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Court Denies Request for Restraining Order in Lab Competitive Bidding Case

A federal court on February 14 denied a request for a temporary restraining order (TRO) to halt the competitive bidding process for clinical laboratories serving Medicare beneficiaries in the California communities of San Diego, Carlsbad, and San Marcos.

The TRO request was filed by Hooper, Lundy & Bookman Inc. on behalf of plaintiffs Sharp HealthCare, Scripps Health, and Internist Laboratory of Oceanside.

In its order, the court denied the TRO based on papers that were filed by the government two days earlier. In those papers, the government argued that any challenge to the competitive bidding demonstration was premature because no winners or losers had yet been decided upon and thus no one could have been harmed yet. *Continued on p. 8*

FDA Issues New Guidance on IVD Waivers

After about seven years of deliberation, the Food and Drug Administration (FDA) on January 30 issued a new guidance document that it says provides more flexibility for companies submitting a waiver application for certain in vitro diagnostic (IVD) tests.

The guidance, *Recommendations for Clinical Laboratory Improvement Amendment of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices*, was shaped by the agency's consideration of comments from stakeholders in response to two preceding draft guidance documents issued in 2001 and 2005, as well as the agency's interactions with stakeholders at several meetings since 2000.

However, while industry welcomes the agency's attention to stakeholder feedback, some maintain the guidance is too similar to the 2005 version, which was criticized for deviating from congressional intent.

"The final guidance is overly burdensome and will force diagnostics manufacturers to perform studies that go beyond what Congress intended in the 1988 Clinical Laboratory Improvement Amendments," said Khatereh Calleja, associate vice president of regulatory and technology affairs at the Advanced Medical Technology Association (AdvaMed).

CLIA requires that labs obtain a certificate *Continued on p. 2*

Kimberly Scott, Senior Editor,
kscott@ioma.com

Inside this issue

Court denies TRO in lab bidding case 1
FDA issues new guidance on IVD waivers 1
President's budget boosts anti-fraud efforts 3
OIG to revise compliance guidance for nursing homes 4
Medicare may have overpaid for hospital & lab services 4
Is your venipuncture procedure stoking a legal firestorm? See *Perspectives* 5
HHS can't cut off funds to hospital challenging CLIA rule 9
OIG approves prompt pay discount plan 9
Merck to pay $650 million in fraud settlement 10
OIG OKs charitable contributions as reward 11
News in brief 12

www.g2reports.com

IVD Waivers, *from page 1*

from the Department of Health and Human Services (HHS) before accepting materials derived from the human body for laboratory tests. According to FDA, labs that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver.

The final guidance document expands the amount of supplementary patient specimens manufactures can use in clinical studies to one-third, specifying manufacturers use banked patient samples, or spiked or diluted prepared samples, according to the agency.

FDA, which announced the availability of the guidance document in the January 30 *Federal Register*, is accepting comments on the guidance, but the agency did not specify a deadline.

The guidance, which recommends an approach for manufacturers to demonstrate in a CLIA waiver application that their devices meet CLIA requirements of methodological simplicity and accuracy, incorporates some changes urged by industry, while maintaining elements of the previous draft guidance that industry did not support.

The final guidance document expands the amount of supplementary patient specimens manufactures can use in clinical studies to one-third, specifying manufacturers use banked patient samples, or spiked or diluted prepared samples, according to the agency. FDA recommended manufacturers perform prospective clinical studies of their devices.

AdvaMed says it appreciates the flexibility in using banked samples but believes the agency should not prescribe the number of patient samples required for clinical studies. The guidance recommends a minimum of 360 samples for tests with quantitative results and a minimum of 120 positive and 120 negative samples for tests with qualitative results.

Clinical study recommendations, including a two-week minimum length of time for the study, a minimum of three intended use sites representative of the intended patient population and intended operators/users of the device, and a minimum participation of nine operators, were preserved from previous draft guidance versions.

David Mongillo, vice president of policy and medical affairs for the American Clinical Laboratory Association (ACLA), says the new guidance is more comprehensive than earlier versions. ACLA's primary concern with the document has to do with how the category of waived testing is defined, he tells *G-2 Compliance Report*.

