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For Hospitals, Laboratories and Physician Practices

Wall Street Journal Puts Spotlight On Physician Billing For Lab Services

A recent *Wall Street Journal* article concerning physician billing for lab tests has generated new debate about just how ethical the practice is.

The article, published September 30, examines arrangements between physicians and clinical laboratories that allow physicians to profit from the tests. Under this type of referral deal, a physician sends a patient sample to an outside lab for testing. The lab charges a discounted price, but the physician is reimbursed by an insurance company for a significantly higher amount, allowing the physician to make a profit.

Industry experts say referral deals have grown in recent years as physicians look for new sources of income and demand grows for costly lab tests, such as those for prostate cancer. Critics say referral deals compromise care by encouraging physicians to send tests "to the cheapest lab, not necessarily the best one" and order more tests than might be necessary, the *Journal* reports.

Although insurers could stop the practice, they are usually unaware of the deals. Blue Cross Blue Shield of Georgia, one of the only private insurers to stop the practice, requires direct billing from labs to avoid deals where physicians bill for services they did not directly provide. Medicare and a few states also require direct billing, although some companies have found a way to let doctors bill Medicare for off-site lab work by creating "condo" or "pod" labs.

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Inside this issue

New Safe Harbors Designed To Promote Use Of E-Prescribing, Electronic Health Records

The Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) have proposed exceptions to the Stark self-referral law and the anti-kickback statute for certain arrangements involving the provisions of electronic prescribing technology.

The protections, announced October 5, are required by the Medicare Modernization Act of 2003 (MMA) and are designed to speed the adoption of health information technologies by hospitals, physicians, and other healthcare providers.

Specifically, the OIG and CMS are proposing the following: 1) an anti-kickback safe harbor for e-prescribing; 2) two anti-kickback safe harbors for electronic health records; 3) a Stark law exception for e-prescribing; and 4) two Stark law exceptions for electronic health records.

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Robert Mazer, Esq.

Wall Street Journal, *from p. 1*

The *Journal* notes that the American Medical Association's code of ethics says under the heading of laboratory services that a "physician should not charge a markup, commission, or profit on the services rendered by others," although a doctor can levy a processing charge on such services. The AMA code says that a doctor "who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit is not acting in the best interest of the patient."

Although federal laws prohibit doctors from receiving inducements for referrals or referring patients for services in which they have a financial interest, labs and physicians that engage in this practice maintain that what they are doing is legal, says the *Journal* article: "Companies say they're just offering a service for a price, and that doesn't add up to illegal inducement."

Robert Mazer, an attorney with Ober/Kaler (Baltimore), notes that it's difficult to judge whether there is anything wrong with such an arrangement. "Clearly there's something 'wrong' if it leads to unnecessary biopsies," he tells *GCR*. "In addition to patient inconvenience and discomfort, there may be a significant payment to the physician for excising the specimen."

But it's not clear that the arrangement necessarily leads to increased payments for the pathology procedures, Mazer adds. "The outside lab which bills the physician $30 for the service – who then bills and receives payments of $100 from the insurer – might very well bill the insurer $100 in the absence of the client-bill arrangement with the physician."

Discount arrangements do raise kickback concerns, Mazer says. In fact, three former executives of UroCor Inc. were indicted last year on charges that they and the company charged discount prices to doctors and then billed private insurance companies at a much higher rate. The indictment, cited by the *Journal*, charges that the discount was a kickback to induce the doctors to also refer work covered by Medicare, which was billed directly by the lab.

UroCor is now a division of LabCorp. The illegal activity alleged in the indictment occurred before UroCor was sold, and none of the three executives named in the indictment still work for UroCor. The case is scheduled for trial next June.

ACLA Defends Practice

In a letter to the editor of the *Journal*, dated October 3, Alan Mertz, president of the American Clinical Laboratory Association (ACLA), argues that the September 30 article lumps competitive discounts and pricing that are fully in accordance with state laws with sham arrangements (pods) that are designed to circumvent federal laws and regulations.

Under this arrangement, a physician practice (typically, a urology, gastroenterology, dermatology, or ob-gyn practice) sets up its own "pod" or "condo" lab in a separate building that also contains labs set up by other practices. While each laboratory operation has its own physical space and equipment, the same technical personnel and pathologists will be employed or contracted, on a part-time basis, by each of the laboratories. The technical personnel and pathologists move between units to provide their services for each of the labs. Typically, there is no hands-on involvement by any of the physicians in the specialty practices.

