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For Hospitals, Laboratories and Physician Practices

Court Denies Lab's Petition to Review Revocation of CLIA Certificate

A federal appeals court June 2 denied a laboratory's petition for review regarding the one-year revocation of its Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate because it checked its answers with those of another lab before submitting its test results to the government (*Wade Pediatrics v. HHS*).

The U.S. Court of Appeals for the Tenth Circuit held that under the plain terms of 42 U.S.C. §263a(i)(4), any intentional "referral" of a proficiency testing sample "for analysis" in another lab is forbidden. The law mandates that a laboratory that intentionally refers its proficiency testing samples to another lab for analysis shall have its certificate revoked for at least one year.

Although Wade Pediatrics argued that it did not "refer" its proficiency testing samples for analysis to Muskogee *Continued on page 9*

How to Minimize Billing Risk in Lab Outreach

Laboratory outreach programs face some special billing challenges since the patients they are serving are registered neither as inpatients nor outpatients in the hospital. As such, outreach programs must be especially careful in how they bill for their services, notes Peter Kazon, an attorney with Alston & Bird (Washington, D.C.).

There is no real definition of "outreach laboratory" in Medicare, although Medicare law does recognize that there are situations where the hospital is furnishing services to a "nonhospital patient"—that is, neither an inpatient nor an outpatient, explained Kazon during Washington G-2 Report's Eighth Annual Lab Outreach Conference, held June 8-10 in San Diego.

Nonhospital patients primarily are individuals from whom a specimen has been taken and sent to the hospital for analysis (generally there is no physical interaction between the patient and the hospital). In contrast, an outpatient is one who has not been admitted as an inpatient, but who is registered on the hospital records as an outpatient and receives services (rather than supplies alone) directly from the hospital.

Hospital outreach programs can be set up in different ways, explained Kazon. They may be part of the overall hospital laboratory, in which case they would not have a separate lab number and would bill to the fiscal intermediary on a UB-92. *Continued on page 2*

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Lab Institute 2009

September 23-25, 2009
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Minimize Billing Risk, *from page 1*

Alternatively, a lab may be organized separately, in which case it may have a separate independent lab number and would bill to the Medicare carrier under claim form 1500.

The basic issues affecting outreach labs are not that different from those affecting other labs, said Kazon. However, the most important thing for outreach programs to understand is what role the hospital is playing when it performs testing. "Different requirements apply depending on whether the lab is acting as a hospital laboratory or an outreach laboratory," he explained.

For example, a hospital laboratory has to bundle testing, while an outreach laboratory can bill Medicare directly. For inpatients, the hospital is paid based on the DRG (diagnosis related group), but for outpatients, the hospital is paid based on the clinical laboratory fee schedule applicable to the hospital's location. For nonpatients, the hospital will also be paid based on the clinical laboratory fee schedule.

Anatomic Pathology Services

Anatomic pathology services are also billed differently depending on the role the laboratory is playing, explained Kazon. For services to hospital inpatients, the pathologist will bill the professional component separately while the technical component is included under the DRG. For services to hospital outpatients, the pathologist will bill the professional component (PC) separately, and the TC is billed and paid under the APC (ambulatory payment classification).

However, for hospital nonpatients, the hospital may be able to bill globally, depending on the arrangement with the pathologists. The hospital can bill for the TC if the testing is done in the hospital laboratory. An independent lab can bill globally, however, if it qualifies for the billing exception allowed by law.

Lab-to-Lab Referrals

Under the lab-to-lab referral provisions, a laboratory referring to another lab is permitted to bill for the referred work. However, not more than 30 percent of the tests for which it receives requests during the year can be performed by an outside laboratory—70 percent of the testing must be done on-site. However, noted Kazon, the Centers for Medicare & Medicaid Services (CMS) never said how this rule applies to hospital outreach testing. Bundling rules require the hospital to bill for other testing it performs, which could be reasonably be expected to apply to nonhospital work, he said. In any case, Kazon advised labs to maintain careful documentation of whatever calculation they use to determine how much testing can be referred out.

Test Ordering

Testing must be ordered by the physician or other authorized person who is treating patients. A physician is not required to actually sign the requisition, noted Kazon. However, there must be documentation in the medical record that shows the physician intended to order the tests. This is a common issue in comprehensive error rate testing (CERT) audits, said Kazon. A special exception is provided for pathology tests where the pathologist—not the treating physician—adds on testing.

