G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Congress to Tackle Physician Pay Cut Again; Lawmakers Look to Extend Two-Month Deal

Congress will have much on its plate when it returns from break at the end of January, including what to do about the two-month deferral of the Medicare physician pay cut that is now scheduled to go into effect March 1. Unless lawmakers act to extend the deferral, physicians will see their Medicare payments drop by 27.5 percent.

In a Jan. 5 G2 Intelligence webinar, Alan Mertz, president of the American Clinical Laboratory Association, predicted that Congress would extend the deferral until the end of 2012, along with an extension of the pathology grandfather protection that allows independent labs to bill Medicare directly for the technical component of pathology services to hospital inpatients and outpatients. That protection is also set to expire March 1 unless extended.

A 10-month "fix" of the pay cut is estimated to cost about $20 billion. Health care groups have advocated for a permanent fix to the sustained growth rate (SGR) formula that is used to calculate the annual update to the Part B physician fee schedule. When physician spending exceeds

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AMA Threatens HIPAA Complaint Over MolDx

The American Medical Association (AMA) has threatened to file a complaint under the Health Insurance Portability and Accountability Act (HIPAA) if Palmetto GBA does not suspend implementation of its new coverage and payment program for molecular diagnostic tests. The program, dubbed MolDx, is scheduled to go into effect March 1.

In a Dec. 19, 2011, letter sent to Marilyn Tavenner, acting administrator of the Centers for Medicare and Medicaid Services (CMS), the executive vice president and CEO of the AMA says that the MolDx program "is contrary to the agency's obligation to comply with standard code use as mandated by [HIPAA] and adds regulatory complexity, cost, and variability while also committing the agency to a path that may very well increase health care costs dramatically."

The program actually violates HIPAA by establishing a new code set—the Z-Codes™, argues James Madara, M.D. Use of Z-Codes by HIPAA-covered entities will place these entities out of compliance with HIPAA and subject them to complaints and penalties under the law. Under the MolDx program, clinical laboratories and makers of

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Congress to Tackle Physician Pay Cut Again, *from page 1*

a target growth rate, the update is negative, as has happened for most of the past decade, prompting Congress to step in repeatedly to cancel the fee reductions.

A permanent fix to the SGR is "near-impossible," says Mertz, noting that it would cost about $300 billion over 10 years. More than likely, Congress will continue to approve short-term freezes on any Medicare cuts for physicians.

Because lawmakers are reluctant to tackle Medicare reform in an election year, Mertz predicts that little will change in 2012. However, he notes that 2013 is a different story altogether. Under current law, an automatic 2 percent cut to Medicare reimbursement will take effect Jan. 1, 2013. Plus, an expiration of the debt ceiling in 2013 will lead to a return of major spending cut proposals, including those affecting Medicare.

What's more, if the Republicans take over the White House in 2013, they may seek a major overhaul of entitlement programs, which also could lead to Medicare cuts. "I see some very serious dangers [for labs and pathologists] in 2013," says Mertz.

Between 1995 and 2011, payment under the clinical laboratory fee schedule has increased only 7.7 percent. In comparison, inpatient hospitals have seen a 51.4 increase in Medicare payments, outpatient hospitals a 35.6 percent increase, and physicians a 27.9 percent increase.

While a lab copay or coinsurance could come up again, Mertz believes the lab industry has done a good job in making its case that such a proposal would be bad policy. Not only would such an initiative be difficult to administer since labs are the only provider without a routine face-to-face encounter with the patient, but it also would not be cost-effective since the cost of collecting the coinsurance would often exceed the amount owed. "I think we've convinced most people on the Hill that this is a bad idea," he says.

Medicare reimbursement for labs has already been reduced substantially, Mertz adds, noting that labs received a zero or negative update to the clinical laboratory fee schedule in 14 of the last 22 years. Even though the lab fee schedule received a 0.65 percent increase for 2012, under current law, labs will see their Medicare reimbursement drop 11.3 percent over the next three years, he explains. Between 1995 and 2011, payment under the clinical laboratory fee schedule has increased only 7.7 percent. In comparison, inpatient hospitals have seen a 51.4 increase in Medicare payments, outpatient hospitals a 35.6 percent increase, and physicians a 27.9 percent increase.

