G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

CLIA QC Standards Revised, Streamlined

Frequency Of Controls Cut For Most Specialties

Clinical laboratories performing CLIA moderate and high complexity testing will face fewer quality control requirements beginning this Apr. 24, under a long-awaited final rule issued Jan. 24 by the Centers for Medicare & Medicaid Services and the Centers for Disease Control & Prevention.

The rule, which completes implementation of CLIA (the Clinical Laboratory Improvement Amendments), reduces the frequency with which labs must perform QC in most specialties and subspecialties and brings all non-waived testing under the same QC requirements, according to CMS. The new requirements apply to laboratory testing in all settings – including hospital, independent and physician office laboratories. Personnel standards will continue to be based on test complexity. ➔ *p. 2*

Hospitals Urged To Review Charge Policies

Govt. Expands Medicare Outlier Probe

Given the government's recent crackdown on billing practices at Tenet Healthcare Corp. (Santa Barbara, CA) and closer scrutiny of Medicare outlier payments, hospitals should examine their charge policies to see whether they could be targeted for review, advises attorney Harvey Yampolsky, a partner with Arent Fox Kintner Plotkin & Kahn in Washington, DC.

Harvey Yampolsky, Esq.

"At the very least, every hospital should look at its financials to determine if it falls into any of the categories that Medicare has told its fiscal intermediaries to flag," Yampolsky tells *G-2 Compliance Report (GCR)*. "If hospitals do fall within a questionable category, they should look at how they got there, and even if they think they got there legitimately, they may want to consult a lawyer to determine whether they are at risk and whether they may need to modify their policies."

At issue is whether hospitals have been raising their gross charges in order to increase Medicare outlier payments. These payments are made for higher-than-average costs incurred in treating and caring for beneficiaries. The Medicare program sets the outlier threshold each year at an amount projected to generate outlier payments equal to 5.1% of total payments under inpatient prospective payment. Late last year, the government began investigating outlier payments to a number of Tenet hospitals and since has expanded the probe to include a review of charge practices at all hospitals. ➔ *p. 10*

Inside this issue

For requirements other than the "grandfather" provision, full compliance will not be enforced until labs complete their CLIA survey cycle, says CMS

CLIA QC Standards, *from p. 1*

Perhaps the most significant impact, says CMS, will be on labs that perform unmodified moderate complexity testing approved or cleared by the Food & Drug Administration. They have been following minimal QC requirements under a special phase-in period which ended last Dec. 31. Now, the QC requirements for these labs will be essentially equivalent to those for modified moderate complexity testing and high complexity testing.

As recommended by the Clinical Laboratory Improvement Advisory Committee, labs will now be required to validate the accuracy of moderate as well as high complexity tests prior to the testing of patient specimens and the reporting of those results.

The rule also "grandfathers" certain lab directors who lack board certification, allowing those with a doctorate who have served, or are serving, as a director of a lab performing high complexity testing to continue in their positions. All new directors of high complexity labs who have a doctorate, rather than a medical degree, will need to be board-certified. The "grandfather" provision takes effect Feb. 24.

According to CMS administrator Thomas Scully, the new rule reorganizes CLIA requirements in a more logical manner to parallel the flow of a patient specimen through the laboratory. "This reorganization should help laboratories understand and apply the requirements more easily and reduce errors." The rule will have the greatest impact on the 38,000 labs that are CLIA-certified to perform high or moderate complexity testing.

Key Revisions

The final rule recognizes improvements in technology and reagent stability by reducing the frequency of QC testing in several specialty and subspecialty areas, including:

- Bacteriology and mycology reagent checks.
- General immunology and syphilis serology: the frequency goes from concurrent with patient testing to daily testing.
- Hematology: the frequency goes from each eight hours of operation to each day of use.

For mycobacteriology, CMS has increased the frequency for checking fluorochrome and acid fast stains and has added a requirement for testing negative controls to check stains and reagents.

