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For Hospitals, Laboratories and Physician Practices

CMS to Delay Anti-Markup Rules for Certain Tests

The Centers for Medicare & Medicaid Services (CMS) has delayed until Jan. 1, 2009, the applicability of anti-markup provisions under the Stark self-referral rules to certain services in certain locations.

The delay applies to the professional component of diagnostic tests. It does not apply to the technical component. It also does not apply to any anatomic pathology testing services furnished in space that 1) is utilized by a physician group practice as a "centralized building" for purposes of complying with the physician self-referral rules, and 2) does not qualify as a "same building" under the rules.

In a final rule published January 3, CMS said it was concerned that the definition of "office of the billing physician or other supplier" may not be entirely clear and could have "unintended consequences."

The agency said in the notice that during the next 12 months, it plans to issue clarifying guidance as to what constitutes the "office of the billing physician or other supplier," propose additional rule making, or both.

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Genetic Testing Oversight Should Stay Under CLIA, Say Industry Groups

Any changes to federal oversight of genetic laboratory tests should be made within the context of the Clinical Laboratory Improvement Amendments (CLIA), say industry groups.

In comments submitted to the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), both the College of American Pathologists (CAP) and the American Clinical Laboratory Association (ACLA) recommended that the Centers for Medicare & Medicaid Services (CMS) continue to have primary regulatory authority over genetic testing services through CLIA.

The groups were commenting on a draft report, *U.S. System of Oversight of Genetic Testing*, released by the advisory committee in November. The draft report concluded that genetic information is not fundamentally different from other health information, but that genetic testing is different. The committee will meet February 12-13 to deliberate on the oversight of genetic testing.

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Genetic Testing Oversight, *from page 1*

In its comments, CAP argues that genetic tests are not unlike many of the other laboratory tests that have been successfully introduced into medical practice. The college also expresses concern that the broad definition of genetic tests used in the draft report captures many non-genetic tests that have not raised public concern.

ACLA agrees that genetic testing should continue to be regulated under CLIA. "We are aware of various concerns raised by the FDA (Food and Drug Administration) and others about the adequacy of CLIA to meet the emerging new challenges posed by genetic testing and similar innovations," writes ACLA in its comments. "However, these concerns (where valid) are best addressed through slight modifications to, or clarifications of, the CLIA regulations rather than through division and/or transfer of principal regulatory authority to other agencies (e.g., as has been proposed by FDA regarding in vitro diagnostic multivariate index assays)."

ACLA shares the committee's concerns about the fact that some providers of certain genetic tests argue that their tests that are marketed and sold directly to consumers do not fall within the scope of CLIA—a position with which ACLA does not agree. Advertisements and sales of these tests can cause much confusion among, and harm to, consumers. As such, ACLA supports the committee's recommendations that the "CLIA regulations, or if necessary, CLIA's statutory authority, should be expanded to encompass the full range of health-related genetic tests."

ACLA believes, however, that a change in the CLIA regulations is not necessary to accomplish this. All that is necessary is a clarification of CLIA's authority over such tests. ACLA proposes adoption of a regulatory oversight model based on a Memorandum of Understanding between CMS and the FDA.

"By strengthening the CLIA regulations and providing for an expanded, clearly defined 'consultative role' for FDA, this model would address known concerns with CLIA, namely the gaps in CLIA quality regulations, the need for public transparency of genetic testing oversight, and the need for improvements in validation of services under CLIA," says ACLA.

OIG Gives Nod to Gainsharing Arrangements

The Department of Health and Human Services Office of Inspector General (OIG) appears to be warming up to the idea of gainsharing. The OIG in January issued two new favorable opinions on gainsharing, bringing to 10 the number of favorable opinions on the subject.

According to the law firm of Alston & Bird (A&B), this is an indication that gainsharing continues to be a viable option for hospitals looking to reduce costs and align their economic incentives with physicians.

Similar to previously issued opinions, Advisory Opinion 07-21, posted January 14, approves a gainsharing arrangement between a hospital and a group of cardiac surgeons. Advisory Opinion 07-22, posted the same day, approves a gainsharing arrangement between a hospital and a group of anesthesiologists for services provided during cardiac surgical procedures, signaling the OIG's willingness to approve gainsharing outside of cardiac surgery and cardiology specialties.

