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For Hospitals, Laboratories and Physician Practices

OIG Issues Safe Harbor For Electronic Arrangements

Labs Allowed To Donate Software, Training For EHR

Clinical laboratories will be permitted to donate computer software equipment and training to client hospitals and physicians to facilitate electronic health records under a final rule issued August 8 by the Department of Health and Human Services Office of Inspector General (OIG).

The final rule establishes a new safe harbor under the federal anti-kickback statute for certain arrangements involving the provision of electronic prescribing technology. In addition, the rule creates a separate new safe harbor for certain arrangements involving the provision of non-monetary remuneration in the form of electronic health records (EHR) software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive EHR. Both safe harbors take effect on Oct. 10, 2006. While there is no sunset date for the electronic prescribing safe harbor, the EHR safe harbor sunsets on Dec. 31, 2013.

Electronic Prescribing Safe Harbor

The final safe harbor on electronic prescribing protects technology necessary and used solely to receive and transmit any prescription information, whether related to drugs ➥ *p. 2*

Inside this issue

CMS Officials Dispute GAO Findings On Lab Oversight

Officials with the Centers for Medicare & Medicaid Services (CMS) believe they are doing a good job enforcing requirements of the Clinical Laboratory Improvement Amendments (CLIA) despite a recent Government Accountability Office (GAO) report critical of the agency's oversight.

The report, released June 27 during a hearing before the House Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources, faulted CMS and survey organizations, saying that real and potential lab quality problems are masked by survey, complaint, and enforcement weaknesses.

"Because most survey organizations announce the timing to biennial surveys, allowing labs to prepare for inspections, surveys may not provide a realistic picture of lab quality," the report says. "Although two survey organizations that generally inspect hospital labs plan to begin unannounced surveys in 2006, they may not be possible at physician office labs that have irregular hours. Survey organizations that typically ➥ *p. 9*

OIG Issues Safe Harbor, *from p. 1*
or to other items or services normally ordered by prescription (such as laboratory tests and durable medical equipment orders).

Protected donors and recipients are hospitals to members of their medical staffs, group practices to physician members, prescription drug plan sponsors and MA organizations to network pharmacists and pharmacies and to prescribing healthcare professionals. Clinical laboratories are not considered permissible donors under this safe harbor.

Donors may not select recipients using any method that takes into account the volume or value of referrals from the recipient or other business generated between the parties. Donations may be in an unlimited amount.

The OIG has abandoned its original proposal to require that recipients provide a written certification that the donated technology is not technically or functionally equivalent to the technology the recipient already possessed or had obtained. Instead, the OIG added language to the final rule that permits arrangements to be memorialized through cross-referencing incorporation of prior agreements between the parties.

The American Clinical Laboratory Association (ACLA) applauds the final rule. "We congratulate [HHS] for recognizing the inherent value laboratory data conveys to physicians, hospitals, and, ultimately, patients," says President Alan Mertz.

EHR Arrangements Safe Harbor

The second safe harbor finalized by the OIG protects arrangements involving electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. This safe harbor does not include hardware.

To qualify for protection, at the time of the donation, the software must be certified as interoperable. Software must contain an electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system.

This safe harbor protects arrangements involving donors that are health plans or individuals or entities that provide covered services and submit claims or requests for payment to a federal healthcare program.

Donors cannot select recipients in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. However, donors may select recipients of donated EHR technology using means that *do not directly* take into account the volume or value of referrals from the recipient or other business generated between the parties.

The rule does not limit the aggregate value of technology that may qualify for safe harbor protection, but it does require that the recipient pay 15% of the donor's costs. No portion of the contribution may be funded by the donor or any affiliate of the donor. The donor's costs and recipient's contribution must be documented in a written agreement between the parties. Recipients do not have to certify that they do not already possess equivalent technology, but the safe harbor precludes protection if the donor knows that the recipient already has equivalent technology.

While the OIG initially proposed not including providers and suppliers of ancillary services under the EHR safe harbor, it has been persuaded that they have a stake in the development of interoperable electronic health records sufficient to warrant safe harbor protection, according to the notice.