CLIA Requirements

Under the Clinical Laboratory Improvement Amendments, labs are to test all proficiency testing (PT) specimens the same as they would any other specimen.

However, labs are not allowed to refer out a proficiency test to another lab (even if they would normally refer the test out). Doing so constitutes improper PT referral and can result in a loss of the lab's CLIA certificate. This loss will affect all labs owned by the same entity, said Kazon, who adds that labs receiving the PT referral must report the error.

Date of Service

"Date of service" (DOS), which once was relatively easy to determine, is now more complicated due to new types of testing. Typically, DOS is the date the specimen was collected. However, many new genetic tests are done on tumor or fine needle aspiration (FNA) specimens collected during a hospital procedure. If those specimens are later tested at an outside laboratory—after the patient has left the hospital—the DOS is the date of the patient's hospital stay when the specimen was collected.

CMS initially took the position that the test should therefore be bundled and billed to the hospital by the laboratory "under arrangement." In this case, the hospital would be responsible for billing and collecting from Medicare, which hospitals objected to. In response, CMS developed the 14-day rule: If a test were ordered on a specimen at least 14 days after the patient's discharge from the hospital, the DOS would be the date the test was performed, not the date the specimen was collected.

This has not really solved the problem, said Kazon, who notes that a legislative solution is now being considered. Under bills introduced in the House and Senate (H.R. 1699 and S. 1220), independent labs could be paid directly by Medicare for complex molecular and genetic tests performed after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected.

Anti-Markup Rule

The anti-markup rule originated from a concern with "pod" labs, in which independent "pods" were set up in a centralized building separate from a physician practice. The pathologist performing the professional component of lab services would move from pod to pod. The group practice would pay a flat fee for the pathology services and then bill Medicare for the PC and TC of the lab work. This allowed the referring physician to share in the revenues earned on their referrals. The anti-markup rule was designed to make such arrangements less profitable.

CMS has indicated that if there is no supervision required, then the anti-markup rule does not apply. However, the agency has also suggested that it may modify this determination.

The anti-markup rule was announced in the 2008 physician fee schedule and then revised for 2009. The anti-markup limits apply when a diagnostic service is performed by one physician or supplier and billed by another physician or supplier in cases where a physician does not share a practice with the billing physician or other supplier.

When the performing physician "shares a practice" with the billing physician or supplier, the anti-markup provisions do not apply. There are two ways of determining if the "sharing a practice" requirement is met: 1) the physician who supervises the TC or performs the PC furnishes at least 75 percent of professional services through the billing physician and 2) the TC and PC are performed in

the office of billing physician or supplier by a physician owner, employee, or independent contractor of the billing physician.

The anti-markup rule has major ramifications for lab services, although it is probably limited in the hospital context, said Kazon. It is unclear what, if any, supervision requirements exist for the pathology TC, he added. CMS has indicated that if there is no supervision required, then the anti-markup rule does not apply. However, the agency has also suggested that it may modify this determination.

Groups Can Help Funding Testing Services, Says OIG

A nonprofit charitable group can help financially needy Medicare and Medicaid patients pay their cost-sharing amounts for advanced diagnostic testing used in treating HIV and colon cancer without risking federal civil penalties, the Department of Health and Human Services Office of Inspector General (OIG) said in a May 18 advisory opinion (No. 09-04).

The OIG said the patient assistance program posed little risk to federal health programs because the structure of the program minimized the risk for improper referrals or influence on beneficiaries' selection of providers and suppliers.

The OIG also noted in the advisory opinion that it had long-standing guidance that cleared aid to financially needy Medicare and Medicaid patients through bona fide charitable assistance programs.

"Under a properly structured program, such donations should raise few, if any, concerns about improper beneficiary inducements," the OIG said.

The organization that requested the advisory opinion is a charitable group that provides financial assistance to needy patients nationwide, including Medicare and Medicaid beneficiaries. The group specifically asked the OIG to analyze its program for helping beneficiaries pay their cost-sharing amounts for diagnostic tests used in caring for HIV-positive patients and colorectal cancer patients.

Previous Approval Noted

The OIG previously approved a separate assistance program operated by the group for helping financially needy patients pay for specialty therapeutics used to treat certain chronic conditions (No. 06-10).

Funding for the assistance program is donated by individuals, foundations, and corporations that include drugmakers, pharmacies, and suppliers of services for which the requestor provides financial assistance.

