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For Hospitals, Laboratories and Physician Practices

Congress Provides Relief To Pathologists

Pathologists got a last-minute reprieve from Congress in December when lawmakers approved a bill that includes a provision to reverse a 5% reduction in Medicare physician payment, as well as a provision to allow independent laboratories to continue billing Medicare directly for the technical component of surgical pathology services provided to hospital patients through 2007.

Congress passed the bill on December 8 just before adjourning for the remainder of the year. The 110th Congress will convene in Washington in early January.

In the waning days of the 109th Congress, key lawmakers were able to cobble together a bill addressing key healthcare and tax issues. Up until the measure, "The Tax Relief and Healthcare Act of 2006," passed the Senate, it remained unclear ➥ *p. 2*

CMS Announces Lab Fee, Coding Changes For 2007

The Centers for Medicare and Medicaid Services (CMS) on December 8 issued the annual update for the clinical laboratory fee schedule and lab services subject to reasonable charge payment.

As in recent years, there is no inflation update for lab fees, marking the fourth year of the five-year freeze (through 2008) that was imposed by the Medicare Modernization Act of 2003. The fee schedule information is contained in Transmittal 1122 (Change Request 5362).

The freeze also bars any update to the national minimum payment for a string of Pap smear codes. The minimum remains $14.76 for the following codes: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

For 2007, the fee for clinical laboratory travel code P9603 is $0.935 per mile. For code P9604, the fee is $9.35 per flat trip basis. The travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient.

Transmittal 1122 also details how CMS will pay for 16 new CPT lab codes added to the Part B lab fee schedule, starting January 1. The new tests are for conditions such as liver cancer, heart disease, West Nile virus, and staphylococcus.

For specifics, see the 2007 Lab Fee Schedule at *www.cms.hhs.gov/ClinicalLabFeeSched*.

Kimberly Scott, Senior Editor,
kimscott@yahoo.com

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Congress Provides Relief, *from page 1*
whether the bill would get congressional approval before both houses adjourned.

In addition to reversing the 5% physician payment cut, the legislation provides for a 1.5% increase in reimbursement for physicians who agree to report data on certain quality-of-care measures in 2007 and establishes a fund to promote physician payment stability and physician quality initiatives in 2008.

The College of American Pathologists (CAP) praised lawmakers for enacting the measure. "We commend Congress for passing this legislation that will provide stability for our healthcare system and help ensure Medicare patients continue to have access to quality care," said CAP President Thomas Sodeman, M.D. "Without this legislation, pathologists would have faced an additional cut in Medicare physician payments, forcing some to no longer participate in the Medicare program and putting seniors access to healthcare at risk."

The measure also:

- Extends the Medicare reasonable cost payments for lab tests furnished in small rural hospitals in low population areas;
- Establishes a floor on the work component of the physician geographic adjustor in 2007 to raise payments in certain rural areas;
- Provides a 1.6% update to end-stage renal disease (ESRD) facilities for 2007;
- Corrects mid-year expiration of the Medicare hospital wage index reclassifications and requires the Medicare Payment Advisory Commission and Centers for Medicare and Medicaid Services to issue reports on the wage index;
- Allows brachytherapy to be paid based on hospital costs for another year and establishes codes for certain brachytherapy devices by July 1, 2007;
- Allows for a post-payment review process to ensure that payment is made for a drug or biological only if the drug or biological is delivered for administration to a beneficiary;
- Provides a full update to hospital outpatient and ambulatory surgical facilities that choose to provide designated quality data starting no sooner than 2009 and requires CMS to develop quality measures for hospital outpatient and ambulatory surgery services;
- Requires physicians to report anemia quality indicators when administering cancer anti-anemia drugs.

Program Integrity Efforts

Pleased with the results of the Recovery Audit Contracting (RAC) demonstration mandated by the Medicare Modernization Act of 2003 (MMA), lawmakers included an expansion of the program. Under the program, RACs identify and correct improper and excessive payments by Medicare under Parts A and B of the program on a contingent-fee basis.

Although the program currently operates only in three states—California, Florida, and New York—it has resulted in the net return of more than $54 million back to Medicare as of November 16, with another $232 million in the queue for collection as inaccurate overpayments. The Ways and Means Committee estimates the RAC will save as much as $10 billion over five years.