Gainsharing is a term that is used to describe arrangements between hospitals and physicians whereby the hospital agrees to share with the physician any reduction in the hospital's costs for patient care attributable in part to the efforts of

the physician, explains A&B in a recent advisory. "Typically, these payments are structured in a variety of ways, including hourly payments for services performed by the physician or as a percentage of the cost savings realized under the arrangement," says the advisory. "While gainsharing has gained increasing acceptance in the past year, the road traveled has not been an easy one."

Background

Historically, the OIG has been extremely suspicious of gainsharing programs, notes A&B. In 1999, the OIG issued a special advisory bulletin outlining its concerns with generalized gainsharing (payments tied to overall cost savings rather than payments tied to specific, identifiable cost savings) and took the position that gainsharing arrangements between hospitals and physicians violated current federal law.

Specifically, the OIG said that gainsharing violated the civil monetary penalty (CMP) provisions that prohibit a hospital from paying a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician's direct care.

"Additionally, the OIG noted that gainsharing arrangements may also raise concerns about the federal anti-kickback law," says the advisory. "The 1999 OIG issuance was viewed by many as signaling the end to gainsharing. Nevertheless, in 2001 gainsharing was given new life when the OIG approved the first of many gainsharing programs under the OIG advisory opinion process."

The two new advisory opinions, while similar to previous ones, do provide some new features and additional insight into the OIG's analysis of gainsharing arrangements, notes A&B. Significantly, the two opinions are for "existing" arrangements rather than "proposed" arrangements. Under OIG authority, the OIG is permitted to issue an advisory opinion for an existing arrangement or a proposed arrangement that the requestors in good faith intend to undertake.

All of the prior OIG-approved gainsharing arrangements were proposed—meaning the programs could not begin until the OIG advisory opinion process was complete and a favorable opinion was issued. In recent opinions, the requestors implemented the gainsharing arrangement and then began performing the specific changes in the operating room practices prior to requesting an opinion from the OIG. The hospital withheld any payments under the arrangement, however, pending the outcome of the advisory opinion request.

"While the OIG's continued willingness to approve gainsharing arrangements and expand into new specialties is promising, caution is still warranted."
—Alston & Bird

"While the OIG's continued willingness to approve gainsharing arrangements and expand into new specialties is promising, caution is still warranted," advises A&B. "The OIG's analysis of each approved program is highly fact-specific and should not be viewed as an overarching approval of gainsharing."

In addition, the OIG opinions do not analyze the gainsharing arrangements for compliance with the Stark physician self-referral law, which falls under the purview of CMS. Whether and how gainsharing programs comply with Stark remain an open issue.

Resources

- Alston & Bird, *www.alston.com*
- Advisory Opinions 07-21 and 07-22 are available on the OIG's Web site at *www.oig.hhs.gov*.

Labs, Community Providers Overbill NY Medicaid: Report

The New York state Medicaid program was billed $5 million in inappropriate charges over a five-year period by community-based providers, labs, and ambulatory care centers, according to two reports released Dec. 10, 2007, by state Comptroller Thomas DiNapoli (D).

One report found that Medicaid overpaid community-based providers by $2.1 million for services that were supposedly provided to patients residing in nursing homes. The other report found that labs and ambulatory care providers were overpaid by $2.9 million for services supposedly provided to patients who were hospitalized.

The report recommended that the state DOH provide greater guidance to ambulatory care and lab service providers on billing Medicaid for services to hospitalized patients. It also recommended that the Office of Medicaid Inspector General re-evaluate its process for identifying inappropriate claims.

Both reports were based on audits conducted by the comptroller's office. Both recommended that the state Department of Health (DOH) recoup the overpayments and adjust the Medicaid claims processing system to prevent and detect the problems in the future.

According to the first report (No. 2006-S-106), community-based services are intended to help patients who live at home, and Medicaid will pay for these services for nursing home residents only in limited circumstances.

The report cited two examples of overpayments: 108 community-based providers were paid $206,090 for hourly services to patients who resided in nursing homes and another 22 providers were paid $323,330 for mental health case management services for nursing home residents.

