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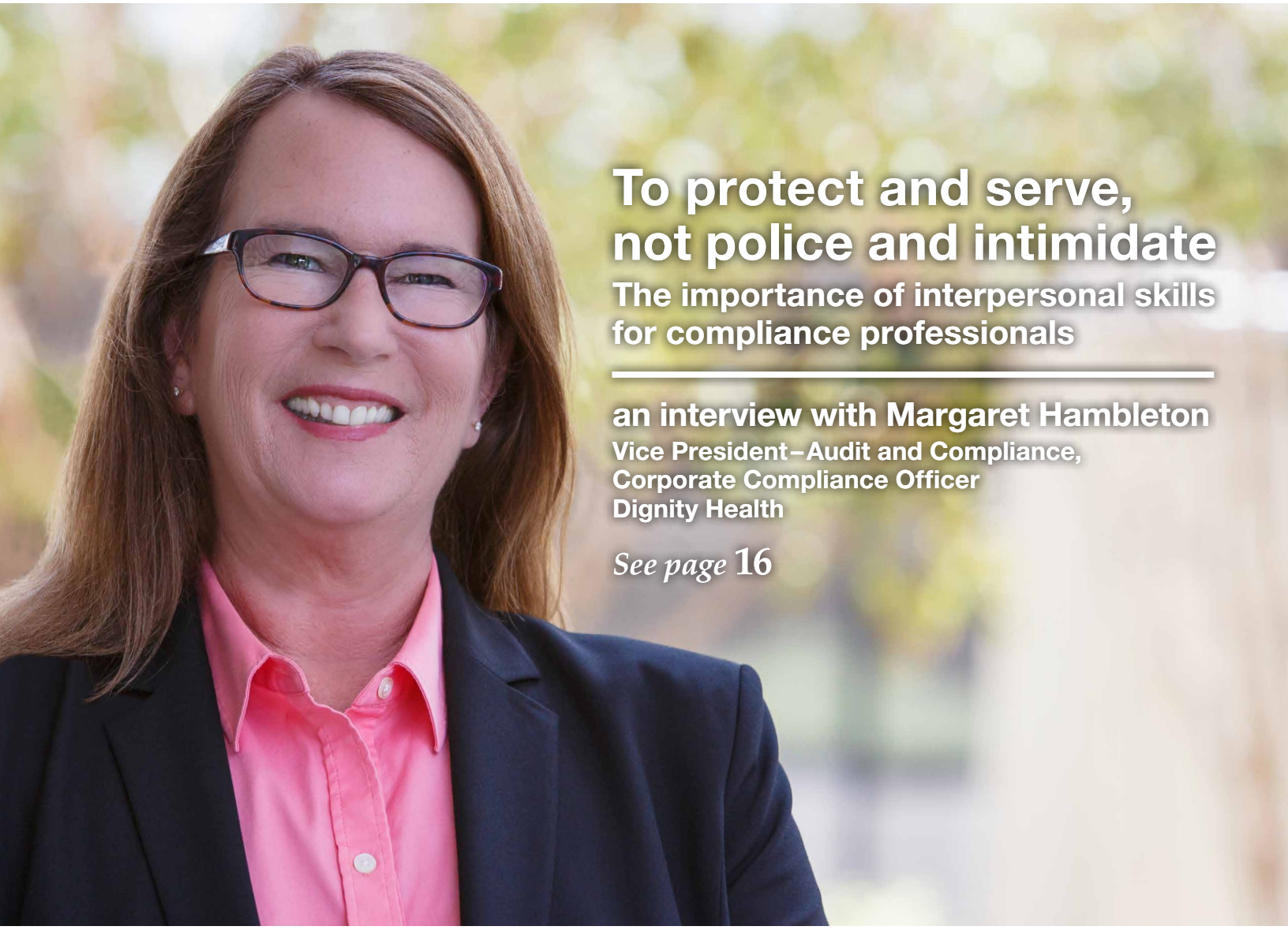

