



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare and Medicaid Services

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

October 9, 2008

Dan E. Harms, COL, MS
Armed Forces Institute of Pathology (AFIP-ZD)
Associate Director
DoD Center for Clinical Laboratory Medicine (CCLM)
Building 54
6825 16th Street, NW
Washington, D.C. 20306-6000

Dear Sir:

The enclosed Memorandum of Agreement (MOU-09-04) has been revised and cleared by CMS. The Acting Director, Center for Medicaid and State Operations and the Acting Administrator of the Centers for Medicare and Medicaid Services have signed the original. Please review the Agreement and have the Assistant Secretary of Defense (Health Affairs) sign the original. Keep the original of the signed agreement for your Agency and return a signed copy to me for CMS' accounting records. My mailing address is:

HHS/CMS/CMSO/FSBG
Attention: Rose Glorioso-Brandt
7500 Security Blvd., Room S3-13-15
Baltimore, MD 21244-1850

Thank you for your review of the Agreement and for your assistance with obtaining the signatures. Please call me at (410) 786-3261 or Denise V. Mason-Johnson at (410) 786-4876 if you have any questions.

A handwritten signature in black ink that reads "Rose .".

Rose Glorioso-Brandt
Management Analyst
Survey and Administrative Budget Staff, FSBG

Enclosure

**MEMORANDUM OF AGREEMENT between the
DEPARTMENT OF DEFENSE
and the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
on the
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988
(CLIA 1988)**

CENTERS FOR MEDICARE & MEDICAID SERVICES

Memorandum of Agreement (MOA)
MOU-09-04

I. Purpose

This agreement between the Department of Health and Human Services (HHS) and the Department of Defense (DoD) concerns laboratory operations within the DoD relative to requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This agreement recognizes the mutual interest within both the DoD and the HHS to establish set standards to improve the quality of clinical laboratory testing in such facilities conducting testing on materials derived from the human body for health assessment or the diagnosis, prevention, or treatment of disease. This agreement recognizes the unique mission requirements within the DoD that are not found within the civilian sector. These requirements necessitate the establishment of comparable, but not necessarily identical, CLIA regulations within DoD for the establishment of such standards to achieve the stated objective. This agreement also recognizes the authority, oversight, and responsibilities vested in the Assistant Secretary of Defense (Health Affairs) for the quality of health care services provided pursuant to Title 10, U.S. Code, Chapter 55.

II. Authority

The responsibility for carrying out CLIA is vested in the Secretary, HHS by Section 353 of the Public Health Service Act, as amended. This agreement is made pursuant to the authority to enter into a Memorandum of Agreement and is granted by further authority as provided in Section 301 of the Public Health Service Act as set forth in 42 U.S.C. 241.

III. Background

The enactment of CLIA was prompted by congressional concerns regarding the performance of clinical laboratories and the enforcement of Federal standards governing those laboratories. Primary concerns involved the lack of oversight, proficiency and quality assurance measures, and regulatory standards and enforcement procedures governing clinical laboratories in the non-Federal sector. The regulations established under CLIA 1967 and 1988 were designed to improve oversight of virtually all laboratories in the country that are involved in the testing of materials derived from the human body for health assessment or the diagnosis, prevention, or treatment of disease. The establishment of regulatory standards was designed to be applicable to all testing sites, but is clearly targeted to the non-Federal sector. Recognizing the jurisdictional authority given to the various Federal agencies in the establishment of regulations required for the normal execution of their mission, the CLIA regulations, while applicable to laboratories under the jurisdiction of an agency of the Federal Government, permit the Secretary, HHS to modify the application of such requirement as appropriate. The initial CLIA agreement with HHS and DoD was dated January 15, 1993, and was extended during various times to present.

IV. Scope of Work

There are no funds or exchanges of resources involved with this agreement. The DoD laboratory regulations incorporate to the maximum extent possible the CLIA regulations set forth in 42 CFR Part 493, modified as may be required to meet DoD readiness, training, and mission requirements during peace, contingency, and war time operations. The regulations recognize the authority and responsibility of the Assistant Secretary of Defense (Health Affairs), as delegated by the Secretary of Defense pursuant to Title 10, U.S. Code, Chapter 55, to establish regulations, issue laboratory certification documents, establish standards and policy, and provide for supervision and oversight of all DoD health resources.

V. Duration of MOA

Upon review and approval of the agreement (MOU-09-04) by the parties named therein, the Memorandum of Agreement between DoD and HHS will be for a six-year period beginning on January 14, 2009. During such six-year period, this agreement may be modified by mutual written consent of the parties.