The state DOH, in its prepared response to the report, said it would change its claims processing system where feasible to incorporate the report's recommendations.

In the second report (No. 2006-S-90), the comptroller identified $2.3 million in Medicaid charges for ambulatory care and laboratory services for patients who were hospitalized. Another $622,937 was billed for ambulatory care and lab services for patients hospitalized at facilities overseen by the state Office of Alcohol and Substance Abuse Services.

The report said state regulations specifically prohibit labs from billing Medicaid separately for services to hospitalized patients. The regulations require that Medicaid's inpatient rates at hospitals include the costs for almost all services, according to the report.

The report recommended that the state DOH provide greater guidance to ambulatory care and lab service providers on billing Medicaid for services to hospitalized patients. It also recommended that the Office of Medicaid Inspector General re-evaluate its process for identifying inappropriate claims.

The state DOH, in its prepared response to the report, said it would implement most of the report's recommendations.

Resources

- The first report (No. 2006-S-106) is available at *www.osc.state.ny.us/audits/allaudits/093008/06s106.pdf*.
- The second report (No. 2006-S-90) is available at *www.osc.state.ny.us/audits/allaudits/093008/06s90.pdf*.

COMPLIANCE PERSPECTIVES

Deadline Looms for Bids Under Demonstration

Groups Continue to Push for Repeal

While the February 15 deadline to submit bids under Medicare's clinical laboratory competitive bidding demonstration project is fast approaching, industry groups and California lawmakers are continuing their push to repeal the demonstration altogether.

House and Senate lawmakers representing San Diego County, the first competitive bid area selected by the Centers for Medicare & Medicaid Services (CMS), in December sent letters to the leadership of the Senate Finance Committee urging repeal of the demonstration. The letters followed on the heels of CMS's bidders' conference, held in San Diego on December 5.

At the bidders' conference, CMS released the final bidders' package and addressed some of the questions and concerns about the evaluation process. According to CMS officials, 66 laboratories in the CBA were invited to the conference. These are labs that are providing greater than $25,000 annually in payment from Medicare for the over 300 demonstration tests provided to fee-for-services beneficiaries residing in the CBA. Labs supplying at least $100,000 annually in demonstration tests for Medicare beneficiaries living in the CBA will be required to bid.

> ***"The reference laboratories that do business outside of this area can bid low to clear all the small players out. But when you look at their bottom line, it won't be as impacted as mine because my whole business comes from this area."***
>
> ***— Gary Stevens, Internist Laboratory***

But at least one required bidder left the meeting confused about how to compile a realistic bid. Gary Stevens, co-owner of Oceanside-based Internist Laboratory, estimates that he probably only performs half of the 303 tests that are part of the demonstration project. "We are required to give a price on each of these tests because that goes into how the composite price for the tests are configured," he explained, adding that he will have to send the rest of the tests to a reference lab.

"Therefore, I'm dependent on reference labs to give me a bid," he said. "But at the conference, Quest established the fact that the bid they give to other labs doesn't have to be as low as the bid they give to CMS." If the reference lab gives him a higher bid than it gives CMS for the same test, Stevens is afraid that he could lose the bid.

After presenting this concern at the conference, Stevens was advised by officials to negotiate a better rate from the reference lab. "I don't have any negotiating power or leverage to get them to lower their bid to me since it's to their advantage to knock me out," he explained.

Stevens estimates that 65% of his business

comes from Medicare fee-for-service, and he believes that his business is the only independent lab in the CBA. "The reference laboratories that do business outside of this area can bid low to clear all the small players out. But when you look at their bottom line, it won't be as impacted as mine because my whole business comes from this area."

Conference Follow-Up

CMS recently issued a Q&A follow-up from the December 5 bidders' conference. Below we highlight some of the questions and answers.

1 ***Will CMS establish an anti-markup rule between laboratories under the terms and conditions of the demonstration?***

ANSWER: Mark-up between laboratories may continue under the demonstration.

2 ***Can referring and reference laboratories share bid prices with each other if the referring and reference laboratories both are submitting bids? Do referring and reference laboratories have to submit bids individually to be declared winning laboratories under the demonstration?***

ANSWER: Each bidding laboratory must provide bid prices for all 303 demonstration test codes. A referring laboratory may request a price list from a laboratory providing its reference testing. Referral and reference laboratory relationships should be identified in the application.