"We have nothing left to give," says Mertz.

CMS Postpones Two Demonstration Programs To Identify, Deny Improper Claims

The Centers for Medicare and Medicaid Services (CMS) Dec. 29, 2011, said it would postpone two demonstration projects intended to reduce improper payments and eliminate fraud, waste, and abuse.

The Prepayment Review and Prior Authorization for Power Mobility Devices demonstration, and the Recovery Audit Prepayment Review, scheduled to begin Jan. 1, were delayed indefinitely. CMS in an announcement to providers said it "is

carefully considering" the many comments and suggestions received. The programs were announced in November 2011.

The recovery audit program is to authorize Recovery Audit Contractors (RACs) to review Part A claims that have high rates of improper payments before they are paid. The prepayment reviews were to focus on inpatient hospital claims involving short stays, which have had high rates of improper payments.

The demonstration was aimed at lowering the error rate by preventing improper payments rather than methods of looking for improper payments after they occur, CMS said. The program, slated to run for three years, was to take place in 11 states—Florida, California, Michigan, Texas, New York, Louisiana, Illinois, Pennsylvania, Ohio, North Carolina, and Missouri.

The power mobility program required a prior authorization process for Medicare beneficiaries who were prescribed a power wheelchair or scooter. CMS had said the demonstration was intended to ensure that beneficiaries' medical conditions warrant their medical equipment under existing coverage guidelines.

CMS said it will provide at least 30 days' notice before the demonstrations begin.

Lab Worker Who Destroyed Expired Samples Could Not Prove Whistleblower Act Violation

A hospital did not violate Michigan's whistleblower protection statute when it fired a lab worker who destroyed specimens received in expired transport media, a federal district court held Dec. 7, 2011, in granting summary judgment for the hospital on the worker's claim (*Hilden v. Hurley Medical Center*).

The U.S. District Court for the Eastern District of Michigan found that defendant Hurley Medical Center (HMC) fired plaintiff Sally Hilden for destroying the samples, not—as she contended—for reporting to hospital authorities that the laboratory was processing expired specimens in contravention of the standards that govern its accreditation.

The court also held that Hilden and co-plaintiff Jerome Flynn could not recover on their claim that the hospital retaliated against them for exercising their First Amendment rights. Even if the plaintiffs' reports were protected speech, their destruction of the samples was not, the court said.

Expired Transport Media Discovered

Hilden and Flynn were medical technologists in HMC's microbiology laboratory. Their duties included receiving swabs containing specimens collected from patients at area doctors' offices and trying to grow bacteria to identify infectious organisms. HMC furnished doctors with kits used to collect samples and transport them to the laboratory. The kits were marked with expiration dates.

According to the court, the expiration date applied to the nutrient liquid in which bacteria could grow after a doctor placed the sample in a tube. A positive result from a specimen grown in a tube with an expired liquid generally was considered reliable, but a negative result was not, it said.

On Jan. 19, 2010, Hilden discovered a specimen that had been sent to the lab in an expired transport media. She discarded the specimen. On Jan. 20, 2010, the direc-

tor of the lab, co-defendant Varuna Tewari, sent an e-mail advising technicians to watch for expired samples but to test the cultures and inform doctors that they might have been compromised.

Hilden and Flynn objected to Tewari's directive and told their supervisor they thought it violated standards promulgated by the hospital's accrediting organization, the Joint Commission.

Hilden discovered and destroyed two more samples transported in expired media. Flynn discarded expired transport media and canceled a culture request, but he did not discard the culture plate, so the lab was able to recover the specimen.

HMC, through co-defendants Sheila Moore and David Szczepanski, terminated Hilden for destroying the specimens and disciplined Flynn for his actions.

Whistleblower Protections

Hilden and Flynn brought suit, claiming that HMC violated Michigan's Whistleblower Protection Act (WPA), Mich. Comp. Laws §15.362. The court said that to state a prima-facie case that she was disciplined in violation of the statute, a plaintiff must show she was engaged in protected activity, she was discharged or discriminated against, and a causal connection between the protected activity and the adverse employment action existed.