While donors are able to earmark their contributions for assistance to either HIV-related services or colorectal cancer-related services, donors are prohibited from specifying which type of provider or product is used, according to the advisory opinion. Donors also are not provided the names of patients assisted through the program. Patients are free to choose or switch products without regard to whether a donor is affiliated with a product or service for which a patient is seeking help, according to the advisory opinion.

The OIG said that among its reasons for approving the program was because the arrangement "insulates beneficiary decision-making from information attributing the funding of their benefit to any donor," making it unlikely that beneficiaries would choose a product or service based on donors to the program.

The advisory opinion is available at www.oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-04.pdf.

COMPLIANCE PERSPECTIVES

Congress Broadens Scope of FCA; President Creates Health Care Fraud Prevention Team

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On May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009 (FERA), which significantly amends the federal False Claims Act (FCA) and expands the potential liability for all companies doing business with the government.[1] On the same day, Attorney General Eric Holder and Department of Health and Human Services Secretary Kathleen Sebelius announced a new Health Care Fraud Prevention and Enforcement Action Team (HEAT), which increases the resources available to investigate and prosecute allegations of health care fraud.

The new FCA amendments create heightened risk for all individuals and companies that do business with or receive funds from the federal government and, when combined with the increased health care enforcement resources, will enhance the risks faced by participants in the health care industry.

Amendments to the Civil False Claims Act

Section 4 of FERA makes the first significant revisions to the civil False Claims Act since 1986. In recent years, the FCA has become the government's principal weapon for recovering damages for fraud in government programs by allowing individual "whistleblowers" (known as "qui tam relators") to bring suits on behalf of the United States for allegations that government programs have been defrauded.[2] The FCA amendments expand the potential liability of businesses and individuals, and change several procedural provisions to make it easier for the government to investigate and litigate FCA claims.[3] Although the stated purpose was to make recipients of Troubled Asset Relief Program (TARP) funds subject to the FCA, the amendments do much more. The key changes include:

- reversing last year's unanimous Supreme Court decision in *Allison Engine* by eliminating the FCA's "specific intent" requirement—thereby making the FCA what the *Allison Engine* court said it was not;
- expanding the definition of what constitutes a "claim" made to the government and facts that are "material" to the government's payment of a claim;
- extending liability for the intentional retention of an "overpayment" from the government;
- extending the statute of limitations to permit the government's complaint to "relate back" to filing of relator's original complaint, which can be years earlier;
- making it easier to serve civil investigative demands and gather information; and
- expanding the class of persons entitled to "whistleblower" protection from retaliation.

[1] *S.386, 111th Cong. §4 (2009) (enrolled), available at http://thomas.loc.gov/cgi-bin/query/z?c111:S.386.*

[2] *False Claims Act, 31 U.S.C. §§3729-3733 (2008).*

[3] *The FCA amendments contained in Section 4 of FERA are different from those contained in the Legislative Update distributed by Alston & Bird LLP on Aug. 11, 2008, that were never passed by Congress.*

Liability Provisions

Congress amended the liability provisions of the FCA in order to legislatively reverse the Supreme Court's unanimous decision in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S.Ct. 2123 (2008). That decision limited liability under the FCA to prevent it from becoming a boundless "all purpose fraud statute" by requiring specific intent to defraud the government.[4]

Specific Intent Not Required

Previously, the FCA allowed businesses and individuals to be held liable for making false statements only if those statements were made "to get" a false claim paid or approved "by the Government." In Allison Engine, the Court applied the "to get" and "by the Government" language in §3729(a)(1) to limit liability only to situations where there was specific intent to defraud the government and not some other party, such as a subcontractor.

The FCA amendments eliminate the specific-intent requirement announced in Allison Engine Co. by eliminating the "to get" and "by the Government" language from the statute.[5] The new language subjects businesses and individuals to FCA liability if they knowingly make a false statement in an attempt to obtain money or property that is "to be spent or used on the Government's behalf or to advance a Government program or interest." There is no further guidance other than this ambiguous language—meaning that the full scope of this broad provision will be resolved in case-by-case litigation.

New Definition of Materiality

FERA also codified the "materiality" requirement into the FCA, which had long been read into the law by the courts. FERA, however, adopted a weaker materiality standard than had been used by some circuits by broadly defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[6] Again, this language will now have to be litigated on a case-by-case basis to determine the parameters of exactly what actions were "capable of influencing" the government's decision.

