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For Hospitals, Laboratories and Physician Practices

Lab Groups Pin Hopes on New Medicare Bill

As *GCR* went to press, Democratic and Republican lawmakers were trying to work out differences between competing versions of Medicare legislation, both of which would repeal the Medicare laboratory competitive bidding demonstration project, extend the so-called "TC (technical component) grandfather clause," and avert a 10.1 percent cut in the Medicare physician fee schedule that begins July 1.

Sen. Max Baucus (D-Mont.), the chairman of the Senate Finance Committee, and ranking minority member Charles Grassley (R-Iowa) returned to the negotiating table in an attempt to reach agreement on Medicare legislation. In mid-June, Baucus introduced the Democrats' bill (S. 3101). A few days later, Grassley introduced a Republican version of the measure (S. 3118).

Both bills would cancel the payment cut and give physicians a 1.1 percent pay hike in 2009, repeal lab competitive bidding, and extend the TC grandfather clause by 18 months, but Baucus's legislation would reduce Medicare managed care funding more than the Grassley bill would. The White House opposes those reductions. *Cont. on p. 2*

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[Editor's Note: This is the second of two articles on non-waived physician office labs.]

CLIA Quality Requirements: An Emerging Barrier for Non-Waived POLs

In the last few years, moderately complex physician office labs (POLs) have undergone a rude awakening, discovering new CLIA (Clinical Laboratory Improvement Amendments of 1988) quality requirements that take significant time and money to perform. The net result is that smaller POLs are giving up non-waived testing.

When CLIA was initially promulgated, some quality requirements for moderately complex tests were delayed until the "final" CLIA regulation was issued in 2003. During this time, POLs escaped some of the more technical aspects of quality control, such as verifying the manufacturer's method performance specifications and calibration verification. In 2003, Centers for Medicare and Medicaid Services (CMS) surveyors notified POLs during their inspections that they were expected to perform these additional quality measures.

Verifying the manufacturer's performance specifications has proved to be *Cont. on p. 9*

New Medicare Bill, *from page 1*

Congress in late 2007 approved a six-month payment increase for doctors after failing to approve a longer-term pay raise because of disagreements among lawmakers and the White House over how to pay for it, including whether to reduce managed care funding in Medicare. That law provides physicians a 0.5 percent payment increase through June 30, postponing a 10.1 percent cut that had been scheduled to take effect January 1.

Both the Baucus and Grassley measures would slice funding for managed care plans' indirect medical education funding, but the Baucus bill also would reduce reimbursement to private fee-for-service plans. Democrats blocked S. 3118 from being considered on the floor.

The American Clinical Laboratory Association (ACLA) supports both measures.

Competitive Bidding Injunction

Even as lawmakers consider repeal of the lab competitive bidding demonstration, a federal court has given the government an additional 60 days to respond to the preliminary injunction that has put the pilot project in San Diego on hold for now. The Centers for Medicare & Medicaid Services (CMS) had planned a July 1 launch.

CMS now has up to and including Aug. 8, 2008, to respond, the agency media office confirmed to Washington G-2 Reports. CMS previously got a 30-day extension from the court, through June 9, to decide on its future course. For now, CMS said, all is on hold and the agency is not commenting about its options, prompting speculation that CMS may just be waiting to see what Congress will do on the repeal language.

In granting the preliminary injunction on April 8, the court agreed with the local lab plaintiffs that the project, as designed, had the potential to cause irreparable harm to local small business labs and the Medicare beneficiaries they serve. The lawsuit was filed by three San Diego-area labs and is supported by the lab industry and professional groups nationwide.

OIG Warns Labs Against Offering 'Freebies'

The Health and Human Services Office of Inspector General (OIG) has given the thumbs-down to a clinical laboratory's proposal to provide free labeling of test tubes and specimen collection containers to dialysis facilities.

The lab requesting the opinion provides testing services to dialysis patients under service contracts with dialysis facilities. Services include tests payable under Medicare's composite rate and tests that are separately billable to Part B (noncomposite rate tests).

The lab proposed to provide the free labeling services to selected dialysis facilities, with preference for those whose business the lab wants to obtain or retain. It would not charge for the services that are currently performed internally by the dialysis facility's own personnel. The lab says its competitors are offering the same type of free services it would offer.

