G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Medicare Reform Includes Changes For Providers

Law Freezes Lab Fees, Modifies Appeals Process

For groups representing clinical laboratories, enactment of the Medicare reform legislation was a bittersweet victory. While defeating restoration of a 20% co-pay, they had to acquiesce to an 11th hour imposition of a five-year freeze on Part B lab fee updates, beginning this Jan. 1. At the same time, Congress approved a major expansion of preventive testing benefits, including cardiovascular and diabetes screening.

The fee freeze cancels the 2.6% update set for 2004. Lawmakers initially toyed with the idea of a longer freeze before settling on one that will run through 2008.

"Things could have been far worse, given the threats we faced over the past four months," notes Alan Mertz, president of the American Clinical Laboratory Association (ACLA). "We were facing a lab co-pay, then a 2% cut in reimbursement, followed by a 10-year freeze and, ➟ *p. 2*

Specialty Hospital Growth Curbed

Congress Imposes 18-Month Moratorium

Physicians who have a financial interest in new specialty hospitals will be barred from receiving Medicare or Medicaid reimbursement for referrals to those facilities under a newly imposed 18-month moratorium on the whole-hospital exception in the Stark law banning most self-referrals.

Congress imposed the moratorium as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173), which President Bush signed into law on Dec. 8.

Under the whole-hospital exception, doctors may refer Medicare/Medicaid patients to a hospital where the doctors have a financial interest in the entire hospital, rather than just a unit or department of the hospital. Many existing specialty hospitals, such as cardiac or orthopedic hospitals, are owned entirely or in part by physicians.

The moratorium applies only to new specialty hospitals. Existing specialty hospitals and those under development prior to Nov. 18, 2003, are "grandfathered" in under the law, though they will be prohibited from adding physician investors and expanding to other specialty categories. Grandfathered facilities also must limit bed expansion to the greater of five beds or 50% of existing beds. While the moratorium is in effect, the Medicare Payment Advisory Commission will study reimbursement issues associated with the facilities, and the U.S. Department of Health & Human Services will examine referral patterns and quality of care issues. ➟ *p. 10*

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For more on the compliance implications of the Medicare reform law, see the February issue of G-2 Compliance Report

Medicare Reform, *from p. 1*

finally, a seven-year freeze."

Since Medicare instituted the lab fee schedule in 1984, Congress has intervened to deny an annual fee update in nine of the last 19 years (1985-2003). Until now, the longest freeze was for five years, from 1998 through 2002.

The compromise Medicare reform legislation was approved by the House on Nov. 22 by a vote of 220-215 and by the Senate two days later by a vote of 54-44. President Bush signed the bill into law (P.L. 108-173) on Dec. 8.

Key Lab Provisions

In addition to the lab payment freeze, the Medicare Prescription Drug, Improvement & Modernization Act of 2003 also requires the Centers for Medicare & Medicaid Services to implement a competitive bidding demonstration for testing furnished by independent labs, similar to previous pilots for durable medical equipment.

The new law also requires that Medicare:

- Let independent labs continue to bill Part B directly, through 2006, for the technical component of anatomic pathology services for hospital inpatients and outpatients if they did so as of July 22, 1999. The Congressional Budget Office estimates this provision will cost about $200 million.
- Cover screening blood tests for cholesterol and other lipid or triglyceride levels, and such other indications of cardiovascular disease that the U.S. Department of Health & Human Services approves. Projected cost: $300 million.
- Cover diabetes screening tests, including fasting plasma glucose, and other tests deemed appropriate for those at risk for diabetes. Projected cost: less than $50 million.
- Cover certain screening procedures as part of a beneficiary's initial preventive care checkup by a physician. The testing covered includes screening Pap smears, prostate-specific antigen tests, colorectal cancer and cardiovascular disease screening tests.
- Reimburse rural hospitals with less than 50 beds at 100% of their reasonable costs in furnishing clinical diagnostic lab tests to outpatients. Projected cost: $200 million.
- Follow a detailed public process when setting payment rates for new lab tests.
- Treat hospital outreach labs the same as independent labs under secondary payer rules. Instead of completing and updating the lengthy Part A questionnaire, these hospital labs would only have to make a "good faith" effort to identify when other payers are primary to Medicare.

