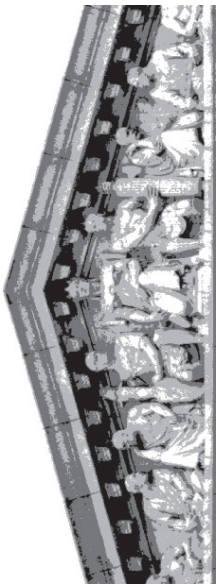

G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Supplemental Guidance A "Must Read"

The Supplemental Compliance Program Guidance for Hospitals, issued by the Health and Human Services Office of Inspector General (HHS OIG) on January 31, is a "must read" for hospitals and those, such as physicians, who work closely with hospitals, says Linda Baumann, an attorney with the law firm of Reed Smith (Washington, D.C.).

The Supplemental Guidance addresses risk areas that have emerged since the OIG issued its original guidance for hospitals in 1998, including physician compensation.

With regard to physician compensation, the OIG restates the long-standing principle that compensation should reflect the fair-market value of the services provided in an arms-length transaction and not take into the account the volume or value of past or future referrals or business between the parties. The OIG also says that arrangements requiring physicians to provide Part A supervision and management for little or no money would "potentially violate the anti-kickback statute and should be closely scrutinized," a stance supported by the College of American Pathologists.

For a more complete discussion of the Supplemental Compliance Guidance for Hospitals, see *Perspectives*, pp. 5-9.

Court Clears Way For Recovery Of Lab Overpayment From Mid-90s

A federal appeals court has upheld the authority of a lower court to try a lawsuit filed by the United States, which is seeking recovery of Medicare overpayments allegedly made to Lahey Clinic Hospital (Burlington, MA) in the mid-1990s for medically unnecessary lab tests (*United States v. Lahey Clinic Hospital Inc.*).

The U.S. government filed a civil complaint in federal district court in January 2003 alleging that the Lahey Clinic Hospital, a teaching and research hospital, billed Medicare and received payment for tests and other diagnostic procedures performed by its clinical laboratory when Lahey knew, or reasonably should have known, that the tests were not reasonable and necessary for diagnosis or treatment of Medicare beneficiaries.

The government contended that between July 1, 1993, and Dec. 31, 1996, Lahey submitted more than 9,300 Medicare claims for unbundled blood chemistry tests that should have been billed in groups, and that Lahey performed a medically unnecessary hematology test every time a complete blood count test was ordered, resulting in more than 88,000 claims during that period. The government sought restitution of more than $311,000.

Lahey argued that the U.S. District Court for the District of Massachu-

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setts did not have jurisdiction over the case because the Medicare jurisdictional statutes barred the government from seeking recovery for overpayments through a direct action in federal court. The district court denied Lahey's motion, but certified the issue for interlocutory appeal at Lahey's request.

In its ruling, the appeals court notes that Lahey did not argue that the United States might not recover overpayments, only that the government chose the wrong approach in doing so. The appeals court also pointed out the government did not allege fraud on Lahey's part.

Unbundling Of Lab Tests

At issue here is unbundling of lab tests. In 1990, the Health and Human Services Office of Inspector General (OIG) conducted a review of a sample of Medicare billings for 1988 and determined that Medicare was paying nearly twice as much as physicians for the same tests, according to the court. These tests were bundled together and performed at the same time, as an integrated group. The OIG found that when physicians ordered these panels of tests, they were billed at a reduced rate. However, when Medicare was billed for these tests, the individual tests within the panel were billed separately for their full rate, resulting in greatly increased costs to Medicare.

A 1998 audit by the OIG found the same problem in claims for clinical tests performed by hospital laboratories serving outpatients. That audit also raised concerns about certain hematology indices, which can be generated from the results of other tests.

Within the narrow category of services of clinical laboratory tests performed by hospital outpatient laboratories, the OIG found that Medicare fiscal intermediaries overpaid hospital outpatient department labs about $43.6 million during a two-year period from Jan. 1, 1994, to Dec. 31, 1995. The OIG recommended that the government seek to recover overpayments previously made.

Statute Of Limitations Extended

In its ruling, the U.S. Court of Appeals for the First Circuit held that the lawsuit filed by the United States is not subject to the administrative review process. The appeals court rejected the argument by Lahey that federal district courts have jurisdiction to review Medicare payment issues only after the Secretary of the Department of Health and Human Services has fully reviewed and made a final decision on the issues under regulations establishing the administrative review procedures.

Robert Mazer, an attorney with Ober/Kaler (Baltimore), tells *G-2 Compliance Report* that ruling effectively extends the "Medicare statute of limitations" on overpayment cases where there is no fraud or similar behavior alleged. By law, Medicare must file for such recoveries using administrative recoupment procedures within four years of the overpayment.