According to CMS payment rules, the OIG noted, lab test preparation services are included in composite rate payments, regardless of whether the services are for a composite or noncomposite rate test. Medicare does not make separate payments for administrative tasks associated with lab tests, such as labeling test tubes and specimen collection containers.

No Safe Harbor

The anti-kickback safe harbor for personal services and management contracts would not apply, the OIG concluded, because the selected dialysis facilities would not pay anything to the lab for the labeling services, despite the fact that these services have value to the facilities, given that lab specimen processing

costs (including those associated with labeling) are included in the composite rate payments that facilities receive from Medicare.

The absence of safe harbor protection is "not fatal," the OIG said, but faulted the arrangement for providing free or below-market goods or services to actual or potential referral sources. The OIG noted that it has long held that free or below-market arrangements are suspect and may violate anti-kickback laws, depending on the circumstances.

Improper Swapping of Business

The OIG further said that the proposed arrangement smacks of improper "swapping" arrangements.

In its 1994 special fraud alert on lab arrangements, the OIG warned labs against offering discounts to a dialysis facility for composite rate tests payable out of the facility's pocket, in exchange for referrals of all or most of the facility's noncomposite rate tests that the lab can bill directly to Medicare or other federal health care programs.

Based on the facts presented by the requesting party, the OIG concluded that the lab would appear to be offering nonmonetary discounts to the selected dialysis facilities for their composite rate business with the intent to induce referrals for the more lucrative noncomposite rate business.

An OIG advisory opinion is issued only to the requesting party and is limited in scope to the specific arrangement described. It has no application to, and cannot be relied on by, any other individual or entity.

Advisory opinion No. 08-06 is available online at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-06.pdf*.

Hearing Raises Questions About Order to Stop Testing

A recent administrative law hearing involving Doctors Lab, an independent rural reference laboratory in Pleasant Hill, Louisiana, and the Centers for Medicare and Medicaid Services (CMS) highlights the question of whether CMS has the authority to issue a stop testing order as part of a directed plan of correction.

Doctors Lab provides laboratory testing services to about 40 nursing homes, as well as various hospices, home health agencies, behavioral centers, and long-term psychiatric facilities in northwest and central Louisiana.

On June 1, 2007, a COLA surveyor conducted its semi-annual survey of Doctors Lab, noting only minor clinically insignificant issues. In July, the Louisiana Department of Health and Hospitals (LDHH) conducted its validation survey. The surveyor told the lab owner and director, Donna Poimboeuf, that he had found deficiencies that might result in an immediate jeopardy situation and advised her to voluntarily cease all testing until the deficiencies could be addressed.

The lab stopped testing as advised, corrected the deficiencies, and faxed documentation to the state authorities. The lab's counsel, Ray Shepard, an attorney with Duane Morris in Baltimore, notified the state that unless there were additional concerns, testing would resume at Doctors Lab. The state acknowledged receipt of the documentation submitted by the lab, requested additional information on a few items, and thanked the lab for correcting the issues identified during the survey. According to Shepard, the state official never indicated that resumption of testing at Doctors Lab was considered by LDHH to be a problem.

Two days later, on August 29, the state official faxed a letter to Poimboeuf saying LDHH had found condition-level deficiencies and was recommending that

principle sanctions be imposed by CMS. During a subsequent phone call, the state official told Poimboeuf that the August 29 letter was a form letter that should be ignored since Doctors Lab had already taken corrective action.

Notice of Sanctions

No further communication occurred until Doctors Lab received a CMS Notice of Sanctions letter on Oct. 24, 2007. Enclosed with the letter was CMS Form 2567, which for the first time gave notice to Doctors Lab of the specific deficiencies being alleged. CMS advised the lab to take immediate action to remove the jeopardy and directed it to submit a plan of correction (POC) and an allegation of compliance (AOC) by November 5. CMS also imposed a directed plan of correction and told the lab to cease patient testing for the subspecialties of chemistry, coagulation tests, hematology, and urinalysis.