Regulatory & Compliance Changes

The Medicare modernization act also includes provisions on administrative improvements, regulatory reduction and contracting reform. Specifically, the law mandates:

- That there be no retroactive application of substantive changes made to rules.
- A study by the Comptroller General on the feasibility of giving authority to make advisory opinions legally binding.
- Increased flexibility in contracting.
- Coordinated funding of provider education along with incentives to improve contractor performance in education and outreach.
- Establishment of a technical assistance program to help small providers with compliance activities.
- Transfer of responsibility for Medicare appeals from the Social Security Administration to the Department of Health & Human Services.
- A process for expedited access to review during appeals.
- Establishment of payment plans for recovery of overpayments.
- Creation of a mediation process for local coverage determinations.

Resources

- Medicare Prescription Drug, Improvement & Modernization Act of 2003, available online at *www.gpoaccess.gov/index.html*
- Alan Mertz: 202-637-9466

Betting On The Private Sector

The new Medicare overhaul is banking heavily on the private sector to handle key components, including a prescription drug discount card program (starting by June 2004 and running through 2005), a comprehensive drug benefit (beginning in 2006), and expanded HMO, PPO alternatives to traditional fee-for-service under a new Medicare Advantage program to replace the current Medicare+Choice (starting in 2006). The measure provides some $12 billion in subsidies to encourage private health plans to enter and stay in the Medicare market. It also offers some $88 billion in tax advantages to prevent employers from dropping drug coverage of retired workers.

Beneficiaries enrolling for the comprehensive drug benefit would pay an average $35 monthly premium, a yearly $250 deductible, a 25% co-pay up to $2,250 in out-of-pocket expenses and a 5% co-pay after $3,600 paid out-of-pocket. Between $2,251 and $3,600, beneficiaries would be liable for 100% of costs.

New Codes, Revised Mapping Under 2004 Clinical Lab Fee Schedule

Although clinical laboratories will not received a planned 2.6% update in 2004, the result of a five-year freeze mandated by the new Medicare modernization act (P.L. 108-173), labs will see implementation of six new CPT lab codes, revised mapping for a number of other codes and an increase in the travel allowance for collecting specimens as of Jan. 1, 2004.

These policy changes and others are detailed in Transmittal 20 (dated Nov. 7, 2003) from the Centers for Medicare & Medicaid Services. Key changes are highlighted below. Fees shown reflect the 2003 national payment limitation amounts (or caps) and the published rates for 2004 prior to congressional action cancelling the 2.6% update (CPT codes © American Medical Association).

At press time, CMS was working on a revised fee schedule reflecting the payment freeze and clarifying how certain price mappings will be affected.

Revised Mapping

Effective Jan. 1, CMS has revised its mapping to price nine codes related to therapeutic drug assays, chemistry, microbiology and transcutaneous procedures:

CPT/ HCPCS Code	Descriptor	Natl. Fee Cap, 2003	Mapping, 2004*
80157	Carbamazepine, free	$13.89	$19.00
83663	Fetal lung maturity assessment; fluorescence polarization	13.22	27.12
83664	Fetal lung maturity assessment; lamellar body density	6.61	27.12
87046	Culture, bacterial; stool, aerobic, addtl. pathogens, isolation & presumptive ID of isolates	3.30	13.52
87071	Culture, bacterial; aerobic with isolation & presumptive ID of isolates, any source except urine, blood, stool	6.59	13.52
87073	Culture, bacterial; quant., anaerobic with isolation & presumptive ID of isolates, any source except urine, blood, stool	6.59	13.52
87254	Viral isolation; centrifuge enhanced (shell vial) technique, includes ID with immunofluorescence stain	6.83	28.03
87300	Infectious agent antigen detection, IF technique, polyvalent for multiple organisms	8.38	17.20
88400	Bilirubin, total, transcutaneous	3.51	7.19

** Published cap with CPI update, Nov. 7 transmittal.*

New Lab Codes

CMS will recognize six new CPT laboratory codes in 2004. These codes relate to kidney function, gastroenteritis, blood platelets and Trichomonas. Payment for the new codes is set by mapping them to existing codes:

CPT/ HCPCS Code	Descriptor	Mapped To	Natl. Fee Cap, 2003	Natl. Fee Cap, 2004*
84156	Protein; urine	84155	$5.12	$5.25
84157	Protein; other source	84155	5.12	5.25
85055	Reticulated platelet assay	86361	37.41	38.38
87269	Infectious agent antigen detection, immunofluorescence; giardia	87272	16.76	17.20
87329	Infectious agent antigen detection, enzyme immunoassay; giardia	87328	16.76	17.20
87660	Trichomonas vaginalis, direct probe	87470	28.02	28.74

** Published cap with CPI update, Nov. 7 transmittal.*

Codes Reassigned

CMS has reassigned codes for the following procedures:

Descriptor Deleted	CPT/ HCPCS Code	New Code	Natl. Fee Cap, 2003	Natl. Fee Cap, 2004*
Starch granules, feces	89355	89225	$4.67	$4.79
Water load test	89365	89235	7.69	7.89

** Published cap with CPI update, Nov. 7 transmittal.*

Labs will have a 90-day grace period during which they can bill CPT/HCPCS codes deleted for 2004. For services performed between Jan. 1 through Mar. 31, 2004, Medicare will recognize codes active in 2003 but deleted in 2004.