"Rather than trying to prove that the clinic committed some type of fraud or was engaged in some type of behavior so it could be considered to be at fault, and not protected by the four-year cutoff, it appears the government decided to file suit under a common law claim," he says.

"You are exposed for much longer than you may have thought," Mazer explains. "You may want to retain documentation for longer than you have been doing. There could be a claim made against you after five years when you have already tossed documentation. Many hospitals have a five-year documentation retention policy. You may not get in any trouble for not keeping the documents longer, but you might not have the documentation available to defend yourself if they're needed."

The ruling in *Lahey* may cause the government to go back and decide to pursue other cases that may have been beyond the four-year statute of limitations for recoupment actions, suggests Mazer. "This may give them a second bite at the apple," he says, noting that *Lahey* may have been a test case to see whether courts would allow a direct recovery action in federal court.

"If there are labs that got past four years and now they're breathing easy, there's a risk they could find themselves as a defendant in this type of action," he cautions.

Resources

- Appellate court decision, *U.S. v. Lahey Clinic Hospital*: *www.ca1.uscourts.gov/cgi-bin/getopn.pl?OPINION=04-1753.01A*
- Robert Mazer: 410-347-7359

CMS Firm On Cytology PT Enrollment Deadline

Lab Industry Upset Over Limited Options

Clinical laboratories that perform gynecological cytology testing must ensure that their employees are enrolled in an approved cytology proficiency testing (PT) program by June 30, 2005, officials of the Centers for Medicare & Medicaid Services (CMS) confirmed during a January 21 "open door" forum.

More than 600 people participated in the forum in person and by phone, which reflects the high level of concern in the lab community about the start of cytology PT, which was first required by CLIA (Clinical Laboratory Improvement Amendments of 1998) but was delayed until this year by the lack of a provider able to operate a national PT program.

Do you want to find out more about the cytology PT program and how to keep your compliance costs down and your pass rates up? Recordings of a February 18 Washington G-2 Report's audio conference, "How To Comply With CLIA's New Cytology PT Mandate," featuring representatives from the CDC and MIME, may be purchased for $159. To order, go to www.g2reports.com and click on "Products."

However, in November CMS announced that it had approved a national PT program operated by the Midwest Institute for Medical Education (MIME). In a December 16 memo to state survey agency directors, CMS said that while it expects compliance with cytology PT requirements in 2005, labs will have until April 2, 2006, to ensure that all individuals have been tested at least once and until Dec. 31, 2006, to ensure they have achieved passing scores. Labs performing gynecological cytology testing must ensure that all employees are enrolled in a CMS-approved cytology PT program by June 30, 2005.

According to the College of American Pathologists' (CAP) *Statline*, agency officials emphasized the enrollment compliance date during the January 21 forum and said laboratories should not interpret the delay in enforcement as a grace period to enroll employees in a PT program. The enforcement schedule was set to allow time for CMS to work with providers to achieve compliance, one agency official said.

"Further complicating understanding of the new requirements was CMS's announcement at the forum that the agency expects all individuals to be tested at least once by Dec. 31, 2005," notes CAP. "The officials characterized the April 2, 2006, enforcement deadline as being only for individuals who can't be tested earlier due to a late hire date, an extended absence, or certain other factors."

Many who participated in the forum were upset to learn that in 2005, MIME will be their only choice as a national PT provider. They had hoped CMS would give them the option of using the College of American Pathologists or the American Society of Clinical Pathology. Like MIME, both offer glass-slide cytology continuing education programs. In response, Judy Yost, the top CLIA official at CMS, noted that the application deadline for 2005 was July 1, 2004. CMS will consider CAP, which applied in December, and ASCP (if, as expected, it files a formal application by July 1, 2005) as potential cytology PT providers for 2006. (Labs that process specimens from Maryland residents can use that state's CLIA cytology PT program for those specimens.)

"I really don't think you've given sufficient notice, and I don't think you're providing enough providers," said Sally Robinson, cytology section head at John D. Archbold Memorial Hospital in Thomasville, Georgia. "I wish you would address this, and I really do object to the CAP and ASCP programs not being included at this point. I realize they are able to apply, but to have their application not be effective for the 2005 testing, you are really cramming one vendor down our throat."

Resources

- CMS Dec. 16, 2004, memo to state survey agency directors: *https://www.cms.hhs.gov/medicaid/survey-cert/sc0511.pdf*
- Information Supplement: *www.cms.hhs.gov/clia/cptinfosupp.*

OIG More Open To Gainsharing Arrangements

Based on four advisory opinions released in February, it appears the Department of Health and Human Services Office of Inspector General (OIG) is becoming more receptive to the concept of gainsharing arrangements between physicians and hospitals.