Under this bill, the RAC program will be expanded to all states by 2010. The measure also provides a four-year funding

MedPAC Staff Suggests 2% Increase In Physician Payments

Physicians should receive a 2% hike in their Medicare reimbursements in 2008, staff for the Medicare Payment Advisory Commission (MedPAC) recommends.

The draft update presented to the commissioners stems from MedPAC's standard annual calculation of cost changes, staff said at MedPAC's meeting December 7 and 8. The advisory panel subtracts the expected productivity growth from projected changes in input prices: For 2008, the forecasted input price inflation is 3.3% and productivity growth is 1.3%, resulting in the 2% increase, said Cristina Boccuti, a MedPAC analyst.

The 2008 recommendations on physician payment will be voted on by the commissioners at their January 2007 meeting and will be sent to Congress in March 2007.

stream to the Healthcare Fraud and Abuse Control Account (HCFAC) through the application of the consumer price index.

Medicare Beneficiary Protections

The bill also includes a number of Medicare beneficiary protections, including a one-year extension of the exceptions process established in the Deficit Reduction Act to allow patients to apply for additional physical, occupational, and speech-language therapy services if their treatment is expected to exceed the annual cap on therapy services;

In addition, the bill includes a provision that ensures all providers will be paid for administering vaccines that are covered under the new Medicare prescription drug benefit (Part D). It also establishes a three-year demonstration on the concept of a medical home model, which is designed to provide targeted and coordinated care to patients suffering from one or more chronic conditions.

The measure also provides that the Health and Human Services Office of Inspector General (OIG) will conduct and report on a study involving the prevalence of, and payment for, "never events" in the Medicare program. Never events are medical services that the clinical community feels should never occur and result in the death or serious disability of a patient (i.e., surgery on the wrong body part).

Resources

House Ways and Means Committee: *www.house.gov*

- College of American Pathologists: *www.cap.org*

CMS Finalizes Physician Payments, Policies For 2007

Starting January 1, the Medicare program will increase reimbursement for flow cytometry technical component services (CPT 88184 and 88185) between 14% and 25% and will pay for a broader range of preventive services.

The changes are included in the Medicare Physician Fee Schedule final rule for 2007, announced in early November.

The final rule also provides for a 5% cut in Medicare payment for physician services beginning in January, but Congress passed legislation in early December reversing the cut. Lawmakers also reversed another provision contained in the final rule: elimination of the "grandfather" protection that allows independent labs to bill Part B for pathology TC services provided to hospital patients. That grandfather protection is now extended until the end of 2007. The Centers for Medicare and Medicaid Services (CMS) is expected to issue revisions to the final rule in early 2007 to reflect these congressional interventions.

While Congress eliminated the 5% cut, it let stand changes to the physician work and practice expense relative value units (RVUs). As a result, pathology still faces a 6% cut that includes the budget neutrality adjustment for evaluation and management from the five-year review (5%) and the short-term effect of practice expense (1%).

No Decision On Pod Labs

To the dismay of pathology and lab groups, CMS decided not to pursue restrictions on "condo" or "pod" labs, arrangements by which certain physician specialty groups seek to increase revenue from pathology referrals. The agency has proposed tightening the Medicare benefits reassignment rule and the Stark safe harbor for in-office ancillary services, but opted to delay final regulations to allow further consideration of the issues.

In a November 20 letter to CMS acting Administrator Leslie Norwalk, Alan Mertz, president of the American Clinical Laboratory Association (ACLA), urged CMS to act quickly to enact regu-

Recordings from the December 4 audio conference on the Medicare physician fee schedule final rule are available for purchase. Go to www.g2reports.com *and look under "Recent Recordings."*

lations to limit the growth of pod labs. While ACLA understands the desire of CMS not to act hastily and to ensure that it does not unduly impact legitimate group practice arrangements, it remains concerned about the growth of pod labs, says Mertz.

"Unfortunately, the delay announced in the recent final rule has been taken as a sign by some promoters of pod laboratories that CMS is not genuinely concerned about these arrangements," he writes, adding that ACLA believes some relatively simply steps can be taken quickly without jeopardizing the ability of true multispecialty group practices to do business.