Travel Allowance

Personnel and transportation costs associated with travel to collect a specimen from a homebound or nursing home beneficiary are increased slightly in 2004. Effective Jan. 1, the personnel payment is $.46 per mile, and the standard mileage rate is $.375.

The payment rate on a per-mile basis for procedure code P9603 will be $0.835. Payment on a flat-rate basis (P9604) will be $8.35. To bill either code requires documentation of the number of specimens performed per trip (for both Medicare and non-Medicare patients) to compute the prorated fee. Use of P9604 requires the lab to determine the appropriateness of billing on an average round-trip basis for all trips during a one-year period, says CMS.

Fecal Occult Blood Codes

For the fecal blood screening immunoassay, which CMS recently decided to cover as part of the colorectal cancer screening benefit for beneficiaries age 50 and older, the agency has created new billing codes, G0328 and G0328QW, with a maximum Medicare allowable in 2004 of $18.57. The pricing was set by mapping these codes to existing CPT 86318 (capped in 2003 at $18.02).

CMS plans to issue a national coverage decision for the fecal blood screening immunoassay because "it appears to have modestly better test performance characteristics and patient compliance, compared to existing methods for detecting fecal occult blood" (*e.g.*, the conventional guaiac-based test). The conventional methods are capped at $4.54 in 2003.

Other Changes

❖ **Pap smears**. The national minimum Medicare payment for Pap smears, fixed at $14.76 in 2003, was slated to rise to $15.14 in 2004. Codes affected include 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148 and P3000. These codes are paid at the lesser of the local fee or the national fee cap, but never below the national payment floor and never more than the actual charge.

❖ **CBC billing & payment**. CMS has spelled out the CPT codes that represent component tests of CBC testing (with differential WBC testing), along with the codes for bundled CBC testing (85025 and 85027), plus new HCPCS codes to permit continued billing of common bundled CBC testing services without a platelet count. The latter are:

• G0306, Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count) and automated differential WBC count. The code is mapped to existing CPT code 85025, capped in 2003 at $10.86.

• G0307, Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count). This code is mapped to existing CPT code 85027, capped in 2003 at $9.04.

Resource

❖ Transmittal 20 (Nov. 7, 2003): *www.cms.hhs.gov/manuals/transmittals*

COMPLIANCE PERSPECTIVES

Hot Topics In Healthcare Compliance For 2004

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Over the past 10 years or so, the healthcare industry has been scrutinized for fraud and abuse. As we have seen from the many multimillion-dollar settlements, the U.S. Department of Health & Human Services, its Office of Inspector General (OIG) and the U.S. Department of Justice have focused enforcement efforts to date on false claims to the Medicare, Medicaid and Tricare programs. The "hot topics" for compliance professionals stem from those very areas that the government finds so interesting. This article explores some of the more recent topics that go beyond simple "upcoding" and lab unbundling, to even more complicated areas such as quality of patient care, privacy, corporate governance/ethics and research compliance.

Quality Of Care

The last five years have seen a plethora of "quality" cases, including one in the Eastern District of Pennsylvania that held a managed care plan accountable for allowing a provider to participate in a network when that provider did *not* hold the appropriate medical credentials—thus putting patients at risk. The government has really begun to focus on patient care (or lack thereof) as a compliance issue.

This initiative has its roots in the abhorrent conditions that some nursing home residents have suffered over the years. We have all heard heartbreaking stories about the elderly with bedsores eating through their frail skin. The government's case is based on a theory suggesting that nursing homes, and the clinicians who work there, are paid to provide appropriate, medically necessary medical services. The government contends that failure to provide services of an adequate quality, if the government paid for those services, amounts to a false claim and is, therefore, actionable under the False Claims Act.