The opinions (Nos. 05-01, 05-02, 05-03, and 05-04) involve arrangements between hospitals and cardiologist or cardiac surgeon groups in which the facilities would pay the doctor groups 50% of any cost savings achieved through specific measures during a one-year period. The opinions are similar to a previous favorable advisory opinion issued by the OIG in January 2001 (No. 01-01).

The main difference in the latest opinions is greater specificity in the areas of product standardization, with the OIG approving a broad spectrum of devices that doctors and hospitals can agree to make standard, based on cost efficiency.

Historically, the OIG has been leery of gainsharing arrangements and issued a special advisory bulletin in July 1999 that most in the healthcare industry took as a sharp warning against entering into such agreements. Since then, hospitals have mostly avoided such arrangements.

Federal law prohibits hospitals from inducing doctors to reduce or limit services and items to Medicare and Medicaid beneficiaries. The OIG in the past has warned that gainsharing can also implicate the anti-kickback statute.

However, in the four February opinions, the OIG said that while each of the arrangements could draw scrutiny, the OIG would not impose sanctions on the hospitals with respect to the gainsharing programs defined in the proposals. It noted that each of the hospitals used "practice pattern reports" to identify areas where the hospitals' cardiology departments could trim costs. Some of the recommendations in each of the proposed gainsharing arrangements revolved around product standardization, in which the hospital and the physician groups would evaluate devices and agree to use, when medically appropriate, those items selected largely for cost-efficiency.

Product Standardization

While advisory opinion 05-01 allowed for the product standardization provision, it provided little specificity. The three later opinions, however, defined a fairly broad range of devices that could be included. For example, the 05-02 opinion specifically cites stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators. Opinion 05-04 specifies certain cardiac heart valves.

D. McCarty Thornton, an attorney with Sonnenschein Nath & Rosenthal LLP (Washington, DC) and former chief counsel to the OIG, says the implication is that the same methodology could be applied to devices in other areas, such as orthopedics, provided the same or similar safeguards are incorporated into the gainsharing arrangement.

"Make no mistake, this is a huge step for the OIG," says Thornton. "This is the first time the OIG has given approval to a methodology for rewarding physicians for changing their referral practice."

The advisory opinions also open the door for hospitals to play a key role in influencing the prices it will pay for devices, believes Thornton. He notes that almost all devices and other items are ordered by doctors (even though hospitals bear the costs) and the OIG's green light to the product standardization provisions gives physicians financial incentives to choose clinically equivalent and medically appropriate devices that are also the most cost-efficient.

Put another way, product standardization "gives hospitals a weapon to use in price battles" with device manufacturers where they previously had no power to influence choices on increasingly expensive devices. Thornton said the OIG should be commended for finally allowing doctors and hospitals to align their financial interest in an important cost center for the hospital.

Resources

- Advisory opinions 05-01, 05-02, 05-03, 05-04 are available at *www.oig.hhs.gov/fraud/advisoryopinions/opinions.html*.
- D. McCarty Thornton: 202-408-6432

COMPLIANCE PERSPECTIVES

The Compliance Evolution: Supplemental OIG Guidance Addresses Evolving Risk Areas

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The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) recently published its Supplemental Compliance Program Guidance for Hospitals (70 Fed. Reg. 4858, Jan. 31, 2005). While the OIG has previously published numerous compliance program guidance documents for various health industry sectors, this is the first such "Supplement." The Supplemental Guidance is a "must read" for hospitals and for those, such as physicians, who work closely with hospitals. However, the Supplemental Guidance also contains valuable compliance advice for organizations and individuals throughout the healthcare industry.

The Supplemental Guidance, which is largely based on a prior draft version that was published in June 2004, is intended to emphasize risk areas that have emerged since the 1998 publication of the OIG's original Compliance Program Guidance for Hospitals (63 *Fed. Reg*. 8987, Feb. 23, 1998). Accordingly, it highlights outpatient procedure coding, admissions and discharges, supplemental payment considerations, and the efficient use of information technology as potentially high-risk areas. There is also a detailed discussion of various fraud and abuse topics, including joint ventures, compensation arrangements with physicians, malpractice insurance subsidies, recruitment practices, gainsharing, cost-sharing waivers, gifts and gratuities, and the offer of free transportation to federal healthcare program beneficiaries. In addition, the Supplemental Guidance provides advice regarding areas of recent concern to hospitals, including discounts to uninsured patients, preventive care services, and professional courtesy practices. Perhaps one of the most important sections of this Supplemental Guidance provides numerous detailed benchmarks to use in evaluating a compliance program's efficacy. This material is particularly relevant to all entities with compliance programs, not just hospitals.