"We remain concerned about the potential for abuse by laboratories, durable medical equipment suppliers, and others, but believe that the safe harbor conditions in the final rule and the fact that the safe harbor is temporary should adequately address our concerns," writes the OIG. "We intend to monitor the situation. If abuses occur, we may revisit our determination."

Resource

- OIG final rule on safe harbors for certain electronic prescribing and electronic health records arrangements, August 8 *Federal Register*: www.oig.hhs.gov.

Lab Competitive Bidding Demo To Begin April 1, 2007

Medicare will implement the competitive bidding demonstration for Part B laboratory services on April 1, 2007, for the first competitive bidding area, the Centers for Medicare and Medicaid Services (CMS) said July 28.

The demonstration in the second competitive bidding area will begin a year later, on April 1, 2008. CMS has yet to announce the two areas selected for the demo, though industry observers expect the announcement soon.

Design of the demonstration, described in Transmittal 48 (Change Request 5205), largely follows the recommendations of the Research Triangle Institute International (RTI), the contractor for the project (*GCR*, June 2006, p. 1).

Both required and nonrequired bidders that bid and lose will not be paid anything by Medicare (neither under the Part B clinical laboratory fee schedule nor under the competitively bid price) for demonstration tests provided to beneficiaries in the CBA.

Laboratory firms with $100,000 or more in annual Medicare Part B (fee-for-service) payments as of calendar year 2005 for "demonstration tests" provided to beneficiaries residing in the competitive bidding area (CBA) will be required to bid in the demo. Labs with less than $100,000 in Medicare Part B payments for those tests will not be required to bid.

Both required and nonrequired bidders that bid and win will be paid the laboratory competitive bidding demonstration fee schedule for demonstration tests provided to beneficiaries in the CBA. These labs will be labeled "winners."

Both required and nonrequired bidders that bid and lose will not be paid anything by Medicare (neither under the Part B clinical laboratory fee schedule nor under the competitively bid price) for demonstration tests provided to beneficiaries in the CBA.

Similarly, required bidders that do not bid will not be paid anything by Medicare for the demo tests. These labs will be labeled "nonwinners."

Nonwinner laboratories that furnish a demonstration test to a Medicare beneficiary residing in the CBA during the demo have no appeal rights when Medicare payment for the test is denied. Moreover, nonwinner laboratories may not charge the beneficiary for the test.

"Passive laboratory firms"—that is, nonrequired bidders that do not bid—will be paid the demonstration fee schedule for demonstration tests provided to beneficiaries residing in the CBA up to an annual ceiling of $100,000. Passive lab firms exceeding the annual ceiling by $25,000 or more will be terminated from the project and will not be paid anything by Medicare for the demo tests for the duration of the demonstration.

Physician office laboratory (POL) testing and hospital outpatient testing are not included in the demonstration, except where the physician office or hospital lab functions as an independent lab by performing nonpatient testing, says CMS.

For demonstration-covered laboratory tests, only the laboratory that performs the test may bill for the service, and only winning or passive laboratories are eligible to receive the lab competitive bidding demo fee schedule payment. Although nonwinner labs may not bill either Medicare or the beneficiary for any demonstration-covered services, those labs may refer such services to a winner lab or a passive lab.

For all other tests (i.e., those not covered under the demonstration or for tests for beneficiaries not residing in the service area), all labs shall be paid according to the clinical laboratory fee schedule.

Resource

- Transmittal 48, Change Request 5205, July 28, 2006: *www.cms.hhs.gov/Transmittals/2006Trans/list.asp*

UroCor Executives Acquitted On Fraud Charges

Three former executives of UroCor Inc., an Oklahoma City urology laboratory, have been acquitted of criminal charges by a federal jury.

William Hagstrom, Mark Dimitroff, and Michael McDonald were charged in 2005 with violating the federal anti-kickback law between 1993 and 1999.

The U.S. attorney in Oklahoma City alleged that UroCor charged discount prices to doctors who turned around and billed private insurance companies at a much higher rate for the lab work.

Doctors were charged as little as $2.75 for a PSA test and received reimbursement of $25 and more, according to the indictment, which alleged that the discount was a kickback to induce the doctors to also refer work covered by Medicare.