A common process for risk assessment begins by reviewing all policies and procedures in your institution to determine whether they meet applicable regulatory and accreditation standards. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) maintains specific standards for patient care. Compliance with these standards is a condition precedent to JCAHO accreditation and, therefore, most hospitals undertake great efforts to comply. The standards are complementary to those used by the Centers for Medicare & Medicaid Services (CMS) and state licensure agencies. In fact, more than 80% of hospitals use JCAHO accreditation to obtain "deemed" Medicare certification (something the OIG mentioned in its 2004 work plan as constituting a reason for it to exert greater oversight over JCAHO). Review of these standards and your hospital's adherence to them is a valuable first step in assessing compliance with patient care standards.

Interviews are valuable too in gaining insight into patient care compliance practices. Some of the individuals you may consider interviewing include the president of the medical staff, members of the quality committee, the director/VP of nursing, administrative and clinical staff in charge of outpatient facilities and the director of risk management.

A comprehensive risk assessment is not complete without a walk-through of various patient care locations, including two or more wings of the hospital, the emergency department, outpatient physician locations, the operating room areas, two or more nursing stations and the location of physician dictation.

One area where any hospital is highly exposed is the pharmacy and the administration of medications. Often, medications are ordered by physicians pursuant to standard protocols

for certain maladies. In many cases, patients improve and do not require all the medication ordered per the established protocol. "Orders," either those administered by nurse practitioners or verbal orders by physicians, are a source of patient care compliance concern in many institutions. It is not unusual to find cases where a physician assistant or nurse practitioner orders something for a patient (either pursuant to a protocol or otherwise) and it is not countersigned by a physician, as required by most state laws and for billing purposes under Medicare and Medicaid. Again, there is patient care exposure and potential billing exposure for these risks.

Some particular areas of patient care compliance exposure include, but are not limited to:

- ❑ Initial patient assessment and documentation of the medical history and physical exam
- ❑ Suspected child abuse or neglect or failure to detect it
- ❑ Suspected family violence or failure to detect it
- ❑ Ordering of tests and procedures by physicians, nurse practitioners/physician assistants, verbal orders
- ❑ Administration of medications to patients, tracking ordered medication not administered yet billed, documenting partial dosage, patient medication brought into the hospital, medication samples, medication expiration dates
- ❑ Specimen labeling
- ❑ Handling of controlled substances
- ❑ Adverse drug reaction reporting
- ❑ Use of restraint devices
- ❑ Withholding of cardiopulmonary resuscitation
- ❑ Use of seclusion
- ❑ Patient transfers
- ❑ Confidentiality of medical records
- ❑ Amending or correcting the medical record
- ❑ Tracking attending physicians upon admission and discharge
- ❑ Compliance with HIV and bloodborne pathogen standards
- ❑ Compliance with new EMTALA standards

It is imperative for the organization to have detailed written policies and procedures requiring countersignatures in accord with legal and billing requirements. It is critical to implement training programs on these issues for the physician extenders and for the physicians so that they understand the rules. Finally, the process must be monitored on an ongoing basis by chart audits looking for required countersignatures.

Research Compliance

For those of us who work in academic medical centers, it has become increasingly more important to expand the scope of the compliance program beyond just documentation, coding and billing reviews. Given the growing federal scrutiny of pharmaceutical companies and clinical research organizations, it is imperative that organizations engaged in research have a comprehensive auditing and monitoring program. An obvious place to start is with research grants—in particular, those funded by the National Institutes of Health. The following is a summary of steps one might follow to audit research grants. The list is not all-inclusive, but identifies some high-risk areas that are important to review periodically:

General Data

- ❖ Grant proposal, including budget submission
- ❖ Notice of grant award
- ❖ Grant budgeting correspondence
- ❖ Any approval notices or other pertinent correspondence from the granting agency
- ❖ Current grant budget to actual analysis (activity in the general ledger account)
- ❖ Detailed grant transactions (including budget transactions)
- ❖ Due dates for submitting progress reports

Salary Data

- ❖ Summary of salary expenditures/transactions for the grant, including employee name, title and role in the grant, percent of effort and amount of salary charged to the grant by pay period
- ❖ All effort reports pertaining to the period under review

Transaction Supporting Documentation

- ❖ This includes all supporting documentation of non-salary transactions: journal entries (transfers, corrections and budget adjustments), purchase requisitions, invoices, approvals, and any other relevant documentation necessary to validate grant expenditures.

Personnel, Other Direct Costs

In addition to reviewing these, be sure to examine supporting documentation to determine if the goods or services are allowable (refer to the *NIH Grants Policy Manual*, A-21, research enterprise policies, etc.) and determine that the cost passes all four tests of allowability per A-21 (Section C).

