



G-2

Compliance

Report



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For Hospitals, Laboratories and Physician Practices

CMS Seeks to Increase Oversight of Waived Tests

With the number of labs performing tests waived under the Clinical Laboratory Improvement Amendments (CLIA) increasing exponentially, the Centers for Medicare and Medicaid Services (CMS) is considering ways of stepping up oversight, including even seeking additional legislative authority, according to Judy Yost, director of CMS's Division of Laboratory Services.

The number of tests waived under CLIA has increased from eight to approximately 100 tests since the inception of the program in 1992, according to Yost. The number of laboratories issued a certificate of waiver has grown exponentially from 20 percent to 65 percent of the more than 214,000 laboratories enrolled.

"We truly believe that Congress did not anticipate this huge growth when it passed the CLIA law in 1988," said Yost.

CMS currently conducts on-site educational visits to approximately 2 percent of labs issued a certificate of waiver (CW) each year. Among common problems encountered: high staff turnover, lack of formal laboratory education, limited training in test performance and qual-

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Gene Patent Case May Be Decided by Supreme Court

An ongoing dispute over whether genes can be patented may ultimately go all the way to the U.S. Supreme Court if not resolved first through legislative action, predicts Beth Arnold, a patent attorney with Foley Hoag in Boston.

Commenting on a recent federal court ruling declaring invalid the patents on BRCA1 and BRCA2 genes granted to Myriad Genetics and the University of Utah Research Foundation, Arnold noted that this is just the beginning of the debate over whether genes and, potentially, other molecules constitute patentable subject matter. Arnold spoke during Washington G-2 Reports' Molecular Diagnostics Conference, held April 14-16 in Cambridge, Mass.

The genes in question in the Myriad case are associated with hereditary breast and ovarian cancer, and the patent holders claim the exclusive right to perform diagnostic testing on these genes, to license the testing to other users, and to threaten litigation for patent infringement against any unlicensed use of the genes.

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For The Last Word In Healthcare Compliance

CMS Seeks to Increase Oversight of Waived Tests, from page 1

ity assurance, lack of awareness concerning “good laboratory practice,” and partial compliance with manufacturer’s quality control instructions.

In 2006, of 1,947 CLIA-waived labs visited by CMS surveyors, 69 percent were following the manufacturers’ instructions while 31 percent were not. On a positive note, of 414 labs revisited for not following manufacturers’ instructions, 85 percent improved upon revisit, Yost explained.

Requirements for Waived Tests

To receive a certificate of waiver under CLIA, a lab must only perform tests that the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have determined to be so simple that there is little risk of error.

These tests are exempted from most CLIA requirements and the laboratories that perform them received no routine inspections. Waived laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Follow manufacturers’ test instructions.

“This shows that basic education is effective and that laboratories really want to do a good job,” she said.

Despite this, more than 6 percent of CW labs still are performing nonwaived tests, which remains a concern, noted Yost. While the site visits have found that immediate jeopardy risk of harm decreased from about half a percent in 2006 to less than a fifth of a percent in 2008, the numbers are still unacceptably high if one were to extrapolate the numbers to the entire population of labs performing waived testing, said Yost.

CMS also has found that CW labs performing voluntary proficiency testing (PT) do better on various quality measures than those that don’t perform voluntary PT. For

example, 95 percent of PT labs performed required quality control while only 75 percent of those not participating in PT did (*see chart*).

“Education is very effective, but unfortunately there isn’t money or resources under CLIA for us to expand the number of visits that we make, so we’re looking at other ways of improving oversight,” Yost says. For example, CMS plans to provide labs applying for waived status with educational material in advance of their approval. The agency also plans to collect more information on the types of tests waived labs are performing.