While the recommendations in the Supplemental Guidance are not legally binding, the OIG's position on these issues, as stated in the Supplemental Guidance, will likely be the benchmark the government will use in evaluating hospital arrangements and compliance procedures for potential investigation and prosecution.

In light of its length and complexity, the Supplemental Guidance will be analyzed in two parts. This first article will provide a broad overview of the Supplemental Guidance, focusing on the risk areas. A second, more detailed article that focuses primarily on the new standards for compliance program evaluation will be published in the next issue of *G-2 Compliance Report*.

Evolving Risk Areas: Claims Submissions

According to the OIG, the "single biggest risk area" for hospitals continues to be the preparation and submission of accurate claims. However, while emphasizing that the assumptions underlying all claims submissions "should be reasoned, consistent and appropriately documented," the Supplemental Guidance discusses new "evolving" risk areas at some length.

Outpatient Procedure Coding

Various risks have emerged since the implementation of Medicare's Hospital Outpatient Prospective Payment System (OPPS) in 2001. The OIG cautions that the improper use of procedure codes and modifiers for outpatient coding may lead to overpayment and subject the hospital to liability for the submission of false

Use of Information Technology

The OIG recognizes that coding and billing under OPPS is more data intensive than under the inpatient prospective payment system, and that implementation of OPPS has required hospitals to focus more attention on computerized coding, billing, and information systems. Since hospitals likely will be increasingly reliant on information technology in the future due to new regulatory mandates, the Supplemental Guidance urges hospitals to be particularly thorough when assessing new computer systems and software that impact the billing, coding, and transfer of information for federal healthcare program.

claims. Consequently, the OIG strongly advises hospitals to pay close attention to coder qualifications and training. Hospitals are urged to review outpatient documentation practices on a regular basis and to make sure that the underlying medical record is complete and supports the level of service claimed.

The OIG identifies the following other specific risk areas associated with outpatient procedure coding:

- Billing procedures identified as "inpatient-only" on an outpatient basis;
- Submitting claims for medically unnecessary services by failing to follow the fiscal intermediary's local medical review policies and local coverage determinations;
- Circumventing the multiple procedure discounting rules;
- Failing to follow the National Correct Coding Initiative (NCCI) guidelines (in strong language, the OIG warns that the intentional manipulation of code assignments in order to avoid NCCI edits constitutes an act of fraud);
- Submitting incorrect claims for ancillary services because the Charge Description Masters have not been updated;
- Failing to select proper evaluation and management codes; and
- Improperly billing for observation services.

Admissions and Discharges

Particular risk areas highlighted by the OIG regarding the hospital admission and discharge process include:

- Failure to follow the "same- day rule;"[1]
- Same-day discharges and readmissions;
- Violation of Medicare's post-acute care transfer policy in order to receive full DRG payment instead of a per diem transfer payment;
- Abuse of partial hospitalization payments; and
- "Churning" of patients from acute care hospitals to co-located long-term care hospitals to take advantage of the PPS-exempt status of the latter.

Supplemental Payment Considerations

In limited circumstances, hospitals may claim payments in addition to normal reimbursement, and the OIG focuses on the following seven risk areas:

- Reporting the costs of "pass-through" items;[2]
- Claims related to clinical trials;
- Abuse of DRG (diagnosis-related groups) outlier payments;
- Claims for incorrectly designated "provider-based" entities;[3]
- Failure to follow Medicare rules on reimbursement for educational activities;
- Claims for cardiac rehabilitation services;[4] and
- Claims related to organ acquisition costs.

Self-Referral & Anti-Kickback Implications

The Supplemental Guidance cautions that both the Stark law and the federal anti-kickback statute remain major risk areas.

Stark Law Implications

The OIG bluntly acknowledges the "significant financial exposure" to which hospitals are subject unless all of their financial relationships with referring physicians fit squarely into regulatory exceptions to the Stark law. To help hospitals understand when the Stark law applies, the OIG offers a three-part analytical tool:

- *Is there a referral from a physician for a designated health service?* If so, then:
- *Does the physician (or an immediate family member) have a financial relationship with the entity furnishing the designated health service?* If so, the final inquiry is:
- *Does the financial relationship fit in an exception to the Stark law?* If not, the Stark law has been violated.