Specific direct costs must be considered, such as travel and equipment (see A-21 Section J, item 48 and *NIH Grants Policy Manual*—

Allowability of Costs, Selected Items of Cost). Cost transfers and cost allocation journal entries must also be examined. In particular, review documentation to determine that the cost allocation is related to specific activities supported by the sponsored project and is not expressly prohibited by the sponsor.

Subcontracts should be reviewed in detail to determine that invoices were prepared to effect timely payment, and that costs were reviewed and approved by the principal investigator as allowable expenditures and were properly prepared to effect timely payment. In addition, reporting and close-out procedures must be reviewed to ensure that all financial reports reconcile to the accounting records and that all necessary personnel have signed off on the final numbers.

Financial Conflict Of Interest

Each key member of a research project must complete a financial conflict-of-interest disclosure form with the Institutional Review Board for each protocol to ensure that any potential conflict of interest is reviewed in detail by the appropriate review committee.

The above outlines the primary areas of risk in research grants. There are other important areas to consider as well, including clinical trials accounting, protection of human subjects, along with environmental health and safety lab compliance. Each of these constitutes an audit area in its own right and should be part of a research enterprise audit plan.

Health Information Privacy, Security

Perhaps no other healthcare compliance issue has generated as much attention—and uncertainty—over the past few years than HIPAA (the Health Insurance Portability & Accountability Act) and the general issue of the privacy and security of individually identifiable health information. The coming year will continue this trend. The final HIPAA privacy rule became effective last April, though there has been little in the way of enforcement to provide compliance guidance, and much uncertainty prevails over the detailed mechanics of the privacy rule. Similarly, HIPAA standards for electronic transactions and code sets (TCS) just took effect this past October, though flexible (some would say lax) enforcement by Medicare and major commercial third-party payers has softened the impact for the time being.

Observers believe the coming year will bring greater clarity to enforcement of the privacy rule by the HHS Office for Civil Rights and enforcement of the TCS rule by CMS. Compliance professionals will have to closely monitor developments in these areas to ensure that their organizations do not run afoul of emerging compliance standards. In addition, preparation for the April 2005 effective date for the final HIPAA security standards will occupy much of the healthcare industry over the coming year.

HIPAA marked a watershed of sorts for healthcare compliance professionals. For many, HIPAA compliance was a dramatic expansion of the responsibilities of the compliance officer and department and moved the scope of these activities from their traditional focus on adherence to complex reimbursement rules and prevention of fraud and abuse, to the broader arena of institutional ethics and patient interaction, a theme that we will discuss, in a different context, in a moment.

HIPAA compliance for the coming year should continue to be focused on the basics. Many healthcare organizations implemented their HIPAA compliance programs with inadequate budgets and short time frames. This year, before enforcement efforts are stepped up, will be a good time to review your entire HIPAA compliance program and fix problems before they become systemic. We suggest a three-step approach:

1. Assess the state of your HIPAA compliance program, addressing privacy, security and TCS separately, and identify HIPAA risks.
2. Develop a HIPAA monitoring work plan, again addressing identified risks in each of the three HIPAA areas separately.
3. Conduct a HIPAA compliance audit based on the work plan.

Assessment should, of course, include coordination with the chief privacy officer (though in many, if not most instances, the compliance officer *is* the privacy officer as well). Assessment should also include meeting with department heads and other significant management personnel, reviewing the HIPAA compliance budget and, in coordination with

the organization's information services department, assessing technology capabilities and issues.

Corporate Responsibility

One of the most challenging developments in the expanding role of the healthcare compliance professional is coping with the new emphasis on so-called "corporate responsibility." Of course, ensuring that the organization conducts itself in accord with applicable legal standards has always been the charge of the compliance professional, but recent developments have both broadened the scope of the mission and raised the stakes, and this trend will continue in the next year.

Starting with the collapse of the Allegheny Health Education and Research Foundation in Pennsylvania in the late 1990s, and continuing with the scandals that have seriously crippled Enron, WorldCom, HealthSouth and other significant corporations, both in and outside the healthcare industry, there has been increasing attention to the not infrequent disconnect between an organization's formal policies/procedures and the way it actually conducts business.

Further, federal and state regulatory authorities, through mechanisms such as the Sarbanes-Oxley Act of 2002 (SOA) and similar state laws, have begun to focus on ensuring that senior management is directly accountable for knowing and, as appropriate, disclosing all relevant facts pertaining to the organization's financial condition, including whether it may be subject to liabilities in connection with its operations.