UroCor is now a division of LabCorp. The illegal activity alleged in the indictment occurred before UroCor was sold, and none of the three executives named in the indictment still work for UroCor. The three executives denied wrongdoing.

The UroCor trial began in early June and lasted only three weeks. The case is significant because it is the first criminal case involving anti-kickback violations brought against executives of a public lab company.

Ex-Impath Officials Sentenced In Fraud Case; Adelson Gets 42 Months Jail Time

Richard Adelson, former president of Impath Inc., a cancer diagnosis testing company, has been sentenced to $3^1/_2$ years in prison, fined $1.2 million, and ordered to pay $50 million in restitution for his role in materially overstating the financial results of the company.

Adelson was convicted in February of conspiracy, securities fraud, and filing false statements with the Securities & Exchange Commission. Judge Jed Rakoff of the U.S. District Court in Manhattan agreed to permit Adelson to remain free on $1 million bond pending his appeal.

In separate sentencing on June 13, four other defendants in the case found out what their punishments would be. David Cammarata, former chief financial officer, pled guilty to five counts and will spend one month in jail for each count, to be served concurrently, followed by five years of supervised release.

Peter Torres, former vice president of finance, pled guilty to four counts. He received credit for time served and will have three years of supervised release.

Karin Gardner, former controller, pled guilty to four counts and also received credit for time served and three years supervised release. Kenneth Jugan, former national billing director, pled guilty to three counts and was credited with time served. He, too, will have three years of supervised release.

Impath's former chairman and CEO, Anu Saad, Ph.D., who pled guilty to three counts, was sentenced in January to three months in prison and two years of supervised release. She also was required to pay a $6,900 fine and a special assessment of $300.

Robert McKie, former vice president, reached a civil settlement with the SEC, although he did not admit guilt. He paid a penalty of $150,000 and returned about $100,000 in bonuses.

According to the March 2005 indictment, the Impath officials conspired to manipulate the company's finances to produce as much as $64 million in "phantom revenue" between 1999 and 2002. Impath filed for bankruptcy in September 2003 and was later purchased by Genzyme Corp.

COMPLIANCE PERSPECTIVES

Legislatures Weigh Benefits & Burdens Of Enacting State *Qui Tam* Statutes

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As state legislatures reconvene this fall, several will again take up measures that would add *qui tam* provisions modeled on the federal False Claims Act (FCA) to the existing tools available to address fraud and abuse of state Medicaid funds. Last spring, legislators in more than a dozen states took up the debate over the costs and benefits of *qui tam* litigation, spurred by financial incentives for states that Congress enacted last February in the Deficit Reduction Act of 2005 (DRA).

Were the state measures to pass, whistleblowers and their attorneys would gain substantial, additional financial rewards from allegations of Medicaid fraud, increasing their shares from a rough average of 12% of state and federal recoveries to 20% of those recoveries, for doing little more than they do now under the federal statute.

Despite the possibility of additional recoveries through the DRA, the actual benefits to the states of a parallel *qui tam* regime is less clear. A few have debated *qui tam* provisions, but as of yet, no state has adopted a new FCA or a new *qui tam* provision. When faced with the prospect of limited financial benefit and increased administrative burdens, few state legislatures appear willing to pursue the DRA incentive and join the ranks of states with Medicaid *qui tam* statutes.

FCA *Qui Tam* Provisions

The *qui tam* provisions of FCA statutes authorize a whistleblower (or relator) to commence an FCA action on behalf of the government and the whistleblower by filing, under seal, a civil complaint alleging that a person or entity has submitted or caused the submission of false claims to a government, and provide that the whistleblower (typically represented by contingent fee attorneys) receives a bounty or "share" of the government's recoveries. Under the federal FCA, the government may recover up to treble damages plus a civil penalty of $5,500 to $11,000 per false claim submitted. The federal statute caps the relator's share at 30% of the federal funds recovered by settlement or judgment.[1]

Qui Tam Provisions Of The DRA

Citing the need for greater vigilance in combating Medicaid fraud, Congress enacted provisions in the DRA that purport to provide incentives to encourage states to enact laws modeled on the *qui tam* provisions.[2] The DRA incentive is available only if the state statute assures that whistleblowers receive a significant share of the state's recovery.

