G-2 Compliance Report

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California AG Investigating Clinical Labs

California Attorney General Edmund Brown reportedly is conducting an investigation of clinical laboratories in the state over allegations of inappropriate billing under the Medi-Cal program, sources tell *G-2 Compliance Report*.

Details are few as labs that have received requests for information have been told not to discuss the investigation, sources say. However, the office reportedly is looking at whether labs are billing Medi-Cal more for testing services than they bill under negotiated fee-for-services arrangements in the state. A spokesman for the California Attorney General says the office will neither confirm nor deny any investigation into billing by clinical laboratories.

The allegations of overbilling reportedly have stemmed from a whistleblower case, say sources. It is unclear just how many California labs are included in the investigation.

Michael Arnold, a lobbyist for the California Clinical Laboratory Association, believes the California AG might be on a "fishing expedition." The requests for information that have been received thus far have been "totally outlandish," he notes. "This appears to be a giant overreaching by the AG."

This is not the first time that the California AG has investigated clinical laboratories. Most in the industry remember the investigation of National Health Laboratories (NHL) in the early 1990s, which resulted in a $111 million fine and prison time for the chief executive officer of NHL. That case led to a national enforcement effort by the Department of Justice dubbed "lab scam," which resulted in extensive fines for every major commercial laboratory.

Lab Compliance Officers Face Host of Challenges

The greatest challenges facing laboratory compliance programs are billing issues, budget constraints, and pressure from the business development and sales and marketing departments, according to a survey of lab compliance officers conducted by Washington G-2 Reports and Laboratory Management Support Services (LMSS) of Phoenix, Ariz.

Also on the list of top challenges is apathy on the part of employees, lack of support by upper management or no access to upper management, and lack of support by other managers in

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Christopher Young

Lab Compliance Officers, *from page 1*

the organization. About 100 lab compliance officers responded to the G2/LMSS survey, which was conducted in summer 2008 and presented at Washington G-2 Report's 26th Annual Lab Institute, held Sept. 17-19, 2008, in Arlington, Va.

The top six major goals of the lab compliance officer, as identified by survey respondents, are: billing and coding, auditing and monitoring, training and education, reviewing and revising policies at the department level, conducting a risk assessment, and measuring compliance program effectiveness.

A majority (66 percent) of laboratory compliance programs are being maintained while 33 percent are being expanded, the survey found. Results of a similar survey conducted by the Health Care Compliance Association (HCCA) found that slightly more (39 percent) of general health care compliance programs are currently being expanded.

High Priority

According to the G2/LMSS survey, 72 percent of respondents say upper management considers compliance a high priority, with another 24 percent deeming it important. Almost half of those responding (46 percent) were from hospital outreach labs, while 22 percent were from independent labs. Other respondents included hospitals with no outreach and physician office labs. More than half (53 percent) of the compliance programs have been in place for nine years or more, with another 30 percent between five and eight years.

When asked about the level of authority of the compliance officer, 48 percent of respondents say the compliance officer is a member of senior management, while 52 percent say that role is considered middle management or supervisory. The HCCA survey found that 86 percent of respondents said the compliance officer was considered senior management and just 14 percent said it was considered middle or supervisory.

This is an important difference, but it is not unexpected, says LMSS President Christopher Young. Laboratories are often part of larger entities like hospitals or health systems, and the laboratory compliance officer is not the "corporate" compliance officer. "It is important that laboratory compliance officers understand that if they are in that situation, they must ensure they have a direct line to the corporate compliance officer," he advises. "If they find themselves in a situation where they have a problem related to a manager who is senior to them in the laboratory, they can consult with the corporate officer to resolve it."

> ***"Laboratories that don't have active compliance committees should correct that situation as soon as possible."***
> ***—Christopher Young***

About two-thirds (65 percent) of respondents to the G2/LMSS survey say their lab has a compliance committee, while 35 percent say it does not have one. Almost all (98 percent) say the compliance committee has sufficient authority to make decisions. The compliance committee is specifically referred to in all of the OIG Compliance Guidance documents, and it is certainly the government's expectation that the laboratory has one, says Young. "It is also important to note that the HCCA survey found that 94 percent of respondents said they had a compliance committee," he notes. "Laboratories that don't have active compliance committees should correct that situation as soon as possible."

