PT referral rules bring regulatory relief for labs

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July 2014—Laboratories now may be saved from draconian penalties, such as loss of a CLIA license and probation periods, for mistakenly sending proficiency test specimens to another facility.

Under new rules published by the Centers for Medicare and Medicaid Services, laboratories have the regulatory relief the CAP advocated during the past decade. The CMS will still severely punish those attempting to cheat on proficiency testing, but laboratories that unknowingly or unintentionally refer PT specimens will face alternative sanctions, according to the regulations.

“We still want to work with CMS to evaluate other scenarios that are the result of ignorance or a mistake and not with intent to cheat,” says R. Bruce Williams, MD, a CAP governor and chair of the CAP Council on Scientific Affairs. “In those instances, we need to make sure the punishment fits the crime.”

For years, revocation of a CLIA certificate and two years of probation for the owner and laboratory director were the penalties for PT referrals regardless of the circumstance. In some instances, the penalties were handed down to laboratories when technicians or technologists just a few months on the job, and following standard operating procedures, sent PT specimens for confirmatory or reflexive testing. The number of unintentional PT referrals grew, jeopardizing patient care and costing hospital systems and other organizations millions of dollars.

In May, the CMS released two regulations addressing PT referrals. The first CMS rule, published in the Federal Register on May 2, outlined the alternative sanctions for PT referrals by implementing provisions in the Taking Essential Steps for Testing Act passed by Congress in 2012 with the support of the CAP. The CAP had advocated leniency and exceptions when violations are less serious, while reserving stiff penalties for egregious conduct. The TEST Act was in response to outrage over levying the most severe penalties for innocent mistakes. For instance, a PT referral caused by an inexperienced employee at a laboratory in Ohio in 2012 led federal lawmakers from that state to push for changes and grant the CMS discretion when it comes to PT referrals.

The second rule, published May 12, modernized PT regulations as part of an effort by the Obama administration to reduce regulatory burdens throughout the federal government. The CAP had advocated and supported the CMS in providing clarification to treat PT sample referrals differently in light of standard operating procedures for patient sample referrals. It also added new definitions the CAP recommended to help clarify when a PT referral should not lead to revocation or two-year probation for the laboratory owner or operator.

While there is now more flexibility, the CMS still says PT samples should never be sent outside the laboratory no matter the circumstance. There always will be a consequence for PT referrals.

Penalty categories for PT referral

Category	Detail of violation	Penalty
First	Repeat PT referrals or cases where a laboratory reports another laboratory's test results.	◆ Revoke the CLIA certificate for at least one year ◆ Ban owner and operator for at least one year ◆ Civil monetary penalty*
Second	A laboratory refers PT sample to a laboratory that operates under a different CLIA number before the PT event close date and, while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the event close date.	◆ Suspend or limit CLIA certificate ◆ Civil monetary penalty*
Third	The referring laboratory does not receive test results prior to the event cutoff date from another laboratory as a result of the PT referral.	◆ Comply with a directed plan of correction such as training ◆ Civil monetary penalty*

**Penalty amounts are determined by several factors, such as nature, scope, and severity. The ranges for penalties can be $3,050 to $10,000 per day of noncompliance or per violation for conditions that pose immediate jeopardy, or $50 to $3,000 per day of noncompliance or per violation for conditions that do not pose immediate jeopardy.*

"Whether or not acts are authorized or even known by the laboratory's management, a laboratory is responsible for the acts of its employees," the CMS says in the May 12 rule. "Among other things, laboratories need to have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to other laboratories even in instances in which they would normally forward a patient specimen for testing."

A narrow exception and alternative sanctions now are options for PT referrals as a result of reflex, confirmatory, or distributive testing. The CMS created specific definitions for these circumstances:

- Reflex testing is the confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.
- Confirmatory testing is performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test. It may be performed by the same laboratory that performs the initial test or by a second laboratory operating under a different CLIA certificate than the laboratory performing the initial testing.
- Distributive testing is when a laboratory test performed on the same specimen, or an aliquot of it, requires sharing it between two or more laboratories to obtain all data needed to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test.

The PT referral incidents would still be improper but not considered intentional as long as the referral was "in full conformance with written, legally accurate, and adequate standard operating procedures for the laboratory's

testing of patient specimens," the CMS says.

For example, protocols require a laboratory to send all HIV-positive test results to a second laboratory for confirmatory testing. However, if a CMS investigation finds that an individual referred only one of two positive HIV PT samples to another laboratory, thus not in conformance with standard operating procedures, the laboratory may be subject to revocation and a ban against the owner and operator, the agency said.

The PT referral also must not be a repeat offense for two survey cycles prior to the time of the incident. "The key to this exception is the expectation that laboratories will ensure that improper referrals are addressed and eliminated, or we will find that future referrals are intentional," the CMS says in the May 12 rule. "The exception is meant to be a one-time exception to a finding of general intent to forward a PT sample to another laboratory. Upon learning that the laboratory's training materials, training, or staff capabilities are inadequate to ensure compliance with the PT referral requirements, we expect the laboratory to correct the problems, and will treat subsequent referrals as 'intentional' in keeping with our long-standing practices."

The alternative sanctions are much less severe. In the May 2 CMS regulation, the agency outlined three categories of sanctions. The sanctions in the third category for relatively minor violations include civil monetary penalties and a plan for corrective action.

For instance, a laboratory places PT samples in an area with other patient specimens for a courier to take to a reference laboratory. The courier takes the PT samples to the reference laboratory, but the original testing laboratory notices the PT samples are missing. After realizing the mistake, the laboratory calls the reference laboratory and orders the PT specimens to be destroyed. The CMS says alternative sanctions would be appropriate in this situation.

The CMS estimates there are about six PT referral cases a year that could be subject to the new alternative sanctions. The average loss to laboratories for revocation as a result of a PT referral violation was $578,000 per laboratory. The penalties under alternative sanctions are estimated to be $150,000.

PT referrals would be in the middle category when a laboratory refers PT samples to a laboratory operating under a different CLIA number before the PT event close date and while the laboratory reports results to the PT program. If an investigator finds the referral does not constitute a repeat offense, the CMS would propose to suspend or limit the CLIA certificate for less than a year and impose the alternative sanctions of monetary fines and a corrective action plan.

In the first category, the most severe penalties are reserved for egregious violations involving repeat PT referral or cases where a laboratory reports another laboratory's results as its own. The penalty for these violations is revocation of the CLIA certificate for one year, at least a one-year ban for the laboratory owner and operator, and possible civil monetary penalties.

The penalties are a message to laboratories that they should never try to cheat a PT, Dr. Williams says. But there are additional incentives that laboratories should keep in mind.

"We understand that failures occur, and when they do, laboratories can then identify problems to be fixed," Dr. Williams says. "That's just one reason why no one should try to cheat a proficiency test. If you are cheating, you are not looking to identify the root cause of a problem and improve testing for your patients."n

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Charles Fiegl is CAP manager of advocacy communications, Washington, DC. The May 2 rule is at www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-09908.pdf. The May 12 rule is at www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf.