

ACCESS TO CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND UNITED STATES RENAL DATA SYSTEM (USRDS) DATA FOR VETERANS HEALTH ADMINISTRATION (VHA) USERS WITHIN THE DEPARTMENT OF VETERANS AFFAIRS (VA) INFORMATION TECHNOLOGY (IT) SYSTEMS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive establishes the policy for providing authorized users access to data from the United States Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) United States Renal Data System (USRDS) as outlined under title 5 United States Code (U.S.C.) 552a and the Health Insurance Portability and Accountability Act (HIPAA) in Department of Veterans Affairs (VA) Information Technology (IT) systems.

2. SUMMARY OF MAJOR CHANGES:

a. Various updates from the original VHA Directive 2010-019 are included in this version. These updates include information reflecting: changes in the VHA/CMS relationship for use of CMS data within VHA; the addition of an Information Exchange Agreement between VHA and NIDDK for distribution of United States Renal Data Systems data within VHA; and changes in responsibilities for distribution of CMS and USRDS data within VHA.

b. Amendment, dated August 20, 2019, adds a minor update to paragraph 6.p.

3. RELATED ISSUES: VHA Handbook 1153.01

4. RESPONSIBLE OFFICE: The Assistant Deputy Under Secretary for Health for Policy and Planning (10P1) is responsible for the content of this VHA Directive. Questions may be referred to 202-461-7100.

5. RESCISSION: VHA Directive 2010-019, dated May 6, 2010, is rescinded.

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of April 2021.

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ACCESS TO CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND UNITED STATES RENAL DATA SYSTEM (USRDS) DATA FOR VETERANS HEALTH ADMINISTRATION (VHA) USERS WITHIN THE DEPARTMENT OF VETERANS AFFAIRS (VA) INFORMATION TECHNOLOGY (IT) SYSTEMS

1. PURPOSE

This Veterans Health Administration (VHA) Directive establishes the policy for providing authorized users access to data from the United States Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) United States Renal Data System (USRDS) as outlined under Title 5 United States Code (U.S.C.) 552a and the Health Insurance Portability and Accountability Act (HIPAA) in Department of Veterans Affairs (VA) Information Technology (IT) systems. **AUTHORITY:** 5 U.S.C. 552a, 45 CFR parts 160 and 164.

2. BACKGROUND

a. 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 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, which includes 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 45 CFR 160.103. 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). 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.

c. An Information Exchange Agreement (IEA) between VHA and CMS, executed in 2009, established the terms, conditions, safeguards, and procedures under which CMS exchanges data with VHA. The information received from CMS pursuant to this agreement is used to conduct statistical studies and analyses that will support VHA research as well as operational planning and policy development.

d. An IEA between VHA and NIDDK, executed in 2011, established the terms, conditions, safeguards, and procedures under which NIDDK exchanges USRDS data with VHA. The information received from NIDDK pursuant to this agreement is used to conduct statistical studies and analyses that will also support VHA research as well as operational planning and policy development.

3. POLICY

It is VHA policy that access to CMS and USRDS data on VA IT systems is granted only by the Medicare and Medicaid Analysis Center (MAC) and the VA Information Resource Center (VIReC), and only to authorized users.

4. RESPONSIBILITIES

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

(1) Establishing and maintaining VHA-wide requirements for access to CMS and USRDS data for operational uses, in accordance with 5 U.S.C. 552a, 45 CFR parts 160 and 164, and VA and VHA policy.

(2) Providing sufficient resources to maintain an oversight function for managing access to CMS and USRDS data for operational uses in VHA.

(3) Reviewing, approving, and overseeing policies and procedures used by the MAC for distribution and oversight of CMS and USRDS data for operational uses.

(4) Provide guidance on special concerns or issues regarding requests for use of CMS and USRDS data for VHA operations.

b. **VHA Medicare and Medicaid Analysis Center.** The MAC is responsible for:

(1) Developing and implementing policies and procedures for the distribution and oversight of CMS and USRDS data for VHA operational uses.