"While ACLA supports direct billing and agrees that it may represent the best policy, until it is mandated by law, it is not fair to equate legitimate and lawful commercial pricing policies with sham arrangements that circumvent federal laws," writes Mertz.

"ACLA is concerned about the proliferation of these 'pod arrangements,' which allow some physicians to share the revenues earned by their own referrals, even though the referring physician exercises no supervision or oversight of the services," Mertz continues, noting that ACLA brought these arrangements to the attention of the Health and Human Services Office of Inspector General and the Centers for Medicare & Medicaid Services in 2004.

Resources

- *Wall Street Journal* article, "Lucrative Operation: How Some Doctors Turn a $79 Profit From A $30 Test:" *www.wsj.com*
- Robert Mazer: 410-347-7359
- Alan Mertz letter to the editor: *www.clinical-labs.org*

Guidance On Waived-Test Studies Called Burdensome

Recently issued draft guidance on CLIA-waived testing potentially places an unfair burden on the end-users of the tests—primarily nurses in doctors' offices—and could be disruptive to the office staff, believes Erika Ammirati, president of Ammirati Regulatory Consulting (Los Altos, CA). Ammirati discussed the draft guidance during a September 29 audio conference sponsored by Washington G-2 Reports.

According to Ammirati, end-users of waived tests who participate in field studies would not receive any training on how to use the tests under the guidance, which the Food and Drug Administration (FDA) issued September 7. This could create problems for both test manufacturers and operators.

The draft guidance says that waived-test manufacturers "should evaluate test performance in a setting designed to replicate, as closely as possible, the actual intended clinical use setting." The study should be conducted at a minimum of three intended use sites at different demographic locations.

The intended operators of the tests should be provided with only the proposed package insert and/or Quick Reference Instructions, says the guidance. "Study participants should receive no training, coaching, prompting, or written or verbal instructions beyond the written test procedures," states the document. "They should have no opportunity to discuss the test with, or otherwise coach or observe each other."

Ammirati believes this expected lack of training is unrealistic if the FDA wants the tests evaluated in a real-life setting. "In the 'old' system, training of the testers was not allowed, and this was sound because the primary purpose of the evaluation was to see how the totally novice user would perform 'cold,'" she says in comments on the draft guidance.

"Now, if we wish to mimic real life, it is unreasonable that no 'training, coaching, or prompting' is allowed because that is not representative of the end-user environment. Sales representatives do not drop off test kits and/or equipment and leave the customer unsupported. They do not do this because doing so would be bad business. If the petition process will now require 'real-life' field studies, then minimal training must be allowed."

The draft guidance potentially presents additional problems for the end users, believes Ammirati. For example, the guidance says the manufacturer should conduct the study with a minimum of 360 patient samples from the intended use population; a minimum of nine operators should participate. The patient samples should be distributed equally among the operators and should be from consecutive patients over "an appropriate period of time"—the FDA suggests a one-month period "may be useful."

"The suggestion of consecutive patients over a month's time is an incredible intrusion to the doctor's office and the patients," says Ammirati in her comments. "When setting up POC IVD (point-of-care *in vitro* diagnostics) clinical trials for 510(k) submissions, companies work with office staff so as to be as unobtrusive as possible, and this usually requires that site study coordinators contact patients ahead of time and make the necessary arrangements. Using a random approach catches everyone off-guard, and study uptake is likely to be very low."

For the suggested field study plan to work, the manufacturer would have to dedicate at least one person per site for the time period to make sure the logistics are covered correctly, which would be "exorbitantly expensive and overly time-consuming," says Ammirati.

As an alternative, she recommends that field studies be conducted using prepared samples —either natural or artificial. "Patients do not need to be involved, and they should not be involved, due to the logistical issues raised," she argues. "Further, the assessment of 'accurate' and 'easy-to-use' can be made with far fewer than 360 results. This exceeds the scope of most 510(k)s."

The deadline for comments on the FDA draft guidance is December 6.

Resources

- FDA draft guidance on waived testing: *www.fda.gov/cdrh*
- Erika Ammirati: 650-949-2768

Recordings of the September 29 audio conference, "CLIA-Waived Testing: Understanding the Impact of FDA's New Guidance," may be purchased for $179 (subscriber rate). To order, go to www.g2reports.com.