Currently, most states do not have *qui tam* provisions and do not pay relators any share of that recovery. These non-*qui tam* states do participate and recover in Medicaid cases investigated under the federal statute. In most non-*qui tam* states, the net impact of enacting a *qui tam* statute will be that the state will recover few, if any, additional dollars; the DRA incentive payments may not even cover the cost of paying whistleblowers their additional rewards.

[1] *See* 31 U.S.C. §§ 3730(d)(1)-(2) (2000). [2] *See* Deficit Reduction Act § 6031.

The DRA incentive would divert funds from federal Medicaid fraud recoveries to reward states that enact statutes modeled on the federal *qui tam* provisions. As amended, the Medicaid statute now provides that "the Federal medical assistance percentage" of any amount recovered in an action brought under a qualifying state FCA will be "decreased by 10 percentage points." In a state where the federal government reimburses 60% of state Medicaid expenses, instead of receiving a 40% share of a Medicaid fraud settlement, the state would receive a 50% share.

To receive the 10% bonus, the DRA requires that the HHS Inspector General, "in consultation with the Attorney General, determine that the State has in effect a law that meets [certain] requirements:"

1 The law establishes liability to the State for false or fraudulent claims described in [the federal FCA] with respect to any expenditure described in [the Medicaid statute];

2 The law contains provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in [the federal FCA];

3 The law contains a requirement for filing an action under seal for 60 days with review by the State Attorney General; and

4 The law contains a civil penalty that is not less than the amount of the civil penalty authorized [by the federal FCA].

Existing Incentives Yield Substantial Recoveries

In enacting the DRA, Congress failed to account for the fact that existing incentives already enable federal and state prosecutors to detect and pursue allegations of Medicaid fraud. Federal investigations of pharmaceutical manufacturers, whose products consume a substantial portion of each state's Medicaid dollars, best illustrate the point. Federal officials have reported that more than 150 such cases were under active investigation as of early 2006. In recent years, joint state and federal investigations of pharmaceutical manufacturers have recovered hundreds of millions of dollars for state Medicaid programs. The DRA provisions offer little, if anything, to improve on these successful enforcement initiatives.

Today, whistleblowers file Medicaid cases under the federal FCA, and when they do even states without *qui tam* statutes recover damages and obtain information to enable prosecution of state crimes. Over the past 15 years of aggressive healthcare fraud enforcement, state and federal prosecutors have developed working protocols through which they share evidence as necessary in investigating each federal Medicaid *qui tam* case. Federal prosecutors work with state employees to determine whether and how the alleged fraud implicated the particular *state* reimbursement scheme at issue.

In cases involving a single state's Medicaid program, federal prosecutors work with the state's Medicaid Fraud Control Unit (MFCU). In national cases, MFCUs have developed a mechanism for coordinating the interactions of multiple states with the federal investigation. Working through the National Association of MFCUs (NAMFCU), teams of MFCU lawyers serve as liaisons to state Medicaid program officials, MFCUs, and state prosecutors to facilitate a coordinated investigation and either negotiation of a "global" resolution or coordinated litigation.

As these cases settle (very few are litigated), the federal government recovers its damages and penalties by compromising federal FCA claims and the states recover their damages by compromising state common law or statutory claims. Relators' shares of the "proceeds" in such cases typically are measured as a percentage of, and paid from, the federal recovery. Indeed, states without *qui tam* statutes have no obligation to share their recovery with the relator and return the full recovery to their state treasuries. The DRA provisions have the potential to alter this successful arrangement.

DRA Incentives Shift Recoveries From States To Whistleblowers

The DRA offers states little financial incentive to adopt *qui tam* statutes. An example offered by Taxpayers Against Fraud (TAF), an advocacy group organized by relators' attorneys, illustrates this point. In a recent settlement of an alleged national Medicaid fraud, New York recovered $80 million. TAF estimates that recovery to be 50% of the $160 million in New York Medicaid program loss attributable to the alleged fraud. Since New York did not have a *qui tam* provision (or a civil FCA), no share of the state's recovery was paid to the whistleblowers, who received over $51 million from the federal government and undisclosed additional amounts from *qui tam* states that participated in the settlement.