[1] *All outpatient services provided to a particular patient at the same hospital, on the same date, generally should be included on the same claim.*

[2] *"Pass-through" items are certain new devices and drugs for which Medicare will reimburse the hospital an additional amount during a limited transitional period.*

[3] *Designating hospital-affiliated entities as "provider-based" can result in higher reimbursement.*

[4] *There have been dozens of OIG audits on this issue recently, and the OIG cautions against both unnecessary services and services not appropriately supervised directly by a physician.*

The OIG emphasizes that in order to fit a Stark law exception, an arrangement must meet all of the (often numerous) conditions set forth in the exception. In this regard, the OIG identifies operational problems that can cause a facility to violate the statute inadvertently. For example, the personal services exception and rental exceptions require signed, written agreements.

The OIG observes, however, that hospitals can be lax in their contracting and leasing processes and often fail to obtain a signed, written agreement (for example, in the case of a short-term project) or fail to obtain appropriate amendments or renewals (for example, in the case of a holdover lease). The OIG notes that such common business practices can trigger significant financial exposure and emphasizes that the new Stark law exception for temporary noncompliance may only be used on an occasional basis – it is not a substitute for "vigilant" oversight of a hospital's contracting and leasing functions.

Other areas identified by the OIG as implicating Stark compliance include record retention; documenting "reasonable, consistent, and objective" fair-market value determinations; tracking the total value of nonmonetary compensation provided annually to referring physicians; and recruiting efforts (especially what are characterized as "high-risk" joint recruiting efforts by hospitals and group practices).

Lastly, the Supplemental Guidance notes that Stark law compliance is only a "minimum" standard and a violation can arise through inadvertence or error. Further, even if a hospital-physician relationship qualifies for a Stark law exception, hospitals must nevertheless ensure compliance with the anti-kickback statute.

Anti-Kickback Implications

The Supplemental Guidance cautions that the anti-kickback statute prohibits hospitals, and others doing business with them, from using practices that are common and permissible in other business sectors. The OIG suggests using the following analysis to avoid trouble in this area:

- *Does the hospital have any remunerative relationship between itself (or its affiliates or agents) and persons or entities capable of generating government business, directly or indirectly, for the hospital*? If so:
- *Could one purpose of the remuneration be to induce or reward the referral or recommendation of business reimbursable under federal healthcare programs?* If so, the anti-kickback statute may be implicated.

If an arrangement should implicate the anti-kickback statute, the Supplemental Guidance lists four aggravating circumstances that are likely to place the hospital at greater risk of prosecution, i.e., if the arrangement: (i) has the potential to interfere with clinical decision making; (ii) includes the potential to increase costs to the government, beneficiaries, or enrollees; (iii) contains the potential for overutilization or inappropriate utilization; or (iv) presents increased risks to patient safety or quality of care.

The OIG further notes that multiple "safe harbors" exist to allow a number of common business arrangements but that it will examine both the written and actual arrangement between the parties in assessing safe harbor compliance. Areas highlighted by the OIG as vulnerable to attack under the anti-kickback statute include:

- The manner in which joint ventures are structured, participants are selected and retained, investments are financed, and profits are distributed. (Contractual joint ventures are suspect, and the ambulatory surgical center safe harbor may not be used to protect any joint ventures other than ASCs. The Supplemental Guidance also lists numerous safeguards that can be used to help reduce the risk of hospital-physician joint ventures);
- Relationships with other healthcare entities (including those with managed-care organizations);
- Disclosure and amount of discounts (with a warning against "swapping" by accepting an unreasonably low price on Part A services for which the hospital pays out of its own pocket, in exchange for referring Part B services billable to federal healthcare programs);
- Medical staff credentialing—this section has language indicating that certain economic credentialing policies would not violate the anti-kickback statute; although language added to the final Supplemental Guidance notes that other federal or state laws

might prohibit or limit this type of credentialing;
- Malpractice insurance subsidies – despite the ongoing disruption in the malpractice insurance markets in some states, the OIG expresses grave concern about potential abuse and warns hospitals to carefully scrutinize such subsidies against certain specified criteria and the Stark law; and
- Compensation arrangements with physicians.

A substantial portion of the Supplemental Guidance addresses physician recruitment agreements, noting that they can pose substantial risk. The OIG recommends considering the size and value of the benefit, the payment duration, the practice of the recruited physician, and the need for recruitment. Observing that the scope of the existing recruitment safe harbor is very limited, the OIG emphasizes that this safe harbor (unlike the Stark exception) does not protect joint recruitment with an existing physician group(s). The bottom line for hospitals is that payment to a recruited physician "may not inure in whole or in part to the benefit of any party other than the recruited physician."

The Supplemental Guidance also indicates the OIG's belief that hospitals have a responsibility to monitor physician compliance in certain settings, *e.g.*, by reviewing the site of service modifier a physician uses when billing for his/her services in staffing the outpatient department.