CMS Issues Guidance On Good Laboratory Practices

The Centers for Medicare & Medicaid Services recently issued its own guidance document for end-users of waived tests, which identifies exactly what the agency expects of waived labs:

1. **Keep the manufacturer's product insert for the laboratory test in use, and be sure it is available to the testing personnel.** Use the manufacturer's product insert for the kit currently in use; do not use old product inserts.

2. **Follow the manufacturer's instruction for specimen collection and handling.**
   a. Are specimens stored at the proper room temperature?
   b. Are the appropriate collection containers used?

3. **Be sure to properly identify the patient.**
   a. Does the name on the test requisition (or prescription) match the patient's name?
   b. Does the name on the patient's chart match the name on the patient's identification?
   c. If more than one patient is present with the same first and last name, how do you determine which one is the test patient? (Look for possible gender differences, social security number, patient identification number, birthdates, different middle names, and relevance of the test to the patient's history.

4. **Be sure to label the patient's specimen for testing with an identifier unique to each patient.**

5. **Inform the patient of any test preparation such as fasting, clean catch urines, etc.**

6. **Read the product insert prior to performing a test.**
   a. Become familiar with the test procedure.
   b. Study each step and perform them in the proper order.
   c. Know the time required for performing the test and achieving the optimal result.
   d. Be sure to have all of the required reagents and equipment ready **before** actually performing the test.
   e. Be able to recognize when the test is finished – e.g., will there be a blue plus or minus sign against a white background?
   f. Follow the manufacturer's instructions and when a new kit is opened, perform the quality control to be sure that the kit works prior to testing patient samples.

7. **Follow the storage requirements for the test kit.** If the kit can be stored at room temperature, but this changes the expiration date, write the new expiration date on the kit.

8. **Do not mix components of different kits!**

9. **Record the patient's test results in the proper place, such as the patient's chart or the laboratory test log, not on unidentified post-it notes or pieces of scrap paper that can be misplaced.**
   a. Record the results according to the instructions in the manufacturer's product insert.
   b. If it's a qualitative test, spell out **positive/negative or pos/neg** because symbolic representations can be altered (the – can be changed to a +).
   c. Include the name of the test, the date the test was performed, and the initials of the testing personnel in the test record. Include the calendar year in the date.
   d. If the same test is performed on a patient multiple times in one day, include the time of each test.

10. **Perform any instrument maintenance as directed by the manufacturer.**

Resource: *www.cms.hhs.gov/clia wgoodlab.pdf*

COMPLIANCE PERSPECTIVES

Preparing For Lab Coding Changes In 2006

Joan Logue is president of Health Systems Concepts, a laboratory consulting firm based in Longwood, Florida

The advent of last year's HIPAA (Health Insurance Portability & Accountability Act) mandate, which no longer allows the 90-day grace period for implementing new and revised CPT® and HCPCS codes, means that laboratories must complete updating their charge file so the new and revised codes are available for billing date of services on or after Jan. 1, 2006. 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 2006 CPT update, HCPCS update, Clinical Laboratory Fee Schedule Instructions from the Centers for Medicare & Medicaid Services (CMS), Outpatient Prospective Payment System (OPPS) update, and, finally, the professional codes and instructions in the 2006 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 2006 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 OPPS and the Physician Fee Schedule.

ICD-9-CM Diagnosis Codes

The first step in the process 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.cms.hhs.gov/medlearn/icd9code.asp*. 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 2005 revisions for the NCDs are substantial and should be considered as the laboratory prepares to revise physician notices and update the internal edit programs to conform to the most recent diagnosis requirements. The new and deleted codes apply to 13 of the 23 NCDs. The changes to the NCD edit software can be viewed at *http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/MM4005.pdf*.

2006 HCPCS Codes

The laboratory uses HCPCS codes for reporting Medicare-approved screening tests, blood and blood products, travel codes, 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 CBC (complete blood count) 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 in early November. The 2006 instructions will be listed on the Medicare and Medicaid 2005 Program Transmittals site at *http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp*. The updates to the HCPCS code will also be available at *http://www.cms.hhs.gov/medicare/hcpcs/*.