Other Major Changes:

- The percentage of required agreement among participant or reference laboratories involved in proficiency testing has been reduced from 90% to 80%.
- Labs are now required to solicit and obtain the age and sex of patients, time of specimen collection and specimen source when relevant for the testing to be performed.
- A lab report must include either the patient's name with an identification number or a unique patient identifier and ID number to ensure positive patient identification. The patient's name alone is not enough.
- CMS has revised requirements related to laboratory information systems (LISs) and the storage and maintenance of electronic patient records. CMS says it intends to publish further LIS requirements at a later date.
- When using unmodified manufacturer's equipment, instrument or test systems, the lab must follow the manufacturer's instructions for maintenance and function check protocols, rather than establish its own.
- The requirement under histocompatibility for each individual performing testing to evaluate previously tested specimens each month is eliminated. The lab's technical consultant or supervisor will now determine the mechanism and frequency of assessment. The frequencies for screening potential transplant recipient sera for HLA-A and B antibodies are also eliminated.
- Labs must ensure a uni-directional workflow for molecular amplification systems that are not contained in enclosed systems.
- Labs must use a control system capable of detecting reaction inhibition when performing molecular amplification procedures in which inhibition is a significant source of false negative results.
- Labs must check immunohistochemical stains for positive and negative reactivity each time of use.
- In the specialty of clinical cytogenetics, sex determination must be performed by full chromosome analysis.

Resources

- Revised CLIA QC rule: *Federal Register*, Jan. 24, 2003, *www.access.gpo.gov/su_docs*

SD Hospital, Docs To Pay $6.5M In Stark Settlement

Case Reflects Growing Use Of False Claims Act

In what is believed to be the largest settlement so far under the Stark physician self-referral law, Rapid City Regional Hospital (Rapid City, SD) and a group of oncologists have agreed to pay $6.5 million to the Federal Government to settle charges of improper Medicare billing.

According to James McMahon, U.S. attorney for the District of South Dakota, the hospital billed Medicare for referrals from doctors with whom it had "improper financial relationships." The Stark statute bars physician referrals for designated health services to outside entities with which the physician (or an immediate family member) has a prohibited financial relationship (by either investment interests or compensation arrangements) and outlaws billing any party for services furnished pursuant to a prohibited referral.

> ***"The settlement is yet another reminder to hospitals that they must continually review their contract arrangements with physicians to make sure these contracts reflect fair market value and otherwise comply with the Stark law"***
>
> ***—Robert Mazer, Esq.***

The government alleged that Rapid City Regional provided Oncology Associates LLP (Rapid City), a physician group, with office space within the hospital and other goods and services for less than fair market value in exchange for referral of patients to the hospital. The hospital will pay $6 million, while Oncology Associates will pay $525,000 to settle allegations that it overcharged Medicare for office visits.

The case was brought under the *qui tam* (whistleblower) provisions of the federal False Claims Act. Karen Johnson-Porchardt, an employee of that hospital's Cancer Care Institute, alleged that Oncology Associates paid Rapid City Regional below market value for office space and services received. According to Johnson-Porchardt, Oncology Associates in 1991 entered into a three-year agreement with the hospital to lease 400 square feet of space for $19,000 per year. The lease was never renewed after it expired, although Oncology Associates expanded its office space and received additional benefits from the hospital. During this time, it continued paying only $19,000 per year for services worth more than $1 million, alleged Johnson-Porchardt.

Robert Mazer, Esq.

False Claims Act A Tool

The settlement reflects the proliferating use of the False Claims Act to collect monetary damages for alleged violations of the Stark law and the Medicare anti-kickback statute, says attorney Robert Mazer, a shareholder with Ober/Kaler in Baltimore, MD.

"Neither law provides for monetary penalties of this magnitude, or for a whistleblower to share in the recovery," Mazer tells *GCR*. "However, by characterizing claims for hospital services ordered by a physician with a non-compliant contract as False Claims Act violations, a *qui tam* plaintiff and the government can share large monetary awards based on a single contract between a hospital and physicians."

Under this legal theory, says Mazer, the government must show only that the hospital charged referring physicians less than the fair market rate for rented space. A legal violation could also be based on a hospital's overpayment of physicians, for example, for services provided to the hospital. Unlike a kickback case, the government doesn't have to show that the hospital attempted to induce physician referrals through the contract, he explains.

"The settlement is yet another reminder to hospitals that they must continually review their contract arrangements with physicians to make sure these contracts reflect fair market value and otherwise comply with the Stark law. A hospital may believe it is doing physicians a favor by giving them favorable contract terms, [but] the government may consider the same contract to be part of an arrangement leading to false claims."

Resource

- James McMahon: 605-330-4400
- Robert Mazer: 410-347-7359

Lab Fraud Ringleader Faces Up To 16 Years In Prison

Investigators are still searching for another alleged confederate, Ron Martin, a Philippines national who has converted to Islam and also goes by the name Nuir Muhammad. Martin, who is currently a fugitive, was allegedly Singh Panshi's "right-hand man"

The alleged ringleader of a massive medical laboratory scheme that defrauded California's Medi-Cal program of at least $11 million faces between 11 and 16 years in prison when he is sentenced May 23. This would be the longest sentence for healthcare fraud ever handed down by a state court.