A laboratory firm expecting to receive annual payments of less than $100,000 for demonstration tests provided to beneficiaries enrolled in Medicare fee-

Determining Capacity

Question: How will capacity be determined under the demonstration—and specifically during the bid evaluation process?

Answer: Capacity is evaluated to guarantee that the projected demand for demonstration test codes will be met under the demonstration. The projected demand for demonstration test codes will be determined from historical baseline utilization data for demonstration test codes trended forward by a factor reflecting the anticipated increase in utilization of demonstration test codes during the demonstration period. Both baseline utilization and the trend factor will be estimated from historical Medicare claims and enrollment data for the San Diego MSA.

Capacity will be determined using information provided by applicants, along with Medicare administrative claims data. Each applicant is required to report current annual test volume and maximum annual test capacity, which will be used to help determine each applicant's capacity.

In addition to the information that applicants provide, CMS will use Medicare paid claims to examine the historical volumes actually supplied to the San Diego MSA Medicare fee-for-service market by applicants. Historical volumes supplied to the national Medicare fee-for-service population will also be used. The Medicare claims data and the CLIA database will serve as additional sources of information and as a validation of the capacities reported by applicants.

The multidimensional selection process is based on the competitive prices submitted *and* quality of care *and* access to care. There are several dimensions to access to care, including capacity, geographic coverage, financial strength and stability, subcontracting and referral relationships, special populations and providers, expansion plans, and multiple winners. The process allows for capacity to be greater than the projected demand so, should a laboratory discontinue participation in the demonstration, beneficiary access to quality laboratory services would not be impacted. In addition, the application allows a laboratory to indicate whether or not there is interest in or capacity to expand services to additional geographic areas under the demonstration.

Source: CMS

for-service (FFS) and residing in the CBA is not required to submit a bid, but would be paid under the competitively set fee schedule. Laboratories required to bid that choose not to submit a bid will be considered nonwinning laboratories and will not be able to bill Medicare directly for demonstration tests provided to beneficiaries enrolled in Medicare FFS residing in the CBA.

Key Target Dates

In a proposed timeline released in January, CMS announced the following key dates in the ramp-up of the Part B lab competitive bidding demonstration in the San Diego-Carlsbad-San Marcos metro area.

- *February 15*—Bids due
- *April 11*—Winners selected
- *July 1*—Payments begin to be made under the competitively bid fee schedule, not the current lab fee schedule

3 ***Under the demonstration, CMS will exempt laboratories providing services exclusively to beneficiaries in nursing facilities or receiving home health services from being required bidders. Does that exemption from bidding extend to other units associated with a nursing facility, such as assisted living and independent living, for example?***

ANSWER: Laboratories providing services exclusively to beneficiaries residing in nursing homes or receiving home health services in the CBA will not be required to bid and will be paid at the competitively set demonstration fee schedule for demonstration tests otherwise paid under the Part B clinical laboratory fee schedule (CLFS). Laboratories that wish to provide services beyond beneficiaries residing in nursing homes or receiving home health services (such as for assisted living or independent care) in the CBA will be required to bid and win under the demonstration.

CMS is exempting laboratories providing services exclusively to nursing facilities from being required bidders, thereby making it easier for nursing facilities to continue to provide continuity of care. In addition, labs providing both Part A and Part B laboratory services to nursing facilities would be able to continue existing business relationships. Laboratories would not be at risk of losing Medicare Part A business as a result of the demonstration and would be paid at the competitively set rate for demonstration tests otherwise paid under the Part B CLFS. Laboratories will also continue to receive payment for mileage, phlebotomy, and the existing payment under any schedule other than the Part B CLFS for those tests included in the demonstration.

4 ***Will CMS make information on the number of beneficiaries in the CBA available? What about utilization information?***

ANSWER: Various Medicare enrollment tables, such as national and state enrollment trends, state enrollment by the aged or disabled, as well as county-level enrollment, are available at *www.cms.hhs.gov/MedicareEnrpts*.