In terms of how many employees are assigned to compliance tasks, 36 percent of respondents report no additional employees, 22 percent report one, 10 report two, 9 percent report three, and 22 percent report four or more additional employees are assigned to compliance tasks.

Only about 15 percent of respondents say they have a specific compliance budget, although 80 percent of those say the budget is adequate. The presence or absence of a line item compliance budget has been cited by government representatives as an element used to assess compliance program effectiveness, notes Young. Almost all respondents (93 percent) say compliance training is mandatory, with 65 percent reporting that HIPAA (Health Insurance Portability and Accountability Act) training is separate from compliance training. The vast majority (88 percent) say they receive annual update training, 53 percent report additional training for high-risk departments, and 25 percent say that temporary employees and contractors also receive training.

The majority (84 percent) of compliance officers responding to the survey say they are self-trained. Almost a third (29 percent) say they attend three or more training events annually.

When asked how many hours employees spend in compliance training, 41 percent of respondents said one hour or less, 40 percent said one to three hours, 10 percent said three to five hours, and 4 percent said more than five hours. The primary training method is computer or Web-based (51 percent), followed by classroom with compliance officer (24 percent), classroom with instructor (10 percent), self-study (8 percent), and video (2 percent).

Well over a third (42 percent) of respondents say the current compliance officer has been in that position for more than six years, with 22 percent reporting three to four years, 15 percent reporting one to two years, 14 percent reporting four to six years, and 7 percent less than one year. Almost half (48 percent) of lab compliance officers were previously a department or laboratory manager. The rest came from quality assurance, administrative, risk management or legal, audit, or other departments.

When asked what other job duties the lab compliance officer has, 45 percent report other management responsibilities, 37 percent quality assurance or something similar, 37 percent HIPAA, 37 percent other, and 6 percent say they have no other duties. The "other" management responsibility category includes duties ranging from safety and occupational health to client services, CLIA and accreditation, billing, and risk management. The main concern with the "other" category is that those other responsibilities are not something such as billing manager, business development, sales manager, or some other position where there could be conflict of interest with the person's compliance responsibilities, says Young.

What other job duties do you have in addition to your compliance duties?

	No other duties	*Quality assurance or similar*	*HIPAA privacy and/or security*	*Chief medical officer*	*General counsel/ attorney*	*Laboratory, department or section director or manager*	*Other*
Single hospital (no outreach)	0.0%	25.0%	25.0%	0.0%	0.0%	75.0%	0.0%
Multi-hospital or health system (no outreach)	0.0	33.3	33.3	0.0	0.0	33.3	33.3
Hospital or health system outreach	10.9	43.5	39.1	2.2	0.0	45.7	37.0
Rural hospital	0.0	33.3	0.0	0.0	0.0	66.7	33.3
Independent-one site	0.0	75.0	50.0	0.0	0.0	50.0	62.5
Independent-multi site (same state)	0.0	0.0	100.0	0.0	20.0	20.0	60.0
Independent-regional (multi-state)	14.3	14.3	28.6	0.0	0.0	14.3	57.1
Independent-national	0.0	0.0	0.0	0.0	0.0	50.0	50.0
Physician Office	0.0	33.3	0.0	0.0	0.0	66.7	33.3
Other	0.0	36.4	36.4	0.0	0.0	45.5	27.3
Overall	6.1	37.4	37.4	1.0	1.0	45.5	37.4

Source: G-2/LMSS *Compliance Survey*

More than two-thirds (77 percent) report that the compliance officer is not certified, and 54 percent say the CO has access to expert legal counsel, with an additional 35 percent reporting they have access to legal counsel with approval. Half (50 percent) say their outside training is restricted by budget constraints.

The majority (84 percent) of compliance officers responding to the survey say they are self-trained. Almost a third (29 percent) say they attend three or more training events annually.