"The category is defined as one where the test is so simple that even if there is error, it should have no impact on the care of that patient. The laboratory industry generally believes that it is a misnomer, and there really is no such laboratory test that if erroneous would have negligible impact on patient care," he says. "But that's always been an issue with the waived test category."

Waived tests do have value, but if there is any question as to the results or the accuracy of the tests, the tests should be confirmed by a centralized lab, Mongillo adds.

The issuance of this guidance document allows the agency to move forward with a pilot project discussed during user fee reauthorization negotiations, according to the FDA. The agency had proposed conducting a pilot program to evaluate integrating the 510(k) review process (premarket notification) with the CLIA waiver review process. The pilot project is intended to help the agency determine if an integrated review process would be beneficial for both industry and the FDA, agency officials say.

The guidance document is available on FDA's Web site at *www.fda.gov/cdrh/oivd/guidance/1171.pdf*.

President's Budget Boosts Anti-Fraud Efforts

Program integrity and anti-fraud efforts in the Medicare and Medicaid programs would get a $200 million boost in fiscal year 2009 under President Bush's proposed budget, released February 4.

Much of the funding increase would come from $198 million in new discretionary funding from the Health Care Fraud and Abuse Control program (HCFAC) that would be directed to the Centers for Medicare & Medicaid Services (CMS) for Medicare program integrity efforts.

The Department of Health and Human Services Office of Inspector General (OIG) would receive $19 million of the proposed new discretionary funding, with the Medicaid integrity program at CMS slated to receive $13 million of the new money. The new Medicare program integrity funding would be used in large part to identify fraud and abuse in the Part D drug and Medicare Advantage programs, according to budget documents.

The addition of new discretionary funding would bring to $1.3 billion the total funding commitment by the administration from the HCFAC program. HHS and other federal agencies, including the Federal Bureau of Investigation (FBI) and the Department of Justice (DOJ), are to receive $1.1 billion in mandated funding for program integrity and fraud and abuse work in federal health programs.

While hospitals and other institutional providers face deep cuts in their Medicare payments under the President's budget request for fiscal 2009, clinical labs have escaped further proposed reductions in the Part B lab fee schedule.

Mandatory funding is allocated in three parts to federal agencies: the Medicare Integrity Program, the FBI, and the HCFAC account. The HCFAC account is then apportioned to the OIG, DOJ, and other agencies through an annual negotiation process.

However, the president's budget for FY 2009 proposed eliminating the annual negotiation process for HCFAC account dollars and instead splitting the current funding provided to HHS and DOJ into two separate funding streams. The proposed budget further calls for the FBI and the Medicare Integrity Program at CMS to contribute to the annual HCFAC report, which details funding and program recoveries each year.

Lab Fees Spared

While hospitals and other institutional providers face deep cuts in their Medicare payments under the President's budget request for fiscal 2009, clinical labs have escaped further proposed reductions in the Part B lab fee schedule. But lab competitive bidding is still a priority for savings in the budget, which proposes a national rollout of lab bidding.

The budget does not address a Medicare physician fee fix. Congress prevented a 10.1% cut scheduled for January 1 of this year under the sustainable growth rate (SGR) update formula and approved a 0.5% increase through June 30. As of July 1, the 10.1% cut is due to take effect unless lawmakers block it again.

Though major cuts are proposed for virtually all providers in traditional Medicare, Medicare managed care would get only a slight trim. The White House has already indicated it opposes any further reductions in Medicare Advantage.

The budget got a frigid reception on Capitol Hill, with Senate and House health leaders calling it "dead on arrival." The Senate Finance Committee has already said it will craft its own Medicare spending legislation later this year.

The HHS portion of the President's budget is available online at *www.hhs.gov/budget/docbudget.htm#brief*.

OIG to Revise Compliance Guidance for Nursing Homes

The Department of Health and Human Services Office of Inspector General (OIG) is seeking recommendations for revisions to its compliance guidance for nursing homes that participate in federal healthcare programs.

The OIG said in a January 24 *Federal Register* notice that it is planning changes to the guidance document because the nursing home industry has undergone numerous changes since the current guidance was finalized in March 2000.

Revisions to the guidance will also reflect the OIG's experience in nursing home industry enforcement and compliance since the current guidance was issued, according to the notice.