"I think one of the reasons CMS wanted to settle was because it didn't want a precedent set that it could not issue a stop testing order as part of a directed plan of correction."
—Ray Shepard

After receiving the letter, Poimboeuf and Shepard spoke with the CMS representative and were advised that as long as the items identified in the CMS Form 2567 were being addressed and documented, the lab could continue its operations.

Doctors Lab submitted its POC and AOC on Nov. 5, 2007. On Jan. 9, 2008, LDHH conducted a revisit survey. On March 13, 2008, CMS notified Doctors Lab that its CLIA certificate would be suspended effective March 18, 2008, along with its right to receive reimbursement from Medicare and Medicaid. According to the notice of sanctions, CMS decided to impose the primary sanction of suspension in part because the laboratory continued testing despite the cease testing order imposed as part of the directed plan of correction. Doctors Lab requested a hearing before an administrative law judge (ALJ) on March 17 and stopped all testing as of March 18.

During the April hearing, the director of LDHH admitted she had made a number of mistakes, including recommending that CMS impose sanctions without first reviewing the corrective action that the lab had taken following the state survey, according to Shepard. Upon hearing this, the CMS representative at the hearing requested a settlement that would reinstate the lab's CLIA certificate retroactive to March 18, allow it to resume testing, and receive reimbursement from Medicare and Medicaid.

One of the issues raised during the hearing was whether a directed plan of correction can include an order to stop testing, explains Shepard. The order essentially amounts to a temporary suspension of a CLIA certificate. "There is a regulatory argument that would reason that CMS does not have the authority to issue a stop testing order as part of a directed plan of correction," says Shepard. "CMS either has to suspend you or not. It can't give you the opportunity to correct the problem and at the same time issue a suspension. That's an important distinction because once CMS has issued a suspension, you have certain statutory rights, including the right to a hearing within 60 days."

Because CMS and the lab settled this case, there was no ruling on the issue of whether CMS has the authority to issue a stop testing order as part of a directed plan of correction, but Shepard believes this issue is ripe for review.

"I think one of the reasons CMS wanted to settle was because it didn't want a precedent set that it could not issue a stop testing order as part of a directed plan of correction," notes Shepard. Based on the questions asked by the administrative law judge at the hearing, Shepard believes the judge was inclined to rule against CMS on this issue.

"The question remains," says Shepard, who hopes the issue will be resolved during future cases.

COMPLIANCE PERSPECTIVES

It Is 2008: Do You Know Where Your Select Agents Are?

Jacqueline C. Baratian

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Laboratories engaged in work on biological agents or toxins categorized as "select agents or toxins" are subject to a complex regulatory regime. Under the Select Agent Regulations, 42 C.F.R. Part 73, the U.S. Department of Health and Human Services (HHS), through the Centers for Disease Control (CDC) and the Office of the Inspector General (OIG), wields substantial authority to mandate strict compliance with the select agent regulations.

The CDC carries out detailed inspections, and the OIG, in its discretion, can impose substantial civil monetary penalties based upon alleged violations discovered during the CDC's inspections. Recent enforcement activities have shown that even minor technical violations can draw the OIG's attention, and several select agent investigations have produced sizeable settlements.

Prior to the passage of the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA), no oversight of select agents existed in the United States. In conjunction with the AEDPA, the Secretary of HHS established a list of biological agents that posed a threat to public health and safety and established procedures for the transfer of those biological agents.

Notably, in 2002, Congress significantly strengthened oversight of select agents with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The act requires that entities register with HHS if they possess, use, or transfer specified select agents and toxins that could pose a severe threat to public health and safety. The act also provides for restricted access to, and transfer of, select agents and imposes criminal and civil penalties for the inappropriate use of select agents.

A CDC workgroup maintains and periodically reviews the select agents and toxins list. Many of these are agents that laboratories will utilize, either for testing purposes or quality assistance. The Secretary of HHS delegated responsibility for promulgating and implementing regulations under the act to the CDC, where the Division of Select Agents and Toxins (DSAT), in the Coordinating Office of Terrorism Preparedness and Emergency Response, oversees the Select Agent Program.