(2) Determining whether requestors are authorized to have access to CMS and USRDS data by:

(a) Verifying that requestors have legal authority to access CMS and USRDS data under 5 U.S.C. 552a, 45 CFR parts 160 and 164, and VA and VHA policy.

(b) Validating that requestors have completed all privacy and security training required by VA and VHA.

(c) 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 CMS and USRDS data for research uses, in accordance with 5 U.S.C. 552a, 45 CFR parts 160 and 164 and 38 CFR part 16, and VA and VHA policy.

(2) Providing sufficient resources to maintain an oversight function for managing access to CMS and USRDS data for research uses in VHA.

(3) Charging ORD's Research Advisory Board (RAB) to:

(a) Review, approve, and oversee the policies and procedures used by the VIREC for distribution and oversight of CMS and USRDS data for research uses; and

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

d. **VA Information Resource Center.** The VIREC is responsible for:

(1) Developing and implementing policies and procedures for distribution and oversight of CMS and USRDS data for research uses.

(2) Determining whether requestors are authorized to have access to CMS and USRDS data by:

(a) Verifying that the requestor has legal authority to access CMS and USRDS data under 5 U.S.C. 552a, 45 CFR parts 160 and 164 and 38 CFR Part 16, and VA and VHA policy.

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

(c) Validating that requestors have completed all privacy and security training required by VA and VHA.

(d) Verifying compliance with all requirements established by applicable VA and 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 the VIREC to obtain access to CMS and USRDS data.

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

5. REFERENCES

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

b. Privacy Act, 5 U.S.C. 552a.

c. 45 CFR parts 160 and 164, HIPAA Privacy Rule.

d. 38 CFR Part 16, Federal Policy for the Protection of Human Subjects.

e. VA Directive and Handbook 0710, Personnel Suitability and Security Program.

f. VA Directive 6500, Managing Information Security Risk: VA Information Security Program.

- g. VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program.
- h. VA Directive 6502, VA Enterprise Privacy Program.
- i. VHA Directive 1605, VHA Privacy Program.
- j. VHA Handbook 1605.1, Privacy and Release of Information
- k. VHA Handbook 1605.02, Minimum Necessary Standard for Protected Health Information
- l. VHA Handbook 1605.03, Privacy Compliance Assurance Program and Privacy Compliance Monitoring.
- m. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- n. “Information Exchange Agreement (IEA) between Department of Health and Human Services, Centers for Medicare & Medicaid Services and Department of Veterans Affairs, Veterans Health Administration,” VHA no. 08-200, CMS no. 2009-02, June 15, 2009.
- o. “Information Exchange Agreement (IEA) between National Institute of Diabetes and Digestive and Kidney Diseases and Department of Veterans Affairs, Veterans Health Administration,” VHA no. 2011-01, July 29, 2011.
- p. System of Records Notice 97VA10P1 “Consolidated Data Information System-VA” (76 FR 25409 (May 4, 2011)).

6. DEFINITIONS

- a. **Access.** Access is the ability to view and use information in any VA IT system resource.
- b. **Authorized Data User.** An authorized data user is an individual who is permitted by 5 U.S.C. 552a, 45 CFR parts 160 and 164 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, signing the VA National Rules of Behavior, and obtaining approval from VHA Medicare and Medicaid Analysis Center (MAC) or the VA Information Resource Center (VIREC). Authorized users include, but are not limited to: VHA employees, VHA contractors and their sub-contractors, who have met these requirements. Hereinafter referred to as “user” in this document.
- c. **Centers for Medicare and Medicaid Services.** CMS is a Federal agency within HHS that administers Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and parts of the Affordable Care Act (ACA).
- d. **CMS Data.** CMS data is individually identifiable data disclosed by CMS. There are two types of CMS data defined in the VHA-CMS IEA for use in VHA:

(1) **Merged CMS Data.** Merged CMS data is CMS data that has been combined with VHA data and maintained in VA System of Records (SOR) 97VA10P1 entitled “Consolidated Data Information System-VA”.