Date Of Service For Specimens

The final rule also modifies the laboratory date of service for specimens. Under rules in effect in 2006, if the date of service (DOS) was during a hospital stay, the laboratory test would be bundled with the inpatient services and paid under the DRG rules. This affected tests on specimens taken during surgery. CMS met with lab groups and, as a result, modified their policy to accommodate the special situations presented by cancer recurrence assays and chemotherapy sensitivity assays, according to Jane Pine Wood, a healthcare attorney with McDonald Hopkins LPA. Wood discussed the fee schedule final rule on December 4, during an audio conference held by Washington G-2 Reports.

CMS's primary concern was to clearly separate the outpatient or nonpatient testing from the inpatient treatment or hospital stay, explains Wood. Under the final rule, for all specimens retrieved from storage for additional tests other than chemotherapy sensitivity, less than 30 days after collection, the DOS equals test performance date only if:

- The test is ordered at least 14 days after hospital discharge;
- The specimen was collected during a hospital surgery;
- It would be medically inappropriate to otherwise collect the specimen;
- Test results do not relate to the hospital stay; and
- The test is reasonable and necessary.

Chemotherapy sensitivity tests performed on live tissue are unique because the tissue must be cultured, not otherwise stored, to preserve it for testing. The decision to preserve the tissue must be made at surgery. So, for these tests, the DOS is the date the test is performed if:

- The decision of what specific chemotherapeutic agents to test is made 14 days after discharge;
- The specimen is collected during a hospital surgery;
- It would be medically inappropriate to otherwise collect the specimen;
- Test results do not relate to the hospital stay; and
- The test is reasonable and necessary.

Other Provisions

In other provisions, the final fee schedule rule:

- Qualifies more beneficiaries for bone mass measurement due to long-term steroid therapy. The dosage equivalent required for eligibility is reduced from an average of 7.5 milligrams per day of prednisone for at least three months to 5.0 milligrams;
- Waives the deductible for colorectal cancer screening;
- Requires that for blood glucose monitoring in skilled nursing facilities, the physician must certify that each test is medically necessary. A standing order is not sufficient; and
- Codifies in regulations the public process that CMS now uses to solicit comments on establishing fees for new tests added to the Part B lab fee schedule.

Resources

- Medicare Physician Fee Schedule final rule for 2007: *www.cms.hhs.gov*. Click on "Medicare," then click on "Fee Schedules."
- ACLA letter to Leslie Norwalk: *www.clinical-labs.org*

COMPLIANCE PERSPECTIVES

What Is The FDA Doing With Lab-Developed Tests?

Paul Radensky, M.D., J.D., is a partner with the law firm of McDermott Will & Emery in Miami.

Concern is growing among laboratories over the Food and Drug Administration's (FDA) recent move to begin treating laboratories developing and marketing some laboratory-developed tests (LDTs—also called "home brew" tests) as medical device manufacturers and requiring these labs to obtain FDA clearance or approval for these tests. What is going on? Will LDTs be subject to FDA regulation as medical devices in the future? First, some background on LDTs and regulation of these tests.

Two Pathways To Develop Lab Tests

Entities developing clinical laboratory assays choose the pathway they take to commercialization: (1) develop a product to sell to laboratories for their own use (in vitro diagnostic devices or IVDs) or (2) develop a clinical laboratory service provided solely by the laboratory developing the test (LDTs). The first pathway requires premarket submission to the FDA, the manufacture of the IVD is subject to FDA's Quality System Regulations (QSRs), and labeling and promotion are subject to various FDA requirements. The latter pathway has not required FDA premarket submission; the laboratories and the tests offered are subject to federal regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), plus state licensure requirements, and promotional claims are subject to the Federal Trade Commission's prohibition against false or deceptive advertising.[1]

History Of FDA Regulatory Policy On LDTs

A 1992 FDA draft Compliance Policy Guide (CPG) stated that LDTs are medical devices. An October 1992 Citizen Petition responded by asking FDA not to regulate LDTs because such regulation would conflict with CLIA 88, is not authorized by the Federal Food, Drug, and Cosmetic Act (FFDCA), and would result in lower quality care. FDA denied the petition, in 1998, asserting that the agency has authority to regulate LDTs—an assertion never reviewed by the courts.[2]