VI. Project Officer

Judith A. Yost, Director
CMS/CMSO/SCG
Division of Laboratory Services
7500 Security Boulevard (Mail Stop S2-12-25)
Baltimore, MD 21244-1850
(410) 786-3407
Fax: (410) 786-1224
Judith.Yost@cms.hhs.gov

VII. Other Contacts

Linda Mansfield
CMS MOU Officer
(410) 786-4193
Linda.Mansfield@cms.hhs.gov

DoD Point of Contact for Interagency Staffing:
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Phone: (202) 782-2514
Fax: (202) 782-6022
Dan.Harms@afip.osd.mil or Dan.E.Harms@us.army.mil

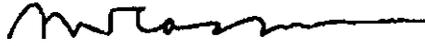
VIII. Duplication

Full implementation of this MOA will not duplicate any existing agreements.

IX. Privacy Act

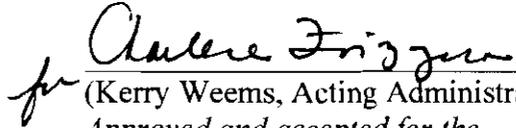
There is no data exchange addressed within this MOA.

X. Signatures



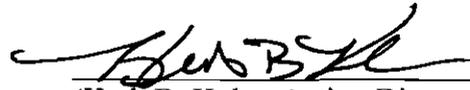
(S. Ward Casscells, M.D.)
*Approved and accepted for the
Department of Defense*

by:
*Assistant Secretary of Defense (Health
Affairs)*
Date: DEC - 5 2008



(Kerry Weems, Acting Administrator)
*Approved and accepted for the
Centers for Medicare & Medicaid
Services*

by:
*Acting Administrator of the Centers for
Medicare and Medicaid Services*
Date: OCT - 9 2008



(Herb B. Kuhn, Acting Director)
*Approved and accepted for the
Center for Medicaid and State
Operations*

Date: 9/30/08

Memorandum of Agreement Between Department of Defense and Health
and Human Services with reference to the Clinical Laboratory Improvement
Amendment of 1988

COORDINATION

Dir, C&PPI

Dr. Jack Smith

HB&FP

Mr. Allen W. Middleton

Handwritten signature and initials

OGC, DoD

Mr. John Casciotti

CoS, HA

COL Thom Kurnel

PDASD, HA

Dr. Stephen Jones



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Centers for Medicare and Medicaid Services

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October 9, 2008

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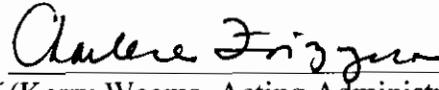
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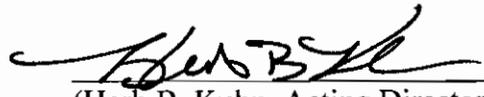
(S. Ward Casscells, M.D.)
*Approved and accepted for the
Department of Defense*

by:
*Assistant Secretary of Defense (Health
Affairs)*
Date: _____

for 

(Kerry Weems, Acting Administrator)
*Approved and accepted for the
Centers for Medicare & Medicaid
Services*

by:
*Acting Administrator of the Centers for
Medicare and Medicaid Services*
Date: OCT -9 2008



(Herb B. Kuhn, Acting Director)
*Approved and accepted for the
Center for Medicaid and State
Operations*
Date: 9/30/08



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

ACTION MEMO

HEALTH AFFAIRS

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Joseph E. Kelley, MD, DASD (Clinical and Program Policy)

JKelley 14 Nov 04

SUBJECT: Memorandum of Agreement Between Department of Defense and Health and Human Services with reference to the Clinical Laboratory Improvement Amendment of 1988

- Memorandum of Agreement (MOA) (TAB A) provides for Department of Defense (DoD) to establish clinical laboratory policy that recognizes the unique requirements of the Military Health System, and to certify DoD laboratories.
- There are no funds or exchanges of resources involved with this agreement. Upon review and approval of the agreement the MOA will be for a six-year period beginning on January 14, 2009. During the six-year period this agreement may be modified by mutual written consent of the parties.

RECOMMENDATION: That ASD (HA) sign MOA at TAB A.

COORDINATION: TAB B

Attachments:
As stated

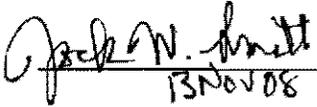
Prepared by: Dr. Gary N Matteson, C&PP, (703) 681-8890, LiveLinks #159962

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Dr. Jack Smith


13 NOV 08

HB&FP

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PDASD, HA

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COORDINATION

Dir, C&PPI

Dr. Jack Smith

Concurred, 11/13/08

HB&FP

Mr. Allen W. Middleton

Concurred, 11/12/08

OGC, DoD

Mr. John Casciotti

John A. Casciotti 11/20/08

CoS, HA

COL Thom Kurlmel

PDASD, HA

Dr. Stephen Jones
