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CLIA PROFICIENCY TESTING MAKES NEWS HEADLINES
- Academic Center Lab faces loss of CLIA License!
- Senate & House Bills filed to fix Proficiency Testing Issues!
- Why Referral of CLIA PT specimens traps unwary labs!

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Time for Congress to Properly Fix CLIA PT Issue

THIS TIME, THE PROVERBIAL CAT MAY BE OUT OF THE BAG when it comes to long-standing dissatisfaction with how federal regulators interpret and enforce CLIA (Clinical Laboratory Improvement Amendments) regulations as they relate to inadvertent errors in the referral of proficiency tests (PT).

For many in the clinical laboratory profession, this issue of THE DARK REPORT will be their first news about the situation at the **Ohio State University Wexner Medical Center** (OSUWMC), where CLIA officials have sent notice that the laboratory's CLIA license could be revoked, effective August 10, 2012, and subject to appeal. The sanction is the result of the unintended referral of proficiency testing specimens. It was a situation that the OSUWMC lab self-reported to the **Centers for Medicare & Medicaid Services** (CMS). *(See pages 3-7.)*

Can you remember the last time it was publicly known that a major, respected laboratory organization had its CLIA license revoked? The closest episode to cancellation that I can recall would be on February 23, 2002. That was when CMS officials issued to **Specialty Laboratories, Inc.**, a "cancellation of approval to receive Medicare payment for all laboratory services." So, even in that dramatic case, Specialty's CLIA license was not revoked. In fact, Specialty's CLIA license cancellation only lasted until June 18, 2002—just 116 days!

So now the entire clinical lab profession will watch as the laboratory of a respected academic medical center could be stripped of its CLIA license because of the inadvertent referral of six proficiency testing specimens since 2009. In the event that CMS prevails at appeal, it could leave OSUWMC officials no option but to transfer ownership of the lab to a new entity and find a new lab director.

This process will likely cost millions of dollars for a lab organization the size of OSUWMC. And what will be achieved by this particular CLIA sanction? The same lab facility will operate with the same lab instruments, manned by the same staff following the same protocols—except as modified in the wake of the root cause analysis for the PT specimen referrals. The only difference will be that the lab will have a new owner and a new laboratory director.

This and similar CLIA license revocations are why members of Congress sponsored bills in both houses to address the CLIA statute's proficiency testing "Catch 22" language that is the cause of this situation. It would be timely for all of us to contact our members of Congress and urge passage of these bills. TDR

CLIA PT Enforcement Ensnares Top Labs

Ohio State University Wexner Medical Center faces loss of its laboratory's Medicare license

CEO SUMMARY: Think it can't happen to you? Think again. Following self-disclosure of inadvertent referrals of proficiency testing (PT) specimens, the laboratory at Ohio State University Wexner Medical Center (OSUWMC) was visited by officials from the Ohio Department of Health and the Centers for Medicare & Medicaid Services (CMS). Following that survey, CMS sent notice to the OSUWMC laboratory that its CLIA license would be revoked, on August 10, 2012, in the absence of an appeal.

In June, newspapers in Columbus, Ohio, reported that the clinical laboratory of the **Ohio State University Wexner Medical Center** (OSUWMC) faced loss of its CLIA (Clinical Laboratory Improvement Amendments) license as a result of unintentional errors in the handling of proficiency testing (PT) samples.

The **Centers for Medicare & Medicaid Services** (CMS) delivered the news to OSUWMC in a letter dated June 11, 2011. It was signed by Marilyn Hirsch, Manager, Division of Survey and Certification.

The letter informed OSUWMC that, in the absence of an appeal, its CLIA license would be revoked as of August 10, 2012. That action would cancel the laboratory's "approval to receive Medicare payments for its services" as of that date.

CMS stated that the sanctions were in response to how OSUWMC was out of compliance in "enrollment of testing of samples" and "laboratories performing high complexity testing; laboratory director." Earlier in the year, OSUWMC had self-reported the inadvertent referral of proficiency testing specimens.

The decision by CMS to take this action against one of the nation's first-rank clinical laboratory organizations is highly unusual. But several lab industry attorneys say this type of sanction is happening elsewhere.

The Dark Report is aware of another sizeable and highly-respected clinical laboratory organization that also had its CLIA license revoked within the past 12 months as a result of inadvertent handling of proficiency testing specimens. This laboratory has not publicly acknowledged

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that it switched its ownership and laboratory directorship in response to the sanctions levied against it by CMS.

The manner in which CMS interprets the CLIA language that governs proficiency testing is at the core of these enforcement actions. Further, since the inception of CLIA, clinical laboratory professionals have regularly pointed out to CMS that its interpretation of the proficiency testing guidelines is overly severe.

Interpretation Is An Issue

It is because of how CMS interprets the CLIA language pertaining to proficiency testing that the OSUWMC lab finds itself facing possible revocation of its CLIA license. This is a laboratory that says it performs more than 9 million tests annually and handles about 9,000 PT specimens per year.

Yet, because of the inadvertent referral of six PT samples since 2009, OSUWMC is facing loss of its CLIA license and its ability to receive Medicare payments. Another interesting twist to this case is that the OSUWMC laboratory self-reported the mishandling of PT specimens to CMS. Thus, it is facing loss of its CLIA license after having done the right thing.

It may not be a coincidence that bills were recently filed in both houses of Congress that would address how CMS interprets and enforces CLIA statutes that govern proficiency testing. Apparently, several Senators and a number of Representatives have heard directly from constituents about the problems resulting from how CMS responds to situations where a laboratory has inadvertently mishandled a proficiency testing specimen by referring it out.

Collectively, the harsh enforcement of CLIA as it pertains to the handling of proficiency testing specimens and the heightened interest of several Senators and Representatives in submitting bills to address this situation are important developments. It may be that a "pain point" has been reached across the clinical laboratory testing profession and support for a legislative fix to the proficiency testing issue has reached critical mass.

For that reason, this entire issue of THE DARK REPORT is devoted to the most recent developments in enforcement of CLIA proficiency testing requirements. It is an issue that directly touches every laboratory in the United States that holds a CLIA license.

