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DATE: April 1, 2002

FROM: Director
Center for Medicaid and State Operations

SUBJECT: Initiating On-Site Visits To Facilities Enrolled In the CLIA Program That Have Certificate of Waiver Certificates

TO: Regional Administrators, DMSO
Associate Regional Administrators, DMSO
State Survey Agency Directors

This memorandum is to notify you that **effective April 2002** the CLIA program is initiating on-site visits to facilities enrolled in the CLIA program that have a certificate of waiver (COW). As you are aware the CLIA program conducted an initial pilot study in the States of Colorado and Ohio, where on-site visits of a random sample of 200 CLIA COW and certificate of Provider Performed Microscopy Procedures (PPMP) laboratories were performed. Significant quality and certification problems were identified in over 50 percent of these laboratories.

CMS expanded this pilot to include eight additional States to verify the scope and seriousness of Colorado and Ohio's initial study findings. As a result of this expanded pilot, quality problems were identified that corroborated the initial study findings, which included:

- 32 percent failed to have current manufacturer's instructions;
- 32 percent didn't perform quality control as required by manufactures or Centers for Disease Control and Prevention (CDC);
- 16 percent failed to follow current manufacturer's instructions;

The Centers for Disease Control and Prevention (CDC), Office of Inspector General (OIG) and New York studies have similar findings.

Due to the significant increase in the number and types of tests waived, the rapidly expanding number of laboratories with no oversight, and the serious findings in COW laboratories, CMS will be visiting two percent of COW laboratories starting early 2002. The professional expertise exhibited by the laboratory consultants in the initial and expanded pilot studies resulted in a comprehensive report that has enhanced public, professional organizations and CMS's awareness. The report highlighted the necessity for education and oversight of the COW laboratories to guarantee the provision of quality laboratory services.

The list of attachments below are to be shared with our Federal Regional CLIA Consultants and your respective State CLIA Surveyors for implementation of onsite visits to COW laboratories. The attached materials necessary for implementation are:

- Questions and Answers
- CMS Fact Sheet
- Surveyor Questions Certificate of Waiver Laboratories

Lastly, I would like to offer our utmost appreciation and recognition to the CLIA Laboratory Consultants in each regional office and your respective State CLIA Surveyors.

If you have any questions or need further information, please contact Judith A. Yost of my staff at (410) 786-3407 or email at jyost@CMS.HHS.gov.

/s/

Steven A. Pelovitz

Attachments

cc: CLIA Consultants, ROs I - X