

TO: Independent Clinical Laboratories

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA)

EFFECTIVE: August 1, 1993

BACKGROUND: On February 28, 1992, regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) were released by the Health Care Financing Administration (HCFA). These regulations govern laboratory testing in all settings (independent clinical laboratories, physicians' offices, hospitals, etc.).

ACTION: Beginning August 1, 1993, Medicaid will implement the billing provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and DENY any claims submitted by independent clinical laboratory providers who have not obtained a CLIA certificate and number. Pursuant to federal (HCFA) implementation guidelines, in order to bill Medicaid as of August 1, 1993, for laboratory services provided after September 1992, you must have been issued a CLIA certificate and identification number. It is also noted that under Section 353(1) of the Public Health Service Act, the Federal Government has authority to seek criminal sanctions against any person convicted of intentionally violating provisions of CLIA. If you have not enrolled in CLIA, moreover, do not attempt to collect payment directly from the Medicaid recipient.

To obtain a CLIA certificate and number or to resolve any questions concerning your CLIA certificate, call (410) 290-5850 or write to:

HCFA CLIA Program
P.O. Box 26689
Baltimore, MD 21207-0489

If you have any questions regarding this Newsletter, please contact Phyllis Valeri-Bruschini, Laboratory Consultant, Division of Medical Assistance and Health Services, at (609)588-2721.

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