First, you will read about the letter sent by CMS to OSUWMC and the response sent back to CMS by OSUWMC. *(See pages 5-7.)* Important details about how OSUWMC came to self-report its PT errors are provided for the first time.

Next, an experienced laboratory director who has participated in national policy activities for the clinical laboratory profession provides insights on how clinical labs typically handle PT specimens. There are also informed observations about certain aspects of the OSUWMC case. *(See pages 8-10.)*

This is followed by information from CMS on their policies relating to the CLIA law and proficiency testing. *(See pages 11-13.)* After that comes the commentary of an attorney who has decades of experience handling important clinical laboratory and pathology cases. He analyzes the OSUWMC case within the context of the ongoing criticism that the lab profession has directed to CMS for its interpretation of the CLIA statute. *(See pages 14-16.)*

CMS Provides Statement

Our coverage is rounded out with a story that provides details about the bills recently submitted in both houses of Congress. These are intended to correct the current problems associated with CLIA regulations that pertain to proficiency testing. *(See pages 17-19.)*

In many ways, every CLIA-licensed lab in the United States has "skin in this game." That's because just one unintended mishandling of PT specimens can result in revocation of the lab's Medicare license. TDR

CMS Proposes Sanctions Against OSU Laboratory

Procedural PT errors cause CMS to send notice of revocation of lab's CLIA license

CEO SUMMARY: As its reward for self-reporting the referral of six proficiency testing (PT) specimens in three years, the laboratory at Ohio State University Wexner Medical Center (OSUWMC) has been told by the Centers for Medicare & Medicaid Services (CMS) that its CLIA license could be revoked, subject to appeal by the laboratory. Here are the details of this story, as presented in a letter prepared by OSUWMC's laboratory director and sent to CMS officials.

THIS IS A NEWS STORY that deserves the full attention of pathologists and clinical laboratory administrators across the nation. CMS has served notice to the **Ohio State University Wexner Medical Center (OSUWMC)** that its CLIA license could be revoked.

That's the headline. The story behind this headline is that the threatened license revocation came after the OSUWMC laboratory self-reported to CLIA (Clinical Laboratory Improvement Amendments) regulators that it had inadvertently referred six proficiency test samples.

Self-Disclosure

CLIA regulators responded to this self-disclosure with an on-site inspection in March 2012. Next, the laboratory director at OSUWMC was sent a letter from the **Centers for Medicare & Medicaid Services** (CMS) informing her that, on August 10, 2012, the OSUWMC laboratory CLIA certificate would be revoked, in the absence of an appeal.

Further, once the revocation becomes effective, both the owner and the laboratory director of the OSUMWMC lab would be prohibited from owning or operating a laboratory for a minimum of two years.

In its letter, CMS justified its decision to levy the most severe CLIA sanctions in its power because of "improper proficiency testing referral." The letter further stated:

> *Your Condition-level noncompliance constitutes* immediate jeopardy *and is likely to cause serious harm to the individuals served by your laboratory and to the health of the general public.*
>
> *The deficiencies found at your laboratory have been determined to be of such a serious nature that they substantially limit your laboratory's capability to render accurate and reliable services and to protect the health and safety of your laboratory clients.*

In fact, the inadvertent PT referrals did not cause harm and were not likely to cause any harm to patients at any time, OSUWMC said in a response to the charges in the letter from CMS.

Officials from CMS and OSUWMC did not return phone calls from THE DARK REPORT requesting comment for this article. However, THE DARK REPORT reviewed the letter and the accompanying list of

deficiencies sent by CMS on June 11 to OSUWMC.

It also reviewed the appeal letter prepared by the hospital in response. This letter was sent to CMS on June 25 and signed by Laboratory Director Amy S. Gewirtz, M.D.

As of press time, it was unclear if CMS had made a final decision or when it would make a decision. If CMS rules against the lab, OSUWMC could further appeal to an administrative law judge within CMS.

Interpreting PT Rules

Each year, the OSUWMC lab network performs about 9.2 million patient tests. It also handles about 9,200 proficiency tests annually.

According to the letter Gewirtz wrote to CMS, this case began on February 15, 2012, when a PT sample (labeled TTD-02) was mistakenly sent to an outside lab (**Mayo Medical Laboratories**). After tests were run on the PT sample that day, some OSUWMC lab staff members discussed the need to send it out. But others identified it as a PT sample that should stay in house. Despite these conversations, it was sent out, Gewirtz wrote.

The next day, February 16, Mayo called OSUWMC to say it received TTD-02, identified it as a PT sample, and did not perform testing on the sample. Mayo also said that it would report the incident as an improper PT referral to the **College of American Pathology** (CAP) and to the **Ohio Department of Health** (ODH), as CLIA requires, according to the OSUWMC letter.

"No inter-laboratory communications regarding the laboratory's PT results occurred," Gewirtz wrote. This statement is important because Gewirtz explained unequivocally that Mayo did not test the sample and that the lab staff at OSUWMC did not discuss its test results with any staff at Mayo. Inter-lab communication about PT sample testing results could be an indication that the lab is cheating.

Gewirtz also instructed the lab compliance manager to notify CAP, ODH, and officials within OSUWMC that it referred the specimen incorrectly. This self-reporting is important because it is one indication that the lab recognized the mistake and was being completely transparent about the error.

Two weeks later, the staff at the OSUWMC lab were implementing corrective action related to the mishandling of PT sample TTD-02, Gewirtz wrote. On February 29, the lab compliance manager discovered that a PT blood culture specimen was accidentally referred to the laboratory at **OSU East Hospital**, Gewirtz wrote.

"She informed me of this discovery right away, and in response I directed her to conduct a review of all PT blood culture specimens received during the previous two years," continued Gewirtz. "As a result of this two-year look back, the compliance manager identified four additional PT blood culture specimens that were accidentally referred to the East Laboratory."

Inspection Expected

Following these actions, the number of incorrect PT referrals identified at the OSUWMC lab totaled six since 2009.

"At my direction, the compliance manager notified CAP of the accidental PT referrals on March 1," she continued. "CAP advised the lab to make a self-report to CMS and ODH during the inspection it anticipated would occur as a result of the accidental PT referral to Mayo."