2006 CPT® Codes[1]

The CPT Editorial Committee added 23 new codes to the Pathology and Laboratory section of the 2006 CPT. Also, there are eight

1. Current Procedural Terminology CPT® 2006; Pathology and Laboratory; American Medical Association; AMA Press Chicago, IL.

code description revisions and five code deletions. New codes appear in the Therapeutic Drug, Chemistry, Molecular Diagnostics, Immunology, Microbiology, Transfusion Medicine, and Surgical Pathology sections. The revised descriptions appear in the Chemistry, Microbiology, and Cytopathology sections. It is important that the laboratory pays close attention to the revised descriptions to ensure that the current codes assigned in their charge file are still appropriate for the tests. In addition, billing with deleted codes for services on or after Jan. 1, 2006, will result in nonpayment.

The five deleted codes are simply a renumbering of current CPT codes. The 2006 CPT has renumbered the code for the lipoprotein electrophoretic technique and revised the description and renumbered the code for the high-resolution separation of the lipoprotein subclasses by ultracentrifugation. CPT also added a new code in this series of codes for the determination of lipoprotein subclasses by nuclear magnetic resonance.

CPT deleted three codes in the Immunology subsection. These codes are the 2005 codes for the *B cell total count*, *Natural killer (NK) cells, total count*, and *Stem cells (ie, CD34), total count.* CPT renumbered the descriptions so all the total count codes group together in the Immunology section, making it much easier for labs to identify the correct CPT code for reporting total counts. These codes are to be used whenever a quantitative analysis for the total count is ordered, such as assessing immunodeficiency, which does not require an interpretive report.[2] You will want to ensure that your charge master contains the new CPT codes for these renumbered procedures. As indicated above, reporting the deleted codes will result in a payment denial.

You may order the 2006 CPT online or by paper order. Information on ordering the AMA 2006 CPT book may be found at *https://catalog.ama-assn.org/Catalog/home.jsp?checkXwho=done* . Updating your charge master requires having the most current CPT book. You can easily identify the changes in the Pathology and Laboratory section 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.

Chemistry Molecular Diagnostics

Perhaps the most significant CPT changes are the new and revised molecular diagnostic codes for human genetic testing. The first change of note is that the phrase "each primer pair" has been changed to "each nucleic acid sequence." This revision has no payment implications as it simply brings the description current with today's terminology. However, the addition of new code 83900 and the revision of CPT code 83901 have significant payment implications for both the laboratories performing molecular diagnostic testing and the labs referring requests for human genetic tests, such as those for Cystic Fibrosis (CF).

Currently laboratories are paid a single $23.42 national limitation amount (NLA), for the multiplex reactions taking place in a single tube, regardless of the number of nucleic acid sequences that occur. In 2006, this payment inequity will be corrected with the addition of code 83900 and the revision of code 83901 as shown below.

- 83900 *Molecular diagnostics; amplification of patient nucleic acid, multiplex, first two nucleic acid sequences*
- 83901 *Molecular diagnostics; amplification of patient nucleic acid, multiplex, each additional nucleic acid sequence (List separately in addition to code for primary procedure)*

CMS has set the payment rates on the Medicare 2006 Clinical Laboratory Fee Schedule for CPT code 83900 at $46.84 NLA. The payment rate for CPT code 83901 will remain at $23.42 NLA, but the ability to bill each additional nucleic acid sequence beyond the first two will require that the laboratory's internal systems allow for billing units for code 83901. This, along with the addition of the new code 83900, will result in a significant difference in the total payment amount for such tests as those for CF. For example, in 2005, a CF molecular assay that tests for 25 mutations using a 20-plex nucleic acid sequence is reported using the multiplex code 83901 x 1 unit. But, in 2006, the laboratory may report

2. CPT ® CHANGES 2005: An Insider's View; American Medical Association; AMA Press Chicago, IL p. 149.

the same CF assay with 83900 x 1 unit plus 83901 x 18 units.

Laboratories may wish to confirm whether their individual state Medicaid programs will allow reporting the molecular diagnostic codes as described. Currently, some state Medicaid programs do not recognize the molecular diagnostic codes 83890 through 83912.