CW Lab Performance With Voluntary PT		
	PT	No PT
Lab has current manufacturers’ instructions	98%	88%
Performs required QC	95%	75%
Performs required function checks or calibration	75%	62%
Performs confirmatory testing	25%	15%

Source: CMS

“We’ll continue to collaborate with the Centers for Disease Control and Prevention and the accrediting organizations in our oversight of waived laboratories. We have also talked with the FDA about standardizing package inserts to help labs understand them better. And I never thought I’d say this in my lifetime, but we probably need to change the CLIA law to make it reflect the current state of problems we’re seeing in these laboratories.” 🏠

Productivity Adjustment, Lab Fee Schedule Cuts Necessary Concessions Under Reform: ACLA

The full productivity adjustment and the five-year, 1.75 percent cut in the clinical lab fee schedule contained in the health care reform legislation will save the government a total of \$10 billion over 10 years and were necessary concessions for the government to expand coverage to an estimated 31 million Americans, explained Alan Mertz, president of the American Clinical Laboratory Association (ACLA), during a conference call in early April.

“We believe that this will allow millions of more Americans to get access to valuable diagnostic laboratory services, which we believe are the foundation to good health care and outcomes for people,” he said. “All providers had to make a contribution to this, and we were willing to do our proportional part to provide savings to the government so they could expand coverage.”

The two initiatives that directly impact labs are, of course, the two reimbursement cuts—the productivity adjustment and the five-year cut to the lab fee schedule that will begin in 2011. The productivity adjustment repealed the 0.5 percent payment that was initially put in place in 2008 and set to continue for five years until 2013. This reduction was agreed to by the government and the lab groups in exchange for the repeal of competitive bidding in 2008. This payment reduction will be replaced with a permanent full productivity adjustment beginning in 2011.

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- Alan Mertz

“For labs, the critical issue is that we are the only provider for which the productivity adjustment could have cut below zero, resulting in a negative update,” said Mertz, who added that there are provisions in the reform legislation protecting against a zero update. The Congressional Budget Office (CBO) estimates that the resulting savings will be \$5 billion over 10 years.

Lab Fee Schedule Cut

The second adjustment is the 1.75 percent annual cut to the clinical lab fee schedules from 2011 to 2015. “This adjustment could drive us below zero if the consumer price index (CPI) update is less than 1.75, but it does end after 2015,” said Mertz.

CBO estimates this cut will also result in \$5 billion in savings over 10 years, even though the cut is for five years. The savings occurs in the outlying years because the cut reduces the baseline spending by between 9 percent and 10 percent, he added.

“This is assuming that CBO’s estimate of the annual consumer price index ranges from 1.3 percent to about 1.9 percent,” said Mertz, adding that this was one of the issues that ACLA factored in when deciding whether to accept this cut in exchange for the repeal of the \$7.5 billion annual tax, which was proposed by the Senate Finance Committee last summer.

“The deal that ACLA and most all of the rest of lab industry groups made in September 2009 was that a 1.75 percent cut for five years on the clinical lab fee schedule was far preferable to a permanent 2 to 3 percent tax on all lab revenue,”

he explained. "We figured out that in any year where inflation is 3 percent or more, we will actually not be cut at all. If the inflation is over 3 percent, then we will actually get an increase."

Positive Provisions

Apart from the reimbursement cuts, ACLA is applauding a number of the reform legislation's provisions. Notably, the legislation contains incentives for prevention and wellness testing. "Under the insurance plans in the new network exchange, there are some helpful provisions that provide testing coverage related to prevention and wellness that would eliminate or sharply limit the copays, deductibles, and out-of-pocket costs for these services," said Mertz.

To be included in these service provisions, the testing had to receive an "A" or "B" rating from the U.S. Preventive Services Task Force (USPSTF). Mertz said that there was concern that certain testing services would be excluded following USPSTF's November 2009 mammography guidelines that recommended against routine mammography screening for women in their 40s, as well as a reduction in frequency for screening older women at average risk of developing breast cancer.

