

May 6, 2010

**ACCESS TO CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) DATA
FOR VHA USERS WITHIN THE VA
INFORMATION TECHNOLOGY (IT) SYSTEMS**

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy for providing authorized users access to Individually Identifiable Information (III) and Protected Health Information (PHI) from the United States Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) as outlined under title 5 United States Code (U.S.C.) 552a and the Health Insurance Portability and Accountability Act (HIPAA) in Information Technology (IT) systems of the Department of Veterans Affairs (VA).

2. BACKGROUND

a. Under the Privacy Act of 1974, 5 U.S.C. 552a (e)(10), “agencies shall establish appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained.” With the enactment of the Privacy Act, Congress required agencies to employ reasonable technological safeguards to protect individually identifiable health information that is stored electronically.

b. HIPAA of 1996, and the implementing regulations at title 45 Code of Federal Regulations (CFR) parts 160 and 164, include general administrative requirements and security and privacy guidelines that pertain to individually identifiable health information, defined as health information that concerns the physical or mental health or condition of an individual, the provision of health care to an individual, or the payment for the provision of health care to an individual, and identifies the individual or can be used to identify an individual. See title 45 C.F.R. §160.103. The HIPAA Security Rule, adopted in 2003, establishes safeguards to ensure the confidentiality of “electronic protected health information” (ePHI) as well as the appropriate access and use of this information. The HIPAA Privacy Rule regulates the use and disclosure of protected health information, that is, individually identifiable health information held by "covered entities" (generally, health care clearinghouses, employer sponsored health plans, health insurers, and medical service providers that engage in certain transactions.)

c. An Information Exchange Agreement (IEA) between VHA and CMS, executed in 2009, established the terms, conditions, safeguards, and procedures under which CMS exchanges Medicare and Medicaid data with VHA. The information received from CMS pursuant to this agreement is used to conduct statistical studies and analyses for VHA research and administrative purposes.

d. The System of Records Notice (SORN) is entitled “Consolidated Data Information System-VA” (97VA105) as set forth in the Federal Register, 72 Fed. Reg. 46130 (Aug. 16, 2007).

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e. Definitions

(1) **Access.** Access is the ability to view and use information in any system resource.

(2) **Administrative Use.** Administrative use is the use of raw CMS and VA-CMS data for VHA program administration, operational, or other purposes within the scope of the VHA – CMS Interagency Exchange Agreement, not including research use as defined in subpara. 2e(10).

(3) **Authorized User.** An authorized user is an individual who is permitted by Federal law, regulation, and VA and VHA policy to have access to VA IT systems and data for official purposes after completing the required privacy and security training, and signing the VA National Rules of Behavior.

(4) **Centers for Medicare and Medicaid Services (CMS).** CMS is a Federal agency within HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (CHIP), and health insurance portability standards. Additionally, CMS has other responsibilities, including the administrative simplification standards from the HIPAA Security Rule.

(5) **CMS Data Research Advisory Board (RAB).** The RAB was established by the VHA Office of Research and Development (ORD) to provide oversight and guidance on policies and procedures that govern the warehousing, management, and distribution of CMS data at the VA Information Resource Center (VIREC), including privacy, data security, and compliance issues. The RAB is comprised of representatives from: Health Services Research and Development (HSR&D) Service; VA Central Office and field researchers; the VHA Office of Privacy Compliance Assurance; the Office of the Assistant Deputy Under Secretary for Health for Policy and Planning; the Office of Information and Technology (OI&T); the Hines VA Hospital Institutional Review Board (Hines IRB); and VIREC.

(6) **Individually Identifiable Information (III).** III is any information maintained by VHA, including health information that pertains to an individual, identifies the individual, or is retrieved by the individual's name or other unique identifier.

(7) **Information Custodian (IC)**

(a) The IC is the person, or Program Office, responsible for permitting the use and disclosure of the VHA data contained in a VHA IT system, and collaborating with Department of Veterans Affairs (VA) Office of Information and Technology (OI&T) officials to reasonably safeguard VHA data.

(b) The VHA Medicare and Medicaid Analysis Center (MAC) serves as the IC for the administrative data repository containing raw CMS and VA-CMS merged data.

(c) VIREC serves as the IC for the research data repository containing raw CMS and VA-CMS merged data.

(8) **PHI.** PHI is individually identifiable health information maintained by a covered entity, including VHA, in any form or medium.

(9) **Raw CMS Data.** Raw CMS data is individually identifiable data maintained in a CMS System of Records (SOR). Pursuant to CMS internal policies, raw CMS data will remain in a CMS SOR and subject to CMS policies even after proper legal disclosures of such information.

(10) **Research Use.** Research use is the use of raw CMS and VA-CMS data within VA approved research protocols. The research protocols must meet the definition of research and be approved by the applicable VA research committee(s) such as the Institutional Review Board and the Research and Development Committee.

(11) **System of Records (SOR).** A SOR is any group of records under the control of a federal agency, or its contractors, from which information is retrieved by the name of the individual, or by some identifying number, symbol, or other personal identifier.

(12) **VA Information Resource Center (VIREC).** VIREC is a resource center within the VHA ORD, Health Services Research and Development Service (HSR&D). The VA-CMS Data for Research project at VIREC is responsible for use of CMS data for approved VA research projects. VIREC receives data from both MAC and CMS.

(13) **The VHA Medicare and Medicaid Analysis Center (MAC).** MAC is a field unit of the VHA Office of Assistant Deputy Under Secretary for Health for Policy and Planning. The MAC is the system manager for the System of Records Notice (SORN) entitled "Consolidated Data Information System-VA" (97VA105) and serves as the IC and main clearinghouse for CMS data used within VHA. The MAC distributes data directly to administrative users. The MAC also distributes CMS data to VIREC for re-distribution to research users.

