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## Laboratories Face Increased Enforcement for Improper Referral of Proficiency Testing Samples

The Centers for Medicare and Medicaid Services ("CMS") is sending letters to Laboratory Directors notifying them of an increased incidence of improper proficiency testing ("PT") referral. PT referral is of particular concern to Laboratory Directors as they are ultimately responsible for laboratory compliance and will be held accountable in accordance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") in instances where non-compliance is found.

In its letter, CMS strongly encourages laboratories to do the following:

- A. Examine their internal processes to ensure maximum integrity of the PT process in their laboratory;
- B. Promote laboratory-wide employee training in the CLIA requirements to process PT samples in the same manner as patient specimens;
- C. Avoid any inter-laboratory communications regarding PT samples during the PT event; and
- D. Promote laboratory awareness that PT samples, or parts of samples, should never be referred to another laboratory for any reason.

Under the CLIA regulations, all laboratories must maintain a current, unrevoked and unsuspended CLIA certificate issued by CMS that is applicable to the category of examinations or tests the laboratory performs, unless the laboratory is CLIA-exempt. While a certificate of waiver allows a laboratory to perform certain simple laboratory examinations, more complex tests require one of the other types of CLIA certificates, such as a certificate of compliance or a certificate of accreditation.

Any laboratory that has a certificate other than a certificate of waiver must enroll and participate in a PT program. These programs require the participating laboratory to examine or test PT samples received from the program in the same manner as the laboratory normally tests patient specimens. However, the laboratory must not engage in any inter-laboratory communications pertaining to the results of PT samples and must not send any PT samples or portions of PT samples to another laboratory for analysis. This is true even if the laboratory's normal process for testing patient specimens involves having another laboratory confirm the original laboratory's test results.

CMS' letter indicates that every PT referral is subject to serious sanction. Importantly, it is CMS' position that the CLIA statute requires the revocation of a laboratory's CLIA certificate for at least one year if the laboratory is found to have made an improper PT referral. This, in turn, could result in the hospital's exclusion from participation in the Medicare and Medicaid programs, since the Medicare Conditions of Participation for Hospitals require that all hospital laboratory services provided to patients are performed in accordance with the CLIA regulations. The CLIA regulations also provide that improper PT referral can result in restrictions on the laboratory owner's or director's ability to own or operate another laboratory for two years following the effective date of such revocation. Revisions made to the Medicare State Operations Manual (CMS Pub. 100-07) as recent as April 2008 confirm that these penalties are some of the most severe sanctions in the CLIA statute and regulations and that there is little room for discretion in enforcement.

Due to the serious consequences of improper PT referral, CMS is encouraging all Laboratory Directors to ensure their laboratories have effectively designed and implemented proper PT policies and procedures to guard against improper PT referral and assure that all laboratory personnel are trained accordingly.

For more information, CMS' Frequently Asked Questions About CLIA Requirements for Proficiency Testing is available at <http://www.cms.hhs.gov/CLIA/downloads/CLIA%20brochure8.pdf>

If you have any questions regarding PT referral or other laboratory requirements, please contact your regular Hall Render Attorney, Scott J. Geboy, Katherine A. Kuchan or Leia M. Chicoine via email at [sgeboy@hallrender.com](mailto:sgeboy@hallrender.com) [kkuchan@hallrender.com](mailto:kkuchan@hallrender.com) and [lchicoine@hallrender.com](mailto:lchicoine@hallrender.com) or by telephone at (414) 721-0442 or Clifford A. Beyler or Todd J. Selby at [cbeyler@hallrender.com](mailto:cbeyler@hallrender.com) and [tselby@hallrender.com](mailto:tselby@hallrender.com) or (317) 633-4884.

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