



# G-2

# Compliance Report



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## For Hospitals, Laboratories and Physician Practices

### OIG Urges Greater Use Of Self-Disclosure Protocol

**H**ealth and Human Services Inspector General Daniel Levinson is urging hospitals to use the self-disclosure protocol to resolve liabilities related to physician self-referral and anti-kickback statute violations.

In an April 24 "open letter to healthcare providers," Levinson said he is announcing an initiative to promote greater use of the self-disclosure protocol (SDP). Levinson's letter builds on former IG Janet Rehnquist's November 2001 open letter that changed corporate integrity agreement (CIA) requirements by establishing new criteria for determining when and to what extent CIAs would be necessary in civil settlements.

Since 1999, the Office of Inspector General (OIG) has imposed

stipulated penalties totaling about \$300,000 in 21 cases where providers have failed to meet explicit requirements of their integrity agreements. In a recent case, the OIG excluded Miami's South Beach Community Hospital from participation in federal healthcare programs after the hospital breached the terms of its CIA (GCR, April 2006, p. 3).

The OIG's November 2001 letter continues to guide decisions about whether to require an integrity agreement and the specific terms of these agreements, notes the April 24 letter. Many providers have independently developed robust and effective compliance programs, which include internal auditing mechanisms.

In appropriate cases, says the OIG, it has agreed to **➔ p. 2**

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### CMS Reports To Congress On Lab Competitive Bidding

**A** long-awaited report to Congress on the Medicare Part B clinical laboratory competitive bidding demonstration contains little new information and fails to address some key questions, according to an attorney who advises the Clinical Laboratory Management Association (CLMA).

The report, delivered almost four months after its Dec. 31,

2005, due date, generally reflects the design recommended by the Research Triangle Institute International (RTI), the contractor for the project. However, the Centers for Medicare and Medicaid Services (CMS), which submitted the report, failed to clarify several key issues raised by laboratory groups and, in fact, has created some new terms, says Jeff Boothe, a partner **➔ p. 9**



Rob Mazer, Esq.

**Self-Disclosure Protocol**, from p. 1

reduce the obligation on providers settling healthcare fraud matters by entering into Certification of Compliance Agreements (CCAs), rather than more extensive CIAs. CCAs require providers to certify that they will continue to operate their existing compliance programs for a fixed term, typically three years, rather than enter into a more extensive CIA with a five-year term. CCAs do not require independent review organizations to conduct or verify audits or claims reviews.

“A provider’s self-disclosure of conduct continues to be an important factor in determining whether a CCA is appropriate because detection and prompt disclosure of potential fraud are evidence of an effective compliance program,” writes Levinson.

**Use Caution**

Healthcare providers should use caution in determining whether to use the SDP to report violations, advises Rob Mazer, an attorney with Ober Kaler (Baltimore). He notes that the SDP seems to be addressed only to hospitals, not physicians or other entities that furnish designated health services (DHS). “Presumably, the IG will make the same procedures available to all,” he says.

In the open letter, the IG defines the unlawful conduct for which the SDP may be used as “situations involving a financial benefit knowingly conferred by a hospital upon one or more physicians.” According to Mazer, that doesn’t tie into the conduct subject to penalties under either the federal anti-kickback statute (payments knowingly and willfully made to induce or compensate referrals) or the Stark law (submission of a claim that the entity knew or should have known is for a service resulting from an unlawful referral, or failure to make a timely refund).

“Hospitals should not interpret this letter as expanding the scope of those laws,” says Mazer. “Use of the SDP should be considered only when a hospital deter-

mines that it has violated the Stark law or federal anti-kickback statute and is subject to related penalties.”

However, the IG may have acknowledged a willingness to settle SDP matters on a basis that is potentially far more favorable than the method of computing CMPs reflected in the statutes and regulations, particularly for Stark violations, believes Mazer.

For example, the anti-kickback statute provides for CMPs to be based on *total* remuneration, including any part of the payments that were lawfully offered or made. The IG indicates that the OIG will generally settle matters based on “a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s).” This might reflect an intention to base the CMP only on the unlawful portion of the payment, says Mazer.