Registration Process

The registration process requires that laboratories demonstrate compliance with the Biosafety in Microbiology and Biomedical Laboratories (BMBL) recommendations published by the CDC, through detailed safety procedures, controlled access to facilities and to select agents, and proper operations manuals.

Laboratories must provide detailed information regarding where select agents will be handled and stored and describe the goals of work to be performed on the specific select agents for which the laboratory seeks to register. Once complete, a laboratory's registration lasts for three years, but the CDC may choose to re-inspect a laboratory prior to the expiration of a laboratory's registration if: 1) any violation of the regulations is suspected; 2) a registered entity requests a significant

change to its registration; 3) or otherwise, at the CDC's discretion.

Inspections provide the CDC with an opportunity to actively exercise oversight authority. Protocol for routine inspections includes extensive review of laboratory safety and security related to possession, use, and transfer of select agents. Inspectors use detailed checklists to record their observations of the facility and its records and documentation.

As of September 2007, CDC had referred 37 entities to HHS OIG for select agent regulations violations.

Following an inspection, CDC provides laboratories with an inspection report detailing any deficiencies which laboratories must then resolve. Problems related to any part of the regulations may be cited, including issues with security, biosafety, training, restricted experiments, incident response, transfers, and records. CDC has published substantial guidance dictating the types of security plans that must be in place and other elements of compliance.

Because the regulations define "access" in this context as including "the ability to gain possession of a select agent or toxin," the CDC may consider individuals to have access to select agents regardless of whether they have actually accessed or possessed such agents.

Deficiencies or violations discovered during an inspection or otherwise can result in CDC administrative action, such as suspension of registration; referral to HHS OIG for possible imposition of civil monetary penalties; or referral to the FBI if violations may amount to criminal negligence or other crimes.

As of September 2007, CDC had referred 37 entities to HHS OIG for select agent regulations violations. The OIG collected civil monetary penalties from 10 of those entities and others since that time, as reported on the OIG's Web site. According to the limited publicly available information on previous settlements, the range of penalties runs the gamut from approximately $12,000 up to $450,000.

Texas A&M Settlement

Recent events at Texas A&M, which may result in the largest select agent settlement to date, helped to bring select agent control under congressional scrutiny and increased awareness of the Select Agent Program. The alleged incident driving the sanctions against Texas A&M involved the use of an aerosol infection chamber by two research assistants, only one of whom was properly approved to work with the select agent in question. While cleaning the chamber, the unapproved research assistant was apparently exposed to *Brucella* and later became ill.

This incident was an alleged violation of the regulations not because a lab worker became sick, but because that lab worker was not authorized to work with the select agent in question and was found to have had "access" to the select agent. Texas A&M was also found to be in violation because the alleged incident was not reported to the appropriate Select Agent Program authorities. After learning of this incident, the CDC immediately suspended select agent research in the laboratory where it had occurred. CDC then inspected the facility and issued a fairly comprehensive report listing numerous deficiencies and violations.

Along with demonstrating the high stakes involved in working with select agents, the Texas A&M case illustrates several aspects of the select agent regulations that make compliance particularly challenging. First, the definition of "access" to select agents as used in the regulations is strictly interpreted and includes not just actual access, but also the *potential* opportunity to gain such access. Second, obtaining the approval necessary before individuals can have access to select

agents can be cumbersome and in some cases confusing. Third, the difficulty of compliance is compounded by the rigor and discretion with which the regulations are enforced. Enforcement can occur for systemic issues and technical violations.

Because the regulations define "access" in this context as including "the ability to gain possession of a select agent or toxin," the CDC may consider individuals to have access to select agents regardless of whether they have actually accessed or possessed such agents. In the recent Texas A&M case, the research assistant who was not approved to access the select agent in question was present primarily to ensure proper use of the aerosol infection chamber. However, in this case, simply observing the experiment while an approved individual handled the select agent may have amounted to constructive "access," given CDC's broad interpretation of the term. Similarly, CDC alleged that storing regulated toxins, packaged for shipment, in an unsecured, unregistered location, permitted "unrestricted access" to these toxins.

Because it can be difficult for a laboratory to determine which individuals working at its facility could be deemed to have access under this broad definition, some laboratories seek approval for all researchers who work in a containment suite where select agents are held, including those individuals who do not directly work with select agents.