The five blood culture testing errors are examples of another source of confusion regarding CLIA PT requirements. Labs frequently send PT samples to other labs within their lab organization or network based on the mistaken belief that sending PT samples to a lab in the same network is allowed. This is what happened at OSUWMC with the five blood culture PT samples, she wrote, also emphasizing that no inter-laboratory communication occurred.

In the letter to CMS, Gewirtz also outlined the corrective steps the lab took, including computer edits to prevent accidental PT referrals, online and in-person training, and new and revised policies. The OSUWMC letter concluded with a list of four reasons that CMS should not revoke the lab's CLIA certificate.

First, the lab did not intentionally refer PT samples to another laboratory for analysis. Second, the lab did not circumvent—nor did it intend to circumvent—CLIA's PT requirements.

Third, the accidental PT referrals did not cause harm and were not likely to harm individuals the lab serves or the general public. "The conduct at issue did not constitute immediate jeopardy because… there is no reason to question the integrity of the PT survey results at issue," she wrote. Also, when it discovered the first accidental PT referral, the lab reported it to ODH and CAP and implemented a correction plan.

"Fourth, and most importantly, revocation of the lab's CLIA certificate and cancellation of the lab's ability to receive Medicare payments would have dire consequences for patients and providers throughout central Ohio and beyond," she wrote in the letter to CMS.

As this issue of THE DARK REPORT went to press, it was unknown how negotiations between OSUWMC and CMS were proceeding. One deadline mentioned in the CMS letter was its intent to revoke the CLIA license of the OSUWMC laboratory effective August 10, 2012, in the absence of an appeal. As of this date, neither party has made a public statement about whether the sanction is to be enforced on this date or, presumably, will be postponed as CMS weighs the response letter sent by OSUWMC.

Further, the information contained in this intelligence briefing was drawn primarily from the CMS letter to OSUWMC and from the response letter sent by OSUWMC to CMS. TDR

—By Joseph Burns

CMS Letter Sent to OSUWMC Summarizes Survey Findings

AFTER REPORTING THAT HER CLINICAL LABORATORY had made a small number of procedural mistakes in its proficiency testing (PT), Laboratory Director Amy Gewirtz, M.D., was expecting a visit from lab surveyors.

On March 28, staff from the Ohio Department of Health and the Centers for Medicare & Medicaid Services (CMS) conducted a CLIA-compliance survey of the lab at the Ohio State University Wexner Medical Center (OSUWMC). CMS officials detailed the results of their survey in a letter to Gewirtz on June 11.

CMS said OSUWMC lab staff failed to follow the proper PT procedures in November 2009, July 2010, July 2011, and November 2011, and twice on February 2012. It wrote that:

Due to the laboratory's failure to comply with certificate requirements and performance standards as evidenced by the finding of improper referral of the laboratory's proficiency testing samples to another laboratory for analysis, the laboratory's failure to meet all condition-level requirements of CLIA, and our determination of serious and immediate jeopardy, the CMS proposed to take action to impose the following sanctions against the laboratory's CLIA certificate:

—42 C.F.R. §493.1806(a)(b)– Principal Sanction: Revocation of your laboratory's CLIA certificate.

—42 C.F.R. §493.1807(a)– Principal Sanction: Cancellation of your laboratory's approval to receive Medicare payments for its services. This sanction will become effective on the date the revocation of the CLIA certificate becomes effective.

In the last 10 pages of the letter, CMS numbered and listed the deficiencies it cited during its compliance survey on March 28.

Existing CLIA Language Drives PT Enforcement

CMS officials interpret CLIA law in a manner that some say does not meet the intent of Congress

CEO SUMMARY: Revocation of a lab's CLIA license as penalty for inadvertent errors in handling proficiency tests (PT) is not a new problem. As explained here, most clinical laboratories have appropriate protocols for handling PT samples. But, when errors occur, the Centers for Medicare & Medicaid Services (CMS), based on its current interpretation of the CLIA law, does not distinguish between an intentional effort to cheat the proficiency test process and an inadvertent PT error.

HOW FEDERAL OFFICIALS REGULATE proficiency testing (PT) has been the source of debate and controversy since the inception of the Clinical Laboratory Improvement Amendments (CLIA) statute. It is a story with two sides.

On one side, officials at the **Centers for Medicare & Medicaid Services** (CMS) are tasked by the law with regulating clinical laboratory testing in a manner that protects the health and safety of patients. Assuring that labs operate a competent proficiency testing program as specified by CLIA is part of this responsibility.

On the other side, clinical lab professionals regularly take issue with two aspects of how CMS regulates PT as part of CLIA. First, it is observed that CMS officials interpret the CLIA language in a most restrictive manner. Second, the enforcement actions levied by CMS as a consequence of its interpretation—including revocation of a lab's CLIA license—can be overly harsh.

Some critics go further, stating that, when it comes to proficiency testing, both the CMS interpretation of the CLIA statute and its enforcement actions are not what Congress intended when it passed the CLIA law. That is why news that the laboratory of the **Ohio State University Wexner Medical Center** (OSUWMC) faces revocation of its CLIA license in the wake of self-disclosures of errors in the referral of PT samples again brings these issues front and center.

Explanation of Mistakes

Because it is a story with two sides, THE DARK REPORT sought an expert who could explain the issues. What follows are the comments from an individual who has managed clinical laboratories and who has participated, at the national level, in different aspects of policy-making and interaction with federal agencies in matters relating to laboratory testing. To encourage full candor, THE DARK REPORT agreed not to identify this individual. The person was able to review the letter sent by CMS to OSUWMC and the response to this letter sent by the OSUWMC laboratory director.

"To those on the outside, I'm sure it looks like there's no logic behind the sanctions that CMS issues for unintentional PT violations," said this former lab director. "But the law is proscriptive on how these cases should be handled. CMS would like

Every Lab Has Procedures for Proficiency Tests, But There Are Several Ways for Mistakes to Occur

IDEALLY, ANY CLINICAL LAB SCIENTIST running a proficiency test (PT) does not know it's a PT sample. The PT sample should be indistinguishable from any other specimen in the lab.