In addition, the Stark law provides for CMPs to be based on the amount claimed for services resulting from a prohibited self-referral. While it’s not perfectly clear, it would appear that under the SDP, the CMP would be based on the hospital payment to the physicians that resulted in the Stark violation, rather than the value of the DHS the physicians referred to the hospital, he says. Because Stark covers inpatient and outpatient services, CMPs computed under the statute are likely to be significant.

“The SDP is not likely to provide a hospital that violated Stark with a ‘free ride,’” notes Mazer. “The OIG could potentially require return of Medicare payments resulting from prohibited self-referrals. The IG indicates that providers will be expected to quantify the ‘full amount of the overpayment.’ Nonetheless, use of the SDP could provide a hospital which discovers a Stark violation with a significant incentive to self-report.”

**Resources**

- ❖ Open Letter To Healthcare Providers: [www.oig.hhs.gov](http://www.oig.hhs.gov)
- ❖ Rob Mazer: 410-347-7359 🏠

## Tenet Agrees To Divest Alvarado Hospital

**T**enet Healthcare Corp. (Dallas) said May 17 that it has reached an agreement with the U.S. Attorney in San Diego and the Health and Human Services Office of Inspector General (OIG) to resolve charges stemming from alleged inducement of patient referrals at Alvarado Hospital in San Diego.

Two separate federal juries deadlocked and were unable to reach a verdict on criminal charges brought by a grand jury in mid-2003 in the case. The U.S. Attorney and the OIG had alleged that Alvarado knowingly and willfully paid kickbacks to induce referrals of patients to the hospital for the furnishing of items

and services payable by federal healthcare programs.

To avert a third criminal trial, as well as potential civil liabilities that could still result,

Tenet agreed to a civil settlement that includes a payment of \$21 million to resolve potential civil claims by the government. In addition, Tenet says it has acceded to the demand of the OIG that the company sell or close the hospital within a specified period of time or have the hospital face exclusion from federal healthcare programs, including Medicare. The OIG had announced the potential exclusion on May 8.

### Physician Relocation Agreements

The OIG had alleged that from 1992 to 2003 Alvarado entered into physician relocation agreements through which Alvarado funneled money to existing physician practices in the San Diego area in exchange for patient referrals. "Although the relocation agreements were purported to benefit the doctor who actually relocated to the San Diego area, in

practice, the agreements primarily benefited the established physician practices where the new doctors were placed," the OIG said in a statement.

Alvarado and the Tenet subsidiary that owns the hospital have consistently denied the government's allegations in the indictment. In both trials, they strongly maintained that physician relocation agreements are a common practice in the hospital industry as a means to bring needed healthcare resources to communities. However, they did agree to include an explanatory statement as part of the settlement agreement acknowledging that "certain host physician practices had obtained excessive payments by representing that they needed money to make tenant improvements to accommodate new physicians when, in fact, they never made improvements."

"We regret that the hospital did not take adequate steps to assure that money provided to relocated doctors, including money earmarked for tenant improvements and office overhead, was in fact used for those purposes and in all instances was justified," the statement continued. "We have always had a disagreement with the government over whether anyone at Alvarado knowingly set out to violate the law in connection with these physician recruitments, but we have never disputed that there are aspects of how the recruitment program operated that are troubling."

Under the agreement, the U.S. Attorney in San Diego will now move to dismiss all criminal charges against Tenet, Alvarado, and the hospital's former chief executive officer, and will not file any civil litigation in the case.

### Resources

- ❖ Office of Inspector General: [www.oig.hhs.gov](http://www.oig.hhs.gov), 202-619-1343
- ❖ Tenet Healthcare, [www.tenethealth.com](http://www.tenethealth.com) 🏠

*"We have always had a disagreement with the government over whether anyone at Alvarado knowingly set out to violate the law in connection with these physician recruitments, but we have never disputed that there are aspects of how the recruitment program operated that are troubling."*

—Tenet Healthcare

## Medco Agrees To \$163 Million Settlement

**M**edco Health Solutions Inc. said May 5 that it will pay \$163 million under a tentative settlement to resolve kickback allegations by two whistleblowers in a False Claims Act (FCA) action (*United States ex rel. Piacentile v. Merck & Co. Inc.*).

Medco said the one-time, pretax settlement charge partly reflects its agreement in principle on financial terms with the government regarding a consolidated FCA whistleblower action filed in U.S. District Court in Philadelphia. "Settlement is predicated on nonmonetary agreements, which are under negotiation and subject to approval by participating parties," said the company in a statement.