When asked how they feel about their training and expertise, 51 percent of respondents say they are well-schooled in the basics of compliance but need additional training or support for complex or specialized compliance problems; 25 percent say they know enough to recognize a compliance problem but most of the time need support to make a decision about the problem, 16 percent say they are fully trained and need to only maintain and update their knowledge, and 7 percent say they are not comfortable with their level of training and expertise.

Almost all (94 percent) respondents say there is an auditing/monitoring component to their program, with 24 percent of audits conducted by the compliance officer and 41 percent conducted by a mix of people, including department managers, the audit or risk management division, and outside entities.

Audits are conducted at all different intervals, from monthly (12 percent) to quarterly (14 percent) to annually (11 percent). The majority of respondents (57 percent) say audits are conducted at a mix of intervals. Typical audits are billing and coding (82 percent), charge master (65 percent), compliance program effectiveness (48 percent), sales and marketing (40 percent), training and education (37 percent), Stark and anti-kickback (33 percent), annual compliance audit (29 percent), special lines of business (19 percent), and other audits (10 percent).

Lab compliance officers have done a good job keeping their compliance plan current, with 63 percent reporting that the plan or code of conduct was updated within the last year, and 13 percent saying it was updated between one and two years ago.

One of the ways a government reviewer can assess the effectiveness of a laboratory's compliance program is to measure it against other programs in the industry, notes Young. That is why it was important to compare the G-2/LMSS survey to the HCCA survey.

"It is important that a laboratory compliance officer is aware of what is the standard for compliance programs in all areas of health care, as well as the laboratory compliance universe," he says. "That information can then be used to focus efforts on those areas where the laboratory's program might be lacking. This survey, the first specifically for laboratories, provides such a benchmark tool for compliance officers."

How often do you conduct audits?

	Monthly	*Quarterly*	*Semi-annually*	*Annually*	*A mix of all of these*
Single hospital (no outreach)	12.5%	25.0	0.0%	0.0%	62.5%
Multi-hospital or health system (no outreach)	0.0	0.0	0.0	20.0	80.0
Hospital or health system outreach	7.3	19.5	7.3	9.8	56.1
Rural hospital	0.0	0.0	0.0	33.3	66.7
Independent-one site	42.9	0.0	0.0	0.0	57.1
Independent-multi site (same state)	0.0	0.0	20.0	20.0	60.0
Independent-regional (multi-state)	33.3	16.7	0.0	0.0	50.0
Independent-national	0.0	0.0	50.0	50.0	0.0
Physician Office	0.0	50.0	0.0	50.0	0.0
Other	20.0	0.0	0.0	10.0	70.0
Overall	12.4	13.5	5.6	11.2	57.3

Source: G-2/LMSS *Compliance Survey*

COMPLIANCE PERSPECTIVES

Joan Logue is president of Health Systems Concepts, a laboratory consulting company.

Preparing for a New Year: Time to Update Your Charge File for 2009

It's that time of year again when laboratories need to update their charge files so the new and revised 2009 codes are available for billing date of services on or after Jan. 1, 2009. This annual end-of-year internal review of the laboratory billing system starts with the October update of the ICD-9-CM diagnosis codes, followed by the 2009 CPT (current procedural terminology) update, HCPCS (healthcare common procedure coding system) update, Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Fee Schedule Instructions, Outpatient Prospective Payment (OPPPS) update and, finally, the professional codes and instructions in the 2009 Medicare Physician Fee Schedule.

Getting a head start on updating your charge file, internal edit program, and your physician communications to reflect current diagnoses requires having the American Medical Association 2009 CPT book and using the CMS Web site as a resource to access the most current information for diagnosis codes, HCPCS codes, laboratory billing instructions, and the final rules for OPPPS and the Physician Fee Schedule.

ICD-9-CM Diagnosis Codes

The first step starts with updating the ICD-9-CM codes. Most laboratories monitor only the diagnosis codes associated with the 23 National Coverage Determinations (NCDs). However, it is a good practice to review the annual update to identify other ICD-9-CM code changes that may apply to physician-ordered laboratory services. The annual updates for the ICD-9-CM diagnosis and procedure codes are posted on the CMS Web site at *www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/icdcnv092.pdf* . The new, revised, and discontinued ICD-9-CM codes are listed separately, and laboratories can quickly identify changes that may be pertinent to their business.