Liability for Retention of Overpayments

The FCA amendments also extend liability for the knowing retention of overpayments—the so-called "reverse false claims" liability. Businesses and individuals are now liable under the FCA if they keep any overpayment of government funds or property, where before the FCA required some affirmative act to conceal, avoid, or decrease a repayment obligation. Arguably, the mere retention of an overpayment, if there is an obligation to pay, is now enough to create FCA liability. This, in essence, would amount to strict liability for retention of overpayments.

Nonliability Provisions

In addition to the expansion of liability, there are four nonliability-related amendments that make significant changes to the FCA.

Relation Back of Government's Pleading

The FCA's statute of limitations is six years, generally, or three years from the date the government reasonably learns of the material facts, up to 10 years after the date of the alleged fraud.[7] While these limitations still generally apply under the amend-

4 Allison Engine Co., 128 S.Ct. at 2130.
5 S.386 §4(a)(1)(a).
6 S.386 §4(a)(1)(b).
7 31 U.S.C. §3731(b)(1)-(2).

ments, §3731 now contains a provision stating that the government's pleading relates back to the date of the original complaint.[8] This is a major shift in the law and means that, once a complaint has been filed and is not dismissed, the statute of limitations does not apply to the government and can adversely affect potential defendants because of the government's delay.

Civil Investigative Demands

Under the previous version of the FCA, only the attorney general could issue civil investigative demands (CID), and the information gained from the CID could not be shared with relators and their counsel.[9] The FCA amendments now allow the attorney general to appoint a designee to issue the CID, and the information gained from the CID may be shared with the relator and their counsel.[10] In addition, the FCA amendments contain a very broad definition of "official use" that essentially allows for information gained from the CID to be shared with other government investigators, auditors, consultants, experts, and others.[11]

The changes to the FCA are expansive and very significant. They expose all individuals and businesses that are government contractors or that receive government funds (even indirectly) to substantial potential liability.

Retaliation

Under the prior version of the FCA, businesses and individuals were liable for retaliation only against employees. The FCA amendments expand the class of persons receiving this protection by now including contractors and agents in the protected class.

Local and State Service

A person bringing the complaint under the FCA, as amended, may now serve the complaint, and any other pleadings, on state and local law enforcement agencies authorized by state law to prosecute fraud claims—and not just the United States.

HEAT Initiative

HEAT is intended to be an expansion of the Medicare Fraud Strike Force efforts currently under way in South Florida and Los Angeles that use a "data-driven" approach to identify unusual billing patterns and possible fraudulent activity.

According to a Department of Justice (DOJ) press release, the Medicare Fraud Strike Force team operating in South Florida has convicted 146 defendants and recovered $186 million since its implementation in 2007, and the Los Angeles strike force, established in May 2008, has already recovered $55 million and charged 37 defendants with criminal health care offenses.[12] This combined DOJ and HHS team is tasked with "strengthening existing programs to combat fraud while also investing new resources and technology to prevent fraud, waste and abuse before it happens."[13]

In addition to increased enforcement activity, HEAT will focus on preventing fraud from occurring by increasing training for providers on Medicare compliance, improving data sharing between CMS and law enforcement, and strengthening program integrity activities to monitor and ensure Medicare Parts C and D compliance.[14]

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8 S.386 §4(b)(3).
9 31 U.S.C. §3733.
10 S.386 §4(c)(1)(A)(i)(II).
11 S.386 §4(c)(3)(c).
12 "Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention & Enforcement Action Team," May 20, 2009, Department of Justice press release, available at http://www.usdoj.gov/opa/pr/2009/May/09-ag-491.html.
13 Id.
14 Id.

Conclusion

The changes to the FCA are expansive and very significant. They expose all individuals and businesses that are government contractors or that receive government funds (even indirectly) to substantial potential liability. And they make it significantly easier for the government to make its case under the FCA. The FCA amendments, combined with the implementation of HEAT, can also be expected to result in increased and expanded enforcement activity in the health care industry.

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The advisory is intended to be informational and does not constitute legal advice regarding any specific situation. This material may also be considered attorney advertising under court rules of certain jurisdictions.

Quest Clarifies Settlement

Quest Diagnostics (Teterboro, N.J.) has issued a clarification concerning its recent settlement with the federal government over charges that a former subsidiary sold misbranded test kits (*GCR*, June 2009, p. 1).

The charges involved Nichols Institute Diagnostics (NID) and Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay, a test kit used to measure parathyroid hormone levels in patients.

