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## What's Lurking in Your Lab? Legal Risks for Hospital Laboratories



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**M**ost health-care lawyers are accustomed to monitoring the high profile areas of regulatory enforcement in health care. However, many hospital lawyers, whether in-house or outside counsel, are unaware of the potential compliance time bombs hidden in plain sight in hospital (as well as independent and physician office) laboratories. Why does the warning alarm need to be sounded for hospital lawyers and administrators, and what contributes to the false sense of security about laboratory operations?

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Simply put, the warning alarm is needed because laboratory testing is a valuable service that is an integral part of medical services in every setting. Laboratory testing affects 70 to 80 percent of physician decisions, and virtually every patient admitted to a hospital has one or more laboratory tests performed.<sup>1</sup> A large hospital system can perform 10 million tests annually, and while laboratory testing may not generate large net revenues, a hospital cannot function without either performing or having access to laboratory testing.

The false sense of security exists because of the overall excellent quality of laboratories in the United States, combined with the fact that the rules governing laboratory operations are highly technical and relate to the science and technology used by the laboratory. Thus, compliance responsibility for the hospital laboratory is often assigned to laboratory directors and laboratory operations personnel. But lawyers (and administrators) who are not familiar with the comprehensive regulations that apply to laboratories may find that their lack of knowledge can have drastic reputational, financial and operational consequences. This article focuses on some of the essentials of the Clinical Laboratory Improvement Amendments of 1988 (CLIA)<sup>2</sup> and its implementing regulations,<sup>3</sup> with an emphasis on proficiency testing (PT). CLIA, one of the many laws governing laboratories, regulates performance and quality assurance and requires that all laboratories that test human specimens to diagnose, monitor or treat disease or mea-

<sup>1</sup> Haverford HealthCare Advisors, Overview of 2013-2014 Laboratory Industry Transactions (April 29, 2014), available at <http://www.haverfordhealthcare.com/wp-content/uploads/2012/01/Overview-of-2013-2014-Laboratory-Transactions-Deal-Values-and-Multiples-and-Forecasting-of-Anticipated-Trends1.pdf>.

<sup>2</sup> P.L. 100-578 (1988) (codified at 42 U.S.C. § 263a).

<sup>3</sup> The CLIA regulations are found at 42 C.F.R. Part 493.

sure health status (i) hold CLIA certifications and (ii) demonstrate compliance with applicable regulations.

Laboratory testing is an essential part of the services hospitals provide, and hospitals must maintain, or have available, adequate laboratory services for their patients to comply with the Medicare Conditions of Participation.<sup>4</sup> Laboratories are highly regulated by federal and state laws, such as CLIA, and if accredited, must also meet the requirements imposed by such accrediting bodies as the Joint Commission and the College of American Pathologists. Failing to comply with these requirements can lead to revocation of the right to conduct laboratory testing and receive reimbursement for testing from Medicare and Medicaid.

### Nuts and Bolts of the CLIA

Clinical laboratories, including hospital laboratories, are regulated under CLIA and must hold a CLIA certificate to perform any testing within CLIA's scope. The CLIA regulations set standards for the qualifications of laboratory personnel, quality control, proficiency testing, quality assurance and inspections. The Centers for Medicare and Medicaid Services (CMS) oversees the CLIA program and delegates laboratory enrollment and survey functions to the states. Laboratories also may choose to be accredited by a CMS-approved accrediting body. States may impose additional requirements on laboratories, and many states also issue clinical laboratory licenses or permits. Some states also require out-of-state clinical laboratories to be licensed if the laboratory performs testing on specimens from that state's residents.

The regulation of laboratories varies based on the complexity of the testing the laboratory performs. CLIA sets out three categories of testing: waived testing, moderate complexity testing and high complexity testing. Waived tests are those that have either been approved by the Food and Drug Administration for home use or are simple examinations with an insignificant risk of erroneous results. Nonwaived tests are categorized as either moderate complexity or high complexity. Test complexity is determined by the Department of Health and Human Services (HHS).<sup>6</sup> Laboratories that perform any nonwaived testing are required to comply with CLIA regulations regarding proficiency testing, quality control, quality assurance, and personnel requirements. Laboratories performing only waived testing have far less stringent requirements.

Based on the type of testing performed by the laboratory and whether the laboratory is accredited, the laboratory will receive one of four types of CLIA certificate:

- Certificate of Waiver,
- Provider Performed Microscopy Procedures Certificate,
- Certificate of Compliance, or
- Certificate of Accreditation

<sup>4</sup> 42 C.F.R. § 482.27.

<sup>5</sup> The six states requiring out-of-state laboratories to hold a license in order to test samples from patients located in the state are California, Florida, Maryland, New York, Pennsylvania and Rhode Island.

<sup>6</sup> The scoring system for test complexity is described at 42 C.F.R. § 493.17.