The ICD-9-CM diagnosis codes for the clinical laboratory tests falling under the Medicare NCDs are updated quarterly. The October 2008 revisions for the NCDs should be considered as the laboratory prepares to revise physician notices and update its internal edit programs to conform to the most recent diagnosis requirements. The changes to the NCD edit software can be viewed at *www.cms.hhs.gov/CoverageGenInfo/04_LabNCDs.asp* .

2009 HCPCS Codes

The laboratory uses HCPCS codes for reporting Medicare approved screening tests, blood and blood products, travel codes, and services that have limited Medicare coverage, such as bone marrow or peripheral stem cell harvest, and for certain tests where CPT may not have a code, such as G0307 for reporting a complete blood count (CBC) without a platelet count. New additions or deletions to the HCPCS codes that apply to clinical laboratory services are defined in the CMS annual update for Clinical Laboratory Fee Schedule instructions, which is usually available early in November. However, at the time of this writing (in mid-December), the instructions have not

been released. Laboratories will need to monitor the CMS Clinical Lab Center at www.cms.hhs.gov/center/clinical.asp for the release of the 2009 instructions and the 2009 updates to the HCPCS codes.

2009 CPT® Codes[1]

Updating your charge master requires having the most current CPT book. You may order the 2009 CPT online or by paper order. Information on ordering the AMA 2009 CPT book may be found at *https://catalog.ama-assn.org/Catalog/home.jsp?checkXwho=done*.

CPT code changes in the pathology and laboratory section are easily identified as CPT indicates new codes with a red bullet and revised codes with a blue triangle. A parenthetical notation is also included at the location of the deleted code to guide the coder to the replacement code.

The CPT editorial committee added seven new codes to the pathology and laboratory section of the 2009 CPT. Also, there are 20 code description revisions, three deleted codes, and revisions to the instructional guidelines for evocative/suppression testing, molecular diagnostics, and the guideline for the microbiology primary source specimens. New codes appear in the chemistry, hematology, microbiology, and transcutaneous sections. The revised descriptions appear primarily in the chemistry section with one revision in the microbiology section. The laboratory should pay close attention to the revised descriptions to ensure that the current codes assigned in their charge file are still appropriate for the tests.

Deleted Codes

CPT deleted three codes—one code was deleted as a result of renumbering and two Category III codes were also deleted. CPT has provided a crosswalk for the three deleted codes.

- 88400 *bilirubin, transcutaneous* is crosswalked to the new code 88720 *bilirubin, total transcutaneous*.
- Category III codes 0058T *cryopreservation; reproductive tissue, ovarian* and 0059T *cryopreservation; oocyte(s)* are crosswalked to 89240 *unlisted miscellaneous pathology test*.

Billing with a deleted code on or after Jan. 1, 2009, will result in nonpayment.

Organ or Disease-Oriented Panels

The 80048 *basic metabolic*, 80053 *comprehensive metabolic*, and the 80069 *renal function* panels were revised to indicate that a total calcium must be performed. The laboratory may not substitute the ionized calcium in place of the total calcium.

Chemistry Nonmolecular

The nonmolecular chemistry section of CPT has eight description revisions and two new codes. The revisions will not only provide clarification for the coder but also for the payers. The descriptions for four codes were revised to broaden the specimen types to clarify that the specimen may be serum, plasma, or whole blood. For example, 82040 *albumin, serum* was changed to *albumin, serum, plasma or whole blood*. This specimen clarification was also added to 84132 *potassium; serum, plasma or whole blood*, 84155 *protein, total, except by refractometry; serum, plasma or whole blood* and 84295 *sodium; serum, plasma or whole blood*.

CPT revised 82375 by deleting the term *carbon monoxide*. The new description for this parent code is now 82375 *carboxyhemoglobin; quantitative*. A cross reference was also added for the transcutaneous carboxyhemoglobin. It is recommended to update the charge file with the new description so that outside coders who do not have a lab background will not inadvertently change the code for carbon monoxide to a method code.