The OIG said it was seeking comments, recommendations, and suggestions for ways in which the guidance could be revised "to address relevant compliance issues."

The OIG began publishing compliance program guidances for various healthcare industry sectors in 1997 to advise providers, practitioners, and institutions on how to avoid running afoul of federal healthcare laws. Guidances have been issued for the hospital, home health, clinical lab, pharmaceutical, and other industries.

Recommendations and comments for revisions to the nursing home guidance must be received by the OIG no later than February 25.

The notice is available at *www.oig.hhs.gov/authorities/docs/08/CPG_Nursing_Facility_Solicitation.pdf*.

Medicare Potentially Overpaid for Hospital & Lab Services

Medicare may have overpaid certain providers nearly $130 million for hospital and laboratory services provided to nursing home patients from 2001 through 2003, the Department of Health and Human Services said in an audit report released February 11.

The HHS Office of Inspector General (OIG) reviewed payments for outpatient hospital, lab, and radiology services included in Medicare Part A payments made to skilled nursing facilities to determine if those services also had been reimbursed by the Part B program.

In 2002, the Centers for Medicare & Medicaid Services (CMS) began implementing payment system edits in the Common Working File, with the intention of preventing Part B payments for the Part A-covered services, the OIG said. There are two kinds of edits: prepayment edits prevent such Part B overpayments to service suppliers and postpayment edits require that the payments be recovered.

OIG auditors found that in 2001 and 2002, before the system edits were fully implemented, Medicare Part B potentially overpaid nearly $107 million to providers for outpatient hospital, lab, and radiology services that should have been paid for under the Part A program.

In 2003, after the system edits were in place, potential overpayments had been reduced to nearly $23 million, of which payment contractors have yet to collect nearly $18 million from providers, the OIG said in its report, *Payments for Outpatient Hospital, Laboratory, and Radiology Services Made on Behalf of Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A* (A-01-06-00503).

The OIG said the unrecovered overpayments in 2003 occurred because the payment system edits did not fully capture all overpayments, and in cases where they were identified, contractors experienced claims-processing system problems.

The report is available online at www.oig.hhs.gov/oas/reports/region1/10600503.pdf.

COMPLIANCE PERSPECTIVES

Is Your Venipuncture Procedure Stoking a Legal Firestorm?

Dennis J. Ernst, MT(ASCP), is director of the Center for Phlebotomy Education (Ramsey, IN) and editor of the e-newsletter Phlebotomy Today.

Managing a laboratory is a lot like managing a controlled burn of dry timber. At any given time, a flare-up can force you to abandon your oversight of the operation and focus on the emergency. It pulls you away from the task at hand just long enough to lose your momentum. You settle back down and then darned if another wildfire doesn't break out. Before you know it you're scrambling from one flare-up to another, and your days descend into the constant chaos of fighting fire after fire, all at the expense of your oversight.

Seasoned laboratory "firefighters" know that one way to keep the flare-ups to a minimum is by making sure their staff is functioning according to the most current standards and by quickly bringing back into compliance those who aren't.

Seasoned laboratory "firefighters" know that one way to keep the flare-ups to a minimum is by making sure their staff is functioning according to the most current standards and by quickly bringing back into compliance those who aren't. That's good risk management. But like the direction of a controlled burn in a crosswind, standards change. If you haven't recently updated your venipuncture procedure to reflect the latest revision, you may be unknowingly fueling a firestorm of litigation.

Some of the most critical standards laboratory procedure manuals should reflect are those maintained by the Clinical and Laboratory Standards Institute (CLSI). CLSI's Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, (H3-A6) was released in November 2007 after nearly a year-long revision, the first since December 2004. The revised document contains key changes that must be implemented into every facility's procedure manual in order to continue operating within the standard of care. In this article, we will discuss changes managers should consider for their procedure manuals based on this revision and bring them to the attention of everyone who draws blood specimens in their facility.

IV Infusion

The simultaneous infusion of intravenous (IV) fluids is a perpetual threat to accurate test results. The revision of H3 includes a completely rewritten passage on drawing blood during IV therapy, including more detailed language on the risks of drawing proximal (above) infusing fluids. While continuing to discourage the practice, the standard cautions facilities on the potential for specimen contamination and urges them to establish their own policies on such draws after considering the risk.