Many nonprofit organizations and for-profit enterprises not currently subject to SOA are, nevertheless, adopting voluntary SOA-like compliance codes to ensure that senior management and the board are informed of all relevant information concerning the organization's financial affairs, including potential liabilities, and that proper disclosures are made to outsiders who have a substantial stake in the organization's financial well-being.

These organizations are requiring their CEOs and CFOs to certify that the organization's financial statements "fairly present in all material aspects" its financial condition and the results of its operations. These officers are expected, in turn, to ask applicable members of management to make written reports and representations to them concerning these matters. The officers' certifications are usually required to contain representations that, among other things, they have designed internal controls to ensure that material information is made known to them, and that they have evaluated the effectiveness of these controls and have disclosed to the organization's auditors and the audit committee any significant deficiencies in the design or operation of these controls and any fraud involving management or significant employees. Clearly, these measures cannot be undertaken without a high level of communication and cooperation between senior management and the compliance department.

In addition, the new corporate responsibility guidelines call for boards of directors to affirmatively seek out information from the organization's compliance department in ways they have not traditionally done. Under these guidelines, board members must make "reasonable inquiry" to ensure that they fulfill their "duty of care" to the organization.

The OIG, in collaboration with the American Health Lawyers Association, has issued an "Educational Resource" to the healthcare industry, which can be found on the OIG Website at *http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf*. It calls for boards of healthcare organizations to understand how the organization's compliance program is structured, how the compliance reporting system works and many other aspects of the organization's compliance program, including what level of resources the compliance department requires to operate effectively. Compliance professionals can expect a greater level of involvement in the compliance program by senior management and board members as a result of these initiatives.

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Tenet Forced To Sell Hospital To Stay In Medicare

Tenet Healthcare Corp. (Santa Barbara, CA) has agreed to sell one of its medical centers where two surgeons were accused of performing unnecessary surgeries. The decision was taken, Tenet says, to avoid being excluded from Medicare, Medicaid and other federal healthcare programs.

This marks the first time a company has agreed to sell a hospital so it would not lose federal funds, according to officials at the HHS Office of Inspector General. This is also the first case in which the OIG has initiated the exclusion process against a hospital based on unnecessary or substandard care.

The OIG in September began exclusion proceedings against Redding Medical Center (Redding, CA) based on allegations that two surgeons furnished unnecessary invasive cardiology services to patients of the hospital over a four-year period. The services at issue included cardiac catheterizations and open-heart surgeries known as "coronary artery bypass grafts."

Under terms of the agreement, Tenet agrees to divest Redding to an unrelated party and the OIG agrees to withhold issuing a formal notice of exclusion for the alleged misconduct. If Tenet sells the hospital in compliance with terms of the agreement, the OIG will not proceed with the exclusion.

"Today's agreement allows for care to continue to be provided to beneficiaries in the Redding area while at the same time maintaining the integrity of federal healthcare programs," said Dara Corrigan, acting principal deputy inspector general, in announcing the agreement on Dec. 11. "This demonstrates our commitment to working with providers to resolve matters in a way that reduces the risk of harm to patients."

Tenet officials said they are seeking a buyer for Redding Medical Center and expect to complete a sale by mid-2004. Selling Redding "is the saddest task I have faced since I became chief executive officer of Tenet," said CEO Trevor Fetter in a letter to employees of the facility. Exclusion from Medicare and Medicaid, however, would have been catastrophic for the hospital and could even have forced it to close, he added.

Tenet, which owns and operates 101 acute care hospitals, agreed in August to pay $54 million to settle allegations against the hospital. That settlement did not include an admission of wrongdoing by the company, but left open the possibility that Medicare would exclude Redding. Among other regulatory matters, Tenet is also contending with investigations into how it billed Medicare for the sickest patients and an indictment against one of its hospitals in the San Diego area for physician recruiting violations.

Resources

- Dara Corrigan: 202-619-1343
- Tenet Healthcare: 805-563-6816

New CMS Acting Administrator Faces Tough Task

Dennis G. Smith, the newly named acting administrator of the Centers for Medicare & Medicaid Services, confronts the difficult task of overseeing initial implementation of the massive Medicare reform bill signed into law by President Bush on Dec. 8. Smith, who is director of the CMS Center for Medicaid & State Operations, steps into the vacancy left by Thomas Scully, who resigned as CMS head effective Dec. 15.

Smith's job will be further complicated by the departure of several senior officials within the agency, including Thomas Grissom, director of the CMS Center for Medicare Management. Leslie Norwalk will remain as deputy administrator and chief operating officer and is expected to take the lead in carrying out the Medicare overhaul. The new Medicare law, P.L. 108-173, gives CMS $1 billion in 2004 and 2005 to implement the statutory reforms.