CPT 83925 *opiate(s), drug and metabolites, each procedure* clarifies for coders and payers that this code is to be reported for each procedure performed. The wording *drug and metabolites* was added and the plural *opiates* was also changed. Units will now be appropriate for this code. The medically unlikely edit (MUE) is not listed on the CMS October MUE table so we do

CPT™ American Medical Association

1. *Current Procedural Terminology CPT® 2009; Pathology and Laboratory; American Medical Association; AMA Press Chicago, IL.*

not know the limit of units. MUEs are adjudicated by claim line and, therefore, each medically necessary opiate procedure should be reported on individual claim lines with the 59 modifier added to each claim line after the first reported as 83925.

CPT added two new important codes to the chemistry section. According to *Insiders View*, the first code 83876 *myeloperoxidase (MPO)* is a biomarker to identify troponin-negative patients at risk for major adverse cardiac events. This test will be ordered in conjunction with other cardiac markers, such as troponin T, CK, and CK-MB.[2] This important code should be added to the charge file as it may have high emergency room use for suspected cardiac patients.

Another important new code is 83951 *oncoprotein; des-gamma-carboxy-prothrombin (DCP)*. DCP is a highly sensitive marker used to follow patients with chronic liver disease at risk for developing hepatocellular carcinoma.

Note that CPT has revised 83950 *oncoprotein; HER2/neu* by adding a semi-colon after oncoprotein and made it a parent code for the oncoprotein series.

Chemistry Molecular Diagnostics

Perhaps the most significant CPT revisions are the new and revised molecular diagnostic codes for human genetic testing. Ten of the codes in this section were revised. Prior to 2009, these 10 codes could only be reported with a single unit of service because CPT did not include the word *each* in the test description. The 10 revisions now allow for billing units of service on the codes. The first revision was to add *each nucleic acid type (ie, DNA or RNA)* to the isolation or extraction codes 83890 and 83891. Most molecular assays will extract just DNA or RNA, which will be reported with one unit of service. However, there are procedures that require the extraction or isolation of both DNA and RNA. In these cases, the unit of service will be two units. The maximum units on either of these codes will be two units. If one is coding a panel with multiple assays, the maximum unit of service will still be two as the same sample extraction or isolation will be used for all the tests listed in the panel.

The second revision was to add *each enzyme treatment* to 83892. If multiple different enzymes are used to digest DNA, the lab should report a unit of service for each enzyme. If the same enzyme is used for multiple treatments, the lab should report a unit of service for each treatment.

The third important change revised the description for four codes, 83893, 83894, 83897, and 83909, by adding *each nucleic acid preparation* to the descriptions. To properly code them, the coder must review the new guidelines to the molecular diagnostic section. A paragraph was added that defines nucleic acid preparation. It states:

"Each nucleic acid preparation may include a digestate, undigested nucleic acid, or other uniquely modified nucleic acid sample (e.g., newly synthesized oligonucleotide." This example in the instructions appears to indicate that you code for each amplicon.

Understanding this definition and then applying it to the codes requires also understanding that there is a possibility of over coding when the *each nucleic acid preparation* definition is applied. For example, correct coding for 83894, *gel electrophoresis* and 83909 *capillary electrophoresis*, requires understanding of what is actually occurring in the reaction. According to CPT Knowledge Base expert advisor, if one loads a single reaction tube containing multiple amplicon/exons on one gel lane or column/capillary to separate for some necessary purpose, then it is one separation.[3] It would be incorrect to code per nucleic acid preparation in these cases.

The second coding issue is reporting both 83904 and 83909 codes with the same number of nucleic acid preparations. Both 83904 and 83909 have the word *identification* in the description. Therefore, billing both codes with the same number of units may be viewed as duplicate billing by the payer.

2. *CPT ® CHANGES 2009: An Insider's View; American Medical Association; AMA Press Chicago, IL pp 127-136.*

3. *Electronic response to Health Systems Concepts Inc. CPT Knowledge Base Electronic Inquiry #2140, May 25, 2008.*

The code 83907 *lysis of cells prior to nucleic acid extraction* (*e.g., stool specimens, paraffin embedded tissue*) was also revised to include each specimen. This clarification was added to clarify that it is one unit per specimen and not per paraffin embedded tissue block.

