



DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

MAR 1 2002

The Honorable Bob Stump
Chairman, Committee on Armed Services
House of Representatives
Washington, DC 20515-6035

Dear Mr. Chairman

I am pleased to provide you this interim report on the development of regulations to improve privacy protections of medical records held by the Department of Defense (DoD), as required by Section 756 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001.

The Act required the submission to Congress of a comprehensive plan to improve privacy protections for medical records maintained by DoD. It also required that such a plan be consistent with regulations issued by the Secretary of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The law further directed that, notwithstanding any other law, DoD issue interim regulations, pending full implementation of the comprehensive plan, to improve privacy protections. Statutory specifications for these interim regulations were that they provide maximum protections for privacy consistent with actions necessary for purposes of national security, law enforcement, patient treatment, public health reporting, accreditation and licensure review activities, external peer review and other quality assurance program activities, fraud and abuse prevention, and other purposes. The recognition of the need to use medical information for these purposes is a critically important feature of this statute.

DoD's interim regulations were signed on October 30, 2000. Consistent with the statute, these regulations establish the general rules that information in DoD medical records shall not be used or disclosed by DoD components except for specifically authorized purposes or with the consent of the individual about whom the information pertains, and that no more than the amount of information reasonably necessary to accomplish the specific purpose shall be used or disclosed. I am attaching a copy of these interim regulations.

DoD's work on the comprehensive plan required by the statute was delayed by the HHS review to determine the finality of the HIPAA regulations issued December 28, 2000. On April 12, 2001 Secretary Thompson announced that the HHS regulations would take effect, beginning with a phase-in period requiring full compliance by April 14, 2003. The Department of Defense has now begun the substantial effort to implement a comprehensive program to improve patient

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privacy protections consistent with the HIPAA regulations. In the interim, the attached DoD regulations will be in effect. A final report will be provided upon completion of the required plan.

Thank you for your continued interest in the Military Health System.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Wolfowitz". The signature is written in a cursive, flowing style with a long horizontal line extending to the right.

Enclosures:

As stated

cc:

Honorable Ike Skelton
Ranking Democrat



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

OCT 31 2000

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE

SUBJECT: Interim Regulations to Improve Privacy Protections for DoD Medical Records

REFERENCES: (a) Section 756 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001
(b) Section 8138 of the Department of Defense Appropriations Act, 2001
(c) Section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)
(d) Privacy Act, 5 U.S.C. 552a
(e) 32 CFR Part 310, "DoD Privacy Program"
(f) 32 CFR Part 219, "Protection of Human Subjects"

Purpose and Applicability.

This memorandum establishes interim regulations to improve privacy protections for medical records of the Department of Defense. Regulations to improve medical information privacy protections are required pursuant to the statutes cited in references (a), (b), and (c). This memorandum applies to all DoD Components.

2. Definitions. Definitions appear in enclosure E1.

3. Background on statutory provisions.

3.1. Appropriations Act. Section 8138 of the Department of Defense Appropriations Act, 2001 (reference (b)) prohibits the use of DoD funds "to transfer, release, disclose, or otherwise make available to any individual or entity outside the Department of Defense for any non-national security or non-law enforcement purposes an individual's medical records without the consent of the individual."

3.2. Authorization Act. Section 756 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (reference (a)), enacted subsequently to the Appropriations Act, requires that not later than April 1, 2001, "the Secretary of Defense shall submit to Congress a comprehensive plan to improve privacy protections for medical records maintained by the Department of Defense." The plan "shall be consistent with the regulations promulgated under" HIPAA (reference (c)). The Act

further commands that “[n]otwithstanding any other provision of law, the Secretary shall prescribe interim regulations, pending full implementation of the comprehensive plan,” to improve privacy protections for DoD medical records. These interim regulations “shall provide maximum protections for privacy consistent with such actions that the Secretary determines are necessary for purposes of national security, law enforcement, patient treatment, public health reporting, accreditation and licensure review activities, external peer review and other quality assurance program activities, payment for health care services, fraud and abuse prevention, judicial and administrative proceedings, research consistent with regulations on Government wide protection of human subjects, Department of Veterans Affairs benefit programs, and any other purposes identified by the Secretary for the responsible management of the military health care system.”

3.3. HIPAA. HIPAA (reference (c)) authorizes the Secretary of Health and Human Services to issue regulations applicable to virtually the entire health care system of the United States for the protection of the privacy of medical information. Final regulations are expected to be issued very soon. They will be applicable to most DoD medical records and will have a significant impact on DoD medical information privacy policy.

3.4. Privacy Act. The “baseline” for DoD medical records privacy is the Privacy Act and its implementing regulations (references (d) and (e)), under which personal information may be used and disclosed within the Department for official purposes and outside the Department for purposes identified in law, regulations and Federal Register notices.