5 ***Will CMS provide total volume per test code for individual laboratories? Will CMS provide information on denied claims?***

ANSWER: No. CMS provided the total Medicare payment for demonstration tests provided to beneficiaries enrolled in FFS residing in the CBA to individual laboratories. A letter was sent to individual laboratories either located in the CBA and/or paid more than $25,000 annually for demonstration tests provided to beneficiaries enrolled in FFS residing in the CBA. Market test code volumes and weights for the entire CBA are provided on page 19 of the bidders' conference materials.

6 ***Can a laboratory participate in the demonstration if it enters the CBA market after the demonstration has started without having participated in the bidding process?***

ANSWER: A laboratory firm entering the CBA market and expecting to receive annual payment under the demonstration to exceed $100,000 is required to submit a bid during the bidding process as described in the *Federal Register* notice published on Oct. 17, 2007. In this example, the laboratory would be considered a nonwinning laboratory for the duration of the demonstration.

A laboratory firm entering the CBA market expecting to receive annual payment for demonstration tests that is less than $100,000 is not required to submit a bid and would be paid under the competitively set fee schedule. In this example, a laboratory would be considered a passive laboratory under the demonstration.

7 ***What happens if a laboratory acquires another laboratory that is a winning laboratory under the demonstration? What if a laboratory acquires another laboratory that is a nonwinning laboratory under the demonstration?***

ANSWER: The status of the laboratory under the demonstration will be defined by the laboratory firm ownership. In other words, a laboratory firm that is a winner under the demonstration and its acquired laboratory will remain a winning laboratory. A laboratory firm that is declared a nonwinning laboratory because it failed to submit a winning bid will remain a nonwinning laboratory (including its acquired laboratory) under the demonstration. Should a laboratory firm that chose to be exempt from bidding as a small business acquire a laboratory during the demonstration period, the $100,000 annual payment threshold for demonstration tests provided under the demonstration will apply to the laboratory annual payment combined.

CMS will validate the ownership of a laboratory firm based on the Medicare enrollment information provided on the CMS-855b form.

MSAs Safe From Competitive Bidding Demo

CMS has confirmed that the following areas are unlikely to be chosen as the second lab competitive bidding demonstration site because they are the current sites of ongoing durable medical equipment demonstration projects:

- Charlotte-Gastonia-Concord, NC, SC
- Cincinnati-Middletown, OH, KY, IN
- Cleveland-Elyria-Mentor, OH
- Dallas-Fort Worth-Arlington, TX
- Kansas City, MO, KS
- Miami-Fort Lauderdale-Miami Beach, FL
- Orlando, FL
- Pittsburgh, PA
- Riverside-San Bernardino-Ontario, CA
- San Juan-Caguas-Guaynabo, PR

8 ***Can a nonwinning laboratory draw blood and bill Medicare directly?***

ANSWER: If a laboratory is enrolled in Medicare as an independent laboratory and is declared a nonwinning laboratory under the demonstration, then the laboratory may not bill Medicare directly for test codes that are paid under the Part B CLFS, including for phlebotomy. Phlebotomy services that are provided by entities other than independent laboratories and paid under fee schedules other than the Part B CLFS are not included in the demonstration.

9 ***Can a laboratory refuse to provide a laboratory test for a Medicare beneficiary residing in the CBA?***

ANSWER: A laboratory that is enrolled as a Medicare supplier cannot legally refuse to provide services to a beneficiary based on payment.

Anti-Markup Laws, *from page 1*

The provisions were included in the final physician payment rule published Nov. 27, 2007. After CMS published the final rule with comment period, CMS said it "received informal comments from various stakeholders" who alleged that the application of the rule is unclear with respect to whether certain types of space arrangements meet the definition of the "office of the billing physician or other supplier."

Further, CMS said, some of these stakeholders asserted that patient access may be disrupted significantly due to the alleged inability of physician groups to render services in a cost-effective manner if medical office space that satisfies the "same building" test is subject to the anti-markup provisions.

"That is, physician groups allege that, in situations in which they are subject to the anti-markup provisions and are limited to billing Medicare for the amount of the net charge imposed by the performing supplier, because they will not be able to realize a profit and will not be able to recoup their overhead costs, they will not be able to continue to provide diagnostic testing services to the same extent that they are currently providing such services," CMS said.