"Quest Diagnostics did not plead guilty to anything," says the company in a statement. "NID, a test-kit manufacturing subsidiary that Quest Diagnostics voluntarily closed three years ago, pled guilty to a single count of misbranding. (We voluntarily closed NID when it failed to meet our quality standards.) NID, which now exists as a legal entity only, agreed to enter a guilty plea to misbranding and to pay a $40 million fine.

"Quest Diagnostics will pay $262 million to settle the civil investigation. The company disagrees with and does not admit to the government's civil allegations, but we agreed to the settlement to put the matter behind [us]."

CLIA Certificate, *from page 1*

Regional Medical Center, the appeals court found that Wade still violated the plain and unambiguous terms of the statute.

"While consultation between labs may be permissible in other circumstances before or after a proficiency test, asking an outsider for help during a test corrupts the process and defeats its purpose," Judge Neil M. Gorsuch wrote. "Indeed, this type of double-checking is exactly what Congress sought to prevent in the CLIA."

Training Recommended

Wade flunked portions of two proficiency tests in 2005, and a field investigator for the Centers for Medicare & Medicaid Services (CMS) advised Wade that it would be beneficial for the lab to receive training and comparison testing of its equipment from another certified lab, such as nearby Muskogee, the appeals court found. Wade followed up on the recommendation, arranging to receive training and technical support from Muskogee.

When Wade took proficiency tests in February 2006 and May 2006, a technician first took samples to Muskogee and tested them on Muskogee's equipment, apparently to double-check Wade's results to ensure their accuracy. When CMS discovered that Wade had twice tested its proficiency testing samples at another lab before submitting its results, the agency revoked Wade's certificate for one year.

An administrative law judge upheld CMS's determination and the Departmental Appeals Board agreed after finding the lab was in violation of the condition for participation. The board affirmed the ALJ's finding that a laboratory must not send samples or portions of samples to another laboratory, intentionally or unintentionally, for analysis when it is certified to perform the testing in its own laboratory.

On appeal, the Tenth Circuit also rejected Wade's argument that it did not refer its test samples for analysis to Muskogee intentionally as the statute requires and that it had no wish to violate the law. Even assuming Wade's ultimate intent was to improve its work product, Wade referred its proficiency test results "knowingly and willfully" to Muskogee, the appeals court found.

Wade Claims Direction, Approval From CMS

Wade also argued that even if it violated the statute, it did so only at the direction and with the approval of CMS, pointing to the 2005 statement urging Wade to seek out opportunities for "training and comparison testing" of its equipment with other certified labs. Further, Wade contended that the government should be barred from complaining that the lab followed CMS's suggestion.

The Departmental Appeals Board affirmed the ALJ's finding that a laboratory must not send samples or portions of samples to another laboratory, intentionally or unintentionally, for analysis when it is certified to perform the testing in its own laboratory.

However, the appeals court found that courts generally invoke a bar against the government only when it does not frustrate the purpose of the statutes expressing the will of Congress or does not unduly undermine the enforcement of public laws.

There was no hint in the record that CMS erroneously advised Wade that it could or should share proficiency testing samples with another lab before handing in its own proficiency test results, the appeals court found.

"Teachers often allow students to work collaboratively to prepare for an exam or to discuss answers after an exam, but that is no license for students to share thoughts and answers during the exam," Gorsuch said. "Under the statute, Wade might have been free to work with another lab to train its personnel and to fix its equipment, but it's a very different thing to compare results during the testing process."

The appeals court found that CMS did not condone or applaud Wade's remedial plan. CMS's silence about Wade's remedial plan did not rise to the level of giving erroneous advice—which was still insufficient to warrant a bar against the government—let alone to the level of "affirmative misconduct" required to warrant a bar against the government, the appeals court concluded in denying the petition for review.

Compliance Officer Sentenced to Prison for Fraudulent Contracts

A federal district court in Hawaii May 29 sentenced a former compliance officer to 40 months in prison and ordered her to pay $639,430 in restitution after she pleaded guilty to fraud by entering into contracts with a hospital for consulting services she actually performed as an employee (*United States v. Syling*).

Patricia M. Syling pleaded guilty in the U.S. District Court for the District of Hawaii to all counts of mail fraud in a scheme to defraud her employer Queens Medical Center, a not-for-profit hospital in Honolulu. The contracts between Syling's businesses, HealthCare Financial & Compliance Management (HFCM) and HealthCare Financial Group (HFG), and the hospital were for consulting services that were Syling's responsibility as the corporate compliance administrator and director of revenue cycle for Queens, according to court records.