Because it can be difficult for a laboratory to determine which individuals working at its facility could be deemed to have access under this broad definition, some laboratories seek approval for all researchers who work in a containment suite where select agents are held, including those individuals who do not directly work with select agents.

Given the potential hazards related to working in a facility where exposure or access to select agents is even a possibility, obtaining approval and providing training for all such workers may be prudent, but it is also extremely cumbersome and time-consuming.

Cumbersome Approval Process

The approval process for individuals requires obtaining a security risk assessment (SRA) for each individual who works with a select agent. This is a multi-step process involving a series of communications between the entity's Responsible Official, the CDC, and the Criminal Justice Information Services Division (CJIS) at the FBI.

Complaints have been voiced regarding delays ranging between two and six months, for each step of this complex process, and achieving final SRA-approved status for new employees can reportedly take well over a year in some cases. Both the CDC and CJIS have experienced backlogs with these applications, and delays can sometimes derail the standard process and further complicate the approval process.

Civil monetary penalties for any violation can be substantial. Entities can be fined up to $500,000 for each violation of the select agent and toxins regulations, and an individual can be fined up to $250,000 for each violation. These lofty per-violation caps give the OIG tremendous discretion to determine an appropriate penalty based on the relevant facts. In determining an appropriate penalty on a case-by-case basis, regulations direct the OIG to consider: the nature of the alleged wrongdoing, the degree of culpability of the person against whom a penalty is proposed, history of prior offenses, financial circumstances, and other matters as justice may require.

The brief settlement narratives posted

on the OIG's Web site describe the nature of the alleged wrongdoing in prior settlements. Most of these cases allege unauthorized transfer or unauthorized possession of select agents. The breadth of violations noted by inspectors also appears to be a factor contributing to the settlement amount such that systemic problems or wide-ranging compliance issues result in higher settlements.

Civil monetary penalties for any violation can be substantial. Entities can be fined up to $500,000 for each violation of the select agent and toxins regulations, and an individual can be fined up to $250,000 for each violation.

Settlements Ran the Gamut

Cases involving either the unauthorized transfer (or receipt of transfer) of a select agent or unauthorized possession of select agents have produced a broad spectrum of settlements. In some cases involving relatively low settlements ($12,000–$25,000), it appears an unapproved individual may have had access in the form of an opportunity to gain possession of a select agent.

These cases may reflect what the OIG considers to be minor violations of regulations. Alleged wrongdoing in these cases included unauthorized transfers of select agents to a facility not registered by the CDC to possess or use such agents, receipt of select agents without appropriate CDC authorization or necessary paperwork, and possession of a select agent without proper CDC certification. A slightly higher settlement ($50,000) was reached in a case where the alleged wrongdoing included both uncertified synthesis of a select agent and transfer violations.

On the other end of the spectrum, a case involving violations of transfer requirements where vials of anthrax, categorized as a select agent, were improperly packaged by an unauthorized individual, and then released during shipment, produced a $450,000 settlement. Another high settlement, for $150,000, resulted from a case apparently involving a single unauthorized transfer of anthrax.

Systematic alleged problems with registered facilities have also produced a number of settlements in the $50,000 range. These cases include laundry lists of alleged wrongdoing such as: failures of the Responsible Official, inadequate security plans, inadequate incident response plans, inadequate training records or programs, inadequate maintenance of inspection and inventory records, or failure to meet biosafety and security standards for certain toxins. Together, these types of violations appear to indicate extensive and systemic compliance problems from the OIG's perspective.

Because we are beginning to see heightened enforcement by the OIG and increasingly higher settlements, it is vital for laboratories to understand the government's enforcement priorities and the importance of strict compliance with select agent regulations. Because select agents could be used in bio-terrorism, the government is exercising increased oversight over how these products are handled in the laboratory.

With one settlement looming at $450,000 and a potential select agent matter possibly settling for well in excess of the prior settlements, coupled with the OIG's demonstrated interest in taking action against more minor violations as well and discretion in determining appropriate civil monetary penalties, the laboratory industry should take notice and adopt any measures necessary to bring facilities into full compliance with the select agent regulations.