Surinder Singh Panshi, MD, pled guilty Jan. 3 to four felony charges. Singh Panshi is charged with masterminding a takeover of 13 clinical labs in Los Angeles, Riverside and Orange Counties. The labs allegedly increased their Medi-Cal and Medicare reimbursements dramatically through fraudulent claims that involved unauthorized use of the names of more than 24 physicians and stolen Medi-Cal provider numbers.

The fraud involved a combination of billing for services never performed and the testing of blood obtained through the black market from drug addicts and homeless people in order to create the semblance of a legitimate laboratory operation. Investigators found that the labs often billed and shut down quickly, leaving blood and urine samples behind, according to California State Attorney General Bill Lockyer, whose office filed felony criminal charges against Panshi and 28 others last June (*GCR, Aug. 02, p. 3*).

Two of Singh Panshi's co-conspirators, Biall Ahmed and Saeed Ahmed, were sentenced Jan. 3 to jail sentences of three years and 16 months, respectively, and ordered to pay restitution totaling $87,000. In addition, four labs used in the scheme were ordered dissolved, with any assets to be paid as restitution to the state Franchise Tax Board.

Authorities believe the fraud scheme netted at least $11 million and possibly as much as $20 million, though they have been unable to trace much of the money stolen from Medi-Cal. They have speculated that Singh Panshi and his colleagues were involved in a Pakistani organized crime ring and were raising funds for something other than personal gain.

Resource

- California Attorney General's Office: 916-324-5500

OIG: Help With Malpractice Insurance Might Be OK

A hospital might be able to help physicians on its medical staff pay for malpractice insurance without violating the anti-kickback statute or the Stark physician self-referral law, according to the HHS Office of Inspector General.

In a Jan. 15 letter responding to a request for an opinion, OIG chief counsel Lewis Morris wrote that malpractice premium support could fall under employee or physician recruitment safe harbors. While Morris noted that the OIG has limited jurisdiction over the anti-kickback and Stark statutes, he acknowledged that the proposed arrangement appeared to have appropriate safeguards in place:

- The assistance would be provided on an interim basis for a fixed period in states experiencing severe access or affordability problems.
- Only currently active or new medical staff members would be eligible for the assistance.
- The criteria for receiving assistance would not be related to the volume or value of referrals or other business generated.
- Each physician receiving assistance would pay at least as much as he or she currently pays for malpractice insurance.
- Physicians receiving assistance must perform services for the hospital and give up litigation rights. The value of the services must be equal to the fair market value of the insurance assistance.
- The assistance would be available regardless of where the physician provides services, including other hospitals.

The OIG's response is posted online at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf*

COMPLIANCE PERSPECTIVES

Countdown To Compliance: How Cleveland Clinic Prepared For HIPAA

John E. Steiner, Jr., Esq., is chief compliance officer for the Cleveland Clinic Health System in Cleveland, Ohio

This article describes procedural issues and steps that the Cleveland Clinic Health System—a large, integrated delivery system in Cleveland, OH—worked through as it prepared for implementation of the medical privacy requirements mandated by HIPAA (the Health Insurance Portability & Accountability Act of 1996).

The new requirements, designed to protect patient healthcare information, go into effect this Apr. 14 for most healthcare providers, health plans and healthcare clearinghouses that conduct certain healthcare transactions electronically (small health plans have until Apr. 14, 2004 to comply).

Perhaps the biggest lesson we learned in preparing for the medical privacy rule, aside from starting as early as possible, was the importance of distilling key privacy principles to a manageable size. Since HIPAA "novices" can easily tune-out the nuances of this federal law or fail to see how the various requirements interrelate, it is critical to involve the right level of personnel from several key functional areas in managing the implementation steps.

At the Cleveland Clinic, we felt it was critical to involve certain personnel, especially at the managerial or supervisory level, in preliminary planning and HIPAA awareness efforts. To accomplish this, we established a Program Management Office within our Information Technology Division (ITD) to oversee the HIPAA project. The privacy rule component of our HIPAA readiness project is guided by a multi-disciplinary Privacy Steering Committee (PSC), with representation from the ITD, compliance, legal, internal audit, admitting and medical records departments.