"PT samples should be totally blinded to the staff," stated an experienced lab director. "The lab director or the compliance officer or both will know that a PT sample is in the lab that day. But they can't tell the bench techs anything.

"In most labs, the PT sample has a bar code label and that label may have a generic name, such as John Doe or Jane Doe," noted the lab director. "This is consistent with policies for live samples where a positive patient identification has yet to be made.

"Some labs put only a unique patient identifier, a test number, and a bar code on every sample, PT or otherwise," continued the expert. "Labs have many ways to make the PT samples anonymous.

"So if the results of the PT sample are such that the next step would be to send it out, the sample would either go into the refrigerator or go to some area of the lab for processing," he added. "Whoever handles the send outs would take it from there.

"All the while, the compliance officer would monitor the send out area and refrigerators to make sure the PT sample doesn't go out," the expert said. "The compliance manager would pick it up and make a log notation that the PT sample testing was complete and that the lab had followed its procedures just as it would for a live patient specimen.

"For certain tests, the lab has told CLIA that it performs only the initial screen and a different laboratory does the rest of the test," stated the lab director. "The lab would thus report a positive or negative—or report the presence of a certain result, but not the level.

"Despite all these procedures, mistakes in handling the PT sample can happen," added the expert. "A PT sample will be referred out because: 1) it was a mistake that the compliance officer didn't catch; or, 2) a failure to train staff properly; or, 3) due to high staff turnover.

"Or, 4) it could be that a lab sends the PT sample to another lab in the same system but because those two labs have different CLIA numbers, that would be a PT violation," concluded the lab director. "This illustrates a few reasons why a PT sample gets referred out and many of them are just simple mistakes. It is also why CMS needs to have some discretion for cases such as at OSUWMC where there was no intent to subvert the PT process."

to be more flexible but there is currently no flexibility in the law. And, there is no way to stop the process once it starts.

"The CMS letter notes that the PT errors at OSUWMC constituted '…immediate jeopardy and is likely to cause serious harm to the individuals served by your laboratory,'" observed the source. "But in fact, no patient was harmed or would have been harmed by this unintended error! Referring the specimen to another lab for further testing was, in fact, the standard of quality patient care for this lab. Theoretically, *not* referring the specimen would put patients at risk—not the other way around.

"Therefore, where is the perspective?" asked the expert. "When you say, 'immediate jeopardy,' that should mean that patients were and are, truly, in danger. But in this case, that's not even close to being true.

"There was no risk of harming a patient," observed the lab director. "So we have to wonder where the immediate jeopardy was. It would be different if that laboratory normally ran the additional testing on its own for all patients and referred just the PT specimen. However, that is not the case in this issue involving OSUWMC.

"Did the OSUWMC lab make a mistake? Yes, it did," added the lab director.

"And both the language of the CLIA law and the way the regulations are written specify that—when a lab sends a PT specimen out to another lab—that action by itself qualifies as putting patient care in immediate jeopardy.

"It is essential to acknowledge that, if a lab sent a PT test out in an effort to cheat—in other words, to make sure it got the right result—severe sanctions, would be required," said the expert. "Because in this instance, there was intent to deceive.

Following Procedures

"But if the lab follows the same protocol with the PT sample as it does with a patient specimen and sends out only a portion of a test and only at a certain stage—which is what OSUWMC did—then CMS should know that the lab is simply following its own procedures," observed the expert. "In this case, the fact that the PT sample went out is clearly an unintentional error.

"However, under its current interpretation of the CLIA law, CMS views this one inadvertent act as being akin to cheating," the former lab director explained. "Keep in mind that those in the regulatory business may see only the bad side of labs. If you only see the bad side of the clinical laboratories, it is understandable that you may start to question the integrity of every process.

Circumstances Of The Case

"Now, there are circumstances in this case that seem to support the actions of CMS when you consider that lab sent up to six proficiency test samples to another lab," stated the expert. "A lab could make a mistake once and maybe twice. But after three or more times, it should surprise no one that regulators conclude that those events represent a potential problem.

"In addition, in the OSUWMC response letter, there is not a full explanation about why just those specific specimens were referred to another lab," observed the lab director. "The letter discussed how lab staff are instructed to handle PT specimens. But the lab did not fill in the details for the surveyors about what exactly happened regarding these PT samples.

"In fact, a lot of people in the lab understood that the PT specimens should not go out but they still went out," continued the expert. "The lack of a full explanation of what happened with those six samples likely raised questions in the surveyors' minds.

"But now—in the defense of OSUWMC—it reported that, from October 2010 to September 2011, its lab performed 9.2 million patient tests and 9,200 proficiency tests," said the expert. "The laws of probability tell you that you are going to make a mistake or have human error when such a huge number of proficiency tests are regularly run in a major clinical laboratory.

How to Define 'Intent'

"What we have in this case clearly demonstrates the problem CMS has in enforcing the rules as written," the former lab director continued. "CMS is aware of this issue and has discussed ways to address the PT referral problem.

"CMS officials know they need to figure out a way not to penalize laboratories where PT samples were sent out inadvertently," noted the expert. "But they have yet to come up with a solution that makes the language of CLIA unambiguous.

"The problem stems from language in the law," said the lab director. "The law says that any laboratory that intentionally refers its PT samples to another laboratory for analysis will have its certificate revoked for at least one year and be subject to fines and penalties as well. And the CLIA regulations included stringent penalties for this 'intentional PT referral.'

"To correct this problem of confusing regulations, we understand that CMS is considering whether and how to revise the definition of 'intentional PT referral,'" commented the expert. "Now that Congress is addressing it as well, we might see some resolution in the coming months." TDR

—By Joseph Burns

CMS and CAP Comment On CLIA PT Matters

CLIA statute is enforced by CMS based on strict interpretation of the law's language

CEO SUMMARY: Federal regulators rely on interpretations from administrative law judges (ALJ) for guidance in how to apply the Clinical Laboratory Improvement Amendments (CLIA) as they pertain to proficiency testing (PT) and the issue of inadvertent PT referrals. Representatives of the Centers for Medicare & Medicaid Services (CMS) and the College of American Pathologists (CAP) provide comments about this issue and offer insight as to how laboratories can comply with the law.