If New York had a DRA-qualifying *qui tam* statute in such a case, as TAF points out, the state would have recovered $96 million (60% of $160 million), or a 20% increase in its recovery. Omitted from that analysis, however, is New York's obligation to pay the relators a share of its recovery. Assuming payment of an average relator's share of 20%, New York would have been obligated to pay $19.2 million to the relators. Thus, in one of the largest Medicaid fraud cases settled to date, enactment of a DRA-compliant *qui tam* statute would have *reduced* the actual recovery to New York by $3.2 million, a *decrease* of 4%. Relators, on the other hand, would have gained a windfall, adding $19.2 million to their other rewards.

The adverse financial effect on non-*qui tam* states would become more pronounced if a trend develops toward increasing the percentage of settlement amounts allocated to relators' shares. The recent *Parke-Davis* settlement provides an illuminating example of the potential costs of state *qui tam* provisions in this context. In settling the federal *qui tam* claims, the U.S. Department of Justice stipulated that the relator should receive a reward of 29.4% of the federal share of Medicaid recoveries, a total of $24.6 million.

As a participant in the parallel state Medicaid settlement, New York received over $12.8 million—50% of the recovery of $25.6 million attributable to New York Medicaid program losses. If New York had enacted a DRA-compliant *qui tam* statute, the DRA incentive would have increased its recovery by $2.56 million (10% of $25.6 million). However, assuming consistency among state and federal relator's share rewards, New York would have been obligated to pay $4.5 million of its recovery to the relator. The amount left to compensate for losses to New York Medicaid would *decrease* from $12.8 million to $10.9 million, *reducing* New York's actual recovery by 15%, a *loss* to the state of nearly $2 million.

No Real Gains To States Absent Increases In *Qui Tam* Filings

Similar examples can be drawn from other states participating in fraud investigations and settlements. The potential impact of the DRA incentive is less significant in states where the federal government pays a larger portion of the state's Medicaid costs. States where the federal government pays over 60% of Medicaid costs may gain rather than lose dollars. On average, however, the net impact on states would most likely be an increase of less than half of one percent (0.5%).

The only creditable gain to a state that accepts the DRA incentive would come from whistleblowers uncovering new Medicaid fraud schemes beyond those they currently allege through federal *qui tam* filings. The DRA provisions presume that offering additional financial rewards will cause potential relators to disclose additional fraud schemes. No empirical data and no practical experience suggest that potential whistleblowers decline to disclose Medicaid frauds because the federal reward alone is insufficient. Absent such evidence, states have little financial incentive to join the ranks of states with Medicaid *qui tam* statutes.

Controversy Threatens To Limit Eligibility

Comments by authors of the DRA provi-

sions suggest that its rewards ought not be available to states that stray from the federal *qui tam* model in their attempts to control or reduce the burdens filings under state *qui tam* provisions would place on already overburdened state programs and law enforcement. For example, on April 26, in a letter to the HHS Inspector General and the Attorney General, Sen. Charles Grassley advanced an interpretation of the DRA that would not allow states to receive the DRA incentive if their statutes "do not permit *qui tam* actions to proceed once [the states] decline to intervene." Sen. Grassley argued that unless a statute allows relators to proceed in a declined case, the state has not met the DRA requirement that the statute be "at least as effective in rewarding and facilitating *qui tam* actions" as the federal FCA.

To the contrary, the DRA provision calling on states to reward and facilitate *qui tam* actions should not be interpreted to undermine the states' discretion in the allocation and use of their limited resources. Because the government must appear in all declined cases, continued pursuit of such cases drains the state's resources despite its determination that the action did not merit intervention. Some states have explored authorizing the state Attorney General to hire a private attorney to pursue meritorious complaints as one alternative to avoid unchecked activity by relators' attorneys. That a state elects to codify its prosecutorial discretion and utilize alternative methods to pursue legitimate complaints does not indicate that the state has failed to reward or facilitate *qui tam* litigation.