Privacy Project Charter

As we moved through the process, legal and compliance staff worked closely with personnel involved in research to address related HIPAA requirements. The PSC established a Privacy Project Charter, which was distributed to privacy implementation teams in each of the five regions of our health system. The primary charges in the charter for each team were to:

- Take direction from the Privacy Steering Committee. Its key obligation to the teams was to create uniform HIPAA policies for distribution across the system.
- Staff the teams with personnel drawn from similar functional areas in each region (admitting, compliance, medical records, legal, human resources, research, fund-raising, marketing and health plans).
- Assign team members who are knowledgeable about their HIPAA "covered functions" and are authorized to make decisions for their area of the healthcare system.
- Analyze the privacy rules directly applicable to that team's functional area in order to later review and critique the privacy policies developed centrally by the PSC (which included legal representatives).

Tips On Drafting Privacy Procedures

- Be able to demonstrate that systems for accessing information meet the "minimum necessary" standard.
- Define access needs for each position.
- Identify the sensitivity of each access.
- Require annual re-certification for access.
- Use systems that effectively limit access.
- Investigate products that centralize security.

- ❖ Review the privacy rule provisions that have general application—such as "Notice of Privacy Practices," the "minimum necessary" standard, verification and confidential communications—since these provisions overlap functional areas.
- ❖ Provide monthly status reports, by team, to the HIPAA Program Advisors Committee, which included "site manager" representation from each region in the system.
- ❖ Develop checklists for key requirements in the privacy rules.
- ❖ Prepare a written method for demonstrating compliance with the privacy requirements applicable to the team's functional area.

Early Efforts

The initial HIPAA readiness efforts started in late 2000, even though the privacy rule was then still in proposed form. Each team was asked to review current policies and procedures governing medical information confidentiality and create a list or inventory to be compared to HIPAA counterpart requirements, if any. At the same time, the PSC and health system attorneys used a HIPAA preemption analysis tool to compare each list of current policies against HIPAA requirements.

At this phase of the project, the single most important task for each team was to review the proposed rule and the July 2001 guidance from the U.S. Department of Health & Human Services and try to identify what would be different between a pre-HIPAA and a post-HIPAA environment. For example, we needed to determine what type of procedures currently existed to honor patient requests to limit access to, or disclosure of, information about their inpatient stay or current health status.

Teams were instructed to identify any policies that likely would be affected by the HIPAA proposed rule, with the understanding that a legal workgroup would draft uniform HIPAA policies in the near future. This delegated review enabled members of each team to better understand HIPAA terminology. Each team leader also was asked to collect "HIPAA teaching points," based on the team's efforts that later could be incorporated in system-wide education and training programs.

Policy Drafting

The next phase of the privacy implementation project began in early 2001. Drawing from discussions and information collected during meetings of the privacy teams, the Privacy Steering Committee and the legal workgroup, the legal team drafted and distributed privacy policies to selected members of each privacy team.

These individuals served as "subject matter experts" to critique each policy and submitted editorial comments to the legal workgroup. At the same time, the PSC established priorities for the privacy policy drafting sequence.

Each privacy policy was then sent to the Privacy Program Management Office for tracking completion status on a single matrix (or "balanced scorecard"). Periodically, our chief information officer would brief the audit committee and senior executives across the health system on the status of the privacy project.

Privacy Rule At A Glance

- ❖ Prior written consent from patients is not required for use/disclosure of personal protected health information (PHI) for routine healthcare delivery. Covered entities must get written acknowledgment from patients that they have received notice of privacy rights.
- ❖ Direct treatment providers must make only a "good-faith" effort to inform patients of their privacy rights.
- ❖ Covered entities may not use or disclose PHI beyond what is reasonable and necessary ("minimum necessary" standard).
- ❖ Written authorization from patients is required for certain "marketing" communications and other non-routine uses and disclosures.
- ❖ Covered entities have up to one year beyond the Apr. 14, 2003 compliance date to alter existing contracts with business associates. A physician does not have to have a business associate contract with a lab to disclose PHI for treatment purposes; likewise, a hospital lab is not required to have a business associate contract with a reference lab to disclose PHI for treatment.
- ❖ Pathologists are designated as "indirect treatment providers" and do not have to document in writing patients' receipt of notice of privacy rights.
- ❖ A single set of authorization requirements applies to all uses/disclosures requiring an authorization, including those for any research purpose.
- ❖ Protected health information does not include employment records held by a covered entity in its role as an employer.

Cleveland Clinic's Guiding HIPAA Principles

❖ ***Quality, Availability Of Care***
HIPAA should not interfere with the delivery of quality healthcare.

❖ ***Notice***
Patients have the right to know what information is maintained about them and how that information may be used or disclosed.

❖ ***Minimum Necessary***
Personnel should request, disclose or use only the minimum necessary protected health information (PHI) to accomplish assigned duties (subject to several exceptions; see Dec. 3, 2002 guidance from the HHS Office of Civil Rights). Key exception: "minimum necessary" does not apply to disclosure to, or requests by, a healthcare provider for treatment purposes.