New in this version is the requirement to append a comment accompanying results obtained from specimens drawn above temporarily discontinued IVs so that physicians can properly interpret results. The standard now warns that add-on tests may not be appropriate for such specimens and requires those drawn proximal or distal to an IV be labeled as such.

Tourniquet Use

The standards organization also addressed several passages discussing the use of a tourniquet in specimen collection. The language was relaxed to make the use of a tourniquet optional as long as the visible or palpable antecubital vein being considered is either a medial or cephalic vein. However, specimen collection personnel are soundly cautioned to use a tourniquet whenever the only visible and/or palpable vein is the basilic, which lies in close proximity to nerves and the brachial artery. Since most nerve injuries that result from venipuncture occur during attempts to access the basilic vein, phlebotomists and other healthcare professionals with specimen collection responsibilities must prioritize the veins for safety. Such prioritization cannot be accomplished without constricting circulation to distend the veins of the area.

Another key change managers must bring to the attention of their staff and implement into their procedure is a passage requiring phlebotomists to discontinue draws should patients feel an electric, shooting-pain sensation or tingling/numbness distal to the site.

Since it is widely known that prolonged application of the tourniquet leads to altered test results, the document contains a refined passage identifying hemoconcentration as problematic when leaving the tourniquet on beyond one minute. As have past versions of the venipuncture standard, when vein location and access take more than one minute, the document continues to recommend removing the tourniquet and allowing two minutes to pass so that hemoconcentration can disperse before reapplying constriction and accessing the vein.

Site Preparation

A completely revised section on drawing blood cultures now includes isopropyl alcohol as a site preparation solution in addition to iodine and chlorhexidine compounds. This addition reflects the results of a study that shows cleansing a site with multiple isopropyl alcohol preps to be as effective as iodine and chlorhexidine.

The section also stresses in greater detail the proper procedure for site preparation and the importance of using safety transfer devices when transferring blood from syringes. Also new is language warning against the insertion of blood culture bottles into tube holder adapters unless using a butterfly. Because of the risk of broth refluxing into the vein, such direct filling is not appropriate for most blood culture bottles.

Anatomical Variation

Perhaps the most visible change in the document is the inclusion of two full-color illustrations on variations of the anatomy of the antecubital area. It marks the first time color images have been used in this standard. The illustrations identify two common variations in the anatomy of the antecubital area known as the "M-" and "H-" shaped orientations of the veins. Text accompanying the illustrations provides substantial detail on anatomical variations specimen collection personnel are most likely to encounter when surveying for veins.

Nerve Damage

Another key change managers must bring to the attention of their staff and implement into their procedure is a passage requiring phlebotomists to discontinue draws should patients feel an electric, shooting-pain sensation or tingling/numbness distal to the site. Since nerve damage is the most common venipuncture complication that leads to litigation, the working group felt it imperative that all healthcare professionals know the signs of nerve involvement and take steps to minimize damage.

Attempts to salvage a venipuncture after being made aware of unusual or excruciating pain has always put facilities at risk of operating beneath the standard of care should an injury lead to litigation. However, with more definitive language

now incorporated into the standards, defending against future claims of phlebotomists continuing with venipunctures after patients express unusual or extreme pain will be considerably more difficult.

Specimen Labeling

Managers will also need to modify their practices and policies in regard to specimen labeling. The new standard now includes a requirement to compare the labeled tube to the inpatient's identification bracelet wherever possible before leaving the patient. Even though patients may be properly identified prior to the draw, this step has been added to prevent the wrong labels from being attached to specimens when the labels of multiple patients are carried into the room. An acceptable alternative to comparing the tubes to the identification bracelet is to have the patient look at the tubes and confirm that they contain his/her information.

Laboratory managers who implement these key changes to the CLSI venipuncture standard into their own procedure manuals and bring them to the attention of their staff can avoid the legal firestorms that liability can ignite.

Exposure Prevention

Exposure prevention was also on the minds of the working group in drafting the revision. In the section that describes anchoring the vein prior to needle insertion, collectors are warned against the common practice of securing it in place from above and below the puncture site. This technique, often referred to as the "C" or "Window" method for anchoring veins puts the index finger above the intended puncture site and in harm's way should the patient jump during needle insertion. Anchoring with the thumb from below the site only is the recommended procedure.