The act of destroying the samples, moreover, was not protected by the First Amendment, the court said. It was "abundantly clear" that the destruction was not intended as a communication but rather to ensure the tests would not be completed, it said.

The court found that Hilden and Flynn could not prove a causal connection between their reporting of the lab's treatment of the expired specimens and the discipline they received. It was clear, the court said, that the plaintiffs were disciplined for disposing of samples, not for making the reports. Moreover, the court said, discarding the samples was not protected activity under the WPA.

The court noted that when the plaintiffs met with Moore to report their concerns, Moore immediately instructed Tewari to contact the Joint Commission to determine whether the testing practice violated its standards. This showed, the court said, that Hilden and Flynn likely would not have been disciplined simply for reporting their concerns.

First Amendment

The court also found that Hilden and Flynn could not succeed on their claim that they were disciplined in retaliation for exercising their First Amendment rights. As public employees, Hilden and Flynn's free speech rights were curtailed, the court said. Their speech was protected only if it related to a matter of public concern.

Assuming for purposes of this case that the plaintiffs' complaints related to a matter of public concern, they still could not overcome the hospital's evidence that they were disciplined for destroying samples, not for reporting a possible violation of Joint Commission guidelines, the court said.

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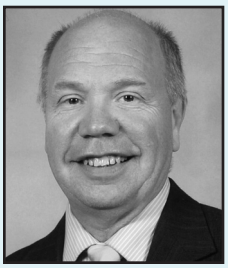
COMPLIANCE PERSPECTIVES

Key Compliance Challenges for Laboratories



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Health care in America is a highly regulated industry. Providers must comply with a myriad of government and private agency rules and regulations. The laboratory sector is one of the most highly regulated areas of health care, with billing being one of the top risk areas. To top that off, the rules and regulations are constantly changing, creating a challenge for laboratories to keep up to date. This article will address current compliance topics and will look at some compliance challenges that are scheduled to happen in the near future.

The message seems to be that while CMS will not require a signed requisition, it is in the laboratory's best interest to obtain one when possible. That will ensure that the test request is valid. The laboratory must accept the risk of not having a valid order when submitting claims.

Signatures on Laboratory Requisitions

The Centers for Medicare and Medicaid Services (CMS) created a lot of angst this past year with the publication of a final rule requiring signatures on lab requisitions, delaying the enforcement, and then revoking the requirement at the end of the year. This created a merry-go-round for laboratory compliance. CMS issued the revocation in the Nov. 28, 2011, *Federal Register*, while at the same time reiterating its concern about proper documentation of the ordering of laboratory tests. Medicare's longstanding policy that requires orders to be signed in a patient's chart remains unchanged.

CMS also gave caution and guidance to laboratories concerning the receipt of valid orders from a physician or nonphysician provider (NPP). The warning from CMS warns labs that they will be required to return Medicare payments if during an audit a valid order cannot be located. A valid order would be a signed notation in the patient's chart or a signed requisition. The message seems to be that while CMS will not require a signed requisition, it is in the laboratory's best interest to obtain one when possible. That will ensure that the test request is valid. The laboratory must accept the risk of not having a valid order when submitting claims.

Specifically, CMS stated in final physician fee schedule, published in the Nov. 28, 2011, *Federal Register:*

> We remain concerned about the costs and impact of fraud and abuse on the Medicare program. The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP. We believe that all parties share in the responsibility of ensuring that Medicare services are provided only in accordance with all applicable statutes and regulations, such as the requirement for a physician or NPP order. In many instances, such as in the case of orders originating in hospitals, we believe that retaining all the other requirements previously discussed, especially requiring the physician or NPP who orders the service to maintain documentation of medical necessity in the beneficiary's medical record according to § 410.32(d)(2)(i),

as well as the hospital CoPs on medical record services at § 482.24, are sufficient. However, we note that hospital CoPs do not apply to other settings, such as private offices. We believe it is the responsibility of the clinical diagnostic laboratory, as it is for the provider of any service, to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP. This proposed rule does not preclude an individual laboratory from requiring a physician's or NPP's signature on the requisition. The laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order. Such procedures could include internal audits, agreements with ordering physicians or NPPs to provide medical record evidence of the order in the event of an internal or external audit, steps to confirm the existence of an order under certain circumstances, or any other measures including the acceptance of risk by the clinical laboratory.