ACLA was also pleased that the health care reform legislation included an extension of the grandfather clause allowing independent labs to receive payment for the technical component of certain pathology interpretation services. The extension is through the end of this year. "We would like a permanent extension of the TC, but when we saw what was happening with the rural extenders provision, as well as the SGR [sustainable growth rate formula-related 21 percent physician fee cut], which are now falling outside of health care reform, had we not had this extension in the Senate bill, I think we would still be in a situation where the TC had not been extended, but it is now, and retroactively extended back to January," said Mertz. 🏛️

CMS Resumes Payment for Pathology TC Claims

CMS is now accepting claims from independent clinical labs that bill for the technical component (TC) for pathology services under the "grandfather" protection. They may now submit claims for these services furnished on and after Jan. 1 of this year and be paid, the agency announced March 30.

The "grandfather" protection allows independent clinical laboratories to bill Medicare Part B separately for the TC of pathology services to inpatients and outpatients. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

CMS acted in response to the extension of the "grandfather" protection granted in the new health care reform law. The protection lapsed at the end of 2009 and was not restored until the president signed the Patient Protection and Affordable Care Act on March 23. It applies to claims with dates of service on and after Jan. 1, 2010, through Dec. 31, 2010.

The agency had previously advised qualified labs to hold these claims pending legislative action and said that until Congress acted, it would not pay any that were submitted. The agency is now advising labs to contact their Medicare contractor if they previously submitted a claim for services covered by the "grandfather" protection that was denied. 🏛️

COMPLIANCE PERSPECTIVES



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Among Health Reform's Hidden Costs: Expanded Reach Enforcement of Fraud and Abuse Laws

Beyond the politics and rhetoric, health reform involves a simple trade-off—in return for expanded coverage and access to more patients, laboratories and other providers can expect lower reimbursement and, over the longer term, substantial changes to the health care delivery system to further control unsustainable growth rates in health care spending.

Mostly overlooked in this equation so far, however, have been the many provisions in the new health care reform law that significantly strengthen the federal government's hand in pursuing fraud and abuse. As access to insurance coverage expands in the coming years, Congress has made clear in the Patient Protection and Affordable Care Act signed into law in March that it expects the expansion to be accompanied by serious efforts to crack down on fraud and abuse in the health care system.

The challenge for laboratories and other providers will be to keep up with the changes and to adapt their internal compliance programs to match the scrutiny that is on its way with health reform.

After nearly two decades of government focus on the anti-kickback statute, the Stark law and the False Claims Act, at first it may be difficult to imagine what remains undone on the fraud and abuse legal front. But the changes are real and will require every laboratory and every provider to revisit and renew their commitment to compliance. Indeed, there is no doubt that the intensity of the government's enforcement efforts will continue to increase as a consequence of health

reform and the expanded fraud and abuse authorities contained in the act.

The challenge for laboratories and other providers will be to keep up with the changes and to adapt their internal compliance programs to match the scrutiny that is on its way with health reform.

New Overpayment Refund Requirements

For example, although it has always been advisable to promptly refund Medicare or Medicaid overpayments, the timelines and legal consequences for failing to do so were somewhat ambiguous. To remove any uncertainty about that, the health reform act sets forth an affirmative obligation for any provider that has received an overpayment to report and return the overpayment to Medicare, Medicaid, or the Children's Health Insurance Program within 60 days after it is identified, along with a written notification of the reason for the overpayment.

Moreover, the act specifically defines overpayments retained beyond the deadline as an "obligation" under the False Claims Act, as well as a basis for civil money penalties. This, of course, opens the door to whistleblower actions and the possibility of treble damages for improperly retained overpayments.

Thus, the stakes have gone up significantly for laboratories and other providers that do not have systems in place to proactively work government program credit balances, identify overpayments, and issue timely refunds. If they are not there already, those systems need to become a core compliance function for every provider.