3.5. Legal obligations under the multiple statutes. In consultation with the DoD General Counsel, DoD’s legal obligations are understood to be: (a) in the longer term, to comply with the HIPAA regulations, when they become effective; (b) immediately, to establish interim regulations under the Authorization Act increasing privacy protections but allowing uses and disclosures necessary and proper for the responsible management of the Military Health System; (c) in the absence of such interim regulations, to comply with the more restrictive Appropriations Act provision; and (d) to maintain Privacy Act compliance throughout. It is clear that the subsequently enacted Authorization Act section – requiring the described interim regulations “notwithstanding any other provision of law” – supersedes the previously enacted and more restrictive Appropriations Act provision.

4. Policy.

It is DoD policy that:

4.1. Information in DoD medical records shall not be used or disclosed by DoD components except for specifically authorized purposes or with the consent of the individual about whom the information pertains.

4.2. Uses and disclosures of DoD medical records are specifically authorized for the following purposes:

Treatment.

4.2.2. Payment.

4.2.3. Health care operations.

4.2.4. Military mission activities.

4.2.5. National security.

Law enforcement.

4.2.7. Public health.

4.2.8. Public safety.

Judicial and administrative proceedings.

4.2.10. Health oversight.

4.2.11. Health data systems.

4.2.12. Approved research.

4.2.13. Department of Veterans Affairs benefits.

4.2.14. As required by other laws.

Other purposes as authorized by the ASD(HA).

4.3. Uses and disclosures of medical records for purposes identified in section 4.2 shall be managed so as to avoid the use and disclosure of more than that amount of information reasonably necessary to accomplish the specific purpose of the use or disclosure.

4.4. Uses and disclosures of medical records shall continue to comply with provisions of the Privacy Act and implementing regulations (references (d) and (e)).

5. Responsibilities.

The Heads of DoD Components shall:

5.1. Comply with this memorandum.

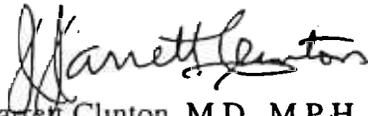
5.2. Review Privacy Act systems of records notices applicable to medical records to assure that the identified routine uses constitute permissible uses and disclosures as authorized consistent with this memorandum.

6. Procedure for clarifications and exceptions.

With respect to uses and disclosures for which this memorandum does not provide adequate policy guidance, requests for clarifications and exceptions, consistent with the applicable statutes, should be made to the ASD(HA) through the Deputy Assistant Secretary of Defense (Clinical and Program Policy).

7. Effective date.

This memorandum is effective immediately.



J. Jarrett Clinton, M.D., M.P.H.
Acting Assistant Secretary of Defense
(Health Affairs)

Enclosure: E1: Definitions

cc: Under Secretary of Defense (Personnel and Readiness)
Surgeons General
Director, Defense Privacy Office

ENCLOSURE 1: DEFINITIONS

For purposes of implementation of references (a) and (b) under this memorandum, the following definitions are applicable:

E1.1. Approved research. Research conducted in accordance with 32 CFR Part 219 (reference (f)).

E1.2. Consent. Actual, representative, constructive, apparent, or assumed consent.

E1.2.1. Representative consent occurs when a person legally authorized to act in behalf of the individual (such as a parent in behalf of a child) gives consent.

E1.2.2. Constructive consent occurs when an individual places into issue in a legal or administrative action in which the Department of Defense or the United States government is a party a matter to which the individual's medical records pertain and the individual has an obligation in that legal or administrative action to provide the medical records involved (or would have such an obligation if such records were in the possession and control of the individual).

E1.2.3. Apparent consent occurs when a patient apparently desires the involvement of a family member or close personal friend in a health care issue and disclosure of information is appropriate for the desired involvement, consistent with good health professional practices and ethics.

E1.2.4. Assumed consent occurs in an emergency when: an individual is unable due to physical, mental, or legal incapacity to make a decision regarding consent; a person lawfully authorized to make decisions in such cases (e.g., spouse, parent, guardian, representative) is unavailable; and a reasonable person would conclude that consent would be given but for such incapacity.

E1.3. Department of Defense. The Department of Defense includes any DoD contractor or subcontractor maintaining, using, or disclosing medical records in the performance of duties under the DoD contract. This is consistent with the long-standing DoD policy (set forth in 32 CFR 310.13(d), reference (e)) of considering contractors to be part of the Department for purposes of Privacy Act implementation. TRICARE network providers are considered subcontractors for this purpose.

E1.4. Department of Veterans Affairs benefits. Health care services, disability benefits, or other services and benefits under programs administered by the Department of Veterans Affairs.

E1.5. Disclose. Transfer, release, disclose, or otherwise make available personally identifiable information. Disclose does not include the transfer of records for safekeeping and storage to a Federal Records Center. Consistent with the Privacy Act regulations (32 CFR 310.41(h), reference (e)), these records remain under the control of

the transferring Component and the Federal Records Center personnel are considered agents of the Component which retains control over the records.