In November 1997, FDA issued a final rule regulating "analyte-specific reagents" (ASRs)—the active ingredients of many LDTs. In the preamble to that rule, FDA reiterated its view that laboratories developing LDTs are medical device manufacturers. Nonetheless, the agency declined to regulate LDTs as medical devices: "FDA recognizes that the use of in-house developed tests has contributed to enhanced standards of medical care in many circumstances and that significant regulatory changes in this area could have negative effects on the public health."[3] FDA also indicated that regulation of LDTs was not necessary because "regulating the active ingredients of in-house developed tests should provide an appropriate level of regulation to protect the public health."[4] Therefore, although FDA maintained that it had the authority to regulate LDTs, it also confirmed that it would not do so—to serve public health interests.

Fast Forward: Signs Of Change At FDA

In early 2006, several clinical laboratories offering highly innovative LDTs received letters from FDA inviting them to meet with the agency to discuss the nature and appropriate regulatory status of their tests and the least burdensome ways to fulfill any premarket review require-

[1] See, e.g., www.ftc.gov/os/2000/04/ehpattachmentb.htm

[2] A copy of the 1992 Citizen Petition and the FDA's response can be found at www.hpm.com/devitem.cfm?RID=74.0

[3] 62 Fed. Reg. 62,243,62,249 (Nov. 21, 1997).

[4] Id. at 62,252.

ments that may apply. The companies were stunned to learn that, despite years of clear agency policy supporting an LDT pathway under CLIA and outside FDA regulations, FDA was considering regulation of their tests as medical devices.

The apparent dramatic change in FDA enforcement policy raised numerous questions. Why these tests? What is the medical device? How can laboratories resolve conflicts between FDA regulations and CLIA and state laws that would still pertain to their premarket validation and postmarket services?

FDA Releases Draft Guidance: IVDMIAs

Responding to questions from stakeholders as to whether FDA was changing its long-standing policy of not regulating LDTs, FDA released a draft guidance[5], In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), acknowledging confusion about the regulation of certain LDTs. In the draft guidance, FDA provided a definition of IVDMIAs: "IVDMIAs are test systems that employ data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment, or prevention of disease."[6] FDA believes IVDMIAs are medical devices.

FDA described IVDMIAs as having the following three characteristics:

1. Use clinical data (from one or more in vitro diagnostic assays and sometimes demographic data) to identify an algorithm;
2. Employ the algorithm to integrate the data points to calculate a patient-specific result;
3. The result cannot be interpreted by clinicians using prior knowledge of medicine without information from the test developer regarding clinical performance and effectiveness.

In discussions about the draft guidance, FDA indicated that an LDT can involve software, an algorithm, or be multivariate without necessarily falling under the IVDMIA definition. FDA has provided some examples of IVDMIAs: (1) a microarray that predicts colon cancer recurrence based on an RNA expression pattern; (2) an assay that integrates quantitative results from seven immunoassays to obtain a qualitative "score" that predicts the risk of Alzheimer's disease; and (3) a test that integrates age, gender, and genotype (five genes) to diagnose cardiovascular disease.[7]

Why Is FDA Taking This Action?

In the draft guidance, FDA reiterated its position that clinical laboratories developing LDTs are medical device manufacturers, but FDA has declined to regulate them as such because it believed (1) FDA already regulates the primary ingredients of LDTs (ASRs, general purpose reagents and equipment, controls) and (2) clinical laboratories certified to perform high complexity testing under CLIA have the ability to use ASRs in test procedures. By contrast, FDA believes IVDMIAs include elements beyond these primary ingredients and are "not within the ordinary 'expertise and ability' of the CLIA high complexity laboratories that FDA referred to when it promulgated the ASR rule."[8]

FDA provided no explanation of the agency's conclusion that it has the legal authority to regulate IVDMIAs beyond the simple assertion that these tests fit the statutory definition of a medical device.

Implications For Laboratories

The consequences of FDA deciding that a laboratory's new assay is an IVDMIA are numerous and serious. As medical devices, IVDMIAs may be subject to premarket review, investigational device exemption regulations, and postmarket compliance requirements and limitations. FDA will assign IVDMIAs to one of the three classes to which all devices are assigned based upon a test's intended use(s) and the level of control FDA believes is necessary to assure safety and effectiveness. According to FDA, most IVDMIAs will be class II or III devices.