The FCA lawsuit combined an action filed by whistleblower Joseph Piacentile, a New Jersey physician, and an action filed by George Bradford Hunt, a pharmacist working in Medco's prescription drug mail order facility in Nevada. The government intervened on Dec. 9, 2003, following the whistleblowers' two qui tam

actions filed in 1999 and 2000 and a four-year investigation, according to U.S. Attorney Patrick Meehan.

"This office filed a False Claims Act and Anti-Kickback Act complaint against Medco," Meehan said. "That complaint charged Medco with destroying and canceling valid patient prescriptions, soliciting kickbacks from pharmaceutical manufacturers, and paying kickbacks to health plans to obtain business."

The violations arose from Medco's contract with Blue Cross and Blue Shield to provide mail-order prescription drug benefits to federal employees, retirees, and their families who received benefits under the Federal Employees Health Benefits Program, according to the whistleblowers' complaints. Medco, which used to be a subsidiary of Merck, is the country's largest pharmacy benefit manager.

The Medco press release pointed out that the settlement involves two other issues in addition to the *Piacentile* action. The second matter is a separate FCA qui tam action that remains under seal, but was first disclosed publicly by Medco with the district court's permission.

The complaint alleges Medco and other defendants inflated the manufacturers' "best price" to Medicare and Medicaid and offered and paid kickbacks to third parties to induce the placement on formularies and promotion of certain drugs, Medco said.

The third issue, which was first disclosed in March 2005, involves Medco's Medicare coordination of benefits recovery program in which Medco detected issues, terminated its participation in June 2005, and self-reported to an oversight agency.

### OIG: Empire Overcharged Medicare

**F**ederal contractor Empire Medicare Services overcharged the Medicare program more than \$4.6 million, much of it attributable to incentive compensation unrelated to the company's Medicare business, the Department of Health and Human Services Office of Inspector General (OIG) said in an audit report issued April 13.

The OIG said that Empire's weaknesses in controls screening for indirect costs resulted in the overpayments. The \$4.6 million represented a little more than 1% of Empire's total costs billed to the Medicare program, the OIG's Office of Audit Services noted. During the audit period, Empire was a division of Empire Blue Cross and Blue Shield.

Not all of the contractor's systems were faulty, the OIG noted in its report, *Review of Medicare Part A and Part B Administrative Costs Claimed by Empire Medicare Services – October 1999 Through September 2002*.

Auditors found that Empire effectively identified costs that should be excluded from cost proposals, effectively accumulated expenses that should be included in cost proposals, and complied with Federal Acquisition Regulations and Medicare contract provisions when reporting expenditures.

The bulk of the overpayments were attributable to more than \$3 million in incentive compensation expenses unrelated to Empire's Medicare contract, the OIG said. Instead, those expenses were bonuses paid as part of the company's private lines of business, the audit found. The report is available online at [www.oig.hhs.gov](http://www.oig.hhs.gov).

### Resources

- ❖ Medco: [www.medco.com](http://www.medco.com)
- ❖ U.S. Attorney's Office for the Eastern District of Pennsylvania: 215-861-8200 🏛️

# COMPLIANCE PERSPECTIVES



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## CMS Makes Extensive Changes To Medicare Enrollment Process

**O**n April 21, 2006, the Centers for Medicare and Medicaid Services (CMS) published a final rule<sup>1</sup> establishing new enrollment procedures for all providers and suppliers, except those physicians or practitioners who opt out of the Medicare program. In addition, CMS has issued new versions of the Medicare enrollment applications, including the CMS 855B, which is used by independent clinical laboratories and other suppliers. The final rule becomes effective on June 20, 2006, and the new enrollment forms are already in use.

The final rule is the first codification of detailed rules relating to enrolling in the Medicare program and maintaining Medicare billing privileges. Important highlights include:

- ❖ Detailed criteria for review of initial enrollment applications;
- ❖ Broad discretion for CMS to deny enrollment, to revoke enrollment and billing privileges, and to deactivate billing privileges;
- ❖ A new process for revalidation of enrollment information currently on file with CMS, including submission of a CMS 855 by providers and suppliers who have not previously done so;
- ❖ Clear authority for CMS to conduct on-site visits to verify information furnished in the CMS 855; and
- ❖ Changes to the procedures for submission of information in connection with a change of ownership or control.