There are several other additions to the molecular diagnostic codes of which labs should be aware. In the 2006 book, CPT added code 83909 for reporting the capillary electrophoresis procedure step in a molecular diagnostic analysis. In 2005, laboratories either reported code 83894 *separation by gel electrophoresis* for this step or 82664 *electrophoretic technique, not elsewhere specified*. In either case, laboratories need to update the charge file so that this step in the analysis can be correctly reported to the third-party payer.

The new codes, 83907 *lysis of cells prior to nucleic acid (e.g., stool specimens , paraffin embedded tissue)*, 83908 *signal amplification of patient nucleic acid, each nucleic acid sequence*, and 83914 *mutation identification by enzymatic ligation or primer extension, single segment, each segment,* should also be added to the charge file. 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.

The anti-rejection medication, Sirolimus, was added to the Therapeutic Drugs section and there are a number of other additions and revisions to the Chemistry section that should be reviewed for possible addition to the charge file.

Immunology

In addition to the renumbering of the three total count codes discussed earlier, CPT added a code for the cyclic citrullinated peptide antibody (CCP), an antinuclear antibody often found in autoimmune disorders, such as rheumatoid arthritis. CPT also changed the TB gamma interferon antigen response test from a Category III code to a Category I code.

The new code 86480 *tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response* is for reporting this new test, which is diagnostic for TB infection. This is a Food and Drug Administration approved test, and it will replace the TB tine test. CPT has, therefore, deleted 86585 *skin test; tuberculosis, tine test* from the 2006 CPT. At the time of this writing, only one TB gamma interferon antigen response test kit is FDA approved, but it is expected that additional companies will obtain FDA approval for their TB test kits. Laboratories should be aware that a few of the Medicaid programs have a test policy in place limiting the testing to a specific company and also, in some cases, limiting coverage. Since the incidence of TB may be higher in the Medicaid population, the laboratory will want to stay current with their state Medicaid policy for this test. The 2006 Medicare Clinical Laboratory Fee Schedule NLA for code 86480 is $86.58.

Microbiology

In Microbiology there are two new codes. The first new code, 87209, is for the interpretation of an ova and parasite special stain, such as trichrome. A number of third-party payers incorrectly deny payment when the laboratories reported the special stain code from the surgical pathology section of CPT with the ova and parasite code. This new code provides clarity for the ova and parasite test interpretation and should be helpful in obtaining payment when a special stain is performed.

The second new code in this subsection, 87900 *infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics*, is a very significant addition to the 2006 CPT book and to the Medicare Clinical Laboratory Fee Schedule. This is the first time that both CPT and Medicare have recognized the need for a separate code to reflect the bioinformatics interpretation portion of the analysis, and it is the first time that Medicare has recognized this as a cost to the laboratory. This code may help establish the precedent for coding and payment of bioinformatics data as we move into the era of arrays and proteomics. The 2006 NLA for code 87900 is $182.11.

Transfusion Medicine

CPT has also added two new blood bank codes to the Transfusion Medicine subsection. New code 86960 is for reporting blood product volume reduction, when performed, and code 86923 is for reporting the electronic cross match. In the past, CMS has not allowed payment for the electronic cross match when billed either with the blood bank miscellaneous code or with code 99090 *analysis of clinical data stored in computers.* If CMS agrees to pay for the electronic cross match, code 86923 will be paid under the Outpatient Prospective Payment System (OPPS) and will be priced at a defined APC rate. In the past, when new CPT codes fell under OPPS, the pricing for the new blood bank codes have not appeared in the OPPS tables until the first update, which usually occurs in the spring of each year. Laboratories will need to monitor the 2006 Medicare transmittals for the pricing information if it is not included in the tables with the 2006 OPPS final rule, which should be available at the end of 2005.

Surgical Pathology

Five new codes have been added to the Surgical Pathology section, and these should be included in the 2006 Medicare Physician Fee Schedule and the 2006 OP PPS APC schedule. Two of the codes are additional codes for pathology consultation codes during surgery. Code 88333 is for the touch prep, initial site, and 88334 is for the touch prep, each additional site. These will need to be added to the hospital charge file to be available for reporting and payment under OPPS for Medicare patients and for billings to private third-party payer for nongovernment inpatients and outpatients.