IT WAS 1988 when Congress passed the law known as the Clinical Laboratory Improvement Amendments (CLIA). Congress asked the **Centers for Medicare & Medicaid Services** (CMS) to administer the requirements laid out in the CLIA statute.

One important element of CLIA was that clinical laboratories meet the law's proficiency testing (PT) requirements. For this article, CMS officials provided information about some of the issues associated with PT compliance. CMS Public Affairs Specialist Don McLeod responded via email to a request from THE DARK REPORT. He sent a written statement that is presented in the sidebar on page 13. McLeod also provided additional comments relating to aspects of CLIA and proficiency testing.

On the question of whether CMS makes a distinction between a clinical lab that self-reports an inadvertent clerical error with a proficiency test sample and a lab that is deliberately trying to cheat the proficiency testing program, McLeod noted that CMS does not make that distinction, because "the sanctions for PT referral originate directly from the CLIA law, which is very clear. There is no language in the section on sanctions or in the regulations that provide for self-reporting," he wrote.

In cases where a laboratory employee has unintentionally referred a PT sample to another lab, McLeod stated that CMS considers any such referral as prohibited, regardless of whether the lab intended to refer the sample in an attempt to cheat or the lab referred the sample mistakenly.

Intentional PT Referrals

"A referral is viewed as intentional if any employee of the laboratory was aware that a PT sample was sent to another laboratory for testing," said McLeod. "To make that determination, CMS reviews all cases in the central office and evaluates policies, procedures, records, documents, and data to consistently verify that referral has occurred.

"CMS defines referral as whether anyone in the lab was aware that the PT sample was sent to another lab, based on previous cases heard by administrative law judges (ALJ)," McLeod wrote. "When this occurs, the statute is invoked.

"It is our advice to labs to have robust policies and procedures in place to prevent referral and to provide training to any employee who might handle a PT sample," he wrote. "The CLIA statute is quite specific that, when a laboratory intentionally sends PT samples to another laboratory, the CLIA certificate must be revoked for one year. In addition, the statute also requires that no person who has owned or operated a laboratory that has had its certificate revoked may operate a laboratory within two years of the revocation."

Confusion About PT Referral

One pathologist thoroughly familiar with CAP's accrediting program is Bruce Williams, M.D., who is a Clinical Associate Professor of Pathology at the **Louisiana State University Health Science Center** in Shreveport. Some labs are confused about the issue of PT referral, he said.

"Under the general instructions for how to handle a PT specimen, labs should treat them as they would a normal patient sample," he explained. "But that doesn't apply when it comes time to send out the PT sample—as would be done with a sample from a real patient.

"It is critically important to understand, that at this point in the PT protocol, you cannot send any PT sample outside the four walls of the lab," noted Williams. "Take the example of reflex testing, where the lab would normally send out that test. If it is a PT specimen, you can't do that.

"A number of labs have done this [inadvertently referred a PT specimen to another lab]," he added. "These labs were sanctioned and lost their CLIA licenses.

"With revocation of the CLIA license, the lab owner is prohibited from owning a laboratory for two years and the lab director is prohibited from serving as a lab director for two years," stated Williams. "This punishment is fairly severe for something that is often an inadvertent mistake.

"This issue has been recognized over the years, but given the way the original CLIA legislation is written one could interpret it to mean that *any* referral outside of the lab would mandatorily result in this sanction," he said.

"CAP has tried to resolve the issue with CMS, but the answer probably rests in legislation now before Congress that would grant CMS discretion in cases where mistakes have been made," he added. "Clearly it is important for legislation that gives CMS the latitude it needs to investigate individual violations and adjust the penalties to fit the crime."

THE DARK REPORT asked how many laboratories have been cited for violations involving inadvertent PT referrals and the number of labs severely sanctioned for inadvertent PT specimen referrals. Officials from the **College of American Pathologists** (CAP), a CLIA accrediting organization, responded that CAP does not have a complete record of the number of labs CMS has sanctioned for PT violations. Helena Duncan, CAP's Assistant Director of Economic and Regulatory Affairs, said that CMS collects this information for all labs regulated under CLIA.

CLIA Laboratory Registry

When asked about the number of laboratories sanctioned for PT violations, CMS responded that it maintains the Laboratory Registry for CLIA enforcement actions at its website (*http://tinyurl.com/cgxgbl5*). This registry currently shows information about actions resolved through the end of 2010.

CMS officials said that, at the end of each year, time is required for regional offices "to close out all of the enforcement actions, survey info, and any other required info" and submit it to CMS for inclusion in the Laboratory Registry. It expects the enforcement actions from 2012 will be available on the Laboratory Registry by the end of 2013. TDR

—By Joseph Burns

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CMS Provides Statement about Interpretation And Enforcement of CLIA Proficiency Testing

EDITOR'S COMMENTS: Following the 1988 enactment of the Clinical Laboratory Improvement Amendments (CLIA-Public Law 100-578), one government agency has had the primary responsibility for enforcement. That is the Centers for Medicare & Medicaid Services (CMS).

Proficiency testing (PT) activities figured prominently in the CLIA statute. THE DARK REPORT contacted officials at CMS and asked for comments on how the federal agency interprets the CLIA law and enforces this interpretation. CMS answered this request with the following statement, reproduced in its entirety:

The Clinical Laboratory Improvement Amendments (CLIA) (Pub. L. 100-578, enacted October 31, 1988) established both CLIA PT requirements to ensure quality testing and strong sanctions for PT violations. Congress strongly believed that PT is a good measure of laboratory test accuracy, but also that 'cheating' at PT could mean misrepresentation of patient test results. CMS, accrediting organizations, and PT programs have regularly emphasized the importance of abiding by the requirements for PT, along with the consequences of not doing so.

The CLIA statute, 42 USC 263a(i)(4), requires that, when a laboratory intentionally sends PT samples to another laboratory, the CLIA certificate must be revoked for one year. In addition, the statute at 42 USC 263a(i)(3) requires that no person who has owned or operated a laboratory that has had its certificate revoked may operate a laboratory within two years of the revocation.