(2) **Raw CMS Data.** Raw CMS data is CMS data maintained in a CMS System of Records. Pursuant to CMS internal policies, raw CMS data will remain in a CMS SOR and are subject to CMS policies even after proper legal disclosure to VHA.

e. **Information Custodian.** The information custodian (IC) is the person, or Program Office, responsible for permitting the use and disclosure of VHA data contained in a VA IT system, and collaborating with the VA Office of Information and Technology (OI&T) officials to reasonably safeguard data. VHA MAC is the IC for operational use and VIREC is the IC for research use of the CMS and USRDS data.

f. **Institutional Review Board.** An Institutional Review Board (IRB) is a board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with the Common Rule (38 CFR part 16) and other applicable regulations. ***NOTE:** For the purposes of this Directive, unless otherwise specified, references to IRB include any IRB that is responsible for approval and monitoring of a particular research project.*

g. **National Institute of Diabetes and Digestive and Kidney Diseases.** The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of the institutes within the National Institutes of Health. It conducts, supports, and coordinates research on many of the most serious diseases affecting public health. NIDDK provides funding to United States Renal Data System (USRDS).

h. **Operational Use.** Operational use is use of CMS or USRDS data for VHA program administration, operational, or other purposes, not including research use. Requests for operational use are approved by the MAC.

i. **Research.** Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

j. **Research and Development Committee.** The Research and Development Committee is the local committee charged with oversight of all R&D activities within a facility and is responsible for maintaining high standards throughout the R&D program.

k. **Research Use.** Research use is the use of CMS or USRDS data within VA-approved research protocols. The research protocols must meet the definition of research and be approved by an IRB and the VA Research and Development Committee. Requests for research use are approved by the VIREC.

l. **System of Records.** A system of records (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.

m. **United States Renal Data System.** The United States Renal Data System (USRDS) is a national data system that collects, analyzes, and distributes information about end-stage renal disease (ESRD) in the United States. USRDS staff collaborates with members of CMS, the United Network for Organ Sharing (UNOS), and the ESRD networks, sharing datasets and actively working to improve the accuracy of ESRD patient information.

n. **USRDS Data.** USRDS data is individually identifiable data disclosed by the NIDDK. There are two types of USRDS data defined in the VHA-NIDDK IEA for use in VHA:

(1) **Merged USRDS Data.** Merged USRDS data is USRDS data that has been combined with VHA data and are maintained in VA SOR 97VA10P1 titled "Consolidated Data Information System-VA".

(2) **Raw USRDS Data.** Raw USRDS data is USRDS data maintained in a NIDDK System of Records. Pursuant to NIDDK internal policies, raw USRDS data remain in a NIDDK SOR and are subject to NIDDK policies even after proper legal disclosure to VHA.

o. **VA Information Resource Center.** The VA Information Resource Center (VIREC) is a resource center within the VHA Office of Research and Development (ORD), Health Services Research and Development (HSR&D) Service, which is the IC for CMS and USRDS data repository for research use. VIREC's activities with regard to CMS and USRDS data are conducted under a VA IRB approved project: VA/CMS Data for Research Project.

p. **VA IT System.** For the purpose of this Directive, a VA IT system is any electronic system, extract, database, or dataset belonging to VHA, and maintained by VA or controlled by VA.

q. **VHA Medicare and Medicaid Analysis Center.** The VHA Medicare and Medicaid Analysis Center (MAC) is a field unit of the VHA Office of the Assistant Deputy Under Secretary for Health (ADUSH) for Policy and Planning (10P1) and the IC for the CMS and USRDS data repository for operational use. MAC is the system manager for the SORN 97VA10P1 titled "Consolidated Data Information System-VA".