Also added to the Surgical Pathology section are three codes for reporting microarrays. CPT recognized the need for professional involvement and interpretation of the array as this new technology moves from the research laboratory into the diagnostic laboratory. The array codes listed in the surgical pathology section will be reported for studies that involve the use of 11 or more molecular probes, such as the pharmacogenic analysis of CY P450. To accommodate emerging microarray analysis, CPT has provided the following three new codes:

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

Arrays using less than 11 probes will continue to be billed with the molecular diagnostic codes listed in the Chemistry section. Guidance on billing arrays will be provided in the 2006 CPT book, the AMA publication, *CPT® Assistant,* and in the *CPT® CHANGES: An Insider's View 2006.* All three publications are available at the AMA online address provided.

Conclusion

In addition to the Category I code changes, laboratories should review the 2006 laboratory-related Category III codes. If the laboratory is performing a test that is described by a Category III code, the test must be reported to the payer with the Category III code rather than a generic method code. The Category III codes are not included on the Medicare Clinical Laboratory Fee Schedule. Also, the laboratory should review the listing of genetic testing code modifiers listed in Appendix I of the 2006 CPT book. CPT has added additional modifiers to the list.

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 correct 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 check of lab billings to verify that all electronic and manual systems involved in the order, results, billing, and payment are functioning correctly.

* CPT™ American Medical Association

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Safe Harbors, *from p. 1*

According to Thomas Jeffry Jr., an attorney in the Los Angeles office of Davis Wright Tremaine, the OIG proposes to create a safe harbor for "donors" to give "recipients" the technology necessary to transact e-prescribing. Permissible donors are hospitals (to members of their medical staff); prescription drug plan (PDP) sponsors and Medicare Advantage (MA) plans (to prescribers and pharmacies); and medical groups (to their members).

In contrast, CMS proposes a Stark exception focused on physicians and their staff as the "recipients" to take into account the more limited application of the physician self-referral law, says Jeffry in a health advisory bulletin. Otherwise, the criteria for the Stark exception and the anti-kickback safe harbor are similar.

"The technology that may be given is broad and includes hardware, software, training, and Internet access," he explains. "However, the other limits on what may be given do much to take away that breadth. The OIG expressed its intent to set a cap on the retail value of donated items and asked for public input on how such a cap is determined."

According to the proposal, the items donated must be necessary for e-prescribing, must be used only for e-prescribing, and must be something that the recipient does not already have. Jeffry notes that the OIG draws some interesting distinctions in its commentary. For example, software suites are frowned upon because valuable general office management, billing, scheduling, or other software might be bundled with the e-prescribing features.

Electronic Health Records

With respect to electronic health records, CMS and the OIG took a different approach, says Jeffry. CMS actually proposed two new Stark exceptions that are mutually exclusive based upon whether the technology and services donated are certified under anticipated guidelines from HHS. The OIG describes a safe harbor that contains similar elements as to those that CMS proposed, but decided to solicit comments before formalizing any language into a rule.

"The OIG recognizes that physicians are not alone in their reluctance to change software programs," he says. "Once a person achieves some level of comfort with their software program, inertia sets in. If the software has a proprietary format that is incompatible with other competing programs, then it might 'tie' the physician to that software and the vendor that makes it available. The solution: require the software to be 'interoperable,' which means it must work with the system of competitors."

Because there are no standards defining an interoperable electronic medical record, this requirement delays indefinitely the necessity to define other components of the safe harbor, notes Jeffry.

First Steps

There is a strong political push to encourage adoption of certain health information technologies, says Jeffry. The proposed rules take the first steps to remove certain obstacles by shifting the costs of adoption from physicians and small providers to hospitals, PCP and MA plans, and other payers. At the same time, these rules seek to maintain the traditional tight controls over arrangements that may lead to referrals.

"Congress and the administration have clearly staked out positions on both sides of a yawning chasm and instructed CMS and the OIG to bridge the gap," he explains. "On one side of the canyon, lawmakers have clearly indicated disdain for the idea of hospitals giving physicians anything. It is a felony if gifts are offered or accepted with the intent of inducing unaffiliated physicians to refer patients to the hospital. The hostility and suspicion with which regulators regard gifts to physicians is now ingrained deeply into the culture of the various agencies charged with fighting fraud and abuse.

"On the other side of the canyon, however, lawmakers have just as clearly encouraged the adoption of e-prescribing and EHR," Jeffry continues. "Unfortunately, this technology costs money, which physicians have not been lining up to spend. The solution is to encourage insurers and hospitals, which also have an interest in promoting technology, to give the physicians what they need."