To protect and serve, not police and intimidate

The importance of interpersonal skills for compliance professionals

an interview with Margaret Hambleton

Vice President–Audit and Compliance,
Corporate Compliance Officer
Dignity Health

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by Jake A. Cilek, JD

Clinical laboratory proficiency testing: The changed landscape for punishing non-compliance

» Proficiency testing is an important quality control mechanism to measure laboratory performance.
» Referrals of proficiency testing samples pose the greatest compliance risk.
» CMS recently adopted a three-tiered framework for sanctioning referral violations.
» The new framework clarifies the compliance risks facing laboratories.
» Providers should revisit proficiency testing policies, procedures, and training programs.

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On May 2, 2014, the Centers for Medicare & Medicaid Services (CMS) published a final rule that significantly changes the regulations that govern proficiency testing (PT) for clinical laboratories. The PT process is a scheduled program used by CMS to ensure the accuracy and reliability of laboratory testing of patient specimens, as required by the Clinical Laboratory Improvement Amendments of 1998 (CLIA).[1] The final rule amends CLIA regulations applicable to PT in order to fully implement major parts of recent legislation, the Taking Essential Steps for Testing Act of 2012 (TEST Act). The TEST Act expanded CMS's discretion in sanctioning laboratories for "intentional" referrals of PT specimens to outside laboratories, which undermines the quality control goals of PT. The final rule replaces automatic revocation of the laboratory's CLIA certification and imposition of a two-year ban on the owner or operator, with a three-tiered sanction framework based on the severity and extent of the PT referral violation. The rule took effect on July 1, 2014. Providers should revisit their compliance policies and procedures applicable to PT to reflect the current regulatory environment, and train laboratory staff accordingly.


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Background

CLIA regulations specify the standards that must be met for laboratories to achieve and maintain CLIA certification. CLIA certification is mandatory for all non-research laboratories—including commercial, hospital, and physician office laboratories—which test human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the assessment of health of human beings."[2]

Clinical laboratory test systems are assigned a moderate or high complexity category on the basis of seven criteria given in

the CLIA regulations. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process. For tests developed by the laboratory or that have been modified from the approved manufacturer's instructions, the complexity category defaults to high complexity per the CLIA regulations. Further, the regulations require laboratories conducting "moderate and/or high-complexity testing" to enroll in an HHS-approved PT program covering the specialties for which the laboratory is certified.[3] As of June 2013, there were 239,922 CLIA-certified laboratories, of which 35,035 were required to enroll in a PT program and comply with all PT regulations.

The PT process itself is designed to verify the accuracy and reliability of a CLIA-certified laboratory's testing, and also to educate the laboratory on its performance. During scheduled PT, an HHS-approved program sends samples with unknown results to the laboratory (samples may be sent from a non-profit organization or a government entity). The laboratory then tests the PT samples and reports the results to the PT program for scoring. The PT process is done on the honor system, without any direct external oversight from the government or other proctor. Thus, to ensure the subject laboratory's true performance is evaluated, CLIA regulations require that PT samples are tested in the exact same manner, and by the same laboratory personnel, as routine testing of patient specimens.

When the CLIA was enacted, Congress recognized that entrusting laboratory directors to self-police the PT process creates strong incentives to act contrary to the intent of PT. For example, a laboratory may improperly deviate from its normal procedure by testing PT samples repeatedly, using higher qualified personnel than would normally be used, or intentionally referring PT samples to another laboratory for analysis to verify the results. The CLIA statute empowered CMS to discourage these practices by imposing penalties on laboratories for violations.

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The final rule addresses sanctions in cases where PT is done with any form of assistance from an outside laboratory. As noted by CMS in the final rule, for each PT event:

> The laboratory is barred from engaging in inter-laboratory communication pertaining to results prior to the PT program's event cut-off and must not send the PT samples or any portion of the PT samples to another laboratory for testing, even if it would normally send a patient specimen to another laboratory for testing.

From a compliance perspective, this broad prohibition against referrals, even in situations where technicians would otherwise refer patient specimens for testing, presents a meaningful risk area.