A separate CLIA certificate is required for each laboratory location, unless an exception for a multisite certificate is met. Exceptions include mobile units or other laboratories that do not have a fixed location and hospitals with several laboratories in contiguous buildings on the same campus with the same street address and under a common laboratory director. As a result, large hospitals and hospital systems may have multiple CLIA certificates of multiple types. As further described below, if a single laboratory's CLIA certificate is revoked, all of the hospital's CLIA certificates may be jeopardized.

### Penalties for Noncompliance

Laboratories that are out of compliance with the CLIA regulations are subject to principal and alternative sanctions imposed by CMS. Principal sanctions are suspension, limitation or revocation of a laboratory's CLIA certificate.<sup>7</sup> Alternative sanctions are a directed plan of correction, state onsite monitoring and civil monetary penalties. Laboratories that participate in Medicare and are out of compliance with CLIA conditions also may have their rights to receive payment under Medicare canceled or suspended.<sup>8</sup> A suspension or revocation of a laboratory's CLIA certificate automatically cancels the laboratory's right to receive payment under Medicare, and a limitation on any specialty or subspecialty cancels the right to receive payment for tests of that specialty or subspecialty.<sup>9</sup> A laboratory that does not have a CLIA certificate cannot perform any tests, regardless of the payer.

### Getting to Know Your Labs

The world of laboratories may be foreign to many lawyers, even those with experience with other healthcare provider types. Getting to know CLIA and your own laboratories is essential to achieving compliance and avoiding the usually costly process associated with the aftermath of self-reporting or government detection of noncompliance. A lawyer initiating a review or audit of a hospital's laboratory compliance is strongly encouraged to begin by determining the number and types of certificates held by the hospital's laboratories and ensuring that all laboratories are properly enrolled in CLIA with the appropriate certificate type.

In the same vein, it is important to understand the operational and administrative structure of the hospital's laboratories. Who is responsible for evaluating laboratory needs, proposing the addition of new laboratories and ensuring that CLIA certificates, state licenses and personnel licenses are appropriately applied for and renewed? Are all laboratory directors aware of their responsibilities, and do they have sufficient resources to carry out their responsibilities? Does the hospital laboratory staff understand their reporting obligations to CMS, state agencies and accrediting bodies? Has the laboratory staff been trained on how to handle PT samples, and are up-to-date protocols in place for PT?

<sup>7</sup> 42 C.F.R. § 493.1806.

<sup>8</sup> 42 C.F.R. § 493.1807. The same sanctions apply to Medicaid. 42 C.F.R. § 493.1809.

<sup>9</sup> 42 C.F.R. § 493.1808. The same sanctions apply to Medicaid. 42 C.F.R. § 493.1809.

## Proficiency Testing: Ground Zero for Severe Noncompliance Penalties

As a condition of certification, the CLIA regulations require all laboratories performing moderate or high complexity testing to perform PT in the specialties and subspecialties in which they are CLIA-certified. Laboratories that fail to successfully participate in PT for a given specialty, subspecialty, analyte or test are subject to sanction by CMS. For initial unsuccessful performance, CMS may choose to require the laboratory to train its personnel or obtain technical assistance rather than impose alternative or principal sanctions (described above), unless: (1) there is immediate jeopardy to patient health and safety, (2) the laboratory fails to provide evidence satisfactory to CMS that the laboratory has taken steps to correct the problem identified or (3) the laboratory has a poor compliance history.<sup>10</sup> Additionally, CMS has historically imposed stringent penalties on laboratories that violate nonreferral rules for PT samples. Although legislation passed in 2012 and regulations promulgated in 2014 added flexibility for CMS in addressing PT sample referrals, reduced sanctions are only available in limited circumstances. Consequently, hospital laboratories must remain vigilant about compliance with PT rules. Hospital lawyers should work with laboratory directors and laboratory personnel to ensure that the PT requirements are understood by the entire laboratory staff and laboratory policies and procedures address PT testing and the non-referral of PT specimens. CMS has published a helpful, “*must read*,” brochure, “CLIA Proficiency Testing - Do’s and Don’ts,”<sup>11</sup> which can guide both lawyers and laboratory personnel.

## Proficiency Testing Basics

CMS itself does not administer PT testing; instead laboratories enroll in HHS-approved PT programs. In a PT event, each laboratory receives samples from its PT program, tests the samples and reports the results back to the PT program. The PT program evaluates the results obtained by the laboratory and issues the laboratory a score for its performance in each specialty or subspecialty. A key concern with PT testing, and an area in which some laboratories have stumbled, is the requirement that laboratories test PT samples “in the same manner as patients’ specimens”<sup>12</sup> and not communicate with or send PT samples to other laboratories. Laboratories must test the PT samples along with their regular workload using the same standard methods and standard personnel. Laboratories are not permitted to run additional testing, outside the normal course, on PT samples. The person testing the PT samples and the laboratory director must “attest to the routine integration of the samples into the patient workload using the laboratory’s routine methods.”<sup>13</sup> Based on these rules, an overzealous employee who runs additional tests on a PT sample jeopardizes the laboratory’s compliance with PT rules.