[5] Issued September 7, 2006.

[6] Id. at 3.

[7] See presentation slides from Courtney Harper, Ph.D. at Professional Roundtable, November 30, 2006.

[8] Draft IVDMIA Guidance at 3.

Class II devices typically require an FDA-cleared 510(k) premarket submission before commercialization. Class III medical devices require approval of a premarket approval application, typically requiring expensive, multi-year clinical trials to prove safety and effectiveness for each "intended use."

Pending clearance or approval of an IVDMIA for any use, these tests would be considered investigational and subject to FDA's human subjects investigation regulations.[9] During this phase, tests must be labeled: "For Investigational Use Only."[10] A clinical study involving an investigational IVDMIA may require FDA approval of an investigational device exemption. Third-party payers are likely to deny coverage of tests with an "investigational" label.

In the draft guidance, FDA confirms that IVDMIAs would be subject to QSRs and the Medical Device Reporting regulation. However, FDA provides essentially no explanation as to how clinical laboratories can conform those requirements to CLIA requirements other than a general assurance that the agency will work with laboratories to identify the least burdensome compliance pathway.

Many Questions—Few Answers Thus Far

The draft guidance raises numerous questions. The broad IVDMIA definition in the draft guidance could include many established tests that incorporate in vitro diagnostic information into algorithms used to inform diagnosis or management. These could range from relatively simple calculations, such as creatinine clearance, to more complex measurements, like triple or quadruple screening for neural tube defects.

In public presentations, however, FDA has assured stakeholders that it is focusing on a small number of highly novel assays. Yet, neither the draft guidance nor subsequent conversations with FDA have provided industry a clear standard for distinguishing between IVDMIAs subject to FDA regulation and other LDTs that FDA will not regulate.

Can a bright line boundary between FDA-regulated and not-regulated LDTs be articulated, or is it inherently a "we'll know it when we see it" standard? The latter "standard" would likely result in too much uncertainty for investors, and payers would likely resist covering tests whose regulatory status is uncertain. This new policy could severely reduce the flow of capital directed to development of promising, innovative diagnostic innovations.

What elements of IVDMIAs comprise the medical device subject to which FDA's pre-market review, labeling and promotion, and QSR requirements apply? How are the operations of a single clinical laboratory to be separated into the "manufacture" of an IVDMIA device versus the use of that device by a clinical laboratory performing a test service? The draft guidance describes an IVDMIA as a whole "test system—a term also used under CLIA regulations—but FDA offers no guidance to harmonize the FDA and CLIA requirements, other than by saying that "test system" in the draft guidance is not linked with use of the same term in CLIA regulations.

FDA recommends that laboratories identify instances where they believe compliance with CLIA would fulfill requirements under the QSRs, but FDA does not acknowledge that the two regulatory frameworks may conflict. For example, CLIA puts an affirmative obligation on laboratories to update test information whenever changes occur that affect test results or interpretation of results.

By contrast, FDA limits the ability of device manufacturers to change labeling without prior clearance or approval by FDA. This may put laboratories in an untenable situation of trying to comply with CLIA's affirmative requirement to keep referring physicians informed while, at the same time, complying with FDA limitations on dissemination of information beyond FDA-cleared labeling.

[9] 21 C.F.R. Part 812.

[10] 21 C.F.R. § 809.10(c)(2)(ii).

The process for adopting test improvements is not clear. Laboratories frequently update laboratory methods and processes. This is especially true in the area of infectious diseases, where new strains of infectious agents are identified or new resistance emerges, and in the area of genetic/genomic analysis, where new mutations and variations are identified. If formal clearance or approval from FDA is required before test changes can be adopted, tests will freeze at specific points in time. Physicians and patients will encounter long delays to have the access to essential information that LDTs have provided, while FDA has moved at its own pace in clearing new assays for the same clinical use.

The fundamental nature of the questions raised by the draft guidance and the substantial impact the proposed change in FDA policy could have on laboratories, treating physicians, and patients highlight the need for thorough, thoughtful, and public consideration of these issues—i.e., the type of policy-making record developed only through public meetings and notice-and-comment rule making.