Prior to July 1, 2014, the mandatory penalty for intentional PT referrals was extremely severe and applied regardless of the egregiousness of the violation. The old rule states: "If CMS determines that a laboratory has intentionally referred its proficiency testing

samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty."[4] The regulations also provided that an owner/operator of the laboratory is excluded from owning/operating another CLIA-certified laboratory for up to two years.[5]

In 2012, Congress enacted the TEST Act to relax these penalties. This was likely due to mounting political pressure, because it came on the heels of a high-profile case in which Ohio State University Wexner Medical Center — a large and well-respected facility — faced possible revocation of its CLIA certification due to apparently inadvertent PT referrals (the case eventually settled for $268,000 and the clinical laboratory director was replaced).[6]

New sanctions for improper PT referrals

In the final rule, CMS reconstituted the prescriptive framework in intentional PT referral cases, in lieu of the automatic revocation of the laboratory's CLIA certificate and subsequent imposition of a two-year ban on the owner/operator. The new regulations amended the CLIA regulations to add three categories of sanctions, as set forth below. CMS believes these categories "achieve a better correlation between the nature and extent of intentional PT referrals at a given laboratory, and the scope and type of sanctions or corrective actions that are imposed on that laboratory and its owners or operators…"[7] When surveyors determine a laboratory intentionally referred PT samples to another laboratory for analysis, the following three categories of sanctions are available to CMS.

Revocation

The first category of sanctions applies to the most egregious violations, including repeat referrals or intentionally submitting another laboratory's results to CMS for scoring. CMS believes alternative sanctions are inappropriate for these serious violations; accordingly, it will revoke the laboratory's CLIA certificate for at least one year, prohibit the owner/operator from owning/operating a CLIA-certified laboratory for at least one year, and it may impose civil money penalties. This category is most akin to the pre-existing sanctions.

Importantly, during the comment period for the proposed rule, several commenters expressed concern that applying the one-year prohibition for owners to all laboratories of that owner is unreasonable for large health systems that own many CLIA-certified laboratories at various locations. The commenters suggested that the one-year ban for the owner should be limited to the isolated laboratory where the improper PT referral occurred. In response to this concern, CMS recognized that some flexibility is needed for owners of multiple laboratories if banning the owner could create patient access issues. As such, the regulations now include a provision allowing CMS to exempt laboratory owners from the ownership ban on a laboratory-by-laboratory basis, as long as it finds: (1) patients would not be put at risk as a result of exempting; (2) the exempted laboratory did not participate in the PT referral at issue; and (3) the exempted laboratory did not receive a PT sample from another laboratory within the last two survey cycles and fail to report it.

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Suspension

The second category of sanctions is for moderately severe violations, such as where the laboratory refers PT samples to another laboratory before the PT event cut-off, but still reports its own results for scoring. This would allow the laboratory to use another laboratory's results to check, confirm, or change its own PT sample results prior to submission. If surveyors determine such a referral is not a repeat violation, which would trigger the first category, CMS can *suspend* or *limit* the laboratory's CLIA certificate for less than one year.

A suspension of the CLIA certificate means that no testing may be performed by that laboratory during the suspension period; however, the owner/operator can contract with another operator to conduct the laboratory's work under the contracted laboratory's CLIA certificate. Further, unlike the ban available under the first category, suspension only applies to the individual laboratory in question. On the other hand, a *limitation* of the CLIA certificate means the laboratory is barred from performing testing, or billing Medicare or Medicaid, for laboratory work related to the specific specialty that committed the PT referral; it may continue to conduct all other testing. The determination of whether to apply a suspension or limitation depends on several compliance-related factors, including the extent and severity of the PT referral practice. Notably, suspension will always apply if surveyors determine that, in the past two survey cycles, there were PT referrals unreported to CMS. In addition to suspension or limitation, at a minimum CMS will impose alternative sanctions in the form of civil money penalties and a directed plan of correction that includes mandatory staff training.