For the most part, the final rule mirrors the proposed rule issued three years ago.<sup>2</sup>

<sup>1</sup> 71 Fed. Reg. 20754 (Apr. 21, 2006).

<sup>2</sup> 68 Fed. Reg. 22063 (Apr. 25, 2003).

The most significant differences are the lengthening of the period that would result in deactivation of billing privileges for failure to submit Medicare claims from six months to 12 months, the implementation of a phased-in approach for requiring submission of enrollment information by currently participating providers and suppliers, and extension of the revalidation cycle from three to five years.

Although CMS intended the final rule to clarify and strengthen the Medicare enrollment process, it may raise more questions than it answers. All providers and suppliers should note the significant administrative obligations imposed by the new regulations and, in light of the penalties for noncompliance, take immediate steps to comply.

### Initial Enrollment

CMS requires all providers and suppliers to submit a CMS 855 to enroll in the Medicare program and to obtain Medicare billing privileges. In response to comments received on the proposed rule, CMS clarified that it has not changed its policy on effective billing dates and therefore will continue to allow retroactive submission of claims after completion of the enrollment process.

Under the new regulations, a provider or supplier must certify that it is in compliance with all applicable federal and state licensure requirements, including Medicare statutes and regulations, and that it does not employ or contract with excluded or debarred individuals or entities. Many providers and suppliers require contractors to affirm they are not

excluded, debarred, or suspended, but this expansive certification requires an affirmative representation about which the provider or supplier may or may not have specific knowledge at the time of certification. Although the new version of the CMS 855 does not include an express certification this broad, CMS could seek to revise it after the final rule takes effect.

In making an enrollment determination, CMS has the right to perform an on-site inspection. CMS clarified that this site visit is separate and distinct from the survey process. For the most part, the scope and nature of these on-site visits, which will be conducted by CMS's fee-for-service contractors, are undefined. Laboratories are likely to see overlap with accreditation inspections as well as with any state and federal surveys.

Each enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, and who has an ownership or control interest in the provider or supplier. The authorized official may appoint a "delegated official" for making updates or changes to the enrollment information, provided that the delegated official is a W-2 managing employee of, or an individual with an ownership or control interest in, the provider or supplier. CMS clarified, for the first time, that a W-2 employee of the parent corporation cannot serve as a delegated official of a subsidiary because he or she must have a "direct relationship and connection with the applicant."

CMS will reject an enrollment application if complete information is not provided within 60 days of notification that it is incomplete, but CMS may grant an extension to an applicant who is "actively working with CMS to resolve any outstanding issues." Providers and suppliers should not count on obtaining extensions under this ambiguous standard. Rejection of an enrollment application is not subject to appeal, but a provider or supplier may

begin the enrollment process anew by submitting a new CMS 855.

### **Reporting Changes To Enrollment Information**

Most providers and suppliers must report any changes to the information furnished on the enrollment application and submit supporting documentation within 90 days of the change, with the exception of a change of ownership or control, which generally must be reported within 30 days. CMS previously required independent clinical laboratories and other suppliers to report all changes within 90 days, so this abbreviated time period applicable to changes of ownership and control is new. Reporting requirements related to changes of ownership and control also are discussed in more detail below.

A number of commenters urged CMS to permit providers and suppliers to update and change enrollment information electronically and to allow the use of electronic signatures. In response, CMS stated that it is developing a Web-based electronic enrollment process to allow for electronic updates and will consider the use of electronic signatures in the future.

### **Revalidation Of Enrollment Information**

According to the final rule, a provider or supplier must resubmit and recertify the accuracy of its enrollment application every five years. CMS initially proposed a three-year revalidation cycle, but was persuaded by commenters to lengthen the cycle to five years. CMS has decided to implement a phased-in approach in recognition of the large number of physicians who currently bill Medicare who have never completed an enrollment application.

CMS will contact each provider or supplier directly when it is time to revalidate enrollment information. Those participating providers and suppliers who have never submitted a CMS 855 must now do so. As a result, those providers and suppliers who participated in the Medicare

program prior to the use of the CMS 855 will need to submit a vast amount of information not previously furnished to CMS. The revalidation process will require CMS's contractors to process a substantial volume of enrollment information. Although CMS has committed to phasing in this process over the next few fiscal years, CMS's claim that its contractors can handle this workload should be viewed with a healthy dose of skepticism.

