

DEPARTMENT OF HEALTH SERVICES

714/744 P Street
P.O. Box 942732
Sacramento, CA 94234-7320
(916) 654-8076

MMCD

cc: Helmer, MD
Seymour, MD
Lord, RN,
Compliance



October 17, 2000

RECEIVED

OCT 25 2000

TO: Medi-Cal Managed Care Health Plans

CORPORATE COMPLIANCE

SUBJECT: REVISION TO SEPTEMBER 7, 2000, MMCD ALL-PLAN LETTER

ENSURING BENEFICIARIES RECEIVE LABORATORY SERVICES FROM CLIA CERTIFIED LABORATORIES

The purpose of this letter is to inform Plans that the MMCD All-Plan Letter dated September 7, 2000 was inadvertently lacking a number and has been revised to correct that deficiency. We appreciate and thank plan representatives who alerted us of the omission.

Should you have any questions, or need additional information or clarification, please contact your contract manager.

**Susanne M. Hughes
Acting Chief
Medi-Cal Managed Care Division**

Enclosures

DEPARTMENT OF HEALTH SERVICES

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September 7, 2000

MMCD All-Plan Letter No. 00011

TO: ~~Medi-Cal Managed Care Health Plans~~
SUBJECT: ~~ENSURING BENEFICIARIES RECEIVE LABORATORY~~
SERVICES FROM CLIA CERTIFIED LABORATORIES

PURPOSE:

The goal of this letter is to ensure that all laboratories from which beneficiaries receive services are CLIA certified.

BACKGROUND:

Enacted by HCFA, Clinical Laboratory Improvements Amendments of 1988 (CLIA) requires all laboratory testing sites have either a CLIA certificate of waiver or a CLIA certificate of registration to perform testing. As stated in Chapter 3, Section 1220 of Division 2 of the California Business and Professions Code:

Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA Subpart H (commencing with Section 493-801) of Title 42 of the Code of Federal Regulations.

POLICY:

Plan contracts require compliance with 42 United States Code 263a, 42 CFR, Part 493, and Chapter 3 (commencing with Section 1200) of Division 2 of the California Business and Professions Code.

PROCEDURE:

For all Plans, documentation of CLIA compliance for all on-site and reference laboratories shall be maintained at Plan headquarters. Copies of valid CLIA certificates must be kept on file and are to be provided to DHS upon request.

These procedures are to be implemented in addition to those set forth in MMCD Policy Letter No. 96-06 (corrected).

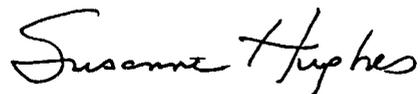


MMCD All-Plan Letter No. 00011

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September 7, 2000

Should you have any questions, or need additional information or clarification, please contact your contract manager.

A handwritten signature in cursive script that reads "Susanne Hughes".

Susanne M. Hughes
Acting Chief
Medi-Cal Managed Care Division

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

JUL 13 2000

Refer to: DEEO1

**Medicaid Clinical Laboratory Improvement Amendments (CLIA)
Implementation**

CLIA

Release No. 35

Dear State Medicaid Director:

Please convey to Medicaid claims processors immediately!

This release focuses on the ways in which States can ensure that clinical tests provided for Medicaid beneficiaries who are enrollees of managed care organizations (MCOs) are performed at CLIA certified laboratories. The release also provides information about a Health Care Financing Administration (HCFA) software update that is designed to reduce the number of records that States download from the Online Survey Certification and Reporting (OSCAR) system.

Assuring that Medicaid Managed Care Beneficiaries Receive Laboratory Services from CLIA Certified Laboratories

Some States now use MCOs exclusively for Medicaid beneficiaries or as an option to obtain medical services. The State pays the MCO a fixed sum per month for each enrolled Medicaid beneficiary to provide medical treatment and services. Since the State does not directly pay the laboratories performing these tests, some other means must be used to ensure that the laboratory is CLIA certified.

Each State must ensure that all laboratories used for testing Medicaid beneficiaries are CLIA certified. The following are examples of some procedures that can be used by States to ensure compliance with CLIA by MCOs.