Other penalties

The third category of sanctions is for the least serious violations, such as situations where PT samples are referred, but the laboratory does not receive the results prior to the PT testing cut-off date. These violations would result in civil money penalties and a directed compliance plan that includes mandated staff training.

Based on past PT referral violations, CMS estimates the average cost of revoking a laboratory's CLIA certificate under the old rule was $578,000 per laboratory. Under the alternative sanctions framework, the average cost for PT referral violations is estimated at roughly $150,000 per laboratory.

Compliance takeaways

The final rule provides much needed flexibility for laboratories ensnared in PT referral investigations under the old rules. Oftentimes laboratories found themselves facing revocation of their CLIA certificate, even in situations where the referral was inadvertent and was self-reported to CMS, as in the Ohio State University case.[8] However, the final rule also stresses that CMS still considers PT referral to be a serious issue. Only a small number of laboratories were sanctioned under the old rules, but compliance professionals should not downplay this risk moving forward. Indeed, PT referral investigations and associated penalties may increase in frequency, because CMS can now impose alternative sanctions consistent with the degree of misconduct. It is no longer limited to taking the disruptive step of shutting down the laboratory, which it may not be inclined to do because it could seriously harm patient access within the community.

From a compliance prospective, it can be difficult for CLIA-certified laboratories to ensure PT specimens are treated exactly like patient samples—even those that would otherwise be referred—while still ensuring PT results are in no way linked to another laboratory. Inadvertent referrals by low-level technicians may occur, which is still sanctionable under the new regulations due to CMS's interpretation of the phrase "intentionally

referred." Laboratory management who oversee the PT program need not affirmatively act with specific intent to violate CLIA regulations in order to establish an "intentional referral" that can bind the laboratory. All that is required is a general intent to refer a PT sample to another laboratory. The final rule states that "[w]hether or not acts are authorized or even known to the laboratory's management, a laboratory is responsible for the acts of its employees."[9]

To mitigate this risk, owners and operators of laboratories should focus compliance efforts on education and training at all staff levels. It will be important to revisit and update policies and procedures on PT samples to ensure they address the conduct that triggers each of the three tiers of sanctions. Once these policies and procedures are in place, providers should train employees to prevent staff from forwarding PT samples to other laboratories under any circumstance. The compliance program should also provide an internal reporting mechanism so the laboratory can promptly report any violations to CMS; this will help ensure that a limitation, as opposed to a suspension, is applied under the second category of sanctions.

In the final rule, CMS clearly recognizes the need for a PT referral compliance program; in fact, the alternative sanctions available include mandatory corrective action that includes staff training. Mistakes can happen during the PT process, but when they do, those laboratories with a robust and up-to-date compliance program are far more likely to avoid the types of conduct that can result in the revocation of their CLIA certification.

1. Clinical Laboratory Improvement Amendments of 1988 (CLIA) —Enforcement Actions for Proficiency Testing Referral, 79 Fed. Reg. 25,463 (May 2, 2014) (to be codified at 45 C.F.R. § 493). Unless otherwise indicated, all material in this article is sourced from the Final Rule itself.
2. *Id.*
3. See 42 CFR 493.17. (CDC test complexities sheet)
4. 42 C.F.R. § 493.1840(b) (amended July 1, 2014).
5. *Id.* at (a)(8).
6. The Pathology Blawg: "Ohio State laboratory will pay feds $268,000 to settle proficiency testing problems." January 18, 2013. Available at http://bit.ly/W3p76N
7. 79 Fed. Reg. at 25,464; the three categories of sanctions are codified at 42 C.F.R. § 493.1480 (b)(1)-(3).
8. Robert L. Michel and Joseph Burns: "Despite Passage of New Law on CLIA enforcement, Ohio State Settles with CMS Agrees to Pay $268,000, and names New Clinical Laboratory Medical Director."*Dark Daily*, February 20, 2013. Available at http://bit.ly/W1Wvex
9. 79 Fed.Reg. at 25,463.