Moreover, practical experience with declined cases argues against their unfettered use. Although procedurally different from the federal model, a state mechanism authorizing the automatic dismissal of declined *qui tam* actions is substantively similar to the federal government's authority to obtain dismissal of declined cases. Declined *qui tam* cases that proceed to judgment typically result in adverse precedents that bind both future relators and the government.

Thus, a state *qui tam* statute with an automatic dismissal provision may go further to facilitate future *qui tam* actions than its federal counterpart. Despite the evidence supporting an expansive and flexible view of the DRA standard, some continue to advance a restrictive interpretation of when a state is eligible for the DRA incentive.

State Legislatures Weigh Benefits Of Enacting *Qui Tam* Provisions

As noted above, of the states known to have introduced FCA legislation since the DRA was enacted, no state has passed new *qui tam* provisions (prior to the passage of the DRA, 17 states had *qui tam* provisions in place). Specific reasons for this inaction are unclear, but it is likely that uncertainty as to what kind of statutes will earn a state an additional share of the recovery and concern about the resources required by such statutes have chilled initial enthusiasm. Recognizing the apparent ambivalence of many state legislators, CMS recently suggested that it will encourage state Medicaid directors to urge their legislatures to enact *qui tam* provisions. In a new report on the Medicaid Integrity Program, CMS announced that it will present state Medicaid directors with a template letter that those state employees should use to encourage states to enact FCA statutes.[3] In light of these developments, the upcoming state legislative sessions ought to prove interesting.

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For further discussion of the problems arising under state FCA statutes, see "The Proliferation of State Qui Tam Statutes and the Increasing Complexity of Multi-State Program Fraud Investigations," available in the Publications Section of www.hhlaw.com.

[3] CMS, Center for Medicaid & State Operations, *Comprehensive Medicaid Integrity Plan of the Medicaid Integrity Program: FY 2006-2001*, (July 2006) available at *www.cms.hhs.gov/Deficit ReductionAct/Downloads/CMIP%20Initial%20July% 202006.pdf.*

CMS Officials Dispute GAO Findings, *from p. 1*

inspect such labs, however, provide more advance notice about upcoming inspections than CMS allows states to provide."

The GAO concluded that weaknesses in surveys, complaint processes, and enforcement mask potential quality problems at labs. "Lab survey findings may not accurately reflect the actual quality assurance process in place on a day-to-day basis because of several shortcomings," says the report.

Despite the GAO's conclusions, CMS does a good job of overseeing lab surveys and accreditation, believes Judy Yost, director of the CMS Division of Laboratory Services. During a July 27 audio conference sponsored by Washington G-2 Reports, Yost said CMS staff are proud of their accomplishments and believe they have helped improve quality while abiding by regulatory authority.

Audio recordings from the July 27 audio conference, "Putting CLIA in the Spotlight: How Will GAO's Findings Affect CMS Policy For Your Lab?" may be ordered from our Web site at www.g2reports.com.

Even so, CMS officials agreed that they can make some improvements and are taking steps to implement them, Yost said. While labs may not see major changes to the survey and accreditation process as a result of the report, there may be some minor changes, including more consistent citations at the appropriate level by CMS surveyors, more follow up on deficiency statements and plans of correction, and a continued educational approach, with deficiencies cited when found, she explained.

The GAO made 13 recommendations to the CMS administrator to improve CLIA oversight. CMS concurred with 11 of the suggestions. The recommendations, and CMS's responses, are highlighted below:

1 Work with exempt state programs and accrediting organizations to standardize their categorization and reporting of survey findings in a way that tracks to CLIA requirements and allows for meaningful comparisons across organizations.

Response: Thomas Hamilton, director of the Survey and Certification Group at CMS, said during the June 27 hearing that CMS will work with exempt state programs and accrediting organizations to promote greater standardization of categorizing and reporting survey findings.

2 Ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS's policy for advance notice provided by state survey agencies.

Response: CMS will require any accrediting organization using announced surveys to reduce its lead time to be more consistent with CMS policy governing actions of state survey agencies.