CMS agreed in the negotiated rulemaking more than 10 years ago that it would request chart documentation if order and diagnosis information needed to be verified. The agency has been trying to push this back to the laboratories ever since.

The suggestion for increased auditing is problematic for the laboratories in many ways. The laboratories will not have access to the patient's chart for most outpatient and outreach patients, especially for nonaffiliated or nonemployed physician practices. Secondly, the sheer amount of time to do this is significant. Laboratories receive hundreds, if not thousands, of requisitions per day. Chart audits take a lot of time and are unfeasible to perform for every patient. CMS agreed in the negotiated rulemaking more than 10 years ago that it would request chart documentation if order and diagnosis information needed to be verified. The agency has been trying to push this back to the laboratories ever since.

Drug Screen Coding

The 2011 Medicare Clinical Laboratory Fee Schedule (CLFS) introduced a new drug screen Healthcare Common Procedure Coding System (HCPCS) G0434 code. G0434 was created in 2011 for the purpose of having a code to bill for the simple, point-of-care drug screening separately from the more complex drug screening methods. The 2011 CLFS notice also revised the description on the existing code G0431. The 2010 description for G0431 was "Drug screen; qualitative, single drug class method (e.g. immunoassay, enzyme assay) each drug class." The description was changed in 2011 without prior notice or an opportunity to comment to "Drug screen; qualitative, multiple drug classes by high complexity test method (e.g. immunoassay, enzyme assay) per patient encounter." The inclusion of "high complexity" is the first time a reference to CLIA complexity has ever appeared in a description of a current procedural terminology (CPT©) or HCPCS code. It is problematic, as there are very few high-complexity drug screen methods that use the immunoassay, enzyme assay methodology. The few that we could find are for hair and saliva samples, not urine.

The laboratory community commented to CMS concerning this dilemma as most drug screens in hospitals and independent laboratories are performed on a urine specimen with a multichannel discrete chemistry analyzer. Laboratories lobbied for a new code for drug screens run on instrumentation but so far have been unsuccessful in a change. For now, CMS is saying drug screens run on large chemistry analyzers should be billed with the same HCPCS code as the simple point of care visual drug screen, G0434.

New AMA Molecular Diagnostic CPT© codes

The American Medical Association (AMA) created over 100 new CPT codes for molecular diagnostics for 2012 in the range of 81200 to 81408. CMS has indicated that it will not recognize the new CPT codes in 2012. However, some private insurance payers may request the use of the new codes this year as they give the insurance organization a much clearer picture of which test was actually performed. Methodology codes that are used for steps in performing the testing are commonly referred to as "stacking" codes. This set of codes, 83890 to 83913, will still be valid in 2012. So we will have two parallel sets of codes for the same testing. The CMS instructions for use of the 2012 CLFS request that laboratories bill Medicare using both sets of codes with prices on all codes. CMS has set payment on the new CPT codes as $0 and a noncovered status, so it will not be paying on the codes, but it wants to see the volume of usage and the prices that will be charged. This also creates problems for the laboratory, since for the first time Medicare is asking laboratories to double-bill the program for a procedure.

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Duplicate Billing With Point-of-Care Testing

Another area for compliance officers to be aware of is the possibility of point-of-care testing and main laboratory testing being performed at the same time on the same patient. This is sometimes seen in the emergency department where the nursing staff will perform a rapid point-of-care test, such as an i-Stat panel, and at the same time collect blood and send it to the main laboratory for the same tests. The results are duplicative because the collection times are within a couple of minutes of each other. One or the other of the tests should not be billed to the patient.

Venipuncture Billing

Most laboratory information systems post charges to a separate billing system. The charges can be posted upon completion of the test (ideally) or upon receipt of the specimen. Venipunctures are usually manually posted using a billing or procedure code upon receipt in the laboratory. Sometimes a specimen processor will get into a habit of receiving everything into the laboratory with the venipuncture code. If this happens, you will see venipuncture charges on nonblood specimens such as urines and cultures. This is something that should be monitored in your laboratory.

