomists, marketing representatives, and human resources. Topics covered should include those specific to those departments and is often best handled in department meetings and in person. Busch suggests using case studies and examples of key risks gleaned from newsletters, OIG prosecutions, and other sources. This type of training presents a valuable opportunity to have an interactive question-and-answer session with staff, she notes.

Communication

Busch suggests teaching a typical four-step communication process to employees:

1. Discuss the issue or concern with immediate supervisor;
2. Discuss the issue or concern with the department manager;
3. Contact the compliance officer or department; and
4. Call the lab's or organization's anonymous 24/7 "hot line" to report the issue or concern.

An effective communications policy ensures that employees are aware of the lines of communication available to them; the availability and approachability of supervisors, managers, department heads, and compliance officers; and the availability of a hot line. The policy must also ensure confidentiality of reports and include a strong nonretaliation policy. Documentation of the issues being reported is critical, as is documentation of investigation and corrective actions taken. A prompt response back to the reporting employee is essential, says Busch.

Internal Monitoring and Auditing

When conducting internal monitoring and auditing, Busch suggests focusing on the following high-risk areas:

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Marguerite Busch is vice president and chief compliance officer, PAML and PAML Ventures.

Order/report/bill review. Review requisitions and orders, reports, claim forms, and other attached documents. Ensure that what was ordered is what was reported is what was billed, the ICD-9 code on the requisition or order matches the claim, and a valid advance beneficiary notice was executed if appropriate. Check to see if a Medicare secondary payer form is attached, if applicable, and if reflex testing occurred, was it ordered as such.

Three-day payment window rule for hospitals. Review inpatient admission reports and lab test orders for outpatients or nonpatients (outreach patients). Check to see if any testing was performed on patients within three days (not 72 hours) of patient's admission to the hospital by a lab wholly owned or operated by the hospital. Also, check to see if any of that testing was billed out to Medicare as a separate claim (rather than being rolled into the diagnosis-related group).

Standing orders. Review standing orders to determine if they meet the requirements that they be for a specific patient for a specific test for a specific time interval. Check to see if the authorized provider signed the standing order and whether it has been reviewed or renewed at least annually.

Custom profiles. Review the custom profile authorization form to see whether it contains the required details so that the provider knows the charges for each component of the profile and that each test in the profile should be medically necessary. Has the provider signed an annual notification regarding the custom profile?

CPT/HCPCS coding. Review the procedure for maintaining current and accurate CPT codes. Determine whether new tests and new methodologies are being coded correctly and communicated to the billing system.

Employee training and education. Review training and education records, attendance rosters, new hire lists, and training and education materials. Check to see if new hires attended compliance orientation within the lab's timeline policy, what percentage of current employees completed annual training within the specified period, and whether training was held for target groups in potentially high-risk areas.

Test utilization. Review the top 30 tests ordered during the past 12 months and the top 30 tests from the previous 12 months. Did any test increase more than 10 percent compared to the previous 12 months? For those that did, what might be the reason for the increase? Provide documentation as to the cause of the increase.

Marketing issues. Review marketing brochures, client supply reports, contracts with sources of referral, standard test requisitions, test directory, marketing expense reports, and client fee schedules. Check to see if the marketing materials are clear and not misleading, ensure that supplies sent to clients are appropriate for the volume of tests, and ensure that leases and phlebotomy service arrangements are at full market value, fully executed, and meet all Stark rules. Check to see if requisitions clearly give ordering providers choices for test orders, make sure gifts and entertainment for sources of referral meet the current "non-monetary compensation" standards, and review client fee schedules to make sure they meet Medicare and specific state Medicaid requirements.

Exclusion checks. Review databases of employees, vendors, clients, and the federal exclusion database (*http://exclusions.oig.hhs.gov and https://epis.gov/*) to ensure that no employees, contractors, vendors, or clients are on either list. Ideally this will be done before hire, before contracting with a vendor, before accepting a new client, and then at least annually.

Specific Elements for Lab Compliance

- Requisition design
- Notices to physicians
- Customized profile acknowledgements
- ABNS
- Test utilization monitoring
- Selection of CPT/HCPCS codes
- Selection of ICD-9 codes
- Tests covered by claims for reimbursement
- Billing of calculations
- Reflex testings

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News-At-A-Glance

STRIKE FORCE TO EXPAND: The Medicare Fraud Strike Force, active in nine cities across the country, is likely to expand in the coming year, an official from the Department of Justice said Nov. 14. "Strike force expansion all comes down to the budget, but I think we'll see more cities," Sam G. Sheldon, deputy chief of the fraud section in DOJ's criminal division, said during the National Health Care Anti-Fraud Association's Annual Training Conference. Sheldon said the strike force concept has been a successful enforcement tool since it was rolled out in Miami in 2007, resulting in quicker prosecutions and increased law enforcement collaboration. In 2007, Sheldon said it was taking three to five years to prosecute a health care fraud case. Under the strike force approach, the time from opening an investigation to issuing an indictment has been trimmed to 90 days, he said. Besides Miami, strike force teams are active in Baton Rouge, La.; Brooklyn, N.Y.; Chicago; Dallas; Detroit; Houston; Los Angeles; and Tampa Bay, Fla. Over the last five years, 723 health care fraud cases have been filed by strike force teams, involving 1,440 defendants, and strike force prosecutors have won 105 trial convictions and garnered 917 guilty pleas.

OIG RECOVERS $6.9 BILLION: The Department of Health and Human Services Office of Inspector General Nov. 27 announced expected recoveries of $6.9 billion from fraud-related audits and investigations in fiscal year 2012, an increase from the $5.2 billion in recoveries the agency made in FY 2011, according to the OIG's *Semiannual Report to Congress*. "The results of OIG's audit, evaluation, enforcement, and compliance work underscore that the Department continues to face significant management and performance challenges in key areas, including reducing improper payments and avoiding waste, ensuring patient safety and quality of care, and overseeing program integrity contractors," OIG Inspector General Daniel R. Levinson said in the report's introduction. The expected recoveries included $924 million identified by OIG audits and $6 billion that resulted from agency investigations, the report said. In addition to the recoveries, the report identified an estimated $8.5 billion in savings in FY 2012 that were due in part to implemented OIG recommendations.

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