Developing Story

The release of the draft IVDMIA guidance should mobilize stakeholders to consider what the requirements for LDTs should be under CLIA, FFDCA, or other regulatory frameworks in order to maintain the patient care and public health infrastructure assured historically by LDT capabilities. Various venues in which these issues have been raised and to which feedback should be provided include:

1 The IVDMIA draft guidance, which is open for public comment through March 5, 2007 (see docket at *www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm [2006D-0347]*).

2 Several stakeholders have asked FDA to hold a public meeting to discuss the draft guidance before it is finalized. FDA has not responded to these requests.

3 A Citizen Petition challenging FDA's authority to regulate LDTs or, in the alternative, arguing that FDA should proceed with regulation of LDTs only after following proper notice-and-comment rule making was filed by the Washington Legal Foundation.[11] There is an open docket where interested parties can submit comments: *www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm (2006P-0402)*.

4 A Citizen Petition was submitted to the Centers for Medicare & Medicaid Services (CMS), which administers CLIA, calling upon CMS to create a "genetic testing specialty" and establish regulations tailored to genetic testing laboratories under CLIA.

5 Senator Obama (D-IL) submitted "the Genomics and Personalized Medicine Act of 2006,"[12] aiming to improve access to and appropriate utilization of valid molecular genetic tests. The bill calls for a study to make recommendations to improve federal oversight and regulation of genetic tests, including genetic LDTs.

6 Senator Kennedy, who will be the chairman of the Senate Committee on Health, Education Labor and Pensions in the new Congress, is also considering legislative alternatives that potentially would make all LDTs medical devices regulated by FDA under the FFDCA.

The regulatory horizon for LDTs is much different at the close of 2006 than at the beginning. Although the exact form and timing of new regulation is unclear, some expansion in regulation of at least some types of LDTs is likely. Interested stakeholders have the opportunity to help shape whatever new regulatory framework may be put in place. Clinical laboratories, treating physicians, and patients all should become familiar with the IVDMIA draft guidance and the other legislative and regulatory proposals being circulated. Feedback to legislators and regulators to let them know how these proposals may affect the appropriate use of and reimbursement for diagnostic information used in clinical decision making is essential.

❖ *Paul Radensky, M.D., J.D., can be reached at McDermott Will & Emery LLP, 201 South Biscayne Blvd., Suite 2200, Miami, FL 33131. Phone: 305-347-6557. E-mail: pradensky@mwe.com.*

[11] A copy of the petition may be found at: www.hpm.com/devitem.cfm?RID=74.0

[12] S. 3822 (submitted August 3, 2006).

Miami Hospital Pays $15 Million In Fraud Settlement

Larkin Community Hospital in Miami and its current and former owners, Dr. Jack Michel, Dr. James Desnick, Morris Esformes, and Philip Esformes, have paid $15.4 million to settle federal and Florida civil healthcare fraud claims against them, according to the U.S. Department of Justice.

Additionally, 34 related companies owned by the Esformes that were used to operate nine assisted living facilities are part of the settlement, along with Claudia Pace and Frank Palacios, two employees.

The government alleged that in 1997, Larkin—then owned by Dr. Desnick—paid kickbacks to physicians in return for patient admissions. The United States contended that the primary recipient of the kickbacks was Jack Michel, who was paid for patient admissions to Larkin by himself and his brother, Dr. George Michel. Jack Michel purchased Larkin in 1998.

In 2000, Dr. Desnick was a party to a $14 million settlement with the United States for a similar kickback scheme at another facility he owned, Doctors Hospital of Hyde Park in Chicago.

The government also alleged in the Michel lawsuit that from 1998 to 1999, Jack Michel, George Michel, Morris Esformes, Philip Esformes, Frank Palacios, and Claudia Pace conspired to admit patients to Larkin for medically unnecessary treatment. The government asserted that some of these patients came from assisted-living facilities owned and operated by Jack Michel and the Esformes brothers.

Court Denies Class Certification In Tenet Outlier Case

A federal judge in South Florida on December 7 refused to certify a national class of private hospitals in a lawsuit seeking more than $1 billion from the Tenet Healthcare Corp. for allegedly inflating reimbursement claims for Medicare outlier patients (*Boca Raton Community Hospital v. Tenet Healthcare Corp*).