❖ ***Patient Rights***
Patients have new federal rights regarding their PHI, including certain rights to control use and disclosure and to request an accounting of certain disclosures.

❖ ***Data Security/Privacy/Integrity***
Those who store, process, transmit or use PHI have an obligation to reasonably protect its confidentiality and to prevent unauthorized alterations.

❖ ***Access***
Patients have the right to inspect their PHI for accuracy and completeness and to request that errors be corrected.

Where We Are Now

The final stage of the HIPAA privacy implementation project involves distribution of a uniform set of privacy policies to each regional site for procedure drafting. Simultaneously, our HIPAA Training and Education Committee has developed a "HIPAA Privacy Overview" videotape and computer-based training modules for the workforce.

For purposes of testing the HIPAA policies and procedures following workforce training, each team has scripted concise scenarios for "walk-arounds" by "mystery patients" that will be used by the Privacy Steering Committee to conduct testing prior to the Apr. 14 compliance deadline.

As we finalize our preparations, each region is developing implementing procedures based on the privacy policies that were written by the legal workgroup. The detailed procedures include specific references to various information technology programs and support software that will be used to comply with certain HIPAA requirements, such as tracking the issuance of the Notice of Privacy Practices.

Stay Up With Current Thinking

Conventional HIPAA wisdom is that in 1996 Congress was principally interested in creating a uniform regulatory scheme for handling health information that could be transmitted, stored and used on the "electronic highway."

I agree with this conventional wisdom and also believe that the sheer complexity of complying with three separate, but somewhat interrelated, HIPAA standards (transactions and code sets, privacy and security) *had to be* tempered by a "reasonable" and "good-faith effort" test for measuring implementation. In support of that view, as covered entities and business associates come to grips with HIPAA requirements, it is useful to keep in mind the important legal concept called "legislative rulemaking" (*see article, p. 8*).

Bearing in mind this point of administrative discretion, it is essential—at a minimum—that your HIPAA privacy team members read the Dec. 3, 2002, HIPAA guidance from the HHS Office of Civil Rights (available online at *www.hhs.gov/ocr/hipaa*). Even though that guidance does not address the approximately 64 HIPAA privacy standards, it reflects the best current thinking we have from the government as to what its "legislative rules" mean.

In addition, appropriate HIPAA privacy team members should be responsible for reading, understanding and developing HIPAA polices and procedures that affect their functional areas. In short, targeted expertise, organized by HIPAA teams, helps ensure that your covered entities can demonstrate a good-faith effort to comply by Apr. 14, 2003.

❖ *Mr. Steiner can be reached at the Cleveland Clinic Foundation, 9500 Euclid Ave., H-18, Cleveland OH 44195. Tel: 216-444-1708. E-mail: steinj@ccf.org.*

HIPAA & "Legislative Rulemaking"

The evolutionary HIPAA rulemaking process, coupled with efforts by covered entities to prepare to meet compliance deadlines, is ripe with opportunities to overreact to HIPAA standards. As a legal matter, it is useful to keep a certain perspective on the relationship between HIPAA as a statute and the privacy rule. By failing to pass privacy *legislation* by 1999, Congress delegated broad responsibility to the U.S. Department of Health & Human Services to interpret privacy provisions through regulation.

In that light, the 1984 U.S. Supreme Court case of *Chevron v. National Resources Defense Council*, 467 U.S. 837 (1984), is an important precedent that attorneys, compliance officers, privacy officers and others directly involved with HIPAA should understand. That case addresses the administrative law principle of "legislative rulemaking," which arose in a matter involving the Environmental Protection Act and regulations published by the Environmental Protection Agency.

HHS has broad authority and discretion to publish and modify HIPAA regulations and already has demonstrated its willingness to do so

The primary importance of *Chevron* to HIPAA is the commonality of certain statutory and regulatory relationships and the effect of those relationships on regulated entities or, for HIPAA purposes, on covered entities. In both situations, the legislative history and the statutes provide minimal or no guidance for interpreting elements of the applicable statute.

In *Chevron*, the EPA's interpretation of a key term in the Act was given significant weight by the Supreme Court. The court was asked by the litigants to interpret congressional intent. The court found that EPA was delegated responsibility for drafting regulations on a matter *not* addressed by the Act.

Therefore, the court concluded, EPA properly engaged in legislative rulemaking and its rules were given controlling weight, unless the court found them to be arbitrary, capricious or manifestly contrary to the Act. Thus, if a statute is silent or ambiguous with respect to a specific issue, the question for a reviewing court is whether the implementing agency's rule is based on a permissible construction of the statute.