The standard also reinforced its passage on hand hygiene to reflect the current Centers for Disease Control hand-washing guidelines.

Laboratory managers who implement these key changes to the CLSI venipuncture standard into their own procedure manuals and bring them to the attention of their staff can avoid the legal firestorms that liability can ignite. Only when one's procedure manuals reflect the standards can the risk be properly managed.

No manager intends to be out of step with the standards. But regardless of how well intentioned you are, if an injured patient retains a standards-savvy attorney, it's likely that the jury who hears the case will not be able to see the forest for the trees.

Dennis J. Ernst MT(ASCP) chaired the revision of CLSI document H3. The venipuncture standard can be obtained from CLSI at www.clsi.org or the Center for Phlebotomy Education at www.phlebotomy.com.


Patric Hooper, Esq.

Lab Competitive Bidding Case, *from page 1*

The government further argued that, in any event, the federal court is precluded from reviewing the legality of the project due to purported jurisdictional and other technical legal impediments that are unique to the Medicare program.

"The court has given the plaintiff laboratories additional time to address these arguments in light of the fact that they were not previously given that opportunity due to the lateness of the government's briefing," said plaintiff's attorney Patric Hooper. "I am not particularly surprised by the court's decision given the representations made by the government at the 11th hour."

Hooper also said that once the plaintiffs are given the opportunity to brief the legal issues raised by the government, he is confident the court will have a clear understanding of why immediate injunctive relief is necessary and why the court is empowered to grant such relief.

Indeed, Hooper noted that he recently overcame similar arguments advanced by the government in another federal court case involving Medicare payment for lab services.

The court set a deadline of Feb. 29, 2008, for the plaintiff laboratories to address the jurisdictional issues raised by the government. Meantime, the bidding process progresses (bids were due February 15). Hooper said he will ask the court to issue a preliminary injunction prior to the April 11, 2008, date for the Centers for Medicare & Medicaid Services (CMS) to decide who the winning bidders are.

Hooper also said that once the plaintiffs are given the opportunity to brief the legal issues raised by the government, he is confident the court will have a clear understanding of why immediate injunctive relief is necessary and why the court is empowered to grant such relief.

The plaintiffs filed suit in federal court against the federal government on Jan. 29, 2008, to halt the Medicare demonstration project slated for the San Diego-Carlsbad-San Marcos region. The plaintiffs argue that the project threatens to irreparably harm vital laboratory testing services for thousands of Medicare beneficiaries if it is allowed to move forward.

The three-year demonstration project singles out the San Diego region for testing of a new competitive bidding program that opponents say, if implemented, will force many small community laboratories out of business and may force systems like Sharp Healthcare and Scripps Health to refuse service to nonhospital patients who have come to rely on their labs for ongoing testing.

The plaintiffs contend that, rather than creating competition, the demonstration project will result in fewer labs, less competition, and increases in Medicare's laboratory expenditures. "The ramifications to Medicare beneficiaries, their physicians, and the labs that currently serve them could be devastating," says Hooper.

In their complaint, the plaintiffs argue, in part, that the federal Department of Health and Human Services:

- Failed to follow a legally required rule-making process by not holding appropriate public hearings and not allowing Medicare recipients, physicians, and others to provide input into the process.
- Failed to incorporate protections for small business, as required by law. The demonstration project requires all labs to perform all 303 tests or obtain the financial and bidding cooperation of reference laboratories, which are now considered competitors.
- Has established a program that "threatens to cause severe and irreparable injury to plaintiffs Internist, Sharp, and Scripps, as well as to their respective employees and patients."
- Has included many policies that are arbitrary.

HHS Can't Cut Off Funds to Hospital Challenging CLIA Rule, Court Says

A federal district court January 10 waived the "usual remedy exhaustion" requirement, preventing the Health and Human Services Secretary from canceling a California hospital's approval to receive Medicare and Medicaid payment for clinical laboratory services (*Victor Valley Community Hospital v. Leavitt*).

More than 60% of the patients at Victor Valley, one of four hospitals in the High Desert region of California with a population of about 500,000, receive Medicare or Medi-Cal, the California Medicaid program.