Medicare Contracting Weaknesses Result in Questionable Payments, Says GAO

Vulnerabilities in the Medicare contracting process resulted in nearly $90 million in questionable payments to contractors since the enactment of the prescription drug benefit and other Medicare reforms in 2003, the Government Accountability Office said in a report released in December.

GAO found that the Centers for Medicare & Medicaid Services (CMS) did not adequately fund or staff oversight efforts for contracting activities despite a significant growth in new contracts to implement provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

CMS paid the bulk of the $1 billion appropriated by Congress for MMA implementation to contractors that performed a variety of implementation services, GAO said in the report, *Centers for Medicare and Medicaid Services: Internal Control Deficiencies Resulted in Millions of Dollars of Questionable Contract Payments* (GAO-08-54). For example, the report noted, $234 million was paid to two contractors to support the 1-800-MEDICARE Helpline.

However, GAO found that CMS did not "fulfill critical contractor oversight" and relied on certain contractor practices, including the frequent use of cost reimbursement contracts, that increased risk to the Medicare program.

"After contract award, pervasive internal control deficiencies increased the risk of improper payments," GAO said.

"This report confirms some of my worse fears that taxpayer money was going to be used to boost the bottom lines of some private contractors and not benefit our nation's seniors."
— John Rockefeller

For example, GAO found that CMS did not have adequate guidance for invoice reviews, resulting in flawed invoice review procedures or the failure to review invoices at all. GAO identified nearly $90 million in questionable payments because of costs that were not compliant with contract terms, costs

that were not adequately supported, and waste that resulted from risks in CMS's contracting process.

For some of the questionable costs, GAO said it could not determine whether, and to what extent, some costs were allowable, meaning CMS would have no way to recover the costs.

GAO's Recommendations

To address the problems, GAO made nine recommendations, saying CMS should:

- develop policies and criteria for pre-award contracting activities;
- develop policies and procedures to ensure federal agency responsibilities are performed;
- develop policies and procedures for reviewing contractor invoices;
- provide guidance to contracting officers about standards for sufficient detail needed to support amounts billed on contractor invoices;
- establish criteria for the use of negative certification in the payment of contractor invoices to consider potential risk factors;
- train staff on invoice review policies and procedures;
- create a centralized tracking mechanism for training and personnel assigned to contract oversight duties;
- develop a plan to reduce the backlog of contracts awaiting closeout; and
- review the questionable payments identified by GAO and determine whether it should seek recovery of some payments from contractors.

In its response to GAO on the report, CMS said it would act on each of the recommendations but that it did not agree with all the report's findings. For example, CMS told GAO, the contract actions that were reviewed for the report did not represent CMS's normal contracting procedures and the contracting circumstances that were reviewed were unique to the implementation of MMA.

In addition, CMS told GAO, it disagreed with the findings of nearly $90 million in questionable payments. CMS said that its contracting officers correctly approved invoices for payment based on the information provided with the invoices and that payments were interim and would be audited at a later time.

Congressional Reaction

The report was requested by Senate Finance Committee Chairman Max Baucus (D-MT) and ranking member Chuck Grassley (R-IA).

Baucus and Grassley said in a Dec. 20, 2007, response to the GAO findings that CMS must fix the "serious and systemic contracting deficiencies." Sen. John D. Rockefeller IV (D-WV) also urged contract oversight improvements by Medicare.

"CMS did not spend this money wisely and responsibly, and so CMS failed to ensure the best service to America's seniors," Baucus said in the release, calling the findings "alarming and intolerable."

Likewise, Rockefeller said the GAO report proved federal money was going to private firms rather than to beneficiaries. "This report confirms some of my worse fears that taxpayer money was going to be used to boost the bottom lines of some private contractors and not benefit our nation's seniors."

The report is available at *www.gao.gov/new.items/d0854.pdf*.

Atlanta Hospital to Pay $26 Million in Settlement

An Atlanta hospital has agreed to pay the federal government $26 million to resolve allegations it overcharged Medicare for outpatient visits between 2000 and 2005, according to the Department of Justice (DOJ).