Respiratory Virus PCR Panels

The increased popularity of polymerase chain reaction (PCR)-based respiratory panels has created a few new compliance concerns. One problem is which CPT to bill, another is custom panels, and a third problem is potentially confusing test orders:

- **Which CPT?**—The CPT codes for respiratory virus DNA testing include 87798 (each organism), 87801 (multiple organisms), and 87501-87503 (influenza viruses). You will need to determine which codes are correct by talking to the laboratory technical staff and reviewing manufacturer's recommendations.
- **Custom panels**—There is no AMA CPT-defined respiratory virus panel. Laboratories have created panels that range from two to 15 different viruses.
- **Confusing test orders**—There must be an agreement and clarity with the physi-

cian as to what tests will be performed if orders such as these are received: "flu test," "resp panel," "mini resp panel," etc. What methodology will be used to perform the testing: PCR, DFA, film array? What tests are in the panel?

ICD-9 to ICD-10 Conversion

Almost all health care providers in the United States will be moving from the ICD-9 coding system to the ICD-10 coding system on Oct. 1, 2013. Laboratories should be preparing now to make the switch as there will be no grace period. Coders and pathologists who assign diagnostic codes will need to be trained on the new system. The national coverage determinations (NCDs) and local coverage determinations (LCDs) will all be converted to the new codes. CMS will be publishing the NCDs with ICD-10 codes well before the switchover date. Laboratories will need to reprogram any medical necessity software programs and redo any forms or requisitions that currently have an ICD-9 code on them.

Top 10 Laboratory-Related CERT Error Findings

Noridian, the Medicare contractor for MAC Jurisdiction 3, recently published the top 10 errors it is seeing in laboratory CERT audits. They are worth noting and paying attention to in your compliance efforts.

1. **Incorrect coding of urinalysis.** UA with micro billed where the order makes no mention of a microscopic exam.
2. **Urine culture must have an order.** Seeing orders only for a UA with no mention of a culture (cannot be a lab protocol, must come from the physician).
3. **Drug screen ordered with no mention of which drug classes to screen for** (this problem is eliminated with 2011 coding, with billing allowed only once per encounter).
4. **Inappropriate use of 59 modifier to bypass National Correct Coding Initiative edits.**
5. **No physician order in the chart; intent was not determined.** Clinical note must support the need for the laboratory services.
6. **Coding of a venipuncture when there were no other services, or no services, requiring blood specimens.**
7. **Monitoring Coumadin levels without a physician order.** An order from the pharmacist is not acceptable. The treating physician needs to be involved by reviewing the results and treating the patient based on the results.
8. **Missing lab results.**
9. **Need to follow the signatures on orders**—transmittal CR6698.
10. **Documentation needs to support preop work.** Will not pay for purely screening purposes.

Summary

As you can see, there are many laboratory compliance issues to be aware of in 2012 and beyond. The documented orders could be quite problematic, as they are out of the control of the laboratory, but the lab will be the one penalized if the order cannot be substantiated. Most laboratories are in a transition period between paper orders and secure electronic orders. Documenting a valid order will not be as difficult once electronic orders are in widespread use.

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AMA Threatens HIPAA Complaint Over MolDx, *from page 1*

diagnostic tests will be required to obtain from McKesson, a health care consulting company, a Z-Code for its molecular diagnostic tests. Failure to obtain and use a Z-Code on claims submitted to Palmetto in the J1 region will result in the claim being rejected.

Madara notes that the AMA has already received reports from the Blue Cross Blue Shield Association and America's Health Insurance Plans of massive confusion among providers, laboratories, and health plans attempting to ascertain when to use the codes in CPT 2012, the "stacking codes," and the proposed Z-Code set.

"In addition, other stakeholders are reporting that the policies of the MolDx program have not been well-developed, are evolving daily, are not memorialized in one place, and are conflicting," writes Madara. "None of the foregoing is surprising given the lack of stakeholder engagement, the failure to provide basic notice and comment, the rapid implementation date, and the fact that this code set did not comply with requirements CMS established for adopting a HIPAA code set."