Physician Compensation

With regard to physician compensation, the OIG restates the long-standing principle that compensation should reflect the fair-market value (FMV) of the services provided in an arms-length transaction and not take into account the volume or value of past or future referrals or business between the parties. However, hospitals that have multiple arrangements with different physicians are warned to assess the totality of the arrangements in light of the hospital's actual needs. Thus, an arrangement that fits a safe harbor when analyzed independently could still violate the anti-kickback statute when viewed in context. The OIG also lists factors that can be used to evaluate whether there is potential fraud and abuse risk in a compensation arrangement. Such factors include: (i) whether the service can be obtained from a nonreferral source at a cheaper rate; (ii) whether the compensation paid is commensurate with the skill level necessary to perform the contracted services; and (iii) whether physicians were selected in whole or in part because of their past or anticipated referrals.

Further, the OIG seems to take a step back from the position it took in a previously issued Management Advisory on Hospital-Based Physicians. While discussing hospital-based physician compensation, the OIG acknowledges that arrangements requiring the provision of Medicare Part A supervision and management services for little or no compensation should be closely examined.

Nevertheless, since an exclusive contract can have substantial value to hospital-based physicians, the OIG opines that an exclusive arrangement requiring a hospital-based physician to perform certain *reasonable* administrative or *limited* clinical duties *directly related* to the hospital-based professional services, at no charge, would not violate the anti-kickback statute under certain circumstances. The key issue is whether the scope and volume of the required services reflect the value of the exclusivity.

However, determining the value of an intangible item, such as "exclusivity," is likely to be challenging. Moreover, it is not clear whether the OIG will now be more receptive to the inclusion of intangibles in evaluating FMV in other settings, such as including "goodwill" in the valuation of a physician practice. The OIG does provide some practical guidance on various procedures to reduce the amount of risk involved in embarking on a joint venture with physicians, which will be discussed in next month's issue.

Gainsharing Arrangements

The Supplemental Guidance strongly cautions hospitals about the use of "gainsharing" arrangements, *e.g.*, arrangements where a hospital provides a physician with a percentage share of any reduction in the hospital's costs for patient care attributable to the physician's efforts. While recognizing that such agreements may legitimately increase efficiency and reduce waste, the OIG advises that gainsharing may violate a CMP provision that prohibits payments made as inducements to limit care to federal healthcare program beneficiaries, the anti-kickback statute and the Stark law. Because of these concerns, the OIG strongly advises hospitals to avoid such arrangements wherever possible. This discussion is surprising in light of several newly released advisory opinions that generally ap-

proved the particular gainsharing arrangements at issue.[5]

Relationships with Program Beneficiaries

The OIG warns that hospitals may be liable for CMPs if they offer valuable items or services to attract the business of Medicare or Medicaid beneficiaries. Particular risk areas highlighted by the OIG in this regard include the offer of gifts or gratuities, the waiver of cost-sharing obligations, and the provision of free transportation. This section of the Supplemental Guidance also includes a discussion of hospital obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA), privacy and security rules under the Health Insurance Portability & Accountability Act, and billing Medicare or Medicaid "substantially in excess" of usual charges.

Unnecessary Or Substandard Care

A fundamental obligation of all Medicare-participating hospitals is to provide care economically and only when, and to the extent, medically necessary; to provide care that is of a quality that meets professionally recognized standards; and to document the provision of medical necessity and quality (42 U.S.C. §1320c-5). The Supplemental Guidance encourages hospitals to develop and implement their own quality-of-care protocols, *in addition* to complying with Medicare's conditions of participation and accreditation standards set forth by the Joint Commission on Accreditation of Healthcare Organizations. Further, such review should extend to the credentialing and peer-review process, not just nursing and ancillary services.

Topics Of General Interest To Hospitals

During the formulation of the Supplemental Guidance, the OIG received numerous inquiries regarding topics that are of general interest to the hospital industry but do not necessarily pose significant fraud and abuse risks. In response, the OIG uses the Supplemental Guidance to provide clarification to hospitals regarding the provision of discounts to uninsured patients, the performance of preventive care services, and the use of professional courtesy practices. The Supplemental Guidance provides some reassurance that these activities generally will not pose a substantial risk of liability as long as hospitals adhere to current regulations and other guidance materials.

[5] *See, e.g.*, Adv. Op. Nos. 05-02, 05-03, 05-04.

Compliance Program Effectiveness

Recognizing that many hospitals have already devoted substantial resources to their compliance efforts, the OIG suggests using the Supplemental Guidance as a benchmark for existing compliance programs as well as a tool to identify new risk areas. One of the most novel aspects of the Supplemental Guidance is the listing of specific factors that hospitals should consider in evaluating the effectiveness of their compliance programs. In several cases, the breadth of these factors may surprise some hospitals that did not previously realize the OIG took such an expansive view of the extent of their compliance obligations. These factors will be analyzed in depth in next month's issue.