The provider or supplier must submit a CMS 855 with complete and accurate information, including supporting documentation, for revalidation within 60 days of receiving notification from CMS. A provider or supplier may seek additional time to respond, but, as with initial applications, CMS did not articulate a defined standard for granting extensions. Given this lack of clarity and the short time frame for response, providers and suppliers should have policies and procedures in place to ensure proper co-

ordination of responses to revalidation requests and timely submission of accurate information.

As part of the revalidation process, CMS reserves the right to conduct further on-site inspections to evaluate compliance with enrollment requirements and to confirm that the provider or supplier is, in fact, operational. The regulations did not establish any other standards regarding when CMS's contractors may decide to conduct an on-site inspection. Given the breadth of the regulations, providers and suppliers will likely have difficulty predicting when such a review may occur.

CMS also may perform nonroutine revalidations of enrollment information and request recertification of the accuracy of enrollment information whenever necessary. Such off-cycle revalidations may be accompanied by site visits. The final rule provided little information regarding the process and time frame for responding to nonroutine revalidations. The list of possible events that could trigger off-cycle revalidation is so broad that it offers little practical guidance regarding when such a review may occur.

#### **Prohibition On The Sale Or Transfer Of Billing Privileges**

**T**he final rule prohibits a provider or supplier from selling, transferring, or allowing another entity or individual to use its Medicare billing number, except in accordance with reassignment or change of ownership rules. In addition, CMS retained broad discretion to deactivate a Medicare billing number at any time before the provider agreement is transferred to the new owner.

A supplier that is not covered by the regulations governing provider agreements, such as an independent clinical laboratory, must report a change in ownership or control within 30 days of the change. As mentioned above, the 30-day deadline replaces the previous deadline of 90 days. The regulation specifically states that a change of ownership resulting in a new tax identification number requires completion and submission of a new enrollment application by the new owner. Suppliers should take note of this new deadline on reporting changes of ownership and control because a failure to comply may result in temporary deactivation or, ultimately, revocation of Medicare billing privileges.

This regulation also addresses changes of ownership for providers governed by part 489, subpart A, of the Medicare regulations. Providers covered by this regulation include hospitals, skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, hospices, critical access hospitals, and others. The current owner and the prospective new owner must each submit a CMS 855 30 days *before* a change of ownership or incur possible penalties.

#### **Denial Of Enrollment**

The final rule expands CMS's discretion to deny enrollment in the Medicare program. The most notable basis for denial relates to a provider, supplier, or owner's conviction for a felony that CMS has determined is "detrimental to the best interests of the program and its beneficiaries." Such offenses include but are not limited to crimes against persons, financial crimes, felonies that pose immediate risk to the program or its beneficiaries, and healthcare fraud. A denial imposed on this basis lasts at least 10 years from the date of conviction.

Unlike rejection of an application, denial of enrollment may be appealed, or the provider or supplier may reapply by submitting a new CMS 855. In addition, CMS may reverse a denial based on the provider's or

supplier's relationship with an excluded or convicted individual or entity if the provider or supplier submits proof that it has terminated the relationship.

Providers and suppliers should note that a denial may have broad implications because, according to the final rule, a denial will cause CMS to automatically review the enrollment of all other locations and determine whether the denial warrants similar adverse action. This requirement could pose particularly serious complications for large laboratories with multiple locations.

#### **Revocation Of A Medicare Billing Number**

The final rule establishes grounds for revocation of a Medicare billing number that are substantially similar to the reasons why CMS may deny enrollment. The revocation becomes effective within 30 days of the initial revocation notice and results in simultaneous termination of the provider agreement (if any). CMS may reverse a revocation based on an association with an excluded or convicted individual or entity if the provider or supplier submits proof that it terminated the relationship.

In determining whether to revoke a Medicare billing number, CMS explained that it will weigh the severity of the offenses, mitigating circumstances, program and beneficiary risk resulting from continued enrollment, possibility of corrective action plans, beneficiary access to care, and any other pertinent factors. A provider or supplier may appeal revocation, but CMS will not make payment while an appeal is pending. CMS promised to establish, in a separate regulation, a process for appealing denials and revocations.