<sup>10</sup> 42 C.F.R. § 493.803.

<sup>11</sup> Available at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf>.

<sup>12</sup> 42 C.F.R. § 493.801.

<sup>13</sup> 42 C.F.R. § 493.801(b)(1).

## PT Referrals: No Margin for Error

To ensure the integrity of testing, laboratories are forbidden from communicating with other laboratories regarding the results of PT samples until after the date on which all laboratories must report their results to the PT program.<sup>14</sup> This prohibition on interlaboratory communications extends to laboratories with multiple testing sites or separate locations. Additionally, the regulations provide that a “laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory” and that a “laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.” These requirements apply even if the two laboratories have the same owner or are part of the same hospital system. For CLIA purposes, each laboratory is distinct. Laboratory policies and staff training should clearly address the fact that communication regarding PT samples and shipping of specimens between hospital laboratories are strictly prohibited.

CMS has been active in sanctioning laboratories for referring PT samples to other laboratories, even when the laboratories argued that such referrals were not intentional or were based on the laboratory’s standard operating procedures for handling patient specimens. The severe sanctions imposed for such referrals could mean that a hospital laboratory would be unable to continue to conduct patient testing. Prior to 2014, CLIA regulations required that a laboratory that intentionally referred PT samples to another laboratory for analysis would have its CLIA certificate revoked for a minimum of one year.<sup>15</sup> Because the CLIA regulations also impose a two-year CLIA certification ban on owners and operators of laboratories that have had their CLIA certificates revoked, in a large hospital setting, all of the CLIA certificates held by the hospital may be jeopardized by a single laboratory’s PT referral. In a 2003 case, the HHS Departmental Appeals Board (DAB) emphasized that the two-year owner-operator prohibition “arises by operation of law immediately upon revocation of a laboratory’s CLIA certificate” and that there is no discretion for the Secretary in enforcing the ban.<sup>16</sup> The DAB has also held that the ownership ban applies to corporate owners, not just to individuals.<sup>17</sup>

In years past, CMS had repeatedly interpreted and argued that the intent required in making a PT referral is a general intent to send or refer the specimen to an outside laboratory; intent to violate the CLIA regulations is not required. The DAB agreed with CMS interpretation in numerous cases, finding that a laboratory employee’s voluntary sending of PT samples outside the laboratory

<sup>14</sup> 42 C.F.R. § 493.801(b)(3).

<sup>15</sup> 42 C.F.R. § 493.801(b)(4) (as amended through Jan. 24, 2003) (“Any 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.”)

<sup>16</sup> *William Komaiko, M.D. v. Cents. for Medicare & Medicaid Servs.*, DAB CR 1111 (Nov. 18, 2003).

<sup>17</sup> *See Evette Elsenety, M.D., et al. v. Health Care Financing Admin.*, DAB CR 1796 (Nov. 8, 2001) & *Millennium Med. Group v. Cents. for Medicare & Medicaid Servs.*, DAB CR 875 (Feb. 25, 2002).

is sufficient to constitute intent.<sup>18</sup> In several instances, laboratories received PT samples and sent those specimens to outside laboratories because the standard practice of the laboratory was to send patient samples to another laboratory for testing. Although the CLIA regulations require laboratories to test PT samples in the same manner as patients' specimens, CMS's position has been, and the DAB has agreed, that following a standard operating procedure for patient specimens that required sending specimens outside the laboratory constituted an intentional violation of the regulation prohibiting referral of PT samples.

## 2014 Updates to PT Rules

To address the draconian results stemming from the mandatory imposition of a one-year revocation of a laboratory's CLIA certificate for an intentional referral of a PT sample, in 2012, CMS began developing an amendment to the PT referrals regulation to permit the agency to impose alternative sanctions for referrals in certain circumstances. Then, in December 2012, Congress amended CLIA by passing the Taking Essential Steps for Testing (TEST) Act.<sup>19</sup> The TEST Act changed CLIA's language to clarify that, although PT samples are to be treated in the same manner as patient specimens and PT samples are not to be referred to another laboratory, CMS would have discretion when selecting sanctions to impose on laboratories that are found to have intentionally referred PT samples to another laboratory. In 2014, CMS finalized two rules<sup>20</sup> addressing PT testing and implementing the TEST Act. Although the preamble to one of these final rules confirms that "a PT referral is a prohibited act and will always involve consequences,"<sup>21</sup> the two final rules reduce those consequences in certain instances.