In an order, U.S. District Court Judge Patricia Seitz of the Southern District of Florida said the proposed class of some 4,000 facilities failed to meet the typicality and adequacy requirements of the Federal Rule of Civil Procedure 23(a).

Specifically, the group that would comprise the class did not distinguish between facilities, such as Tenet, that may have engaged in similar billing practices—known as turbocharging—and those that did not, Seitz said.

Other Hospitals Profited

"Indeed, the fact that some of the hospitals in the putative class profited from the same types of overcharges as Tenet (and therefore injured other class hospitals) undermines class cohesiveness and exposes serious class conflicts," Seitz wrote in the 44-page order.

Turbocharging occurs when providers seeks excessive Medicare reimbursements under the outlier cost system by charging higher prices for medical services without a corresponding increase in the cost of those services, the order said.

In March 2005, attorneys for Boca Raton Community Hospital filed the lawsuit in West Palm Beach, stating a claim for violations of the federal Racketeer Influenced and Corrupt Organizations Act. The lawsuit brought treble damages from Tenet that could total more than $1 billion.

Among other things, the hospital alleged that it and other acute-care hospitals nationwide were damaged when Tenet took

more than its "fair share" from the 2004 outlier pool at the expense of other participating facilities.

The lawsuit was filed the same day that Florida's attorney general brought a similar action in the federal court (*Florida v. Tenet Healthcare Corp.*, filed 3/2/05). That action was settled in February, when Tenet agreed to pay some $7 million.

Similar Overcharges Cited

In arguing against class certification, attorneys for Tenet asserted that turbocharging was "rampant" in the hospital industry at the time of the allegations and that as many as 80% of facilities in the proposed class had increased their charges out of proportion to their costs, according to the order.

"While the record evidence indicates that Tenet may have been one of the most, if not the most, egregious turbochargers, the difference between its conduct and that of the other hospitals is simply a matter of degree," Seitz wrote. "And since the rise in the [Fixed Loss Threshold] was caused by the industry as a whole, only a small percentage of hospitals in the class are truly blameless."

Tenet officials hailed Seitz's decision, but officials at Boca Raton Community Hospital said they would appeal the decision.

Lab Owner Convicted In Florida Kickback Trial

The owner of a Miami laboratory and diagnostic testing facility was found guilty November 2 in connection with an alleged Medicare kickback conspiracy, according to federal prosecutors.

Following a two-week trial in the U.S. District Court for the Southern District of Florida, defendant Armando Jose Figueredo was convicted on five criminal conspiracy counts, U.S. Attorney R. Alexander Acosta said in a written statement.

According to evidence submitted during the trial, from October 2002 through October 2004, Figueredo—an owner of National Medical Laboratory Inc.—paid kickbacks to a doctor in exchange for the referral of patients for medical tests reimbursable by Medicare.

Figueredo faces a maximum of five years' imprisonment on the conspiracy charge and five years' imprisonment on each of the four substantive charges of paying kickbacks. Sentencing is scheduled for Feb. 2, 2007.

OIG Approves Gainsharing Proposal Given Safeguards

A gainsharing arrangement under which a hospital would pay a group of cardiac surgeons a percentage of the hospital's costs savings arising from their use of cost-reduction measures generally got the green light from the Health and Human Services Office of Inspector General due to certain safeguards, but the opinion warned that some aspects of the proposal implicate the civil monetary penalty law.

The findings are contained in OIG Advisory Opinion No. 06-22, posted on the Web November 16. Based on the facts as described, the OIG said the proposal involving limitations on the use of certain surgical supplies, limiting the use of Aprotinin (a medication to control postoperative hemorrhaging), and product standardization would constitute an improper payment to induce reduction or limitation of services pursuant to the civil monetary penalty law, but that the OIG would not impose sanctions.

The opinion also said that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the required intent to induce or reward referrals of federal healthcare program business were present, but that it concluded that intent was not present.

Under the proposed gainsharing arrangement, the hospital would pay the surgeon group 50% of the cost savings achieved by implementing 24 recommendations involving: limiting the use of certain surgical supplies; substituting, in whole or part, less costly items for items currently being used by surgeons; and standardizing the use of certain cardiac devices where medically appropriate.