Jurisdiction 1 Part B MolDx Exempt Tests

MolDx EXEMPT NO Z-CODE OR TA REQUIRED	Z-CODE REQUIRED NO TECH ASSESSMENT REQUIRED	Z-CODE REQUIRED TECH ASSESSMENT REQUIRED
Tests specifically described by a single CPT/HCPCS code and submitted with one unit of service	Any test that meets the following: • 101 New MDT CPT codes • FDA cleared/approved (unmodified) tests • Current New York State (NYS) approved tests • Grandfathered NYS tests developed prior to 2003 • National Institutes of Health Genetic Testing Registry (GTR)	A laboratory developed test (LDT) producing a single result and billed with multiple CPT codes including any combination of the following: • methodology-based stacking CPT codes (83890-83914) • microarray CPT codes (88384-88386) • microdissection CPT codes (88380-88371) • other pathology/laboratory codes
Infectious disease molecular diagnostic testing described by CPT codes (87001-87905)	Coverage Determination by Palmetto GBA LCD or Article, i.e. • Tumor of origin assays • OncotypeDx Breast™ • OncotypeDx Colon™ • Allomap™ • HERmark™	MDT/LDT that provides • diagnostic determination • prognostic/predictive determination • risk assessment • screening
Cytogenetics – CPT codes 88230-88291		Pathology and Laboratory Not Otherwise Classified (NOC) codes
Surgical Pathology (CPT codes 88300-88372) including the following: • Flow cytometry – CPT codes 88182-88189 • Immunohistochemistry (IHC) CPT code 88342 • in situ hybridization (ISH) testing CPT code 88365		Modified FDA cleared/approved tests
Reagents • Analyte Specific Reagents (ASR) • Research Use Only Reagents (RUO)		

Source: Palmetto GBA

The AMA is not the only group expressing concerns about MolDx. The American Clinical Laboratory Association (ACLA) in December submitted comments to Palmetto detailing issues it has with the program, including concerns that labs would be required to provide valuable commercial information to McKesson, a third-party vendor, and that McKesson "could use and profit from the information in its other private business arrangements" (*GCR, Jan. 2012, p. 1*).

ACLA and other groups also complained about the licensing agreement with McKesson that labs would be required to sign. In response to concerns raised by ACLA and others, the program manager for MolDx said modifications would be made to protect proprietary information and to address licensing issues issues.

Mike Barlow, vice president and program manager for Palmetto, said the contractor would simplify the Z-Code process "to capture only critical basic, demographic, and general test descriptions. Specific test elements will only be required as part of the tech assessment process." Barlow also said that under changes to the licensing agreement, "users will be asked to acknowledge the use limitations of the Z-Code in a manner similar in content and intent to other familiar type user agreement disclaimers. As with other software licenses, the user will be required to acknowledge the proprietary rights of the owner organization at the time of submission."

Palmetto GBA also has published a chart to show which categories of tests would be required to obtain a Z-Code and which ones would be exempt either from getting a Z-Code or from a technical assessment (*see chart page 9*).

Rina Wolf, vice president of commercialization strategies for XIFIN, a San Diego company that offers revenue cycle management software and solutions, says she has not seen any major changes to the MolDx program yet, but she believes Palmetto is listening to the lab industry and she remains optimistic that modifications will be made.

OIG: No Sanctions for Proposed Online Referral Service for Health Professionals

The Department of Health and Human Services Office of Inspector General (OIG) would not impose administrative sanctions or civil monetary penalties on a company that provides Web-based services to physicians for a proposed plan to facilitate referrals between health professionals, the OIG said in an advisory opinion posted Dec. 7, 2011 (No. 11-18).

The proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute if there was the requisite intent to induce or reward referrals, the OIG said. However, the OIG declined to impose sanctions under Sections 1128(b)(7) and 1128A(a)(7) of the Social Security Act.

"[T]he facts and circumstances of the Proposed Arrangement, in combination, adequately reduce the risk that the remuneration provided under the Proposed Arrangement could be an improper payment for referrals or for arranging for referrals of Federal health care program business," the OIG said.