The effect of a revocation is significant and could have adverse effects on providers and suppliers, especially those with multiple locations. Like the regulations governing denial of enrollment, the revocation regulations state that, once a provider or supplier number is revoked,

CMS must automatically review the files of associated providers or suppliers.

#### **Deactivation Of A Medicare Billing Number**

Under the final rule, CMS may deactivate the billing number of a provider or supplier that does not submit any Medicare claims for 12 consecutive calendar months or that fails to report a change in the information supplied on the enrollment application within 90 days of when the change occurred (or within 30 days for changes of ownership and control). The proposed rule would have shortened the inactivity period to six months, but CMS decided to retain the current rule, which permits deactivation after 12 months.

When a billing number is deactivated, billing privileges are temporarily suspended but can be restored upon the submission of updated or recertified information. Providers and suppliers whose billing numbers are deactivated for any reason other than nonsubmission of claims must submit a new enrollment application and re-enroll in Medicare. If deactivation is for nonsubmission of claims, a provider or supplier must simply recertify that the enrollment information currently on file with Medicare is still correct.

#### **Conclusion**

While the final rule clarifies certain procedures for providers and suppliers, it also imposes significant new administrative burdens and serious consequences for noncompliance. All providers and suppliers should study the final rule and the updated CMS 855 forms carefully to ensure that they are aware of the obligations imposed, especially given the tight time frames and the possible penalties involved.

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**Lab Competitive Bidding**, from p. 1 with Holland & Knight (Washington, DC) and counsel to CLMA.

For example, the report notes that physician office laboratory testing and hospital outpatient testing are not included in the demonstration, *except where the physician office or hospital laboratory functions as an independent laboratory performing testing for a beneficiary who is not a patient of the physician or hospital outpatient department* (emphasis added).

“A nonpatient for a physician office laboratory doesn’t exist,” notes Boothe. “And there still isn’t sufficient clarity as to who is a nonpatient of a hospital so the hospital knows what business it needs to include in calculating its revenues for purposes of the demonstration.”

It’s also unclear whether labs would be able to bid as part of a consortium if they don’t qualify to bid on their own, he adds.

#### **Demonstration Structure**

According to the report, the bidding pilot would run for three years in two demo sites, with a staggered start date. Early data from the demonstration may be used to assess the feasibility of expanding com-

*CMS is soliciting public comment on a single application form that all clinical labs providing Part B lab services to Medicare beneficiaries would have to complete, whether bidding or not. Comments are due June 20. For details, see the April 21 Federal Register, [www.access.gpo.gov/su\\_docs/fedreg/a060421c.html](http://www.access.gpo.gov/su_docs/fedreg/a060421c.html). Select CMS Notice 20697 (E6-5833).*

petitive acquisition areas and to estimate the range of achievable savings from competitive bidding.

The recommended structure of the demonstration uses Metropolitan Statistical Areas (MSAs) to define demonstration sites. RTI recommends selecting an

MSA that is located within a single state and one with a moderately large Medicare population. It also suggests an MSA that has neither very low nor very high Medicare-managed care penetration (defined as greater than 5% but less than 50%). Under these terms, 23 MSAs are po-

tential candidates, according to Boothe (see chart on pg. 10).

The demonstration would set competitively bid fees in the demonstration areas for all tests paid under the Medicare Part B clinical laboratory fee schedule, with the exception of Pap smears, colorectal cancer screening tests, and new tests added to the lab fee schedule during the course of the demonstration.

The project would cover demonstration tests for all Medicare Part B beneficiaries who live in the demo sites. Hospital inpatient testing is covered by Medicare Part A and therefore exempt from the demonstration. As mentioned above, physician office laboratory testing and hospital outpatient testing are not included in the demo, although testing on nonpatients (outreach testing) is included.

#### **Bidding**

Independent, hospital, and/or physician office laboratories with \$100,000 or more in annual Medicare Part B fee-for-service payment for nonpatient services would be required to participate in the demonstration. Small laboratories, defined as those that fall below the \$100,000 threshold, would not be required to bid. Bidding labs won’t have to bid to provide coverage to the entire demo site, but would have to provide information on their capacity and geographic services area. They are also subject to prohibitions against collusion or antitrust behavior that are enforced by the Federal Trade Commission and the Justice Department.