These rules create an exception to the interpretation of "intentional" PT referrals for reflex, confirmatory

and distributive testing and create definitions for each type of testing. These types of testing are part of many laboratories' standard operating procedures and had been an issue in many of the cases in which CMS had previously disciplined laboratories for referring PT samples to other laboratories. The new regulations provide that where a laboratory's testing procedures would call for reflex, distributive or confirmatory testing at another laboratory, the laboratory should "test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing."

The new regulations create a narrow exception to the interpretation of an intentional referral of a PT sample, which would normally subject a laboratory to a one-year revocation of its CLIA certificate. That exception permits CMS to impose alternative sanctions, rather than revocation, if the PT sample referral is limited to reflex, distributive or confirmatory testing that would have been in "full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens" and the PT referral is not a repeat PT referral by the laboratory. A repeat referral is defined as a second instance within the time period encompassing the two prior survey cycles in which a laboratory refers a PT sample, or a portion of a sample, for any reason to another laboratory. Even if the repeat referral is based on reflex, distributive or confirmatory testing, CMS would consider the referral intentional, and the exception would not be applicable. Laboratories that receive PT samples as referrals are required to report the receipt to CMS, even if the samples were received as part of reflex, distributive or confirmatory testing.

The new rules give CMS flexibility, but laboratories must still ensure that they have appropriate, written policies and procedures in place for the testing of PT specimens. Where a repeat PT referral will make the laboratory ineligible for alternative sanctions, laboratories with a previous PT referral must be particularly careful.

The 2014 regulations also created a three-tiered sanction structure for improper referrals, as described in the chart below.

<sup>18</sup> See, e.g., Victor Valley Community Hospital/Clinical Laboratory & Tomasz Pawlowski, M.D., DAB Decision No. 2340 (Oct. 22, 2010).

<sup>19</sup> P.L. 112-202, 126 Stat. 1483 (2012) (codified at 42 U.S.C. § 263a(i)(4)).

<sup>20</sup> 79 Fed. Reg. 25,436 and 79 Fed. Reg. 27,106.

<sup>21</sup> 79 Fed. Reg. 27,106, at 27,139.

Type of Referral	Severity of Sanctions, Available Actions
Repeat proficiency testing referrals (defined above); or laboratory refers a PT sample to another laboratory and on or before the PT event close date, the laboratory <i>receives</i> the outside laboratory's results and <i>reports</i> those results to the PT program	<p><b>Most Serious</b></p> <ul style="list-style-type: none"> <li>■ Revocation of the laboratory's CLIA certificate for at least one year,</li> <li>■ Prohibition on the owner/operator for owning/operating a CLIA certified laboratory for at least one year and</li> <li>■ Possibility of civil monetary penalties</li> </ul>
Laboratory refers a PT sample to another laboratory and on or before the PT event closes, the laboratory <i>receives</i> results from the outside laboratory but <i>does not report</i> the outside laboratory's results to the PT program	<p><b>Moderately Serious</b></p> <ul style="list-style-type: none"> <li>■ Suspension or limitation of the laboratory's CLIA certificate for less than one year and</li> <li>■ Imposition of alternative sanctions, which must include a civil monetary penalty and a directed plan of correction that includes required training of staff</li> </ul>
Laboratory refers a PT sample to another laboratory but <i>does not receive</i> results from the outside laboratory	<p><b>Least Serious</b></p> <ul style="list-style-type: none"> <li>■ Imposition of alternative sanctions, which must include a civil monetary penalty and a directed plan of correction that includes required training of staff</li> </ul>

Finally, the 2014 regulations also give CMS the authority to exempt a laboratory owner from the prohibition on owning a laboratory if it finds that there is no evidence that: (a) patients would be put at risk because of the exemption, (b) the laboratory that would be exempted was complicit in the PT referral, and (c) the laboratory that would be exempted received a PT sample from another laboratory in the prior two survey cycles and failed to immediately report the referral to CMS. Such exemptions are to be made on a laboratory-by-laboratory basis.

Although the 2014 final rules softened the penalties for certain PT referrals, laboratories at all hospitals must continue to be vigilant about not referring PT samples to outside laboratories. As the final rules make clear, PT referrals remain a serious issue and the reduced sanctions are only available in limited circumstances. Laboratories need to continue to ensure that their testing protocols prohibit the referral of PT

samples and that personnel are trained on proper procedures regarding PT samples. In particular, laboratories that engage in reflex, distributive or confirmatory testing should ensure that their personnel are appropriately trained on how PT samples are handled under these testing protocols.

### **Conclusion**

The stringent penalties for noncompliance with clinical laboratory requirements may expose a hospital to significant financial and reputational risks and jeopardize its ability to deliver quality care. Counsel for hospitals should educate themselves and monitor how laboratories are operating within their hospital or system, ascertain the types of testing that are being performed and determine whether there is an effective administrative structure to address both clinical and administrative duties that affect laboratory operations and compliance.