New and Enhanced Penalty Provisions and Investigative Powers

In a number of areas, the health reform act amends the Medicare and Medicaid civil money penalty provisions to add to and enhance the penalties for health care fraud. Most notably, in addition to the overpayment refund provision noted above, the act authorizes civil money penalties for:

- ❖ Knowingly making false statements, an omission, or a misrepresentation of a material fact on a provider enrollment application, which also is made grounds for exclusion from federal health care programs;
- ❖ Knowingly making or causing to be made any false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal health care program; and
- ❖ Failure to grant timely access to the Health and Human Services Office of Inspector General (OIG) upon reasonable request for the purpose of audits, investigations, evaluations, or other statutory functions.

Along with these new penalties, the act also expands the OIG's subpoena authority and its ability to obtain any records necessary for evaluating "the economy, efficiency, and effectiveness" of the federal health care programs. These expanded

Other changes will make it easier for whistleblowers to bring a False Claims Act action based on information that already is in the public domain.

powers come at time when the OIG already has made clear its intent to focus more attention on the conduct of individuals responsible for health care fraud—including physicians and health care company executives—and to increasingly use its now enhanced civil money penalty and exclusion authorities against such individuals.

In addition, the act enhances the government's ability to suspend Medicare payments pending the investigation of any credible allegations of fraud.

Making Kickback and False Claims Cases Easier for Government and Whistleblowers

Despite the new penalty provisions in the health reform act, the anti-kickback statute and the False Claims Act will continue to be the government's two primary weapons against health care fraud and abuse. Recognizing this, the act includes a number of important changes designed to ease the legal burdens for the government and whistleblowers—who, under the "qui tam" provisions of the False Claims Act, initiate as many as 80 percent of health care fraud investigations—in pursuing cases under the anti-kickback statute and the False Claims Act. This, in turn, is likely to lead to the filing of even more cases.

In particular, the act provides that claims resulting from a violation of the anti-kickback statute also constitute false or fraudulent claims for purposes of the False Claims Act. The act also amends the intent requirement under the anti-kickback statute to state that a person need not have actual knowledge of the statute, or specific intent to violate it, for there to be a violation.

Other changes will make it easier for whistleblowers to bring a False Claims Act action based on information that already is in the public domain. Under prior law, cases were dismissed if the allegations were based on "public disclosures," such

as government audits or news media reports, unless the whistleblower was the original source of the information.

Now, under the act, state or local government publications are no longer considered public disclosures, and whistleblowers may proceed with a case based on federal sources or news media reports, as long as they have some independent knowledge that adds to the publicly disclosed allegations. Moreover, even where a whistleblower does not qualify as an original source, dismissal of the case is no longer required if the government opposes it. As a result, providers can expect to see more opportunistic—some might say parasitic—whistleblowers trying to capitalize on government audits and other public information as the basis for their own False Claims Act cases.

In addition, the act provides that once the state-run insurance exchanges at the heart of health reform's primary goal of extending coverage to the uninsured become operational in 2014, claims submitted to plans purchased through those exchanges will be subject to the False Claims Act.

Stark Law Changes Bring Bad News to Physician-Owned Hospitals, Good News to Others

After years of debate on the merits of physician-owned hospitals and their threat to community hospitals, hospital interests have prevailed through a provision in the health reform act that amends the Stark physician self-referral law to prevent the formation of new physician-owned hospitals. Subject to certain exceptions, the Stark law generally prohibits physicians from referring Medicare patients to entities with which they have a financial relationship for certain designated health services, including hospital services.

Under the change, existing physician-owned hospitals may continue to qualify for the hospital ownership exception to Stark, but the act prohibits such hospitals from increasing the percentage of their physician owners, significantly restricts their ability to expand, and imposes additional compliance and safety requirements.

While the manufacturers subject to this so-called "sunshine" provision include the makers of test kits approved or cleared by the Food and Drug Administration as devices, it will have limited direct application to laboratories.

At the same time, an important enhancement to Stark was made with the creation of a new self-disclosure protocol for violations. This was made necessary by the government's belief that it previously lacked the legal authority to compromise the repayment obligations in Stark, which require the refund of all Medicare payments made pursuant to a prohibited referral relationship. As a result, even minor, technical violations

of the Stark law could lead to outsized liability if a laboratory, hospital, or other provider was forced to refund all Medicare payments related to a noncompliant relationship. The creation of False Claims Act liability for overpayments further highlighted the need for a rationale mechanism for settling Stark law matters. The act helpfully gives the Centers for Medicare and Medicaid Services authority to compromise any amount due and owing for Stark law violations.