"HHS's largest operating division will be in good hands with Dennis Smith as interim chief until a new administrator is nominated and sworn in," said HHS Secretary Tommy Thompson in announcing Smith's appointment. "At the same time, it is very important that Leslie Norwalk should carry on in the deputy administrator and COO position. We will rely on her leadership to direct the very complex and demanding task of implementing the hundreds of changes to be made under the Medicare improvement act."

Scully, who served as CMS head for some three years, was the ninth administrator of the agency, formerly known as the Health Care Financing Administration. He led an intensive effort to improve the responsiveness of the agency, with a new name, adopted from suggestions made by its employees. He also significantly expanded efforts to inject quality measurement into the agency's programs, according to CMS.

Hospital To Pay $6.25 Million In Stark Settlement

The settlement also resolves issues presented by Metropolitan and its affiliates in a self-disclosure to the HHS Office of Inspector General in June 2002.

Metropolitan Hospital, an acute care facility in Grand Rapids, MI, and several related entities will pay the Federal Government $6.25 million to settle allegations that they submitted false claims to Medicare, the U.S. Department of Justice said Dec. 10.

The settlement resolves allegations that from 1995 through 2003, the hospital engaged in financial relationships with various physicians that were prohibited under the federal Stark self-referral statute, and subsequently received Medicare reimbursement for patients referred to the hospital by those physicians.

Specifically, the settlement focuses on the compensation Metropolitan paid to vascular surgeons, which the government contends exceeded fair market value; the hospital's lease of office space to two primary care physicians, which the government says was leased below fair market value at terms that were not commercially reasonable; and the purchase by the hospital of the practice of a primary care physician in 1996.

The settlement also resolves allegations that the hospital submitted wound care and detoxification claims that were unsubstantiated by the medical records, and that a hospital affiliate submitted Medicare claims for services provided by an employed primary care physician that were unsubstantiated by the medical records.

The allegations arose from a lawsuit filed in 2002 by Mary Scott, a former vice president of a Metropolitan affiliate. As a result of the settlement, Scott will receive $1.125 million.

Specialty Hospital Growth Curbed, *from p. 1*

Charles Oppenheim

Conflict Of Interest

The moratorium will effectively limit growth of specialty hospitals, at least in the short-term, says attorney Charles Oppenheim in the Los Angeles office of Foley & Lardner. He believes the specialty hospital exception to the Stark statute could eventually be eliminated altogether.

> ***"I think there's a decent chance that [the moratorium] may be extended indefinitely"***
> ***—Charles Oppenheim***

"I think there's a decent chance that [the moratorium] may be extended indefinitely. One study that came out on this indicated that specialty hospitals take the healthier, and therefore more profitable, patients, and the concern is that they hurt community hospitals which provide all services."

While the moratorium does not go as far as what the Senate originally proposed—an outright end to the whole-hospital exception—it signals that lawmakers recognize the potential conflict of interest posed by physician owners of specialty hospitals, notes Oppenheim.

The American Hospital Association, which believes that specialty hospitals do have a harmful effect on larger community hospitals, supports the moratorium and elimination of the exception. Not surprisingly, groups representing specialty hospitals oppose the moratorium, contending there's no proof that niche facilities hurt traditional hospitals.

"In the absence of any evidence of harm to traditional hospitals, the moratorium unfairly penalizes those hospitals and physicians working to improve our healthcare system through innovation and competition," according to statement from the American Surgical Hospital Association.

"The ultimate losers are Medicare beneficiaries who may not have had the opportunity to choose the setting for their elective surgical procedures."

Resources

- Charles Oppenheim: 310-975-7790
- American Surgical Hospital Association: 858-490-8085
- American Hospital Association: 312-422-3000

Medicare Unravels Payment Snag For Referred Testing

During 2004, Medicare will institute a revised payment policy aimed at helping clinical laboratories that refer business across carrier jurisdictions (*GCR, Nov-Dec 03, p. 3*). Once the new policy is fully implemented, all carriers are to have access to all local Part B lab fee schedules in effect throughout the U.S. and are to pay for referred testing at rates in force where the testing is performed.

Previously, carriers have not been required to adjudicate claims for referred services furnished in another jurisdiction unless they happened to have the particular fee schedule for that jurisdiction. As a result, some have paid for referred services, some have not. Some labs have tried to surmount the problem by enrolling as a reference lab with the carrier having jurisdiction where the test was performed and obtaining a special provider identification number (PIN). However, not every carrier has been willing to issue "reference-use-only" PINs, notes the Centers for Medicare & Medicaid Services.

