

**MEMORANDUM OF UNDERSTANDING 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 Understanding (MOU)
MOU15-46

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 DOD and 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 the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment of, or the assessment of the health of human beings. 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 Understanding, by further authority as provided in Section 301 of the Public Health Service Act as set forth in 42 U.S.C. 241, and by the Secretary's authority under section 493.3(c) of the Code of Federal Regulations (CFR), Title 42, to modify as appropriate the application of the CLIA requirements to laboratories under the jurisdiction of an agency of the Federal Government.

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. 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 CLIA agreement with HHS and DOD is negotiated, modified and reissued with updated signatures and content each subsequent MOU's final release and publication.

IV. Scope of Work

There are no funds or exchanges of resources involved with this agreement. Per Subpart E-Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program of 42 CFR Part 493, a crosswalk was completed between the CLIA regulations and the DOD CLIP regulations. Upon review of this crosswalk by HHS, HHS finds, and DOD acknowledges and agrees, that the substantive requirements of the DOD Clinical Laboratory Improvement Program (CLIP) regulations are equivalent, to the maximum extent possible, to the substantive requirements of the CLIA regulations set forth in 42 CFR Part 493.

Therefore, in recognition of the modifications required to meet DOD readiness, training, and mission requirements during peace, contingency, and war time operations, and in recognition of 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, HHS hereby exercises its authority under section 42 CFR 493.3(c) to modify the application of the CLIA regulations to laboratories under the jurisdiction of DOD so as to allow such laboratories to comply with the requirements of the DOD CLIP regulations in lieu of the equivalent CLIA regulations. Furthermore, each agency agrees to notify the other in the event that there is a change in the CLIA regulations or the DOD CLIP regulations and, should any such changes be made, to work together to determine equivalency of the revised regulations and modify this agreement as necessary in accordance with Section V below.

V. Duration of MOU

Upon review and approval of the agreement by the parties named therein, the MOU between DOD and HHS will be for a six-year period beginning on January 14, 2015. During such six-year period, this agreement may be modified by mutual written consent of the parties.

VI. Program and Project Manager

Karen W. Dyer, Director (Acting)
Division of Laboratory Services (DLS) CMS Center for Clinical Standards and Quality
(CCSQ)
Survey and Certification Group (SCG)
7500 Security Boulevard (Mail Stop C2-21-16) Baltimore, MD 21244-1850
Phone: (410) 786-7910
Fax: (410) 786-6091 or (410) 786-9643
karen.dyer@cms.hhs.gov

VII. Other Contacts

Tyra C. Jeffries, Certified Federal Contract Manager
CMS InterAgency (IA) and Memorandum of Understanding (MOU) Coordinator
Phone: (410) 786-5156
Fax: 410-786-3432
tyra.jeffries@cms.hhs.gov

CAPT Cindy E. Wilkerson, MSC, USN
Director, Center for Clinical Laboratory Medicine Office of Assistant Secretary of
Defense for Health Affairs Health Care Operations
Defense Health Agency Defense Health Headquarters, Rm 3M203
7700 Arlington Blvd
Falls Church, VA 22042
Phone: (703) 681-6040
cynthia.wilkerson@dha.mil

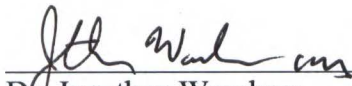
VIII. Duplication

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

IX. Privacy Act

There is no data exchange addressed within this MOA.

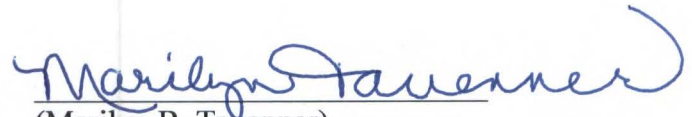
X. Signatures



Dr. Jonathan Woodson

*Approved and accepted for the
Department of Defense*

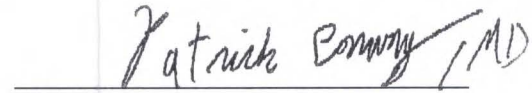
by:
*Assistant Secretary of Defense (Health
Affairs)*
Date: 3/11/2015



(Marilyn B. Tavenner)

*Approved and accepted for the
Centers for Medicare & Medicaid
Services*

by:
*Administrator of the Centers for
Medicare & Medicaid Services*
Date: JAN 29 2015



(Patrick Conway, M.D., M.Sc.,
CMS Chief Medical Director)
*Approved and accepted for the
Center for Clinical Standards and
Quality*
Date: 2/4/15