Key Principle

This key administrative law principle, as stated in *Chevron* and other federal cases, is useful to consider in the context of HIPAA readiness plans, HHS guidance and policy drafting by covered entities. As the healthcare industry proceeds with HIPAA implementation, we should appreciate the broad discretion that HHS and its Office for Civil Rights have when drafting HIPAA regulations. We should also bear in mind HHS's repeated reference to "reasonableness" in the preamble to the privacy rule and in HIPAA guidance documents when we, in turn, attempt to interpret and implement HIPAA requirements.

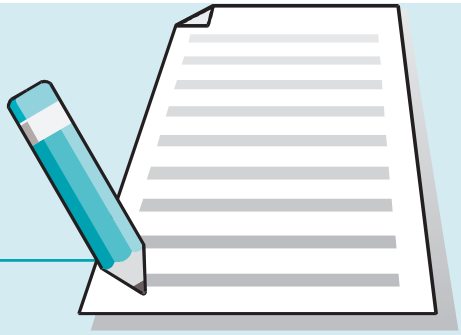
In *Chevron*, the court acknowledged that it has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer … and the principle of deference to administrative interpretations is consistently followed" (467 U.S. 837, 844). These basic points should be kept in mind as HIPAA policy and procedure drafting continues, both before and after the Apr. 14, 2003 compliance deadline. HHS has broad authority and discretion to publish and modify HIPAA regulations and already has demonstrated its willingness to do so.

HHS also has advised the field to use common sense and "reasonableness" when implementing HIPAA requirements. As a final observation, the broad delegation of rulemaking authority to HHS, together with government guidance to covered entities to interpret and implement the requirements in a "reasonable" manner, have the potential to create a patchwork or variable approach to HIPAA privacy programs (and, perhaps, security programs) across the country.

This is a somewhat ironic possible outcome, given that Congress's objective in passing HIPAA was to create a uniform regulatory scheme for protecting the security and privacy of medical information, regardless of how it is transmitted, used or disclosed.

—John Steiner, Esq.

For the Record



Beginning Apr. 1, 2003, Medicare fiscal intermediaries and carriers must notify healthcare providers when claims are denied based on a local medical review policy (LMRP), so they can decide whether to appeal and can determine how to avoid such denials in the future. Contractors already must give notice to beneficiaries when claims are denied based on LMRPs.

According to Transmittal AB-02-184 (Jan. 3, 2003), the Centers for Medicare & Medicaid Services has created a new Remittance Advice (RA) remark code to be used in conjunction with existing messages:

"N115—This decision was based on a local medical review policy (LMRP). An LMRP provides a guide to assist in determining whether a particular item or service is covered. A copy of this policy is available at *www.LMRP.net*, or if you do not have Web access, you may contact the contractor to request a copy of the LMRP."

Beginning Apr. 1, 2003, all *newly established* LMRP edits must contain the new RA remark code (if applicable) in addition to the current messages. By Oct. 1, 2003, *every* LMRP edit must contain the new remark code, CMS says.

Transmittal AB-02-184 is online at *http://cms.hhs.gov/manuals/pm_trans/ab02184.pdf*

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*.

OIG OKs Venture Involving Ambulatory Surgical Center

A hospital and a physician group may jointly own an ambulatory surgical center without risking administrative sanctions for anti-kickback statute violations, the HHS Office of Inspector General said in a Jan. 21 advisory opinion.

Under the proposed arrangement, the hospital would purchase an ownership interest of up to 40% in the center in exchange for certain capital contributions and loans. The proposal also is contingent on additional ancillary agreements addressing management services, facility support, non-competition provisions and leasing of the center and the physician group's office space.

"Although joint ventures by physicians and hospitals are susceptible to fraud and abuse, the OIG recognizes that precluding ownership of ASCs may place hospitals at a competitive disadvantage by forcing them to compete with ASCs owned by physicians, who principally control referrals," said the advisory opinion.

While the OIG has promulgated a safe harbor for jointly owned ASCs that meet certain conditions, the proposed arrangement does not qualify for this protection, notes the opinion.

Even so, the proposed arrangement includes enough safeguards to limit the hospital's ability to direct or influence referrals to the surgical center or the physician group, the OIG says, concluding that the agreement would not be subject to administrative sanctions in connection with the anti-kickback statute.