3 Ensure that regulation of labs is the primary goal of survey organizations and that education to improve lab quality does not preclude the identification and reporting of deficiencies that affect lab testing quality.

Response: CMS agrees that education to improve lab quality should never preclude the identification of deficiencies that affect lab-testing quality. In the case of significant new requirements, and only within certain areas for the time period specified by CMS, the educational approach may include the possibility of identified deficiencies being communicated to labs without a concomitant citation (such as cytology proficiency testing implemented in 2005). CMS will refine surveyor guidance to ensure an appropriate balance between the enforcement and educational functions of the survey process.

4 Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements.

Response: CMS's policy is to use a progressive enforcement approach for successive offenders, says Yost, noting that not all subsequent citations that are similar are true repeats. CMS will develop a system to monitor repeat deficiency citations more closely and will ensure that appropriate enforcement actions are imposed more consistently when these circumstances are confirmed.

5 Require all survey organizations to develop, and require labs to prominently display, posters instructing lab workers on how to file anonymous complaints.

Response: Most states already have a complaint line in place, says Yost. In March 2006, CMS implemented a new, more sophisticated data system to receive and track complaints. It also has placed a notice on the CLIA Web site and added language to Surveyor Interpretive Guidelines describing how to file a complaint.

6 Consistent with CLIA, require quarterly proficiency testing, except when technical and scientific considerations suggest that less frequent testing is appropriate for particular examinations.

Response: CMS already made this determination, concluding on both technical and scientific grounds that proficiency testing three times per year was appropriate.

7 Ensure that evaluations of exempt state and accrediting organization inspection requirements take place prior to expiration of the period for which they are approved to ensure the continued equivalency of their requirements with CLIA.

Response: CMS has approved each accrediting organization (AO) several times and determined them to be equivalent to CLIA. Therefore, CMS is now focusing its oversight on performance; that is, the AO's enforcement of its standards.

8 Ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.

Response: CMS agrees and will make the necessary changes.

9 Allow the CLIA program to use revenues generated by the program to hire sufficient staff to fulfill its responsibilities.

Response: CMS continues to consider adjustments to CLIA staffing in CMS central and regional offices to meet statutory requirements and priorities.

10 Ensure that federal surveyors validate a sufficient number of inspections conducted by each state survey agency to allow a reasonable estimate of their performance, including a minimum of one independent validation review for each state agency surveyor.

Response: CMS will increase its efforts to ensure that federal monitoring surveys are performed annually in each state in numbers sufficient to allow a reasonable estimate of state agency performance, including increasing the number of independent reviews.

11 Require that almost all validation reviews of each accrediting organizations' surveys be an independent assessment of performance.

Response: CMS will continue to monitor and ensure that the vast preponderance of validation surveys for accrediting organizations takes the form of independent assessments.

12 Collect and routinely review standardized survey findings and other information for all survey organizations to help ensure that CLIA requirements are being enforced and to monitor the performance of each organization.

Response: CMS will explore methods to expand its collection, review, and analysis of survey findings and the follow-up actions of accrediting organizations in order to monitor, sustain, and improve performance of accrediting organizations.

13 Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation.

Response: CMS will complete the development of the CLIA enforcement database to track labs that necessitate any potential federal enforcement actions.

Resources

- GAO report, "Clinical Lab Quality: CMS and Survey Organization Oversight Should be Strengthened," (GAO-06-416), available at *www.gao.gov.*
- Judy Yost: 410-786-3407

U.S. Patents On Medical Diagnostics Valid . . . For Now

Patent owners on medical diagnostic technologies can breathe a sigh of relief in the wake of the U.S. Supreme Court's June 22 decision to dismiss the case of *Laboratory Corp. of America Holdings v. Metabolite Labs Inc.*

Linda Truong, Esq.

Seth Levy, Esq.

A ruling in the case could have "rendered invalid a host of patents on medical diagnostic technologies as claiming unpatentable subject matter," say attorneys Linda Truong and Seth Levy in an advisory bulletin issued by the law firm of Davis, Wright, Tremain LLP.