Within the course and scope of her employment responsibilities with Queens, Syling was authorized to solicit and negotiate vendor and service contracts involving the hospital's billing and collection operations from both private health insurance providers and government health care providers, such as Medicare and Medicaid, an August 2007 indictment said.

Consulting Services

The scope of the services called for under the terms of one contract included a review by HFCM of the hospital's Health Insurance Portability and Accountability Act (HIPAA) compliance and risk assessment and the submission of a final report. The "consulting services" called for in the contract, to the extent they had been provided at all, were provided by Syling within the course and scope of her employment as the corporate compliance administrator for Queens, the indictment said.

Another contract—an agreement for professional services compliance management with HFC—called for providing "various compliance management services" to "prompt the physicians to document medical necessity in a more detailed manner" and other obligations, according to the indictment. The contract's services also were provided by Syling within the course and scope of her employment with the hospital.

The indictment also said that other services billed to the hospital under Syling's contracts included reviewing the charge master for the hospital's oncology unit and finding revenue opportunities for Queens and payment recovery. The ser-

vices were as well within the course and scope of Syling's employment with the hospital. The court also ordered Syling to pay an assessment of $800 and ordered her to complete three years of supervised release after her prison term.

'Date of Service' Clarified for Pathology Global Billing

The Centers for Medicare & Medicaid Services (CMS) has ruled that global billing is "not appropriate" for the professional component (PC) and the technical component (TC) of pathology services performed by the same independent laboratory but on different dates of service. In this case, the TC and the PC are to be billed as separate line items.

CMS clarified the policy in response to a question from a commenter on the rule establishing a new date of service (DOS) for the pathology TC (Change Request 6018, May 21, 2008). The agency alerted Medicare contractors that it is adding the revised DOS policy on pathology billings to its manual instructions, effective Aug. 24, 2009 (Change Request 6457, Revision 1744).

As a general rule, the DOS for either the TC of pathology services or a clinical laboratory test is the date the specimen was collected. If a specimen is collected over a period that spans two calendar days, the DOS must be the date the collection ended.

There are two exceptions. If a specimen was stored for 30 calendar days from the date it was collected or less, the DOS must be the date the test was performed only if:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary to treat an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived, and the DOS of the test must be the date the specimen was obtained from storage.

The other exception applies to the DOS for chemotherapy sensitivity tests performed on live tissue. The DOS must be the date the test was performed under the conditions for stored specimens noted above. A "chemotherapy sensitivity test" is defined as one that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies these tests through program instructions to Medicare contractors.

Meantime, the American Clinical Laboratory Association is advocating another revision to Medicare DOS policy. It supports House legislation (H.R. 1699) that would allow an independent laboratory to be paid directly by the program for complex molecular and genetic tests performed after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected. "Today, when a lab test is ordered within 14 days of discharge, the hospital, not the lab, must bill Medicare for the service," ACLA said, "creating access problems for this category of tests that are ordered after the patient's hospital stay."

News-At-A-Glance

RAC Requests: Medicare providers in some parts of the country will begin receiving records requests from recovery audit contractors by July as the full post-payment review program begins rolling out nationwide, according to a spokesman for the Centers for Medicare & Medicaid Services (CMS). CMS does not expect RACs to begin conducting complex reviews that would include medical necessity reviews until 2010, after the contractors have established themselves in their respective regions, the spokesman said.

Physician Sanctions: Nearly half of U.S. hospitals have never reported any physician sanctions to a national database designed to collect such information, according to a recent report by Public Citizen. The report found that 49 percent of hospitals registered with the National Practitioner Data Bank (NPDB) have not reported any physician sanctions, which the group said undermines efforts to protect patients. Hospitals are required to report to the NPDB when they revoke or restrict a physician's hospital privileges for more than 30 days because of medical competency or conduct problems, according to the report. The report, *Hospitals Drop the Ball on Physician Oversight*, is compiled based on a review of existing studies, as well as previously unpublished data from the Health Resources and Services Administration, which operates the database.

OIG Recommendations: The federal government could have saved at least $7.7 billion as of December 2008 if the Department of Health and Human Services had implemented recommendations made by the HHS Office of Inspector General, according to a new report from the OIG. The OIG released on May 29 its annual *Compendium of Unimplemented Office of Inspector General Recommendations*, which compiles previously issued monetary and nonmonetary recommendations to the Centers for Medicare & Medicaid Services and other HHS agencies that had yet to be executed. The report is available at *www.oig.hhs.gov/publications/docs/compendium/compendium2009.pdf*.

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