In July 2007, the Centers for Medicare and Medicaid Services (CMS) determined that Victor Valley was not in compliance with the proficiency testing condition because it improperly referred proficiency testing samples to an outside laboratory. CMS informed the hospital it would postpone the proposed revocation of the CLIA certification if Victor Valley requested an administrative hearing. However, CMS warned, the cancellation of all Medicare and Medicaid payments would go into effect regardless of whether a hearing was requested.

The district court found that, if Victor Valley lost Medicare and Medi-Cal payment for laboratory services, the hospital would have to struggle to provide basic services, maintain necessary equipment, and would likely have to trim its operations or shut down. The court's decision effectively stops the federal government from cutting off payments while the issue is resolved. The case is now at the administrative hearing level to determine whether the revocation of the CLIA certificate was justified.

OIG Approves Health System's Plan to Give All Patients Prompt-Pay Discounts

A healthcare system can give prompt-pay discounts to patients, including those covered by Medicare and Medicaid, without running afoul of the law, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion released February 8.

The health system proposed offering discounts to all patients, including those covered by Medicare, Medicaid, and private insurers, for prompt payment of their cost-sharing amounts and for services not covered by their insurers, the OIG said in Advisory Opinion No. 08-03.

Discounted fees through the prompt-pay arrangement would constitute a reduction in beneficiary coinsurance and deductible amounts for Medicare and Medicaid patients, raising potential concerns under the anti-kickback statute, the OIG said in its analysis.

However, while the arrangement could generate improper kickback payments to federal healthcare program beneficiaries, the OIG said it would not impose administrative penalties on the healthcare system.

The OIG further determined that the proposed arrangement did not constitute grounds for the imposition of civil monetary penalties.

The health system proposed offering discounts ranging from 5% to 15% depending on the amount of patients' bills and how quickly they were paid, according to the advisory opinion. The discounts would apply to inpatient and outpatient services.

The prompt-pay program was proposed as a way to reduce the health system's accounts receivables and the cost of debt collection, the OIG noted, and the hospital certified in its request for the advisory opinion that the amount of the discounted fees "would bear a reasonable relationship to the amount of the collection costs that would be avoided."

Safe Harbor Met

The OIG determined that the discounted fees for inpatient services met the anti-kickback statute safe harbor for waivers of coinsurance and deductible amounts. However, it said a separate analysis of the arrangement for discounts applied to outpatient services was necessary to ensure such payments were not a disguise for referrals.

Nevertheless, the OIG concluded that the health system had "incorporated various commitments that suggest that the prompt pay discount would be a legitimate prompt payment incentive and not a means to induce patients to self-refer." For example, the OIG said, the health system certified it would not advertise the discount opportunity but rather advise patients of the discount only during the billing process. The health system also said it would advise other third-party insurers of the policy and that all costs of the arrangement would be paid by the health system.

"We believe that these features reduce the likelihood that the proposed arrangement would be used as a means to draw additional patient referrals to the health system and is consistent with the characterization of the proposed arrangement as a prompt payment discount implemented for the purpose of more successful bill collection," the OIG said in its analysis.

As is the case with all advisory opinions, the OIG redacted the name and location of the health system that requested the opinion.

The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-03A.pdf*.

Merck to Pay $650 Million in Fraud Settlement

Merck & Co. has agreed to pay more than $650 million to the federal government and states to resolve allegations in two separate lawsuits that the pharmaceutical manufacturer failed to pay proper rebates to Medicaid and other government health programs, the Department of Justice (DOJ) announced February 7.

The settlement agreements represent the third-largest civil recovery for healthcare fraud, behind a $900 million case involving hospital operator Tenet Healthcare and a $730 million case involving hospital chain HCA.

Under the combined settlement agreements, Merck will pay the federal government $355.5 million plus interest and pay the states $293.5 million plus interest.

The settlement agreements also resolve allegations that Merck paid illegal remuneration to healthcare providers to induce them to prescribe the company's products, the DOJ said.

The two whistleblower lawsuits were filed under the False Claims Act in the U.S. District Court for the Eastern District of Pennsylvania by H. Dean Steinke and in the U.S. District Court for the Eastern District of Louisiana by William St. John LaCorte.

In a press release, Merck said the settlements do not constitute an admission by Merck of any liability or wrongdoing. The company said that nearly all of the states that reached an agreement with Merck acknowledged that the drug maker voluntarily began to put in place substantial compliance initiatives in 2001, before Merck was contacted by the government concerning an investigation.