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CLIA Quality Requirements, *from page 1*

a major barrier for POLs to start a moderately complex testing program. For example, a practice that buys a moderately complex analyzer that uses expensive, unitized test cartridges must test at least 20 cartridges with expensive quality control material over a period of a few days and then manually calculate and interpret standard deviation and coefficient of variation statistics before using it to test patients. Method verification also requires POLs to verify the manufacturer's normal ranges (another 40 test cartridges) and reportable ranges (three more test cartridges and very expensive linearity materials).

Granted, some manufacturers of moderately complex instruments help POLs perform a part of method validation during instrument installation, but most don't. Small POLs that don't employ clinical laboratory technicians or technologists, but rather cross train medical assistants or nurses to test, are confused when their new moderately complex instrument does not automatically calculate mean, standard deviation (SD) or coefficient of variation (CV). Most physician laboratory directors have no idea how to interpret these statistics and compare them to the manufacturer's slope and intercept data.

To comply, POLs must run the new lot of quality control (QC) material in parallel with the old lot number of controls for several days. The exact number of QC samples that must be tested is a mystery, but the number 20 is mentioned throughout CMS's CLIA Interpretive Guidelines.

Transition Ends

Following criticism from the Government Accounting Office (GAO) that lab oversight wasn't sufficient to ensure quality, the educational approach to help POLs transition to new CLIA quality requirements ended in January 2008. Judy Yost, director, Division of Laboratory Services, Survey & Certification Group, CMS—who has always been a proponent of high-quality testing regardless of the lab setting—claims that CMS surveyors still explain and clarify the requirement and offer resources to POLs to facilitate compliance. Still, POLs that fail to perform method verification, or don't perform it to the satisfaction of the CMS surveyor, are now cited for a deficiency requiring corrective action.

That method verification causes financial hardship for all POLs is certain, but does it contribute to better test results? Unfortunately, no data was collected from 1992 to 2003 when 25,000+ POLs didn't perform it. One can only wonder whether patient test results were compromised during that time. The same can be said for the next new quality requirement looming on the horizon for POLs.

New Rules

The New Year had just begun when CMS dealt another blow to non-waived POLs. CMS surveyors began to spell out rules to POLs that were previously implied but not enforced for moderate complexity tests, such as a requirement to verify new lot numbers of commercial assayed controls before using. Specifically, CFR§493.1256(d)(10)(ii) states that a laboratory may use the stated value of a commercially assayed control, provided the stated value is for the methodology and instrumentation employed by the lab and *is verified by the laboratory*.

To comply, POLs must run the new lot of quality control (QC) material in parallel with the old lot number of controls for several days. The exact number of QC samples that must be tested is a mystery, but the number 20 is mentioned throughout CMS's CLIA Interpretive Guidelines.

This new requirement will have an immense impact on POLs, especially those

that are low-volume testers who currently perform CBCs and expensive or unitized tests. Thousands of POLs that acquired hematology analyzers in the past 10 years signed legally binding, multi-year lease arrangements that include automatic shipments of CBC controls every 28 days (whole blood hematology controls expire 28 days after opening).

Up to now, most POLs using assayed QC simply ensured that it fell within the manufacturer's assayed ranges listed on the package insert. Now, to comply with the new requirement, POLs must run the new lot number of QC in parallel with the old lot number several times a day for a few days and then calculate a mean and standard deviation (often manually on POL instruments) that falls in the assayed range.

CMS suggests consulting Clinical and Laboratory Standards Institute's (CLSI) document C24-A3, *Quality Control and Reference Intervals*, for guidance on establishing the value of the mean for new lots of QC material, although Yost admits, "While 20 data points from 20 days is desirable, it is recognized that it is not always practical.

"It's not recommended to use more than four control measurements per day for a series of five days when run in parallel with the old lot number," she continues. "If the new lot of control material has similar target values as for previous lots, CLSI C24-A3 allows the laboratory to use the established standard deviation for the new QC material as long as there is a history of stable operation of the measurement procedure."