Because neither the law nor the regulations define the phrase "intentionally refers," we have utilized determinations made by Administrative Law Judges (ALJ) as a guide affirming that "intentionally referred" requires not specific intent, but general intent, that is, an intent to act. A referral is viewed as intentional if any employee of the laboratory was aware that a PT sample was sent to another laboratory for testing. To make that determination, CMS reviews all cases in the central office and evaluates policies, procedures, records, documents and data to consistently verify that referral has occurred.

Guidance for laboratories to help prevent violations is included in PT program materials, accreditation organization requirements, and the CMS/CLIA website. Additionally, all non-waived laboratory directors were sent a letter and enclosure detailing important information regarding CLIA requirements for PT; specifically, information to clarify the regulations and to help prevent referral situations, based on current laboratory practices. CMS has also addressed this information in multiple public presentations in various venues.

A condition-level requirement pertains to significant, comprehensive requirements of CLIA, as opposed to a standard-level requirement which is more detailed, and more specific. A condition-level deficiency is an inadequacy of the laboratory's quality of services that adversely affects, or has the potential to adversely affect, accuracy and reliability of patient test results. Laboratories who intentionally refer PT samples to another laboratory for analysis are out of compliance with the CLIA condition for enrollment and testing of samples (§493.801(b)(4)). Based on the outcome-oriented survey process, CMS surveyors make the determination of immediate jeopardy when deficiencies are determined to be of such a serious nature that they substantially limit the ability to render accurate and reliable services.

CMS does not comment on cases that are currently involved with the enforcement process.

Lawyer Questions CMS Over Inadvertent PT Errors

➤Revoking Medicare license and suspending lab's medical director not likely intent of Congress

➤➤CEO SUMMARY: In the case of the Ohio State University Wexner Medical Center (OSUWMC) clinical lab, one attorney with long experience in CLIA regulatory matters says that the facts do not support the severe sanctions that CLIA officials may impose on a healthcare organization that is widely-respected nationally. While the lab did commit errors in its handling of PT specimens, the errors were inadvertent; it self-reported the errors; then instituted systemic changes to prevent recurrence of the same errors.

WOULD A REASONABLE PERSON agree that the **Centers for Medicare & Medicaid Services** (CMS) should impose Draconian sanctions for an inadvertent violation of the proficiency testing (PT) rules? This is the question being asked by one attorney with long experience in clinical laboratory legal issues.

It is the **Ohio State University Wexner Medical Center** (OSUWMC) laboratory, located in Columbus, Ohio, that faces the Draconian sanctions. The attorney raising this question is Jack R. Bierig, a partner with the law firm **Sidley Austin LLP** in Chicago, Illinois.

Bierig has worked on several cases involving PT violations under the Clinical Laboratory Improvement Amendments (CLIA). Given the facts as explained in the appeal letter sent to CLIA officials from OSUWMC Clinical Lab Director Amy Gewirtz, M.D., Bierig said that imposition of serious sanctions would be contrary to the intent of Congress.

"There is no way that a reasonable person could conclude that CMS should revoke the lab's license or cite the laboratory director [Gewirtz] for failing to supervise the lab properly," declared Bierig, who is not associated with this lab in any way. He saw the letter CMS sent to OSUWMC and the letter of appeal that the lab sent to CMS. "Assuming that the facts are as stated in that letter, the whole case is a travesty," he commented.

➤'A Very Minor Glitch'

"It would be very unfair to impose sanctions on the OSUWMC lab, given four important facts," he said. "First, the laboratory runs 9,200 PT samples per year—nearly all without incident. Second, there was a very minor glitch with one PT specimen that hurt no one.

"Third, OSUWMC self-reported that PT issue to CMS," continued Bierig. "Fourth, on its own initiative, OSUWMC's lab then implemented a number of changes in its procedures to correct those problems promptly.

"Even a cursory review of the facts shows that it wouldn't be fair to impose these severe penalties against the OSUWMC lab. That would not be what Congress intended when it wrote the language of CLIA," noted Bierig.

Facts in OSUWMC Lab Case Create Opportunity For Congress to Change the Existing PT Law

IT MAY BE THAT AN UNUSUAL OPPORTUNITY EXISTS in the proficiency testing (PT) case of the Ohio State University Wexner Medical Center (OSUWMC) clinical lab, said Jack R. Bierig, a lawyer familiar with this matter.

"Given that OSU is a state institution, one would hope that members of Congress from Ohio would take an interest," said Bierig. "These members should spearhead an effort by Congress to make it clear to CMS that severe sanctions should not be imposed for inadvertent PT referrals that are promptly corrected."

In June, officials in the PT enforcement office in Chicago for the Centers for Medicare & Medicaid Services (CMS) sent a letter to the lab. In the letter, the CMS officials explained the alleged PT violations under the Clinical Laboratory Improvement Amendments (CLIA) and declared their intent to revoke the lab's CLIA license, pending appeal.

"From the facts presented in the letters I've seen from CMS to the lab and from the lab to CMS, it looks like this situation is a major injustice under the CLIA rules," he said. "The severity of the sanctions is contrary to what Congress intended when it passed CLIA.

"The PT referral provisions of the 1988 CLIA law are ripe for review," noted Bierig. "CMS enforcement policy in this area needs to be consistent with what Congress intended when it drafted and passed the law in 1988. And, the fact that this case involves OSU's Wexner Medical Center should have some influence because it's a prestigious medical center in Columbus, Ohio, that serves hundreds of thousands of Ohio residents every year.

"If I were OSU, I would march into the office of my U.S. senator and my U.S. representative and say, 'You need to change this law,'" he said. "No one is in favor of subverting the PT process. Everyone is opposed to that. But the way the law is currently written has caused enormous problems and costs.

"It has diverted money that these labs and hospital systems should be spending on patient care and causing all these legal and administrative fees for things that Congress never intended to be violations," observed Bierig. "Over the years, CMS has taken an extremely harsh approach toward the application of the law in this area.

"Therefore, I believe the law needs to be changed," he concluded. "CMS needs to understand that it should not be imposing serious sanctions in cases like this where there was no intent to subvert the PT process."