After release of the bid solicitation package and prior to bidding, CMS would hold a “bidders’ conference” for potential bidders to learn about the rules and ask questions. There would be a single bidding competition, and the agency expects multiple winning labs in each demo site.

Bidders would be required to submit a bid price for each HCPCS/CPT code in the demonstration tests menu. They

would also be asked to identify covered tests that they do not perform and to explain their plans for responding to requests for tests that are referred or sub-contracted out. Further, bidding labs would be required to provide information on ownership, location of affiliated labs and drawing stations, CLIA certification, laboratory finances, and quality.

A lab's bid for individual tests would be weighted and summed to form a single composite bid. The composite bids would be arrayed from lowest to highest, and the array would be used in conjunction with other criteria to determine the "pivotal" composite bid that would determine the winners. Bidders with composite bids less than or equal to the pivotal composite bid would be winners; those with composite bids greater than the pivotal bid would be losers. The government would establish a maximum acceptable bid, or "reservation bid," that would be slightly less than the composite bid obtained using the

Part B lab fee schedule. Labs whose composite bids exceed the reservation bid would automatically be losers.

#### Reimbursement

Recommendations for the reimbursement rules include a new fee schedule for individual demonstration tests, which will be set after the pivotal bid is selected and winning laboratories are determined. After considering quality, capacity, geographic coverage, and other non-price criteria, win-

ning labs would be selected that can offer the full menu of demonstration tests at lower total costs than under the existing clinical laboratory fee schedule. All winning laboratories would be paid the same price for each test under the demonstration.

For nonpatient testing, small laboratories would receive payment for demonstration tests under the demo fee schedule (not to exceed \$100,000 in annual Medicare Part B payment for nonpatient services). The existing Medicare Part B clinical laboratory fee schedule will continue to apply to nondemonstration tests. Payment for nondemonstration tests will be unaffected by a laboratory's status as a winner or loser in the demo.

#### Service Quality, Access

To assure quality, the project would rely on compliance with CLIA rules and add standardized measure for turnaround time—total testing, specimen transport and processing, stat work, reporting of critical values, and public health disease notification. Log-in error rates, physician satisfaction, and the number of unusable or lost specimens would also be monitored. Labs in the demo would have to designate a quality assurance staff member as a contact point for CMS, physicians, and beneficiaries. The labs would have to submit information on service and quality standards that CMS would send to physicians in their communities. CMS also would run a toll-free complaint hotline.

To ensure access, the project would pick sites where there are enough labs to provide needed services and would monitor testing rates per beneficiary for diabetes, congestive heart failure, and coronary artery disease.

#### Resources

- ❖ Jeff Boothe: 202-828-1896
- ❖ CMS report to Congress: [www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b\\_NewCongress.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MMA302b_NewCongress.pdf) 📄

#### Competitive Bidding Potential Sites

Austin-Round Rock, TX  
 Birmingham-Hoover, AL  
 Buffalo-Niagara Falls, NY  
 Cleveland-Elyria-Mentor, OH  
 Columbus, OH  
 Denver-Aurora, CO  
 Jacksonville, FL  
 Las Vegas-Paradise, NV  
 Milwaukee-Waukesha-West Allis, WI  
 Nashville-Davidson-Murfreesboro, TN  
 New Orleans-Metairie-Kenner, LA  
 Oklahoma City, OK  
 Orlando-Kissimmee, FL  
 Phoenix-Mesa-Scottsdale, AZ  
 Pittsburgh, PA  
 Riverside-San Bernardino-Ontario, CA  
 Rochester, NY  
 Sacramento-Arden-Arcade-Roseville, CA  
 San Antonio, TX  
 San Diego-Carlsbad-San Marcos, CA  
 San Jose-Sunnyvale-Santa Clara, CA  
 Seattle-Tacoma-Bellevue, WA  
 Tampa-St. Petersburg-Clearwater, FL  
 Source: Jeff Boothe, Holland & Knight

## OIG Finds 90% Of Claims For Physical Therapy Wrong

**M**ore than 90% of all physical therapy claims paid by Medicare to physicians in the first six months of 2002 did not meet program requirements and resulted in \$136 million in overpayments, the Health and Human Services Office of Inspector General (OIG) said in a report released May 4.

The OIG further found that unusual physician billing patterns and high volumes of claims between 2002 and 2004 indicate Medicare physical therapy claims are vulnerable to abuse.

