DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
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Office of Clinical Standards and Quality/ Survey & Certification Group

Ref: S&C: 12-28-CLIA

DATE: **May 11, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Process Change for Histocompatibility Laboratories

Memorandum Summary

- **Discontinue use of the Centers for Medicare & Medicaid Services (CMS) Form 2007 Tie-In Notice:** The CMS-2007 Tie-In Notice is not required for histocompatibility laboratories.
- **Discontinue assignment of HL-number for Histocompatibility Laboratories:** HL numbers are obsolete for CMS purposes and are not to be assigned for freestanding histocompatibility laboratories.

Background

A laboratory applies for a Clinical Laboratory Improvement Amendment (CLIA) certificate using the CMS-116 application form. After payment of fees, the laboratory is issued a registration certificate under which testing may be performed until compliance with the applicable CLIA regulations can be determined. Compliance is determined by a survey that verifies the quality of the laboratory's testing and a certificate of compliance or accreditation is issued by CMS. However, CLIA does not address the Conditions of Coverage for Medicare reimbursement and CLIA has no regulations concerning ownership. Prior to the implementation of the CLIA program, a laboratory's transplant status was verified through the survey and certification process and the laboratory was issued a provider number with an "HL" identifier. In September 1992, the numbering and identification system established for CLIA was applied to all laboratories, eliminating the need for an HL-number. However, the Regional Offices (RO) continued to assign HL-numbers for the intermediary.

Certain laboratories that qualify as freestanding histocompatibility laboratories are reimbursed and serviced by a Medicare Administrative Contractor (MAC) and are paid on a reasonable cost basis. As of August 3, 2009, Cahaba is the MAC for all histocompatibility laboratories. Cahaba maintains a list of these laboratories with assigned HL-numbers. MACs generally are notified about additions, deletions, and changes in provider status by the CMS-2007 Tie-In Notice.

Discontinue use of Tie-in Notices for Histocompatibility Laboratories

The tie-in notice is used for initial enrollment for Medicare, change of ownership, acquisition or merger, consolidation, addition or deletion of a home health agency branch, hospital unit, or outpatient physical therapy extension site, and voluntary and involuntary termination of billing numbers. The Program Integrity Manual (PIM), Chapter 15, Section 4.1.5, does not require a tie-in notice. The intended use of the tie-in notice goes beyond the authority of CLIA and the PIM does not instruct its use for histocompatibility laboratories. Therefore, CLIA RO and State Agency (SA) staff will no longer issue tie-in notices.

Discontinue Assignment of HL-Numbers for Histocompatibility Laboratories

The HL- number was used for identification and billing purposes. It has been replaced by the CLIA number for laboratory identification and by the National Provider Identifier (NPI) for reimbursement purposes. The comprehensive list of HL-numbers is maintained by Cahaba and not by CMS. Therefore, CLIA RO and SA staff will no longer assign or use HL-numbers.

Effective Date: Immediately. This information should be shared with all survey and certification staff, their managers, and the State/RO training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management