Resource

- OIG advisory opinion No. 03-2, *http://oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0302.pdf*

***Hospitals Urged To Review**, from p. 1*

For fiscal 2003, the outlier threshold is set at $33,560 per case, up from $21,025 for FY 2002

The government's focus on outlier payments, Yampolsky believes, may be similar to its recent targeting of the way pharmaceutical companies set their average wholesale price (AWP). While this essentially is a "list price" and may not bear any relationship to the actual "discounted" prices at which the drug is sold, the government has signaled that it considers any manipulation of the AWP to increase profit improper and possibly illegal (*GCR, Oct. 02, p. 1*).

"As the pharmaceutical industry knows very well, even in cases where there is no explicit violation of the applicable Medicare statutory and regulatory framework, the government does not like it when organizations increase their prices to boost Medicare reimbursement," Yampolsky notes.

Regarding outliers, "this is not a black-and-white issue," he adds. "Here you have a situation where it will depend on a number of variables and whether, taken in their totality, they suggest to the government circumstantial evidence of an attempt to fraudulently increase Medicare payments or whether they don't really rise to that level, even though a hospital may be getting quite a chunk of outlier payments."

CMS Issues Instructions On Hospital Outlier Payments

The Centers for Medicare & Medicaid Services is initiating a "progressive compliance strategy" to ensure that Medicare payments for outliers and services paid outside inpatient prospective payment are appropriate.

CMS has told its fiscal intermediaries to identify hospitals with high outlier payments and to perform comprehensive field audits, uniform charge reviews and medical reviews. Random inpatient claims will be sent to the appropriate Quality Improvement Organizations for cost outlier review.

Field work for the audits is to begin by Feb. 1, 2003, and medical reviews are to completed by July 31. Providers should have already received letters announcing the reviews, according to CMS.

The new focus on outlier payments is due, in part, to allegations that hospitals—particularly a number owned by Tenet Healthcare Corp.—have received unusually high outlier payments in the past several years. CMS announced Dec. 3 that it was instructing intermediaries to begin data analysis to identify hospitals with high outlier payments (*GCR, Jan. 03, p. 11*).

Resource

❖ CMS transmittal A-02-126, *http://cms.hhs.gov/manuals/pm_trans/a02126.pdf*.

Justice, CMS Join Probe

Tenet has been under investigation since December 2002 by the HHS Office of Inspector General, which is auditing outlier claims at 100 Tenet hospitals in response to allegations that the company charged excessive amounts.

Tenet announced Jan. 2 that the U.S. Department of Justice had joined the probe and had subpoenaed outlier records from 19 of its 114 hospitals from Jan. 1, 1997 to the present. Of the 19 hospitals, 15 are in California; four are in Texas, Pennsylvania and Louisiana. (In a separate action, Justice has filed suit against Tenet, saying the company violated the federal False Claims Act by upcoding certain inpatient claims - *related story, p. 11*).

The Centers for Medicare & Medicaid Services has initiated its own review of Medicare outlier payments. Last Dec. 20, the agency instructed fiscal intermediaries to determine the extent of hospitals with an unusually high number of Medicare outlier payments.

Tenet Adopts New Policy

In a show of what it calls "good faith," Tenet said Jan. 6 that it will adopt a voluntary new billing policy that would reduce its Medicare outlier payments by as much as $57 million each month. In a letter to CMS chief Thomas Scully, Tenet president Trevor Fetter said that effective Jan. 1, the company would adopt two specific measures to adjust the ratio of cost-to-charges (RCCs) used to calculate outlier payments. Specifically, Tenet will:

- ❖ Use the most recent cost reports available to set the RCCs, and
- ❖ End use of statewide averages to calculate RCCs.

With these two changes, Fetter estimates, outlier payments to Tenet hospitals will drop from approximately $65 million per month to $8 million. While Fetter maintains that Tenet hospitals properly followed existing rules, he says the company is volunteering to make the billing changes as a show of good faith to CMS, based on an assumption that these modifications may be central components in any change the agency makes to the rules.

Resource

❖ Harvey Yampolsky: 202-857-6149

Justice Sues Tenet Over DRG Upcoding

The U.S. Department of Justice on Jan. 9 filed suit against Tenet Healthcare Corp. (Santa Barbara, CA), the nation's second-largest for-profit hospital chain, saying the company had violated the federal False Claims Act by overcharging Medicare on some inpatient claims.

The government alleges that Tenet upcoded claims in order to obtain higher federal reimbursement. At issue are claims filed between September 1992 and December 1998 for four diagnosis-related groups (DRGs): 79, pneumonia; 415, operating room procedures for infectious and parasitic diseases; 416, septicemia; and 475, respiratory system diagnosis with mechanical ventilator.