- Require MCOs to identify the laboratories they intend to use. The State must then verify that the laboratory is CLIA certified and inform the MCO of the type of certificate. Waived and Provider Performed Microscopy Procedure (PPMP) laboratories can only perform specific tests. The State must also inform the MCO whenever there are updates to the laboratories' status.

- Provide the MCO with a list of CLIA certified laboratories that contains the certificate type. The MCO must obtain prior approval to use a laboratory not on the State provided list. This procedure requires the State to update the list on a routine basis.
- Require MCOs to obtain copies of the valid CLIA certificates from the laboratories they intend to use. Follow up will be necessary by the MCO to ensure that laboratories keep their certifications current.

These are only a few examples of procedures States can use to ensure compliance with CLIA. States must develop a procedure that will verify that the MCO is paying only for tests performed at CLIA certified laboratories. Although the MCO directly pays for laboratory testing, the ultimate responsibility for ensuring that only CLIA certified laboratories are paid with Medicaid funds rests with the State. All States were alerted at the onset of CLIA to include contract requirements that laboratories paid with Medicaid funds be CLIA certified. States should ensure that these requirements are met.

HCFA Software Update

A few States have had problems when comparing the CLIA laboratory data on the State system with the OSCAR data residing at the HCFA Data Center. It is essential that the downloads be accomplished routinely and timely to avoid problems related to erroneous claim denials. When downloading a file from HCFA the downloaded files' expiration date will be "bumped-up", or extended, 6 months. The "bumped up" date allows the State time to accomplish the certification process before claims are denied. If a download is missed, those updates will not be made on the State system and this may result in denying claims erroneously. States should be aware of these potential problems. Also, States should monitor the CLIA certification status of any out-of-State laboratories participating directly or indirectly in its Medicaid program.

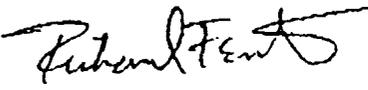
In May of 2000, HCFA updated our CLIA software to reduce the number of records that States need to download from the OSCAR. Prior to May, data downloaded using Report 91 included laboratory records that were updated for any reason during the selected time period. This resulted in States often receiving a very large number of records on a download. The update modified the selection criteria for this report to include only those laboratories with changes that directly affect the CLIA certificate information needed by Medicaid State Agencies, which reduces the overall volume of records to be downloaded.

Page 3 - State Medicaid Director

The updated software will also give States and HCFA Regional Offices the ability to reactivate a terminated laboratory record, either with or without a gap in CLIA certificates, if the laboratory has not been terminated more than 6 months. If reactivating a laboratory that has been terminated longer than 6 months, a gap in certificate will be mandatory. This change will remedy two long standing problems: 1) billing a laboratory retroactively to pay for certificates that were not warranted and were never issued, or, 2) issuing a second CLIA number to the same laboratory. When a laboratory's record is reactivated after having been terminated for more than 6 months, the laboratory will be processed as an initial certification but will retain its original CLIA number.

Comments or questions may be directed to Medford J. Campbell, Jr. at (410) 786-4457.

Sincerely,


Cindy Mann
Director

Page 4 - State Medicaid Director

cc:

All HCFA Regional Administrators

All HCFA Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors' Association

JOB AND

DEPARTMENT OF HEALTH SERVICES

14744 P Street
 .O. Box 942732
 Sacramento, CA 94234-7320
 (916) 654-8076



September 7, 2000

RECEIVED**SEP 12 2000****BUSINESS SERVICES****RECEIVED****SEP 13 2000****CORPORATE COMPLIANCE****TO: Medical Managed Care Health Plans****SUBJECT: ENSURING BENEFICIARIES RECEIVE LABORATORY SERVICES FROM CLIA CERTIFIED LABORATORIES****GOALS:**

The goal of this policy is to ensure that all laboratories from which beneficiaries receive services are CLIA certified.

POLICY:

Plan contracts require compliance with 42 United States Code 263a, 42 CFR, Part 493, and Chapter 3 (commencing with Section 1200) of Division 2 of the California Business and Professions Code.

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MMCD All Plan Letter

Page 2

September 7, 2000

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A handwritten signature in cursive script that reads "Susanne M. Hughes". The signature is written in black ink and is positioned above the printed name and title.

**Susanne M. Hughes
Acting Division Chief
Medi-Cal Managed Care Division**