E1.6. Health care operations. Management functions necessary for the support of treatment, payment, or military mission fulfillment, including quality assessment activities; accreditation, licensing, certification, credentialing and similar activities; evaluations of health care personnel, facilities, equipment, systems, procedures, and activities; audits, fraud and abuse prevention, detection and compliance activities; and compiling and analyzing information for use in potential judicial and administrative proceedings.

E1.7. Health data systems. Systems operated by or on behalf of an authorized government agency that collects health data for analysis in support of policy, management, regulatory, or management functions authorized by law.

E1.8. Individual. Consistent with the definition in the Privacy Act (5 U.S.C. 552a(a)(2), reference (d)) and implementing regulations (32 CFR 310.3, reference (e)), an individual is a living United States citizen or permanent resident alien.

E1.9. Judicial and administrative proceedings. Authorized proceedings of courts and administrative agencies of competent jurisdiction.

E1.10. Law enforcement. Law enforcement includes:

E1.10.1. A legally authorized investigation or inquiry or official proceeding inquiring into a possible violation or failure to comply with any law or regulation, a criminal, civil, or administrative proceeding arising from a suspected violation of or failure to comply with any law, or official action by a legally authorized officer or agent to prevent a future violation or failure to comply.

E1.10.2. Activities of prosecutors, correctional, probation, pardon, or parole authorities.

E1.10.3. Any activity authorized by applicable law or regulations relating to the prevention of child abuse and neglect or spouse abuse.

E1.10.4. Any activity authorized by applicable law or regulations relating to the detection or prevention of health care fraud and abuse.

E1.10.5. Activities of coroners or medical examiners investigating deaths.

E1.11. Medical records.

E.1.11.1. Medical records are any items or any collection of personally identifiable information maintained in any form by the Department of Defense regarding

health care by a health care provider of the Department of Defense pursuant to health care programs and activities of the Department of Defense.

E.1.11.2. Medical records do not include:

E1.11.2.1. Information reported by Department of Defense components for purposes of official birth and death certificates.

E1.11.2.2. Information maintained in military or civilian personnel records not derived from health care of a patient by a health care provider of the Department of Defense. This may include such matters as applications or requests for enlistment or employment; employee benefits, disability accommodations, transfers, and other personnel actions.

E1.11.2.3. Information pertaining to donations of blood, organs, or tissue.

E1.11.2.4. The Armed Forces Repository of Specimen Samples for the Identification of Remains and any similar specimen repositories.

E1.11.2.5. Medical records from which patient names and other personal identifying information have been removed.

E.1.11.3. With respect to any records not included in this definition of medical records, the provisions of the Privacy Act and DoD implementing regulations (references (d) and (e)) continue to apply. In the event that any such records are determined to be within the scope of reference (b), these interim regulations permit (under the superseding authority of reference (a)) their use and disclosure consistent with references (d) and (e).

E1.12. Military mission activities. Any action by appropriate military command authorities pertaining to Armed Forces personnel (including deployed nonmilitary personnel supporting military forces) deemed necessary by those military command authorities to assure the proper execution of the military mission, including any matter relating to the fitness for duty, physical, mental, or emotional suitability, or readiness of such personnel.

E1.13. National Security. Matters concerning the conduct of military and other operations of the armed forces; military mission activities; the safety and security of military and civilian personnel and their dependents or military property; security clearances; intelligence and counterintelligence; and diplomatic activities of the government.

E1.14. Oversight. Review activities of authorized agencies and persons performing under applicable authority any audit, investigation, inspection, or civil, criminal, judicial, administrative or other proceeding or action.

E1.15. Payment. Activities pertaining to payments by or to DoD for health care services provided to beneficiaries of DoD health care programs, including: billing; claims processing and adjudication; determinations of coverage; determinations of amounts to be paid or sought on a per-service, per-capita, or other basis; review of medical necessity, appropriateness of care, justification of charges; actuarial evaluations; and resolution of complaints or disputes concerning payment.

E1.16. Public health. Activities carried out by or under the authority of an authorized Federal, State, or local governmental entity responsible for public health matters as part of its official mandate.

E1.17. Public safety. Activities carried out for the purpose of preventing or lessening a serious and imminent threat to the health or safety of an individual or the public.

E1.18. Required by other law. A disclosure of information from a medical record that is specifically required by another Federal statute, a treaty, or an order of a Federal court with which the Department is required to comply (and, where applicable, for which a routine use has been established in the pertinent Privacy Act system of records). Examples of disclosures required by other laws are disclosures to third party payers required under 10 U.S.C. 1079(j)(1), 1086(d), 1086(g), or 1095(g).

E1.19. Treatment. The provision of health care by health care providers or activities related to such provision, including health care management, coordination, assessment, case management, referrals for care, related social services, and similar activities of authorized persons.