While the effective date of the new policy is Apr. 1, 2004, carriers will be given additional time to fully implement the changes, according to agency staff. More details will be released in future transmittals, they say. When fully implemented, the following changes will be in place:

1. An independent clinical laboratory may bill only the carrier with which it is enrolled by reason of having a physical presence in that carrier's jurisdiction.

2. An independent clinical lab may not enroll with a carrier as a "reference-use-only" lab.

3. The referring lab must identify a referred service as such on the claim as well as the reference lab that performs the test. Referred services are identified by using the CPT modifier 90 for each service. Reference labs are identified by completing line 32 of the 1500 claim form or the equivalent electronic claim field.

4. Both the referring and the reference lab must be enrolled in Medicare.

CMS stipulates that each carrier must adjudicate a claim for a referred service, regardless of where the service was performed, if the claim is submitted by a lab in its jurisdiction. Carriers also must cancel all existing "reference-use-only" enrollments and PINs and refrain from any further such enrollments.

Resource

❖ CMS Transmittal 23 (Oct. 31, 2003): *www.cms.hhs.gov/manuals*

Use GY Modifier For Non-Covered Lab Services

Beginning Jan. 1, 2004, labs should add the GY modifier to CPT procedure codes for any service whose diagnosis is on the "not covered by Medicare" list of diagnoses. Use of the modifier will trigger a "not covered" response from the software used by local Medicare contractors to edit claims.

The change affects the 23 national coverage determinations (NCDs) implemented in November 2002 for a large majority of frequently ordered tests (*GCR, Jan 02, p. 1; Nov-Dec 02, p. 1*). The NCDs include lists of ICD-9-CM diagnosis codes recognized by Medicare and those that are not. The NCDs further specify diagnosis codes that do not support medical necessity and those that are excluded from coverage based on statutory or technical denials, such as routine screening. Labs may bill beneficiaries for services not covered by Medicare for reasons other than medical necessity without first obtaining an Advance Beneficiary Notice (ABN).

For details on use of the GY modifier, see CMS Transmittal 11 (Oct. 24, 2003), online at *www.cms.hhs.gov/manuals.*

Lab Director Sentenced: Mary M. Solis, former director of Bio-Scientific Clinical Lab Inc. in Chino, CA, has pled guilty to tax evasion and grand theft, reports the *Los Angeles Times*. She was sentenced to two years in state prison and required to pay $92,000 in restitution by a San Bernardino County Superior Court judge. Solis was charged with defrauding Medi-Cal by submitting false claims totaling $720,000 for services never rendered or authorized. She has also been charged with failing to report corporate income of more than $669,000 in 1999.

Enforcement Savings Touted: The HHS Office of Inspector General says it "saved" $23 billion through audit and enforcement activities in 2003, up nearly $1 billion from the amount saved in fiscal 2002. In its semiannual report to Congress, issued this month, the OIG says the "savings" include more than $21.5 billion in implemented recommendations that put federal program dollars to better use and $988 million in funds returned to federal programs through investigative efforts. In 2003, the OIG also excluded 3,275 individuals and entities from federal healthcare programs and took part in 576 convictions related to crimes against HHS programs. The semiannual report is posted at *www.oig.hhs.gov/publications/docs/semiannual/2003/03fallsemi.pdf*.

Improper Payments Tallied: A new analysis of recently paid Medicare claims shows that 5.8% have errors, representing $11.6 billion in incorrect payments, according to the Centers for Medicare & Medicaid Services. Who had the most errors? Chiropractors, physical therapists and internists. The least errors? Ambulance services, podiatrists and urologists. The findings represent an expanded effort to measure improper payments and will allow CMS to target problem areas, say agency officials. The report, "FY 2003: Improper Medicare FFS Payments", is available at *www.cms.gov/providers/psc/cert.asp*.

Safe Harbor Input Sought: The HHS Office of Inspector General is seeking recommendations for developing new safe harbors under the Medicare/Medicaid anti-kickback statute and for existing safe harbors. The safe harbors protect business arrangements that otherwise could run afoul of the kickback prohibitions on giving or receiving, offering or accepting any thing of value to induce referrals of federal healthcare program business. The agency also invites input on development of new OIG Special Fraud Alerts, according to a Dec. 12 *Federal Register* notice. The notice is posted at *www.oig.hhs.gov*.

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