The requester, a publicly traded company that provides Web-based business services to physician practices, asked the OIG to advise whether its proposed new service would violate the anti-kickback statute. The requestor said it designed the service to reduce

the expense and opportunity for error associated with communications between health care professionals.

The service would assist health professionals in making referrals. It would help them send demographic information, medical records, as well as a patient's insurance and billing data, the requestor said. Also, the professionals would be able to enter into "trading partner" agreements with the requestor, enabling the professionals to customize their profiles and electronically submit comprehensive referrals.

"[T]he facts and circumstances of the Proposed Arrangement, in combination, adequately reduce the risk that the remuneration provided under the Proposed Arrangement could be an improper payment for referrals or for arranging for referrals of Federal health care program business."

— OIG

Terms of the Proposal

Under the proposal, health professionals would not have to be "trading partners" to receive referrals. Where the person receiving the referral is a nontrading partner, the trading partner would pay the fee, which in no case would exceed $1 per transaction, the requestor said.

"We must consider whether such payments, when they are made by the Trading Partners, constitute remuneration in return for the Requestor's: (i) influencing Ordering Health Professionals to refer Federal health care program beneficiaries to Trading Partners, or (ii) otherwise arranging for the furnishing of items or services for which payment would be made by a Federal health care program," the OIG said.

Safeguards Against Kickbacks

The OIG said the proposed arrangement adequately reduced the risk that the remuneration included in the proposal would violate the anti-kickback statute, citing the safeguards it would provide:

- The requestor would offer a comprehensive network, within which all health care professionals in the marketplace could participate, and from which a referral could be selected.
- The requestor certified that the fees charged would reflect the fair market value of the actual services the requestor would provide to the health professional.
- The fee structure would be unlikely to influence the referral decision.
- The coordination service is intended to facilitate the interchange of information, not to limit the pool of health professionals from which referrals might be chosen.
- The trading partner's payment of the fees to the requestor would not provide the trading partner with enhanced access to a referral.
- The proposed pricing model is reasonable under the circumstances.

"Importantly, under the Proposed Arrangement, the Requestor would assess the Transmission Fee each time an Ordering Health Professional makes a referral to a receiving Health Professional using the Coordination Service, regardless of whether the patient follows through and actually receives items or services from the receiving Health Professional," the OIG said.

News-At-A-Glance

HHS SEEKS SAFE HARBOR SUGGESTIONS: The Department of Health and Human Services (HHS) Office of Inspector General (OIG) is seeking recommendations from the public to help it develop new or revised safe harbors from the federal anti-kickback statute. In a Dec. 29, 2011, *Federal Register* notice, HHS also seeks comments on developing new OIG Special Fraud Alerts, which provide guidance to health care providers on practices that the OIG finds could be fraudulent or abusive and that the agency wants to emphasize to providers. Comments are due Feb. 27. Safe harbor exceptions to the anti-kickback statute are required by Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 because of the sweeping nature of the statute. Safe harbors are exceptions to the statute's reach and are determined by OIG in consultation with the Department of Justice. The harbors limit the regulatory controls to allow "beneficial and innocuous arrangements" while also protecting the integrity of federal health care programs.

YET ANOTHER REASON TO ELIMINATE SELF-REFERRALS: Physicians with financial interests in magnetic resonance imaging (MRI) equipment referred patients for 86 percent more exams that had negative results than physicians with no financial interests, raising the possibility that financial interests may lead to medically unnecessary tests, according to a study presented at the Nov. 30, 2011, annual meeting of the Radiological Society of North America. The study, which has yet to be published, examined 500 consecutive diagnostic lumbar spine MRIs that were ordered by two referring orthopedic physician groups located in the same geographic area. Half of the MRIs were referred by physicians who had a financial interest in the equipment, and the other half by physicians with no financial interest. The physician self-referral law, or Stark law, prohibits referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship if the referral is for the furnishing of designated health services. However, an in-office ancillary services exception allows physicians to provide certain services in their offices that otherwise would be prohibited, including imaging, clinical laboratory tests, physical therapy, and radiation therapy.

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