"The error was inadvertent, the lab self-reported the error, and the lab imposed systemic changes to prevent a recurrence," he added. "Given these facts, it is ridiculous to impose sanctions against the OSUWMC lab and pull its CLIA license. The cure would be far worse than the disease. I hope that CMS reads the letter from Dr. Gewirtz and realizes how wrong that would be.

"Looking at the facts of this case, there are five specific issues that obviate the need to impose sanctions," said Bierig. "First, the lab tried to do the right thing when it received the PT specimen but made a mistake that was completely inadvertent.

"Second, upon learning that it made the mistake, it did the responsible thing by self-reporting the error to CMS," he stated. "That factor alone should count for something. Once the lab learned about the referral of the specimen to another lab, the letter shows that the lab acted completely responsibly.

"If CMS wants to encourage self-reporting, it shouldn't throw the book at a lab that acts responsibly," added Bierig. "Here's a question for CMS: If a lab that self-reports an inadvertent PT referral gets severe sanctions in a case like this, why would any lab self-report?" he asked. "If you self-report and still get sanctions, CMS is removing the incentive for self-reporting.

"Third, after it determined that it had violated the PT specimen-handling proce-

dures, the lab implemented appropriate systemic changes so that the same problem would not recur," he added. "Dr. Gewirtz explains those changes in her letter to CLIA officials. Sure, the lab made a mistake, but, again, it did the right thing in response.

"Fourth, you have the patient care issue. If CMS shuts down this lab, it would have a significantly adverse impact on patient care," emphasized Bierig. "Moreover, if they bar Dr. Gewirtz from directing a lab for two years, they punish an individual who has acted entirely responsibly and they deprive clinicians and patients of her expertise in directing a laboratory."

Language Of The Statute

Bierig's comments are rooted in common sense. "What should happen is that CMS should tell the lab, 'Make sure this doesn't happen again,' and that should be the end of this matter," he said. "I believe that CMS has this discretion. But if you ask CMS, the agency is likely to say they do not. If CMS were to take this position, it would be incorrect both as a matter of the language of the statute and its purpose.

"Were you to ask members of Congress about this PT issue, I believe they would all agree that deliberate efforts to subvert the PT process need to be addressed with severe sanctions," noted Bierig. "But treating PT specimens as you would treat patient specimens is not a lab action that Congress intended to punish severely.

"Since the early 1990s, I have seen cases like this, and I called for changes in CMS enforcement positions back then," Bierig offered. "I have been through a number of these PT cases. In most of them, the facts are strongly in favor of the lab and its director. Sometimes justice prevails and sometimes it doesn't. It may depend on the region of CMS in which the issue arises. That's why Congress needs to look into the issue unless CMS clearly indicates that it will not impose serious sanctions in a case involving inadvertent referrals which are promptly corrected.

"The regulations in this area are quite confusing," noted Bierig. "Specifically, 42 C.F.R. section 493.801(b) provides that '(t)he laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.' At the same time, section 493.801(b)(4) recites that '(t)he laboratory must not send PT samples or portions of samples to any laboratory for analysis which it is certified to perform in its own laboratory.' What is a lab to do that normally refers out a specific sort of specimen? By complying with the first provision, the lab violates the second.

"As far as I can tell, OSUWMC treated the PT sample in the same way that it treats patient samples, which was send it out," he added. "That's what they usually do. Should such conduct lead to harsh sanctions? I don't think so, and I don't believe Congress thinks so either.

"Next, Section 493.801(b)(4) provides that '(a)ny laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year'," noted Bierig. "In my view, the use of the word 'intentionally' bespeaks a congressional intent that, before certification is revoked, CMS must determine that the laboratory in question deliberately intended to subvert the PT process. I don't see how, on the facts of this case, CMS could fairly come to such a conclusion.

"If I were representing OSUWMC and had any sort of serious sanction imposed by CMS against the laboratory or its director after final administrative action, I'd be in court the next day for a preliminary injunction to prevent CMS from implementing such sanction," stated Bierig. "Based on the evidence, OSUWMC has a very strong case. Let's hope that Congress becomes aware of this case and takes steps to do justice." TDR

—Joseph Burns

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Congress May Respond to Tough CLIA PT Penalties

Two bills are a response to laboratory sanctions imposed for inadvertent PT violations under CLIA

CEO SUMMARY: For years, severe penalties in cases where a laboratory has inadvertently erred in handling proficiency testing (PT) specimens have been a point of contention between the Centers for Medicare & Medicaid Services (CMS) and the clinical laboratory profession. Two bills proposed in Congress would give CMS more discretion in how it interprets the language in the Clinical Laboratory Improvement Amendments (CLIA).

In Congress, overly-severe penalties for labs deemed to have violated proficiency testing (PT) requirements have caught the attention of certain elected officials. Bills to fix this problem have been filed in both the Senate and the House.

The bills are designed to provide more precise guidance to resolve an ongoing issue with the Clinical Laboratory Improvement Amendments (CLIA) statute as it is currently written. One important point of contention between the clinical laboratory profession and CLIA regulators centers around how federal officials interpret the language of the law that pertains to proficiency testing, then levy tough enforcement actions based on this interpretation.

These penalties can go so far as loss of the medical lab's CLIA license and banning the laboratory director from holding any medical directorship for two years. Lab organizations caught in the jaws of this enforcement vice are asking their congressional representatives to address this matter.

The Dark Report contacted staff members at several congressional offices who are supporting the two bills, known as H.R. 6118 in the House and S. 3391 in the Senate. *(See sidebar on page 19.)*

The bills would address a lack of regulatory flexibility in CLIA enforcement by granting CMS the discretion not to revoke a clinical laboratory's CLIA certificate for the unintentional referral of proficiency testing samples to other laboratories. The bills are supported by the Clinical Laboratory Coalition.

Inadvertent PT Errors

Speaking off the record and for background, a congressional aide said members of Congress are looking into CMS' practices of imposing sanctions and pulling CLIA certificates in situations where a laboratory has made inadvertent PT errors. Also, CMS has threatened to pull certificates for all labs in a hospital network for some violations, according to another congressional aide familiar with the issue.

For its part, CMS says that it must interpret the law as written. Thus, it has no choice but to impose sanctions as prescribed by law, the aide said.