The Supplemental Guidance concludes with a discussion of self-reporting, noting that prompt voluntary reporting will be considered a mitigating factor by the OIG when considering administrative sanctions. (The OIG continues to promote use of the provider self-disclosure protocol, which has not been used frequently in the past due to its inherent limitations.)

Conclusion

The Supplemental Guidance is notable for several reasons. First, the OIG identifies evolving risk areas that have developed since publication of the original guidance and identifies numerous factors that should be considered in evaluating these risks. The Supplemental Guidance also provides guidance and reassurance on several common industry practices.

In addition, the Supplemental Guidance clarifies how it expects compliance programs to be structured and evaluated. These materials, in particular, are relevant to all providers and suppliers, not just hospitals, and generally signal what the OIG expects any organization to have done (and documented) if called upon to demonstrate the effectiveness of its compliance program. For this reason, many providers and suppliers will find the Supplemental Guidance to be very helpful.

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DOJ Stresses Adherence To Sentencing Guidelines

In the wake of the U.S. Supreme Court's January 12 landmark ruling in *United States v. Booker* (*GCR*, Jan. 2005, p. 5) declaring that U.S. sentencing guidelines must be treated as advisory rather than mandatory in nature, the Department of Justice January 28 issued a memorandum instructing federal prosecutors to "take all steps necessary" to ensure that sentences imposed in the post-Booker era adhere to the guidelines scheme.

Prosecutors were instructed to report cases in which judges impose sentences outside the applicable guidelines range or decline to calculate a range in the first place.

The court in *Booker* held, 5-4, that mandatory sentence enhancements provided by the federal guidelines on the basis of judge-found facts violated the Sixth Amendment right to a jury trial. The court declared that, unless and until some other substitute scheme is implemented, the sentence ranges provided by the guidelines are to be advisory only, and that the court of appeals are to review sentences for "reasonableness" in light of the guidelines and other statutory sentencing objectives. The DOJ had urged the Supreme Court to uphold the mandatory guidelines regime against constitutional challenge, but to no avail.

"Consistency, Fairness"

In the Justice memo, Deputy Attorney General James Comey said that the guidelines have contributed to "consistent, fair, determinate and proportional" sentencing, and to much lower crime rates. He said that the DOJ "must do our part" to make certain that the guidelines continue to comprise the benchmark for federal sentencing.

Accordingly, the memo advises federal prosecutors to continue to charge the "most serious" readily provable offenses, which it says should be those that would yield the highest penalty under the guidelines, any applicable mandatory minimum, and/or any statutorily required consecutive sentences.

Additionally, prosecutors are to purse guidelines sentences "in all but the most extraordinary cases," the memo instructs, and must get supervisory approval to recommend or stipulate to a sentence outside the guidelines range.

The memo further directs prosecutors to preserve the government's ability to appeal "unreasonable" sentences by objecting to any sentence they believe to be outside the appropriate guidelines range and making sure the record is adequate to support an appeal.

Report Forms Required

Finally, the memo emphasizes that the DOJ needs "accurate, real-time" information on sentencing trends to participate effectively in the public debate over the fallout from the decision and notes that the U.S. Attorney's Manual already sets forth requirements for reporting "adverse decisions."

Prosecutors are instructed to complete a "Booker Sentencing Report Form" accompanying the memo to transmit information about cases in which a judge fashions a sentence that does not fall within the guidelines range, refuses to compute a guidelines range at all, or imposes a sentence lower than that agreed to by the government in moving for a downward departure.

Resources

DOJ memo: *http://sentencing.typepad.com/sentencing_law_policy/files/dag_jan_28_comey_memo_on_booker.pdf*

CMS Outlines Contractor Reform Plans

The Centers for Medicare & Medicaid Services (CMS) plans to begin transitioning from traditional claims payment contractors to Medicare Administrative Contractors (MACs) this month with a formal request for proposals for the Durable Medical Equipment Regional Carrier (DMERC) workload.

CMS laid out its contractor reform plans in a February 8 report to Congress. Section 911(g) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that CMS streamline contractor activities.

President Bush's fiscal year 2006 budget, released February 7, calls for $58.8 million in discretionary funding for Medicare contractor reform. CMS has already allocated more than $27 million in fiscal years 2004 and 2005 to MAC implementation.

Among the biggest changes required are single contractors that process both Part A and Part B claims, resulting in Primary A/B MAC contracts.