Sunshine on Relationships Between Physicians and Industry

The health reform act also requires that pharmaceutical and medical device manufacturers track and report payments to physicians and teaching hospitals for posting on a publicly available Web site. The first of these disclosures will be due on March 31, 2013, for payments made during calendar year 2012. Annual disclosures

will follow and will need to include not only research, advisory board, consulting, and intellectual property payments, but also gifts, meals, travel, entertainment, and other “transfers of value.”

For all laboratories, the enhanced fraud and abuse provisions of the act are another seminal event that requires them to review the adequacy of existing compliance controls to ensure they will stand up to the increased legal scrutiny that is certain to come.

While the manufacturers subject to this so-called “sunshine” provision include the makers of test kits approved or cleared by the Food and Drug Administration as devices, it will have limited direct application to laboratories. The fact of the disclosures, however, will continue to affect attitudes on what are the acceptable norms for the provision of gifts, meals, and other business courtesies to referring physicians. Voluntary codes of ethics in the pharmaceutical and device sectors

adopted by organizations like PhRMA and AdvaMed have become much more restrictive in recent years, essentially deeming out-of-bounds all forms of gifts and entertainment, such as sporting events and theater tickets.

In an era of increased transparency and scrutiny of the relationship between physicians and industry, laboratories out of step with the evolving standards will be at greater risk under the fraud and abuse laws.

Now Is the Time to Revisit Compliance Efforts

There is no question that health reform has brought with it new pressures to eliminate fraud and abuse, and that pressure no doubt will increase compliance burdens for the entire health care industry. More cases will be brought, and more novel legal theories will be pursued as part of the government’s broader efforts to stem the growth of health care costs.

In the 1990s, a series of high-profile settlements was a wake-up call to the laboratory industry that it needed to develop compliance programs to help prevent legal violations. Many have not felt the need to seriously revisit their compliance programs since, while others have entered the industry without the perspective gained from the prior experience. For all laboratories, the enhanced fraud and abuse provisions of the act are another seminal event that requires them to review the adequacy of existing compliance controls to ensure they will stand up to the increased legal scrutiny that is certain to come.

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Beth Arnold, Esq.

Gene Patent Case May Be Decided by Supreme Court, *from page 1*

The ruling is the latest in the lawsuit filed in May 2009 by the American Civil Liberties Union (ACLU) on behalf of individual women at risk, women's health groups, pathology groups, medical organizations, and research centers (*Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*).

Myriad Genetics has said it will appeal, the next step to what legal analysts see as a long and winding road. The case will go to the federal circuit court of appeals in Washington, D.C., which handles all patent law challenges. And it is likely to go from there to the U.S. Supreme Court.

Core of the Case

In the 1990s, Myriad Genetics obtained several patents on the isolated genes BRCA1 and BRCA2 and the methods of using these genes to identify certain mutations in an individual's genetic makeup. Of these patents, seven were at issue in the lawsuit, and the judge invalidated them.

Attorneys for Myriad cited several case precedents in its defense, arguing that it did not hold a patent on information, but rather on a chemical composition, and noting that the U.S. patent office has ruled that genes can be patented if they are "isolated from their natural state and purified." The attorneys also said that a decision to invalidate the patents would "lead to the invalidity of thousands of biotechnology patents and effectively unravel the foundation of the entire biotechnology industry. Numerous therapeutic drugs and diagnostic tests in development would be jeopardized."

ACLU attorneys countered that "isolating" a gene, no matter how difficult and ingenious, does not alter the structure of the DNA itself, which is a product of nature and cannot be patented.