Tenet's chief general counsel Christi Sulzbach said in a statement that the company expected the lawsuit after lengthy negotiations over a possible settlement collapsed in early January. "We regret that we have been unable to reach an amicable resolution of these issues."

Justice has been investigating DRG coding at Tenet and other health systems for several years. Last June, Tenet agreed to a $17 million settlement to resolve allegations of fraudulent coding for laboratory services (*GCR, Jun-Jul 02, p. 1*).

According to Justice, most of the alleged upcoding took place when Tenet was under a corporate integrity agreement with the U.S. Department of Health & Human Services. One of the issues in the case involves allegations that Tenet falsely certified that it was in compliance with Medicare regulations and the terms of the integrity agreement when, in fact, it knew of a significant number of upcoded claims that had been submitted to Medicare.

OIG: Hospital Vendor May Hire Excluded Physician

A software and data analysis company that provides products and services to hospitals and radiology clinics may hire a physician excluded from participation in federal healthcare programs without incurring administrative sanctions, the HHS Office of Inspector General said in a Jan. 21 advisory opinion.

Though the company does not directly bill Medicare or Medicaid for its products and services, hospitals and other healthcare organizations may submit claims directly related to the cost of the products and services, which could preclude the company from hiring the physician.

However, noted the OIG, the physician in question would have no contact with federal program beneficiaries or providers of healthcare and would not be involved in the division of the company that supports and markets the product.

The physician's responsibilities would primarily include business development, writing reports and developing a smoking cessation program for industrial clients.

The OIG determined that because the physician's role would be sufficiently separate from the products and services that ultimately could be reimbursed by federal programs, the company would not be subject to administrative sanctions.

Resource

❖ OIG advisory opinion No. 03-01, *http://oig.hhs.gov/fraud/docs/advisoryopinions/2003/ao0301.pdf*

Rep. Fortney "Pete" Stark (D-CA) has asked the Department of Health and Human Services OIG to investigate possible conflicts of interest between the Joint Commission on Accreditation of Healthcare Organizations and the healthcare entities it represents, saying JCAHO's business practices "appear fraught with potential for conflicts of interest"

ABN Guide: The Centers for Medicare & Medicaid Services has posted on its Beneficiary Notices Initiative Web page a color brochure, "What Doctors Need To Know About the Advance Beneficiary Notice." Available for download in two different sizes, the brochure includes decision trees for determining whether or not to obtain an ABN, as well as a complete list of services excluded by law from Medicare benefits. The brochure is available at *http://cms.hhs.gov/medicare/bni*.

Management Firms Plead Guilty: Two management firms that ran Edgewater Medical Center (Chicago, IL) during a six-year period of fraud pled guilty to criminal charges Jan. 15 and were sentenced to one-year probation. Braddock Management LP and Bainbridge Management LP also agreed to pay $2.9 million to settle a related civil lawsuit. The companies were charged with providing kickbacks and inducing physicians to perform needless medical procedures and admit patients to the hospital unnecessarily. The guilty pleas are the latest in a series previously entered by Edgewater physicians and a vice-president of the now-shuttered hospital.

Former Managers Sentenced: Two former managers at General American Life Insurance Co. were sentenced to prison Jan. 17 for falsifying and concealing information about payment errors made by General American as a Medicare contractor. Carl Messina, who was the company's Medicare director, was sentenced to 27 months in prison and a $6,000 fine. Mary Wimbley, who reported to Messina, was sentenced to three months in prison and three months of home confinement. The charges against them arose from a whistleblower suit brought under the federal False Claims Act by two former General American employees. That case led to a $76 million settlement with the company in June 2002.

Written Orders Required: Effective Feb. 1, Medicare contractors must have written orders from doctors for durable medical equipment, prosthetics, orthotics and supplies before processing claims for such items, says the Centers for Medicare & Medicaid Services in a Jan. 17 update to the Medicare Program Integrity Manual (Transmittal No. 37). The transmittal is posted at *http://cms.hhs.gov/manuals/pm_trans/R37PI.pdf*.

Improper Medicare Payments: The HHS Office of Inspector General estimates that in fiscal 2002 Medicare issued improper payments of about $13.3 billion, or about 6.3% of the $212.7 billion fee-for-service payments. Improper payments, notes the OIG, can result from inadequate documentation to outright fraud and abuse. The FY 2002 estimate of improper payments is significantly less than the $23.2 billion estimated for FY 1996. The rate of error is about the same as last year's and less than half of the 13.8% reported for FY 1996.

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Tel: (202) 789-1034. Fax: (202) 289-4062. Order Line: (212) 629-3679. Website: www.g2reports.com.