Laboratories referring molecular diagnostic testing often report the codes recommended by the testing laboratory. To ensure proper reporting and payment, both the testing and referring laboratories must validate that their charge files have been updated to incorporate these important clinical laboratory molecular diagnostic coding changes. Also, it is expected that the human genetic molecular diagnostic codes will have MUE units assigned in 2009.

Hematology

CPT added 85397 *coagulation and fibrinolysis, functional activity, not otherwise specified* (*e.g., ADAMTS-13,*) *each analyte* to the hematology section. This will be a fairly low-volume code for many laboratories, but should be added to the charge file so it is available for use. This is a generic method code that will allow for the coding of analytes not specifically named in CPT.

Immunology

CPT added a very important instructional parenthetical in the tissue typing section that now clarifies for coders and, more importantly, the payers that molecular diagnostic techniques are to be reported with the molecular diagnostic procedure codes. The guideline states: "(*For HLA typing by molecular pathology techniques, see 83890-83914 with appropriate genetic testing modifiers 4A-4G*)."

This has been an issue with many of the payers as they only paid on the serologic codes in the past. Most HLA laboratories are performing molecular diagnostic techniques, and these guidelines now support reporting with the appropriate codes.

Microbiology

New instructional guidelines were added for codes intended for primary source only. These instructions will be important in reporting panels that detect different species or strains as a portion of the instruction reads: "*Use modifier 59 when separate results are reported for different species or strains that are described by the same code*."

CPT added a new code 87905 *infectious agent enzymatic activity other than virus* (*e.g., salidase activity in vaginal fluid*). This code is a rapid test for detecting salidase activity produced by bacteria in vaginal fluid. CPT also added a parenthetical note following 87905 that instructs coders on reporting virus isolation.

Transcutaneous Laboratory Procedures

The subheading following code 88399, *transcutaneous procedures*, has been deleted and replaced with "*In Vivo* (*e.g., transcutaneous laboratory procedures*).

CPT deleted 88400 b*ilirubin, total, transcutaneous* and recoded it as 88720 *bilirubin total, transcutaneous*. Also new codes 88740 *hemoglobin quantitative, transcutaneous, per day*; *carboxyhemoglobin* and 88741 *methemoglobin* were added to this section. Code 88400 will need to be recoded in the charge file to 88720 as 88400 will not appear on the 2009 CLFS and will not be paid.

Conclusion

Year-end is also a good time to review the OIG's compliance guidance documents and Chapter 3 of the *Program Integrity Manual*. Compliant billing requires evaluating the effectiveness of your overall compliance program and documenting that you are monitoring for potential errors, taking corrective action when necessary, and improving compliance through a meaningful education program.

Knowing what resources are available and referring to them often will help ensure coding and billing compliance. In addition to updating your charge file, consider performing a random audit of lab billings every quarter to verify that all electronic and manual systems involved in the order, resulting, billing, and payment are functioning correctly.

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Enforcement Efforts Focus on Physicians In Kickback Cases, OIG Counsel Tells ABA

Physicians continue to be a key focus of health care fraud enforcement efforts as doctors' financial relationships with health industry organizations—such as drug and device manufacturers—increasingly are scrutinized, Health and Human Services Office of Inspector General (HHS OIG) Chief Counsel Lewis Morris said November 18.

In addition to recent enforcement actions against individual doctors for their roles in accepting kickbacks from companies, Morris cited a September settlement involving drugmaker Cephalon Inc. that included a five-year corporate integrity agreement with the OIG that mandates the company publicly report payments it makes to doctors.

Morris spoke as part of an enforcement panel at the American Bar Association Washington Healthcare Summit.

The Cephalon reporting mandate follows similar requirements made of five orthopedic device firms in 2007 and efforts by Sen. Chuck Grassley (R-Iowa) to require disclosure of physicians' financial relationships with certain health care firms.

Federal law enforcers will continue for the foreseeable future to focus on the influence that drugmakers and medical device companies may have on physicians' clinical decisions through financial arrangements, an HHS OIG official told a recent conference of device firms. The Medicare Payment Advisory Commission also approved recommendations to Congress to require public reporting of financial relationships between doctors and drug and device makers.