Judge Robert Sweet of the U.S. District Court for the Southern District of New York agreed with the plaintiffs' argument, saying that purifying a product of nature alone does not create subject matter that is patentable. The purified product must have "markedly different characteristics" from naturally occurring substances. But the BRCA genes as claimed are not "markedly different" from their native DNA, he ruled, and thus cannot be patented.

He also dismissed Myriad's argument that the isolated genes can be patented like other chemical compounds found in cells, saying the genes have "informational quality" that makes them unique. The judge released the U.S. patent office as a defendant in the lawsuit. He said that because he ruled in favor of the plaintiffs, it was unnecessary to address the ACLU's constitutional challenge to human gene patents on First Amendment grounds.

Diagnostic Method Claims

The boundaries of patent eligibility for biotechnology process, including diagnostics, have been the subject of recent debate and speculation following the *In re Bilski*, *Classen*, and *Prometheus* decisions, says Arnold. For the method claim-in-suit, Sweet relied on the Federal Circuit's decision in *In re Bilski* as "the definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself."

Under this "machine or transformation" test, "[a] claimed process is surely patent-eligible if: (1) it is tied to a particular machine or apparatus, or (2) it

transforms from a particular article into a different state or thing.” Applying the *Bilski* test, the court held that the method claims-in-suit are directed only to the abstract mental processes of “comparing” or “analyzing” gene sequences and thus are not patent-eligible subject matter.

Reaction to the Ruling

Myriad Genetics President and CEO Peter Meldrum said, “While we are disappointed that Judge Sweet did not follow prior judicial precedent or Congress’s intent that the Patent Act be broadly construed and applied, we are very confident that the [appellate court] will reverse this decision and uphold the patent claims being challenged. More importantly, we do not believe that the final outcome will have a material impact on [our] operations due to the patent protection [we have on our] remaining patents.”

There are 164 claims under the seven patents that were not challenged, and Myriad holds an additional 16 covering its BRACAnalysis® test that were not challenged.

The ACLU hailed Sweet’s decision, noting “it is the first time a court has found human gene patents invalid and calls into question the validity of patents now held on approximately 2,000 human genes.” These include, among others, genes associated with Alzheimer’s disease, muscular dystrophy, colon cancer, and asthma.

“This is a victory for the free flow of ideas in scientific research,” said ACLU staff attorney Chris Hansen. “The human genome, like the structure of blood, air, or water, was discovered, not created. There is an endless amount of information on genes that begs for further discovery, and gene patents put up unacceptable barriers to the free exchange of ideas.”

The ACLU also said Myriad’s monopoly on the BRCA genes makes it impossible for women to access alternate tests or get a comprehensive second opinion about their results. The high cost of Myriad’s tests (roughly \$3,200) further limits access, the ACLU said.

“The court correctly saw that companies should not be able to own the rights to a piece of the human genome,” said Daniel B. Ravicher, co-counsel in the ACLU lawsuit. “No one invented genes. Inventions are specific tests or drugs, which can be patented, but genes are not inventions.”

The American Society for Clinical Pathology (ASCP), a co-plaintiff in the lawsuit, said the ruling gives women more test options to assess their risk for breast and ovarian cancer. “It lets patients have the right to choose who will perform the test that determines whether they are at greater risk—a right they never should have been denied,” said ASCP President Mark H. Stoler, M.D., FASCP. “We have won back our natural right to own our own genes.”

SACGHS Recommends Legislative Solution

The Department of Health and Human Services (HHS) Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) weighed in earlier this year on the gene patenting issue and its implications for personalized medicine.

The panel on Feb. 5 recommended that HHS Secretary Kathleen Sebelius limit the ability of gene patent holders to keep others from using those genes for diagnostic and research purposes. The report included a statement of dissent from three committee members.

The committee approved six formal recommendations, beginning with statutory changes that would exempt from liability for gene patent infringement “anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes” and those who use patent-protected genes in research.