The government charged that Saint Joseph's Hospital of Atlanta violated the False Claims Act by inappropriately coding certain services as inpatient admissions when the services should have been billed as outpatient visits, DOJ said in a news release. Other violations also were covered by the settlement, DOJ noted.

"Every hospital that submits claims to the Medicare program must ensure that its services are billed appropriately. We will continue to vigorously pursue Medicare providers who disregard billing rules."
— David Nahmias
U.S. Attorney for Northern District of Georgia

Saint Joseph's also entered into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General (HHS OIG) as part of the settlement.

The case initially was brought by *qui tam* relator (whistleblower) Tami Ramsey, who had worked at the hospital as a registered nurse, according to the DOJ release. Ramsey will receive nearly $5 million as the relator's share in the case.

Inpatient Admissions, Stents

DOJ said the settlement covers claims for short inpatient admissions that should have been billed as outpatient observations or as emergency room visits. The hospital stays generally were for one day or less, but on some occasions for longer periods, according to the release.

The settlement also covered some claims for three-day stays so that beneficiaries could meet Medicare rules for covered skilled nursing facility stays. DOJ said the claims were for stays that did not meet the criteria for covered admissions.

Hospital claims for the placement of carotid artery stents not covered under Medicare also were covered by the settlement.

"This significant settlement demonstrates our commitment to protect public funds from fraud and abuse," U.S. Attorney for the Northern District of Georgia David E. Nahmias said in the DOJ release. "Every hospital that submits claims to the Medicare program must ensure that its services are billed appropriately. We will continue to vigorously pursue Medicare providers who disregard billing rules."

Nahmias's office handled the investigation with the commercial litigation branch of DOJ's civil division and the HHS OIG.

Hospital's Comment

In a statement, Saint Joseph's Hospital said the government's audit of the hospital related solely to billing and reimbursement matters and was not indicative of quality of care at the facility. The hospital acknowledged it would pay the settlement amount, but said the settlement would not adversely affect the hospital's operations, staff, or patient care.

"Saint Joseph's Hospital is committed to our community and to providing the very best patient care," Saint Joseph's Health System Chief Executive Officer Kirk Wilson said in a news release. "We regret a mistake relating to admission status occurred. However, we are pleased that we are using this opportunity to become an industry leader."

Wilson said the hospital has implemented new staff training and developed new procedures to prevent future admissions and billing problems. In addition, the hospital said in the release that it was developing a "best practice Case Management Protocol program with the support and cooperation of the Medicare program" that would be implemented as part of its corporate integrity agreement with the OIG.

Subsidized Cost-Sharing OK: A nonprofit tax-exempt charitable foundation can subsidize cost-sharing and premium amounts for financially needy patients without risking administrative or civil monetary penalties, the Department of Health and Human Services Office of Inspector General (OIG) said in a January 3 advisory opinion. The foundation provides cost-sharing assistance to patients with certain chronic conditions, including those covered by Medicare and Medicaid, the OIG said. The foundation also proposed a new arrangement under which it would similarly provide subsidies to patients to meet insurance premium obligations, including Medicare and Medicaid premiums. The OIG said the structure of both arrangements posed little risk of fraud and did not raise significant kickback concerns. The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-18E.pdf*.

Specialty Hospitals Faulted: A study of physician-owned specialty hospitals finds deficiencies in how they handle medical emergencies and concludes that the federal government could do more to ensure such facilities do a better job. Among the findings by the OIG is that 66% of specialty hospitals "instruct staff to call 911 as part of their medical emergency response procedures." Furthermore, 34% of hospitals used 911 "to obtain medical assistance to stabilize a patient," a practice that could violate Medicare's hospital participation requirements, OIG says. The report is available at *www.oig.hhs.gov/oei-02-06-00310.pdf*.

Free Radiology Reports Cleared: A radiology practice group can prepare, without charge, written reports of its interpretations of radiology tests for a critical access hospital without risking administrative sanctions or civil monetary penalties, the OIG said in a January 3 advisory opinion. Under the current arrangement between the radiology group and the hospital, the group bills only third-party payers, including Medicare and Medicaid, for professional radiology services and does not charge the hospital for the interpretations. The OIG concluded that the free reports do not constitute remuneration to the hospital. The opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-19C.pdf*.

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