There's no relief from this requirement for small POLs who use very expensive unitized tests; CMS maintains that assayed QC material still needs to be verified and that CLSI document C24-A3 applies to unitized tests as well. Imagine a POL that screens, per U.S. government guidelines, five men per day for prostate cancer, using a moderately complex PSA test on an immunoassay analyzer. Each PSA test costs about $15, and 20 tests are run for each new QC lot number. Without even

taking into account the cost of the control material, knowing that the maximum Medicare reimbursement is about $25 for PSA tests, a POL would be forced to discontinue its screening program.

CMS intends to issue further guidance about exactly how to verify new lot numbers of QC through Appendix C (Interpretive Guidelines) of the State Operations Manual, but after revisions are made, it must undergo several formal reviews, so there is no firm release date at this time.

Segment Shrinking

The weight of these additional quality requirements will undoubtedly shrink this already declining segment of the laboratory industry. Small POLs will continue to opt out of non-waived testing, mostly because of declining reimbursement, more CLIA-waived tests and more unreimbursable and difficult CLIA quality requirements.

Despite these obstacles, some POLs will continue to offer moderate- and high-complexity tests for the sole purpose of providing better patient care. According to one dedicated POL manager on a recent blog post:

> *"I run a POL for a six physician pediatric practice in Austin, Texas. We participate in PT, do QA, QC and maintain a quality operation. Our POL provides CBC results in a matter of minutes. If we sent our patients out for labs, they would have to drag their sick babies out to wait at a reference lab or emergency room. Or, we can order a "stat" pickup and our doctors wait for hours for results.*
>
> *Because we do neonatal bilirubin tests, we consequently have a lower rate of hospital readmissions than other practices. I have long-term experience working with pediatric patients (and their moms) and know for a fact we provide a valuable service. I can tell you many stories where we may have saved lives because of rapid test results.*
>
> *We don't make much money. We lose money doing some testing (like bilirubin) because our volume is low. So it's not about the money. It's about giving the highest possible patient care."*

When the first HIV test kit was granted the coveted CLIA-waived status, the FDA heralded the reclassification by saying, "CLIA-waived tests can be performed and interpreted in a physician's office or other settings without having to be sent out to a special CLIA '88-certified lab."[1] One could speculate whether FDA believes that CLIA'88 intends to limit POLs to CLIA-waived and PPMP testing. Perhaps this perception at high government levels is at the heart of the decline of non-waived POLs.

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[1] *http://www.fda.gov/cdrh/oivd/CLIA-oraquick.html*, July 19, 2004

False Claims Act: The U.S. Supreme Court ruled June 9 that the False Claims Act (FCA) does not merely require proof that a false statement was presented to the government, but that the statement was made with the intent of getting a false claim paid or approved by the government (*Allison Engine Co. v. United States ex rel. Sanders*, U.S., No. 07-214.) In a unanimous decision, the Supreme Court determined that a ruling by the U.S. Court of Appeals for the Sixth Circuit, which decided that the FCA does not require proof that a false claim must be presented to a federal official, was based on an incorrect interpretation of the FCA provisions.

CMS Clears EHR Proposal: The Centers for Medicare & Medicaid Services has concluded that a hospital system's proposal to pay for development of customized software that allows the hospital's electronic health records system to communicate with similar systems owned by staff physicians does not constitute a compensation arrangement under physician self-referral laws. As such, the hospital would not have to meet a so-called Stark law exception in order to pay for the development of the custom "interfaces," according to a CMS advisory opinion issued May 28 (Advisory Opinion No. CMS-AO-2008-01). *The CMS advisory opinion is available at www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf.*

Suing State Officials: An appeals court decision allowing private whistleblowers to sue state officials would interfere with the administration of state programs, such as Medicaid, according to a friend of the court brief filed May 23 with the U.S. Supreme Court by attorneys general in 24 states (*Wilcox v. United States ex rel. Stoner*, U.S., No. 07-1336). The attorneys general supported a petition asking the Supreme Court to review the appeals court decision, which held that state officials may be sued by qui tam relators under the federal False Claims Act. The treble damages, civil penalties, costs, and attorneys' fees available to qui tam relators under the FCA, combined with the size of most federal grants to the states, mean that the damages would quickly exceed the personal assets of most civil servants, the attorneys general contended.

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