Morris also told the audience of health care attorneys that the OIG is using a new five-point plan to guide its efforts in preventing fraud, waste, and abuse in the Medicare program.

Federal Enforcement Efforts

Responding to a question about whether doctors should be concerned that future migration of medical information to electronic health records (EHRs) could make them more vulnerable to enforcement efforts, Morris said that he sees EHRs as a way to improve patient care and communication among providers.

He acknowledged that for doctors who are billing the Medicare program and other insurers improperly, EHRs could be troublesome, but not for physicians who are following the rules. He added that for those doctors, EHRs, in fact, are a better way than the current system to prove they are billing appropriately and providing quality care to beneficiaries.

Morris also told the audience of health care attorneys that the OIG is using a new five-point plan to guide its efforts in preventing fraud, waste, and abuse in the Medicare program. The fundamentals of the plan that Morris laid out reflect long-standing OIG approaches to fraud in health care programs.

Morris said the OIG plan calls for:

- scrutinizing potential providers before allowing them to participate in the Medicare program;
- establishing Medicare payment methodologies that better respond to market changes;
- helping health care providers adopt compliant practices;
- using claims data to detect fraud, waste, and abuse; and
- responding quickly with enforcement action to cases of identified fraud.

Morris also noted new federal contracting requirements effective in February that mandate federal contractors self-disclose any payment problems to the government. The federal contracting rule from the General Services Administration was published November 12.

Morris touted the OIG's existing self-disclosure protocol as a way to satisfy that mandate. He added that failure to disclose payment problems under the new contracting rule was grounds for contractor debarment or suspension.

RAC Program Expected to Move Forward After Delay Expires in Early 2009, CMS Says

Chief among changes to the permanent RAC program over the earlier RAC demonstration is the limit on the medical records that RACs can request at one time from providers.

Despite a recently announced delay concerning when recovery audit contractors (RACs) will start their post-payment reviews of Medicare claims, the Centers for Medicare and Medicaid Services (CMS) officials expect the program to move forward early next year.

Melanie Combs-Dyer, a senior technical adviser in CMS's Division of Demonstrations Management, said November 17 that she expects the RAC implementation schedule to be compressed because of the delay. She said that work in the first states where RACs were to begin will be started at the same time in February as work in the second round of states where RAC work was to begin. Combs-Dyer spoke at the American Bar Association 6th Annual Washington Healthcare Summit.

The program delay was prompted by contract award protests by two firms questioning CMS's selection of the RAC award winners. The Government Accountability Office (GAO) has 100 days to review the protests and issue a decision.

The RACs are audit contractors hired by CMS to conduct post-payment reviews of Medicare claims to ensure the program paid properly for services and products. Despite some criticism of a six-state RAC demonstration program, Congress called for a permanent nationwide RAC program in the Tax Relief and Health Care Act of 2006.

Reduced Provider Burden

Chief among changes to the permanent RAC program over the earlier RAC demonstration is the limit on the medical records that RACs can request at one time from providers, Combs-Dyer said.

CMS has not yet determined the exact number of records RACs will be allowed to request at one time from providers, but she said that the limits would vary by provider size and that RACs could request medical records only once every 45 days.

Combs-Dyer also said that providers would be able to submit records to RACs via mail, facsimile, or on a CD or DVD. She said CMS may also allow for records to be sent on other electronic media, such as flash drives, and that in the future the agency may allow for sending records via a secure Web portal.

Combs-Dyer acknowledged that providers have asked for a Web-based option for sending records, especially since the Social Security Administration allows medical records for disability claims to be sent online. However, she added that the option would not be available in the near term.

Contractor Performance Reviews

While RACs will be reviewing provider claims for payment errors, Combs-Dyer said CMS would review the contractors' performance in audits. She said that there was not a "magic score" for audit accuracy rates, but that RACs' accuracy rates would be made public and that the rates would be used in CMS's annual contract renewal process.

Combs-Dyer said providers can prepare for upcoming audits by reviewing past RAC findings from the demonstration projects, as well as areas of concern in Medicare payments that have been identified in recent Health and Human Services Office of Inspector General reports and in GAO reports.