The OIG initially reported its interim results to the Centers for Medicare & Medicaid Services (CMS) in October 2003, and the recent findings represent the completed medical review of physical therapy claims data. The final results were sent in a memo, titled "Physical Therapy Billed By Physicians," to CMS Deputy Administrator Leslie Norwalk.

Nearly 60% of the inappropriate claims from the first half of 2002 were physician therapy services furnished under incomplete plans of care, the OIG's Office of Evaluation and Inspections found. Those findings, when projected to the national

population of therapy billed by doctors, represent about \$87 million in claims allowed by Medicare in the first half of 2002, the report stated.

More than 25% of the claims were for services not medically necessary, and all of those services were provided under incomplete plans of care, according to the report. Additionally, 34% of claims were submitted without appropriate documentation, which also prohibited reviewers from evaluating the quality of therapy services provided.

In its analysis of a wider range of claims data, the OIG found that about 4% of all physicians who submitted physical therapy claims between 2002 and 2004 accounted for more than half of all allowed claims. In addition, the OIG found that small numbers of physicians billed significantly more for physical therapy and for more patients with higher cost, noting that the doctors' specialties did not account for the variations.

### Resource

OIG report, *Physical Therapy Billed By Physicians*, (OEI-09-02-00200), [www.oig.hhs.gov/oei/reports/oei-09-02-00200.pdf](http://www.oig.hhs.gov/oei/reports/oei-09-02-00200.pdf). 📄

## OIG Issues Several New Advisory Opinions

**I**t's been a busy past few weeks for the Health and Human Services Office of Inspector General (OIG). Since April 18, the agency has issued four new advisory opinions. The following are highlights of the OIG's conclusions:

- ❖ **No. 06-03:** Prescription drug makers can offer patient-assistance program benefits to financially needy Part D enrollees without incurring federal sanctions under the anti-kickback statute.
- ❖ **No. 06-04:** A proposed arrangement by a charitable corporation to help financially needy Medicare beneficiaries with premiums and cost-sharing obli-

gations would not trigger sanctions under the civil monetary penalties provisions.

- ❖ **No. 06-05:** A proposal by a pediatric research facility to provide drugs and supplies to affiliates for administration to patients would not generate prohibited payments under the anti-kickback statute.
- ❖ **No. 06-06:** Even though a city's proposed exclusive arrangement for emergency ambulance services potentially implicates the anti-kickback statute, the OIG would not impose administrative sanctions in connection with the proposal.

All four advisory opinions are available online at [www.oig.hhs.gov](http://www.oig.hhs.gov). 📄

**Blues Settlement:** The New York-based insurer Empire Blue Cross Blue Shield will stop sending out misleading balance-billing notices for covered ambulance services and offer restitution for policyholders who were overcharged by providers, under terms of a settlement announced May 5 by New York Attorney General Eliot Spitzer (D). The Empire settlement was the latest in a series reached by Spitzer under his office's statewide Project Clean Bills of Health initiative to eliminate improper medical billing. In February, two prominent New York City hospitals agreed to reform their billing practices and offer restitution for improperly balance-billed consumers for services already covered by health insurance. Previous settlements under the Spitzer initiative covered MDS Labs, Quest Diagnostics, WellCare of New York, and Vineall Ambulance.

**Concerns Over Whistleblower Protections:** Senate Finance Committee Chairman Charles Grassley (R-IA) said April 26 that he is concerned that states enacting

new false claims legislation are failing to include adequate qui tam provisions that would allow whistleblower action to proceed after state attorneys general decline to intervene in matters. Grassley expressed his concern in letters to U.S. Attorney General Alberto Gonzales and Health and Human Services Inspector General Daniel Levinson. The federal False Claims Act does not prevent qui tam cases from moving forward if the government declines to intervene in a case, and Grassley said states must consider that provision if they expect to benefit from an incentive in the Deficit Reduction Act of 2005.

**MAC Transition:** The Centers for Medicare & Medicaid Services (CMS) plans to announce the award of the first Medicare Administrative Contractors (MAC) by the end of this month. MACs are designed to replace the current claims processing system of carriers and fiscal intermediaries. The first award will be for Jurisdiction 3, which includes Arizona, Montana, North and South Dakota, Utah, and Wyoming. The complete handover of the work to the new MAC is planned for July 2007. 🏠

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