In its legal analysis, the OIG stated its concern about such arrangements. "Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes," the OIG wrote. However, the OIG said, the same arrangements can "potentially influence physician judgment to the detriment of patient care."

Specifically, the OIG is concerned about 1) stinting on patient care; 2) cherry picking healthy patients and steering sicker and more costly patients to hospitals that do not offer such arrangements; 3) payments in exchange for patient referrals; and 4) unfair competition among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.

However, the OIG said it would not seek sanctions in this case because multiple safeguards have been put in place, including clear identification of the specific cost-savings actions and resulting savings, credible medical support for the position that implementation of the recommendations would not adversely affect patient care, and limited financial incentives.

Resource

- Advisory Opinion No. 06-22 is available at *www.oig.hhs.gov*. Click on "Fraud Prevention and Detection," and then click on "Advisory Opinions."

For the Record

Processing Of Diagnosis Codes Reported On Claims

The ANSI 837P 4010 allows a maximum of eight diagnosis codes to be reported for each claim. In processing the claim under the format established by the Health Insurance Portability & Accountability Act (HIPAA), the Multi-Carrier System (MCS) applies the first four diagnosis codes on the claim. The remaining diagnosis codes are not used in the payment determination for Medicare.

The clinical laboratory negotiated rule making committee agreed that Medicare would consider all diagnosis codes reported in the processing of claims for clinical laboratory services. Until now, the enforcement of this requirement was generally done manually, but this process has not always worked effectively, notes the Center for Medicare & Medicaid Services (CMS) in a transmittal issued October 27 (Transmittal 1095, Change Request 4276).

The transmittal implements the negotiated rule making agreement to automatically consider all diagnosis codes reported. The change request also requires the MCS to process all diagnosis information submitted on the approved HIPAA claim format for all other types of claims. Generally, paper claims should have only four diagnoses. If more are reported, MCS should capture up to the maximum allowed by the ANSI 837 4010A1 claim format.

Effective for claims processed July 1, 2007, and later, the carrier standard system shall capture and process up to eight diagnosis codes reported on a claim, says the transmittal. For claims processed July 1 and later, the Common Working File (CWF) shall accept all diagnosis codes reported by the MCS to CWF. Within 45 days of the implementation of the coding changes effective on July 1, 2007, the carriers shall make the appropriate updates to their edits and audits to read all diagnosis codes reported on the claim.

Final Patients' Rights Rule: The Centers for Medicare and Medicaid Services (CMS) has issued a final rule setting standards for patients' physical and emotional health and safety in Medicare- and Medicaid-participating hospitals. The rule, which takes effect Jan. 8, 2007, finalizes provisions in a July 2, 1999, interim final rule with comment. It sets out the Patients' Rights Conditions of Participation Requirements, which address the notice of rights to patients; the exercise of rights, privacy and safety; confidentiality of patient records; restraint for acute medical and surgical care; and seclusion and restraints for behavior management. The final rule, published in the December 8 *Federal Register*, is available at www.archives.gov/federal-register/index.html.

OIG Reports Record Recoveries: The Health and Human Services Office of Inspector General (OIG) has achieved a record $38.2 billion in savings and expected recoveries in fiscal 2006, according to the agency's semiannual report to Congress. That amount encompasses $35.8 billion in implemented recommendations and other actions to put funds to better use, $789.4 million in audit receivables, and $1.6 billion in investigative receivables. During the year, OIG excluded 3,425 individuals or organizations for fraud or abuse of federal healthcare programs and/or their beneficiaries and reported 472 criminal actions and 272 civil actions.

CMS Issues Final HOPPS Changes: Hospitals would receive an estimated $32.5 billion in CY 2007 under a final rule that revises policies and payments under the Hospital Outpatient Prospective Payment System (HOPPS). As provided by statute, the rule includes a 3.4% market basket update to Medicare payment rates for services paid under the system. The rule, announced November 1, ties HOPPS rate increases to the reporting of quality measures beginning in 2009 and includes an expansion of the hospital reporting of additional quality measures for inpatient services beginning in FY 2008.

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