Subsequent recommendations, which could be accomplished more quickly, include promoting adherence to norms (such as nonexclusive licensing) that are designed to ensure access. SACGHS also called for more transparency in licensing, an advisory body on the health impact of gene patenting and licensing practices, and close work with the U.S. Patent and Trademark Office to provide expertise on genetic testing issues. 🏛️

HHS May Be Forced to Return Bid Applications From Lab Competitive Bidding Demo

The Department of Health and Human Services (HHS) may be forced to return bid applications submitted by clinical laboratories in the San Diego area as part of the now-aborted Medicare competitive bidding demonstration for Part B independent lab services.

A California court on March 18 denied a request from HHS to dismiss a challenge filed by Sharp Healthcare, Internist Laboratory, Scripps Health, the American Association of Bioanalysts, and the American Clinical Laboratory Association.

The plaintiffs in 2008 had filed a complaint with the U.S. District Court for the Southern District of California seeking an order from the court to compel the secretary of HHS to return bid applications and to preclude her from using or improperly disclosing the information set forth in those applications for any purpose.

The bid applications were submitted in early 2008, but an announcement of the winning bidders was delayed when the labs filed a motion for a temporary restraining order to enjoin the demonstration project before the Feb. 15, 2008, deadline. The court granted the motion in April 2008, and in July 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008, which repealed the original statutory authority for the demonstration project, essentially killing the project.

The labs subsequently sought to have their bid applications returned to them, but the secretary of HHS argued that the claim should be dismissed because, in part, “her retention and anticipated analysis of the bid applications is within her general authority to make recommendations concerning Medicare operations.”

In its ruling, the court says it strongly disagrees with the secretary’s position. “Because she has been purposefully coy, only the Secretary actually knows what she intends to do with the bid applications,” stated the court in its ruling. “But in the instant motion, she has the audacity to ask this court to dismiss plaintiffs’ claim because they can not accurately define her secret intent. The court will not endorse this tactic.”

Patric Hooper, an attorney with Hooper, Lundy & Bookman, says the ruling is important because it indicates that HHS will be forced to return the bid applications and not use the information contained in them to cut reimbursement for clinical laboratories. Hooper represented the plaintiffs in this case. 🏛️

HIGH COURT RULES ON QUI TAM SUITS: The False Claims Act's ban on qui tam actions founded on disclosures made in "administrative" reports, audits, and investigations extends to disclosures made in state and local forums as well as their federal counterparts, the U.S. Supreme Court ruled March 30 (*Graham County Soil and Water Conservation District v. United States ex rel. Wilson*, U.S., No. 08-304, 3/30/10). The court noted that the scope of its decision was limited by the March 23 signing into law of the Patient Protection and Affordable Care Act, which amended the relevant portions of the statute to focus exclusively on disclosures made in federal settings. However, the court said, the ruling likely will apply to all claims arising before that date. In an opinion written for the court majority by Justice John Paul Stevens, the court found nothing "inherently federal" about the word "administrative" as used in the FCA. Further, the fact that "administrative" was "sandwiched" between two terms that are "federal in nature" was not enough to persuade the court that Congress intended to strip the term of its ordinary meaning.

CMS FAULTED IN RAC ENFORCEMENT: The Centers for Medicare and Medicaid Services did not take corrective actions against 60 percent (35 out of 58) of the most significant improper payment vulnerabilities identified during the three-year recovery audit contractor (RAC) pilot program, according to a March 31 report from the Government Accountability Office (GAO). The significant vulnerabilities were defined as more than \$1 million in improper payments for medical services and more than \$500,000 for durable medical equipment. On the remaining 40 percent of significant improper payment vulnerabilities, CMS took a variety of corrective actions, including system edits, provider education, and the issuance of new regulations. The report also determined that CMS failed to establish adequate policies and procedures for handling improper payment vulnerabilities. The unaddressed improper payment vulnerabilities totaled \$231 million. The Department of Health and Human Services estimated that improper Medicare payments totaled \$24 billion in the period between April 2008 and March 2009, the report said. The GAO report is at www.gao.gov/new.items/d10143.pdf. 🏛️

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