The comments on the proposed regulations indicate internal skepticism as to whether the rules will result in more than one-in-five physicians

embracing the new technology, Jeffry adds: "Unless and until the underlying policy directives are resolved, the regulatory ambivalence towards promoting technology will remain."

Resources

- Thomas Jeffry Jr.: 213-633-6882
- OIG proposed rule, Oct. 11, 2005: *www.oig.hhs.gov/authorities/docs/05/101105e-prescribingPR.pdf*
- CMS proposed rule, Oct. 11, 2005: *http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20322.pdf*

FDA Will Not Pursue Needlestick Proposal

The Food and Drug Administration (FDA) has withdrawn an advance notice of proposed rule making regarding a ban on some nonsafety needles.

In a September 8 *Federal Register* notice, the agency said that its action to prevent needlesticks, along with action taken by the Occupational Safety and Health Administration under its bloodborne pathogens standard, are sufficient to address the risk of needlesticks related to the use of some medical devices.

The FDA has cleared several hundred devices with needlestick prevention features and is working with manufacturers to clear more, the agency said. As evidence of its actions to prevent needlesticks, the agency pointed to a guidance document on determining when a needlestick is reportable as an injury or as a malfunction; a guidance document on submitting permit applications for sharps needle destruction devices; and its cosponsorship of several national meetings on needlestick prevention issues.

Petition Initiated Proposal

The FDA sought comments on the advance notice in September 2002 after the Service Employees International Union (SEIU) and Public Citizen's Health Research Group (HRG) filed a petition with the agency in March 2001, seeking a ban on certain medical devices because safer replacement products were available.

The targeted products included glass capillary tubes, intravenous infusion technology that does not use "needleless" technology or recessed needles, IV catheters, blood collection devices (needles and tube holders), and blood collection needle sets that do not meet the design criteria in a previously issued FDA safety alert.

FDA denied the groups' petition in September 2001. The agency said "it did not have sufficient information to conclude that there is a legal basis for banning the devices identified in the petition," according to a letter sent to Public Citizen.

In the latest withdrawal, FDA said that it has not received any information since the notice's publication that would lead it to reach a different conclusion. "FDA, therefore, does not intend to take any of the specific actions requested in the HRG, SEIU petition at this time and is withdrawing the [rule making]," the agency said.

Lives 'Endangered'

The FDA's rejection of the ban "shows a profound indifference to the safety of workers," said Peter Lurie, deputy director of HRG, in a written statement issued September 8.

While the agency claims there is not enough data to warrant action, Lurie said "an extensive body of research documents the ability of the safety devices to reduce needlesticks." According to Lurie, "the agency has retreated in the face of industry pressure."

Each year, U.S. healthcare workers sustain 590,000 needlesticks, and many have contracted HIV, hepatitis B, or hepatitis C after accidental sticks with infected needles, Lurie said. "By allowing considerably more dangerous devices to stay on the market when equally effective, safer alternatives are available, the FDA has endangered the lives of hundreds of thousands of healthcare workers in this country."

Resources

- September 8 *Federal Register* notice: *www.fda.gov/OHRMS/DOCKETS/98fr/05-17733.pdf*
- Public Citizen: *www.citizen.org*

OIG: Gainsharing Deals Should Be Evaluated Individually

While gainsharing arrangements between hospitals and physicians may help reduce and eliminate unnecessary medical costs, the Department of Health and Human Services Office of Inspector General (OIG) continues to believe that the risks of such programs are best evaluated on a fact-specific, case-by-case basis, OIG Chief Counsel Lewis Morris said October 7.

Morris was addressing the House Ways and Means Subcommittee on Health, which heard testimony on gainsharing as part of a long-range effort to develop a policy that would allow hospitals to share with doctors the savings from cost reductions attributable to physicians. Gainsharing arrangements are prohibited except in cases where hospitals seek approval from the OIG through the advisory opinion process.

More information about the hearing, including testimony, is available at http://waysandmeans.house.gov.

Johnson Seeks Broad Policy

Subcommittee Chairman Nancy Johnson (R-Conn.) challenged the OIG's position on gainsharing, saying a broad-applying policy should seek to establish a universal standard for such arrangements, rather than expecting each hospital to seek OIG approval before instituting a gainsharing program. Johnson also said she was concerned that the civil monetary penalty (CMP) law—which the OIG has used as its basis for essentially outlawing gainsharing—does not include medical necessity as a consideration for evaluating when the CMP provision should apply.