OIG OKs Charitable Contributions as Reward

The Department of Health and Human Services Office of Inspector General (OIG) will not impose administrative sanctions on a proposal to encourage healthcare professionals to complete online surveys by offering to designate a public charity to which a marketing and research company would make a monetary contribution.

The requesting company services pharmaceutical and medical products and device manufacturers and the entities that distribute and market their products, according to Advisory Opinion No. 08-02, posted February 5. The company is not a healthcare provider or supplier, does not participate in any federal healthcare programs, and is not owned or controlled directly or indirectly by any company with products or services reimbursed by federal healthcare programs.

The company owns and operates an interactive Web-based platform that provides a means of surveying physicians. The platform can be used to collect information from, and transmit information to, physicians, and is capable of performing various tasks as a research, educational, and promotional tool, the opinion said.

Under the proposed arrangement, the designated charity would have to be organized under section 501(c)(3) of the Internal Revenue Code, qualify as a public charity, and meet the public support test.

No Tax Deduction

The contributions would be made directly to the charity by the requestor or its client and use of the donated funds would be solely at the discretion of the recipient charity. While donations would be made in recognition of the healthcare professional, the professional would not be entitled to a tax deduction or otherwise receive any monetary benefit from the contribution, the OIG said.

Because the actual or expected benefits to the healthcare professionals who complete a survey and designate a charity would be wholly intangible in the form of potential personal satisfaction, the OIG said it could discern no economic or other actionable benefit that would inure to the professionals as a result of the contributions.

The OIG reviewed the proposed arrangement in light of concerns that in some circumstances, payments characterized as "charitable donations" are nothing more than disguised kickbacks intended to induce referrals, directly or indirectly. The proposed arrangement could implicate the anti-kickback statute if the charitable contributions resulted in any actual or expected economic or other actionable benefit, whether direct or indirect, for the healthcare professionals, the opinion said.

Links to Charity

In addition, before making any contributions, the requesting company would obtain certifications from the healthcare professionals that neither they, nor any immediate family member, held a position on the board of the designated charity, was employed by the charity, or had any other financial relationships with the charity, the OIG noted.

Because the actual or expected benefits to the healthcare professionals who complete a survey and designate a charity would be wholly intangible in the form of potential personal satisfaction, the OIG said it could discern no economic or other actionable benefit that would inure to the professionals as a result of the contributions.

The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-02A.pdf*.

Fraud Recoveries: The Medicare Trust Fund received $1.5 billion in fiscal 2006 as a result of federal enforcement activities in the Medicare program that year, according to a February 12 report from the Department of Health and Human Services Office of Inspector General. An additional $177 million was sent to the Treasury in FY 2006, a result of related federal enforcement actions involving the Medicaid program. The report is available at *www.oig.hhs.gov/publications/docs/hcfac/hcfacreport2006.pdf*.

Faulty Payments: Health insurers using a billing database offered by a unit of UnitedHealth Group systematically underpay providers by relying on faulty methods for determining reasonable and customary fees, New York Attorney General Andrew Cuomo charged February 13. In announcing an industrywide investigation, Cuomo said that he would sue United and its Ingenix Inc. health billing information provider unit, as well as its New York health plan subsidiaries. He also said he has issued subpoenas to 16 large health insurance companies. In the six-month probe, investigators have found that Ingenix "operates a defective and manipulated database that most major health insurance companies use to set reimbursement rates for out-of-network medical expenses." United defends the methodology, characterizing the reference data as "rigorously developed, geographically specific, comprehensive, and organized using a transparent methodology that is very common in the healthcare industry."

Quality Improvement: Responding to wide-ranging concerns that quality improvement organizations (QIOs) have been performing poorly, the federal government is making new demands of the contractors starting later this year. Centers for Medicare & Medicaid Services (CMS) Acting Administrator Kerry Weems said during a February 5 call with reporters that contracts under the Ninth Statement of Work (SOW) will define QIO duties in greater detail and will require QIOs to meet more defined performance goals. CMS also has named "targeted" nursing homes and hospitals in each state that it expects QIOs to work with in improving quality of care in defined areas.

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