She said that, unlike in the demonstration project, RACs would be required to submit new areas of audit review to CMS before beginning such reviews. Once approved, those new review areas would be made available to providers. Additional information about the permanent RAC program is available at *www.cms.hhs.gov/rac*.

Cleveland Clinic Discloses Ties as Part of Transparency

Every Cleveland Clinic doctor's business relationship will be disclosed on its Web site, the Ohio multispecialty medical center said December 3, making it the nation's first health care institution to initiate such a "transparency" move.

Industry connections have been added to individual listings within the clinic's physician directory. This section lists companies with which a doctor collaborates, identifying whether they have equity, the right to royalties, a fiduciary position, or a consulting relationship that pays $5,000 or more per year, although specific payments are not included.

Doctors are being asked to disclose any trade relationships yearly, and currently the clinic is relying on physician self-reporting to identify potential conflicts of interest.

The enhanced physician directory and related disclosures are "an affirmation of Cleveland Clinic's commitment to transparency," the center said in its announcement, noting that as part of this effort it is also making medical records available electronically, with limited exceptions, to patients who wish to review their own files during their hospital stay.

Sen. Chuck Grassley (R-Iowa), ranking member of the Senate Finance Committee, who has introduced legislation that would require drug and medical device manufacturers to divulge payments made to doctors, said in a statement: "This kind of positive development shows the reform movement is gaining traction. Patients deserve easy access to information about their doctors' relationships with drug companies, and the Cleveland Clinic is making that possible.

"I'm also working to make it easy for the new Congress to quickly pass my bill to require disclosure of specific payments from drug and device companies to doctors across the country. Transparency builds trust," Grassley added.

Cleveland Clinic employs about 1,800 full-time salaried physicians and researchers representing more than 100 medical specialties and subspecialties. The clinic says roughly 400 have relationships with companies and of those, only 30 are significant enough to be closely monitored.

Associations between Cleveland Clinic doctors and outside companies have drawn public attention since 2006 when the hospital removed a nationally prominent cardiologist from its staff, following an internal investigation into his conflict-of-interest disclosures.

The doctor filed a lawsuit against the clinic last December, which has yet to be resolved, claiming defamation and discrimination.

In his complaint the doctor alleged "widespread and pervasive conflicts of interest" at the Cleveland Clinic. The clinic has declined to comment on the pending lawsuit.

Red Flags Rule Delayed: The Federal Trade Commission (FTC) has delayed enforcement of the new "Red Flags Rule" until May 1, 2009. This delay gives creditors and financial institutions additional time to develop and implement written identity theft prevention programs. The Red Flags Rule was adopted to require financial institutions and creditors to implement identity theft detection and prevention programs. The FTC has taken the position that the rule applies to any entity, including a hospital or other health care provider, that regularly arranges for the extension, renewal, or continuation of credit. Enforcement of the rule initially was set to begin Nov. 1, 2008.

OIG Clears Arrangement: Two Medicare-participating durable medical equipment suppliers will not risk violating the anti-kickback statute by entering into arrangements with hospitals to place inventory and licensed personnel on-site for hospital patients who are prescribed respiratory equipment, according to a November 26 advisory opinion (No. 08-20) from the Department of Health and Human Services Office of Inspector General (OIG). The OIG said that because no remuneration would flow between the suppliers and the hospitals, the proposed arrangement would not implicate the anti-kickback statute and therefore would not constitute grounds for administrative actions. The advisory opinion is available at *http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-20.pdf*.

Joint Commission Revises Policy: Beginning Jan. 1, 2009, under a new Joint Commission policy, laboratory accreditation decisions will no longer immediately impact hospital accreditation decisions. This policy establishes comparability in the way that a laboratory with an adverse accreditation decision rendered by the Joint Commission or one of its cooperative partners, the College of American Pathologists or COLA, impacts the hospital or other organization with which the laboratory is affiliated. Currently, a laboratory's accreditation has a direct impact on the accreditation status of its affiliated organization. Details are available at *www.jointcommission.org*.