A committee staff member said Johnson is considering introducing legislation—perhaps next year—that would give the Centers for Medicare & Medicaid Services (CMS) the ability to allow for gainsharing. Committee members may be considering a proposal that would establish a national gainsharing demonstration project – similar to a pilot project among New Jersey hospitals abandoned by CMS in 2004 because of legal troubles.

Johnson said during the hearing that she believes allowing for gainsharing could improve patient quality of care by providing more choice than what is negotiated between doctors and hospitals and device manufacturers. Currently, the CMP law prohibits direct or indirect remuneration to doctors to limit services to Medicare and Medicaid beneficiaries. CMP violations can be cited regardless of whether reduced services were medically unnecessary, Morris noted. In 1999, the OIG issued a special advisory bulletin warning hospitals and physicians against "black box" gainsharing arrangements in which institutions paid doctors for overall cost-savings without defining specific actions physicians should take to achieve greater efficiencies, Morris said.

Since 1999, the OIG has issued seven favorable advisory opinions allowing hospitals to implement gainsharing arrangements with doctors. In each case, Morris explained, the hospitals provided sufficient evidence that payments to doctors would be based on specific, measurable actions by physicians and that quality of care to beneficiaries would not be compromised. Furthermore, the arrangements provided little opportunity for doctors to gain financial reward for unnecessarily reducing care to patients.

Three Criteria

Morris encouraged Johnson and the subcommittee members to include in future legislation provisions that would curb fraud and abuse in a gainsharing program. According to Morris, the OIG has used three measures for evaluating gainsharing arrangements submitted for approval through the advisory opinion process.

First, arrangements should be structured in such a way that they are transparent and clearly identify the actions that will result in cost savings. In that way, hospitals and doctors would be accountable for quality of care and would be responsible for disclosing financial interests to patients.

Second, Morris said, quality controls should be implemented as part of gainsharing arrangements to ensure monitoring of their possible impact on patient care. Finally, hospitals should ensure that arrangements contain safeguards to prevent gainsharing payments from being used to reward patient referrals in violation of the anti-kickback statute.

OIG Subpoenas IASIS Healthcare: Provider contracts involving hospitals owned or operated by Franklin, Tennessee-based IASIS Healthcare are the subject of a Department of Health and Human Services Office of Inspector General investigation, the company announced September 19. According to the company, the OIG issued a subpoena requesting the production of documents primarily related to contractual arrangements between physicians and the company's hospitals. The information sought covers leases, medical directorships, and recruitment agreements and dates back to January 1999, IASIS said. IASIS owns or leases 14 acute-care hospitals and one behavioral health hospital with a total of 2,225 beds in Arizona, Florida, Nevada, Texas, and Utah. The company also owns a Medicaid managed health plan in Phoenix and has ownership interest in three ambulatory surgical centers.

IT Key To Curbing Fraud: While health information technology is key to improving healthcare outcomes and reducing costs, health IT systems also promise to provide innovative ways to reduce fraud and abuse in federal healthcare programs, Health and Human Services Inspector General Daniel Levinson said September 26. Levinson said his office is working with others to promote health IT, with its goal being to make relevant data more accessible to law enforcement agencies. Levinson spoke at the American Health Lawyers Association and Health Care Compliance Association Fraud and Compliance Forum in Baltimore. Health IT provides "transparency that makes fraud difficult," Levinson said.

DME Fraud Watchdog Gets Failing Grade: The Medicare contractor responsible for detecting fraud among suppliers of durable medical equipment, prosthetics, orthotics, and supplies is doing an inadequate job of verifying compliance with program standards, the Government Accountability Office said in a report released Oct. 12. National Supplier Clearinghouse – responsible for ensuring that durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers comply with 21 Medicare contracting standards – was deficient in checking state licenses and conducting on-site inspections, GAO found. Specifically, the report noted that NSC relied too heavily on self-reported information about items DMEPOS suppliers intended to furnish and failed to compare what suppliers said they would provide with actually billing. GAO also found that NSC did not conduct required on-site inspections of 605 suppliers. The report is available at *www.gao.gov/cgi-bin/getrpt?GAO-05-656.*

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