Some labs are facing sanctions that make no sense, said one congressional aide who asked not to be named. Congress knows of PT issues at two hospital labs in Ohio and at hospital labs in Arkansas,

California, Illinois, Indiana, New Jersey, New Hampshire, and Minnesota.

It is difficult to get information on how many hospitals have faced sanctions or revocations of CLIA certificates, aides said. That is because most of these cases are not public knowledge unless a case goes through the administrative law process. When a lab appeals a sanction imposed by CMS, it goes to an administrative law judge (ALJ).

"We are trying to find hospital labs that have had problems with proficiency testing," commented this congressional staffer. "Unless we hear about a case from another congressional office or a hospital lab director, we don't always know the specific cases."

Members of Congress have asked CMS for information about the labs that have faced sanctions for PT violations.

A number of lab directors have told members of Congress that CMS has come down hard on labs regarding the issue of PT referrals. "We have heard where CMS has required a change in lab ownership and that CMS will revoke a lab's CLIA certificate for two years and require the lab to pay another lab director to run the lab for those two years," an aide said.

➤'CMS Is Playing Hardball'

"Sometimes CMS tells labs they must settle or face even harsher sanctions," continued this aide. "CMS says, for example, 'We will revoke your CLIA certificate unless you settle and we will require you to bring in a competitor to run your lab for two years. At the end of those two years you can reapply for a new CLIA certificate."

To bring in a competitor to run its lab, the hospital being cited has to pay millions of dollars to have another lab run the operation, added the aide.

CMS also has told labs that, if they pursue the ALJ appeal process and lose, then the hospital lab and every lab in the hospital's network could lose their CLIA certificates, an aide reported.

Without a laboratory, a hospital would have trouble delivering patient care. "Where is the logic in having a hospital pay millions of dollars to bring in a competing lab to handle its laboratory testing?" asked this congressional staffer.

➤Sanctions for PT Violations

CMS has threatened sanctions even in cases when a lab self-reports a PT violation, reported this aide. Staff in one congressman's office said that, after a lab director self-reported a PT violation, federal regulators threatened to pull all CLIA certificates for an entire hospital network.

"It's seems crazy but it's true: The worst thing a lab can do is self-report a PT mistake," commented this staff member, explaining that, "A lab director who discovers a PT violation faces a difficult dilemma. He or she can self-report the violation but then the lab would lose its CLIA certificate. If the lab doesn't report the violation, you hope no one finds out. If CMS finds out, the lab could lose its certificate. Either way, it's an impossible choice."

Staffers from several Congressional offices told THE DARK REPORT that members of Congress have discussed these issues with officials from CMS. One source noted that regulators recognize that they might appear to be unreasonable but, the regulators also assert that no discretion is allowed under current law. The law says that CMS shall revoke the CLIA certificate after a PT violation and it must do so for every hospital in the network. Because hospitals have consolidated over time, hospital networks have become larger.

At the same time, regulators and administrative law judges have decided that, when a lab intends to send out a PT specimen to another lab, the mere intention to do so results in a PT violation, the aide said. There is no distinction between a lab that makes a mistake and a lab that acts in bad faith by trying to undermine the PT system.

Bills in Congress Would Allow CMS to Apply Intermediate Sanctions for Some Situations

MEMBERS OF THE U.S. CONGRESS are considering two bills to give lab regulators more flexibility when clinical labs make inadvertent errors.

In the U.S. House of Representatives, Rep. Michael Grimm (R-N.Y.), introduced H.R. 6118, which is called the "Taking Essential Steps for Testing Act" (the TEST Act). The co-sponsors are Reps. Peter Roskam (R-Illinois), Mike Ross (D-Arkansas), Steve Womack (R-Arkansas), and Steve Austria (R-Ohio).

Three U.S. senators have introduced a similar bill, S.3391, with the same name. Senators Amy Klobuchar (D-Minnesota), Jeanne Shaheen (D-New Hampshire), and John Boozman (R-Arkansas), introduced this bill. Both bills are supported by **American Clinical Laboratory Association** (ACLA), **Clinical Laboratory Management Association** (CLMA), and the **Clinical Laboratory Coalition**.

"CMS maintains that the CLIA statute requires the agency to revoke the CLIA certificate for any laboratory that intentionally refers its proficiency testing samples to another laboratory for analysis," ACLA wrote in a press release. "In several recent cases, laboratories' CLIA certificates were revoked because they referred proficiency test specimens for an HIV test. But for HIV and certain other tests, the laboratory's standard operating procedure is to refer all samples to another laboratory.

"For example, the HIV test involves both an initial screening test—called ELISA—as well as a confirmatory test—a Western Blot," ACLA said. "However, many laboratories do not offer the Western Blot due to limited resources and, as a result, refer the confirmatory test to a laboratory that does offer it."

The legislation would permit CMS to impose intermediate sanctions before revoking a laboratory's CLIA certificate in cases where a proficiency testing sample was referred to another laboratory for confirmatory testing or because the laboratory does not offer a specific test.

"As a result of this important statutory change, laboratories would no longer be unfairly punished when they follow the usual practice and refer a specimen to another laboratory," explained ACLA President Alan Mertz. "The TEST Act will prevent the wasteful time and expense that occurs when a laboratory's CLIA certificate is revoked, and allow laboratories to continue providing vital services to patients."

In encouraging members to support these bills, CLMA said, "CMS would be permitted to impose intermediate sanctions prior to revoking a CLIA certificate under circumstances where a proficiency testing sample was referred to another laboratory for confirmatory testing or because the laboratory in question does not offer a specific test."

Definition of Intent

Another congressional staffer pointed out that the bills' sponsors would prefer that the House and Senate bills address the issue of the definition of intent. According to this individual, at this time, it has been difficult to get everyone—CMS, the Republicans, and Democrats—to redefine the word 'intent' in the statute, an aide said. Instead members of Congress aim to give CMS some discretion in such cases. Members of Congress have been working on this issue for a year and have heard about more labs that have had CLIA licenses revoked, concluded the aide. This may suggest that federal regulators have become more stringent in how they address this issue with labs, the aide said. **TDR**

—Joseph Burns

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