Under the current contractor system, Part A claims and certain Part B claims are handled by fiscal intermediaries, while most Part B claims, including those for physicians, are handled by carriers. Four DMERCs are responsible for all DME claims, and four Regional Home Health Intermediaries (RHHIs) process home health and hospice claims.

CMS plans to award 23 MACS through a competitive bidding process during the initial implementation phase (2005-2011). These will include 15 primary A/B MACs servicing the majority of all types of providers (both Part A and Part B), four specialty MACs servicing the home health and hospice providers, and four specialty MACs servicing durable medical equipment suppliers. The jurisdictions for the eight specialty MACs will reflect a realignment of the existing jurisdiction and will overlay the boundaries of the 15 primary A/B MAC jurisdictions.

The first DME MAC contract will be awarded by December, with the first Primary A/B MAC contract awarded by June 2006, CMS says in its report, "Medicare Contracting Reform: A Blueprint For A Better Medicare."

Contractor reform was driven in part by the need to improve customer service to beneficiaries and providers by giving them single points of contact for information about bills and claims, CMS says in the report. Under the current system, patients and doctors often must contact more than one contractor about related services.

Ultimately, beneficiary data would be accessible in a comprehensive format, so that an individual's history could provide for greater comprehensive care, notes CMS. Other contractor reforms include competitive bidding for contracts and performance incentives for contractors.

Resources

- Medicare Contracting Reform: A Blueprint For A Better Medicare: *www.cms.hhs.gov/medicarereform/contractingreform/544563report_to_congress.pdf*

Purchased Diagnostic Test Fix Delayed For Physicians

Medicare officials have delayed until further notice a change affecting pathologists and other physicians who purchase diagnostic tests/interpretations from suppliers outside their carrier jurisdiction. As of April 1, physicians filing claims for these services were to bill their carrier and be paid under the Part B physician fee schedule for the purchased services at the rate applicable to the zip code where the services were performed (*GCR*, Nov.-Dec. 2004, p. 11). Instead, they will continue to be paid for these services at the rate set by their local carrier.

In Transmittal 464 (Change Request 3694), issued February 4, the Centers for Medicare & Medicaid Services (CMS) says it needs to address locality reporting issues in the edits that contractors use to process these claims. The agency is providing contractors with a national abstract file containing all local fee schedules for services subject to the rules on purchased diagnostic testing.

The delay does not affect clinical laboratories and independent diagnostic testing facilities that purchase diagnostic tests/interpretations from out-of-jurisdiction suppliers. As of April 1, they will be paid for these services at the rate in effect for the zip code where the service was performed.

Transmittal 464 is available at *http://www.cms.hhs.gov/manuals/pm_trans/R464CP.pdf*.

Tenet Mistrial: A U.S. District Court judge in San Diego declared a mistrial February 17 in the almost four-month trial in which a Tenet Healthcare Corp. San Diego hospital and its former chief executive officer were accused of funneling millions of dollars in bribes to area doctors in the guise of physician relocation agreements, in return for patient referrals, after the jury told the judge it could not reach a verdict. Tenet, Alvarado Hospital Medical Center, and former Alvarado CEO Barry Weinbaum were charged with one count of conspiracy and 19 counts of violating the federal anti-kickback statute. U.S. Attorney Carol Lam has indicated she may seek a new trial.

New JCAHO Billing Process: Effective January 2006 for all accreditation programs, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will begin annual subscription billing that will allow organizations to spread their survey fees over the two-year accreditation cycle. The annual fee will vary by accreditation program and will be based on an organization's size and service complexity. JCAHO also plans to enter into a new accreditation contract with all accredited organizations effective January 2006. Organizations should receive the contract by April 1, 2005.

NIH Adopts Tougher Ethics Policy: The National Institutes of Health (NIH) on February 3 published an interim final conflicts-of-interest rule that will require scientists employed by NIH to sever ties with industries and associations that could create ethical issues for their research. The regulations, which apply to about 5,000 intramural scientists employed by NIH, restrict engaging in outside activities, having financial ties, or receiving awards that could constitute an actual or perceived conflict of interest. NIH also will examine policies for scientists who receive grant money.

Federal Fraud Recoveries: The federal government recovered more than $1.8 billion in judgments and settlements in healthcare fraud matters in fiscal 2003, according to the annual report of the Health Care Fraud and Abuse Control Program operated by the Departments of Health and Human Services and Justice. Also during that time, federal prosecutors filed 362 criminal indictments in healthcare fraud cases. A total of 437 defendants were convicted. There were also 1,277 civil matters pending and 231 civil cases filed in 2003. The report is available at *www.usdoj.gov/dag/pubdoc/hcfacreport2003.htm*.

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