(14) **VA IT System.** For the purpose of this Directive, a VHA IT system is any electronic system, extract, database, or dataset containing III belonging to VHA, and maintained by VHA or another component of VA.

(15) **VA-CMS Merged Data.** VA-CMS merged data is identifiable data disclosed by CMS and subsequently combined with VHA data and maintained in a VA System of Records (SOR). Any merged data is subject to VA and VHA policies. In addition, this data must be destroyed in accordance with the VA security policy and VHA Records Control Schedule (RCS) 10-1 as approved by the National Archives and Records Administration (NARA).

(16) **Research.** Research is a systematic investigation, including research development, testing and evaluation, and is designed to contribute to general knowledge.

3. POLICY: It is VHA policy that only authorized users may be provided access by the MAC and VIREC to raw CMS and VA-CMS merged data in VA IT systems.

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4. ACTIONS

a. **Assistant Deputy Under Secretary for Health for Policy and Planning.** The Assistant Deputy Under Secretary for Policy and Planning is responsible for:

(1) Establishing and maintaining VHA-wide requirements for access to raw CMS and VA-CMS merged data for administrative uses, in accordance with Federal law, regulation, and VA and VHA policy.

(2) Providing sufficient resources to maintain an oversight function in managing VHA information access to raw CMS and VA-CMS merged data by administrative users.

(3) Formalizing policies and procedures to be used by the MAC for distribution of raw CMS and VA-CMS merged data to VHA administrative users.

(4) Overseeing the implementation and any future modification of these policies and procedures.

b. **The MAC.** The MAC is responsible for:

(1) Implementing the Assistant Deputy Under Secretary for Policy and Planning office policies and procedures for the distribution of raw CMS and VA-CMS merged data to VHA administrative users.

(2) Verifying that the requestor has legal authority to access raw CMS and VA-CMS merged data under Federal law, regulation, and VA and VHA policy.

(3) Validating that requestors of raw CMS and VA-CMS merged data have completed all privacy and security training required by VA and VHA.

(4) Verifying compliance with all requirements established by applicable VA and VHA policy.

c. **Chief Research and Development Officer.** The Chief Research and Development Officer is responsible for:

(1) Establishing and maintaining VHA-wide requirements for access to raw CMS and VA-CMS merged data for research uses in accordance with Federal law, as well as VA and VHA policy.

(2) Providing sufficient resources to maintain an oversight function in managing VHA information access to raw CMS and VA-CMS merged data for research use.

(3) Charging ORD's RAB to:

(a) Oversee VIREC's policies and procedures; and

(b) Provide guidance on special concerns or issues regarding requests for use of raw CMS and VA-CMS merged data for research.

d. **VIReC**. The VIReC is responsible for:

(1) Implementing policies and procedures for distribution of CMS data for Research Users including:

(a) A formal process for requesting access to raw CMS and VA-CMS merged data.

(b) A method of tracking requests.

(c) Processes and policy to manage user access to raw CMS and VA-CMS merged data.

(2) Determining whether an individual requesting access is an authorized user before granting access to raw CMS and VA-CMS merged data by:

(a) Verifying that the requestor has legal authority to access raw CMS and VA-CMS merged data under Federal law, regulation, and VA and VHA policy.

(b) Verifying compliance with Federal and VA ORD policies governing human subjects' research.

(c) Validating that the requestor has completed all privacy and security training required by VA and VHA.

(d) Verifying compliance with all requirements established by the RAB and applicable VHA policy.

e. **Authorized Users**. Authorized users are responsible for:

(1) Submitting required documentation as prescribed in policies and procedures implemented by the MAC and VIReC to obtain access to raw CMS and VA-CMS merged data. Such documentation may include, but is not limited to:

(a) Completion certificates for privacy and security training,

(b) Signed VA National Rules of Behavior, and

(c) Supervisory approval of access.

(2) Complying with all applicable VA and VHA policy.

5. REFERENCES

a. Title 38 U.S.C. 7332, and 527.

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- b. Privacy Act of 1974, 5 U.S.C. § 552a.
 - c. HIPAA of 1996, 45 CFR parts 160 and 164.
 - d. The Common Rule, 45 CFR 46, Part A.
 - e. VA Directive 0710, Personnel Suitability and Security Program, and Handbook 0710.
 - f. VA Directive and Handbook 6500, Information Security Program.
 - g. VA Directive 6502, VA Enterprise Privacy Program.
 - h. VHA Directive 1605, VHA Privacy Program.
 - i. VHA Handbooks 1605.1, 1605.2, and 1605.03.
 - j. VHA Handbook 1200.5.
 - k. VA General Counsel Advisory Opinion 7-2007, Department Information Ownership, (Dec. 31, 2007).
 - l. “Information Exchange Agreement (IEA) between Department of Health and Human Services, The Centers for Medicare & Medicaid Services and Department of Veterans Affairs, Veterans Health Administration,” VHA no. 08-200, CMS no. 2009-02, June 15, 2009.
- 6. FOLLOW-UP RESPONSIBILITY:** The Assistant Deputy Under Secretary for Policy and Planning (10A5) is responsible for the content of this VHA Directive. Questions may be addressed to 202-461-7100.
- 7. RESCISSION:** VHA Directive 2004-063, Operating Procedures for the Management of Centers for CMS Data is rescinded. This VHA Directive expires May 31, 2015.

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