Though the court did not elaborate on its rationale for suddenly dismissing the case, it is widely believed that it was for procedural and not substantive reasons, the attorneys write. A 15-page dissent by Justice Stephen Breyer, joined by Justices John Paul Stevens and David Souter, "suggested that not only was this case ripe for review by the court, but that at least these justices would have found the patent claims at issue to be invalid," says the bulletin.

Can Natural Phenomenon Be Patented?

The specific question in this case was whether the correlation of a test result to a medical condition constitutes unpatentable subject matter as a mere "law of nature." At stake was whether a patent held by the defendant, University of Colorado-affiliated Metabolite, covers a natural phenomenon or scientific principle and is therefore not patentable under U.S. law.

Breyer's opinion suggests that he places the testing method in the category of "phenomenon of nature" that is excluded from patent protection. "The reason for the exclusion is that sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection," Breyer wrote.

The case stemmed from a 1990 patent on a widely used method for detecting vitamin B12 and folate deficiencies: the "total homocysteine-only" test, which directly assays the amino acid homocysteine.

The Supreme Court had originally granted *certiorari* to determine the question of whether a patent can claim rights to a basic scientific relationship used in medical treatment if the claim is limited to "correlating lab results."

"If the court had issued a ruling in this case, it could have had a profound impact on the patent protection sought, obtained, and enforced by the medical diagnostics industry and, depending on the breadth of the ruling, perhaps to numerous other industries as well," write Truong and Levy.

Furthermore, as recognized by the dissent, a decision upholding the patent claim could have inhibited doctors from using their best medical judgment and force them to spend unnecessary time and energy entering into license agreements, they say, citing Breyer's dissent.

However, if the patent was rendered invalid for claiming unpatentable subject matter, thousands of similar "correlation patents" could have been invalidated and the substantial investments by patentees would have been lost.

"Although the court's dismissal of LabCorp and the corresponding dissent are not binding legal precedent, this may provide some insight into the way in which the issue will be decided in the future," the attorneys write. "Today, 'correlation patents' remain valid under 35 U.S.C. section 101, but the ground on which they stand has been shaken."

Resources

- U.S. Supreme Court Opinion in *Laboratory Corp. of America Holdings v. Metabolite Labs Inc.:* www.supremecourtus.gov/opinions/05pdf/04-607.pdf
- Linda Truong: 213-633-6874
- Seth Levy: 213-633-6869

Physician Fee Schedule Changes: The Centers for Medicare & Medicaid Services (CMS) has proposed changes to reassignment and physician self-referral rules directed at ending pod and condo labs. The regulations would be amended to clarify that any reassignment of billing rights pursuant to a contractual arrangement is subject to program integrity safeguards that relate to the right to payment for diagnostic tests. The changes are included in the 2007 Medicare physician fee schedule proposed rule, announced August 8. CMS is also proposing amendments to the physician self-referral regulations to place restrictions on what types of space ownership or leasing arrangements will qualify for the in-office ancillary services exception or the physician services exception to the physician self-referral prohibition. In addition, the agency is proposing changes to the current archived specimen requirements and says it intends to terminate the technical component grandfather provisions for physician pathology services furnished to hospital patients beginning Jan. 1, 2007. The proposed rule is scheduled to be published in the *Federal Register* on August 22.

Court Recommends Tougher Sentence: A federal appeals court on July 26 recommended a 36-month minimum sentence for a former executive of a laboratory testing supplier convicted of conspiring to defraud Medicare of $5 million after finding a three-month prison sentence too lenient. The U.S. Court of Appeals for the First Circuit vacated and remanded a lower court's decision to impose a sentence of three months for William Thurston, an executive of Damon Clinical Laboratories (Needham, MA). The appeals court set a minimum sentence of 36 months. A lower court had reduced Thurston's statutory maximum sentence of 60 months to three months, saying the longer sentence would result in a disparity with the sentence of a co-defendant. The appeals court, however, found that the two co-defendants were not so similarly situated that nearly identical sentences were warranted.

New JCAHO Requirement: The Joint Commission on Accreditation of Healthcare Organizations has approved a new Accreditation Participation Requirement (APR) for the laboratory program, effective July 10. This APR requires labs to comply with a predetermined process for resolving unsuccessful proficiency testing.