

**USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND
UNITED STATES RENAL DATA SYSTEM (USRDS) DATA IN THE VETERANS
HEALTH ADMINISTRATION (VHA)**

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides the policies and procedures for using, disclosing, storing, processing and disposing of data from the Centers for Medicare and Medicaid Services (CMS) and the United States Renal Data System (USRDS). It addresses both research and operational uses of the data.

2. SUMMARY OF CONTENT:

a. This Veterans Health Administration (VHA) Handbook provides the policies and procedures for VHA use of data from the CMS and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) USRDS.

b. Amendment, dated August 20, 2019, adds minor updates to paragraphs 8.d.(2).

3. RELATED ISSUES: VHA Directive 1153.

4. RESPONSIBLE OFFICES: The Office of the Assistant Deputy Under Secretary for Health for Policy and Planning and the Office of Research and Development are responsible for the content of this VHA Handbook. Questions may be addressed to the VHA Medicare and Medicaid Analysis Center (MAC) at 781-849-1837 x200

5. RECISSIONS: None.

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

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CONTENTS

USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND UNITED STATES RENAL DATA SYSTEM (USRDS) DATA IN THE VETERANS HEALTH ADMINISTRATION (VHA)

1. PURPOSE 1

2. BACKGROUND 1

3. DEFINITIONS 1

4. SCOPE 4

5. OVERSIGHT 4

6. CMS DATA ADVISORY COMMITTEE (CMS-DAC) 5

7. MANAGEMENT OF CMS and USRDS DATA IN VHA 5

8. DISTRIBUTION OF CMS and USRDS DATA IN VHA 6

9. PROVIDING DATA TO NON-VHA OFFICES WITHIN VA 10

10. DATA PROVIDED DIRECTLY FROM CMS/NIDDK 10

11. DE-IDENTIFIED CMS OR USRDS DATA 10

12. DELEGATION OF ADDITIONAL INFORMATION CUSTODIANS 10

13. REFERENCES 10

USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND UNITED STATES RENAL DATA SYSTEM (USRDS) DATA IN THE VETERANS HEALTH ADMINISTRATION (VHA)

1. PURPOSE

This Veterans Health Administration (VHA) handbook provides policies and procedures for using, disclosing, storing, processing and disposing of data from the 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). It addresses both research and operational uses of the data.

AUTHORITY: 5 U.S.C. 552a, 45 CFR parts 160 and 164.

2. BACKGROUND

a. VHA purchases CMS and USRDS data to improve understanding of quality and cost drivers in delivering healthcare to Veterans, to better anticipate Veteran healthcare needs, to accurately forecast financial requirements for providing appropriate healthcare, and to provide a resource for researchers. CMS and USRDS data help broaden our understanding of Veterans' use of healthcare systems outside of VHA. Procurement of CMS and USRDS data through a centralized process significantly reduces VHA costs and makes possible the oversight of use of this data within VHA.

b. VHA and CMS signed an Information Exchange Agreement (IEA) allowing for the exchange, use, and distribution of CMS data for operational and research uses within VHA. VHA and the NIDDK also signed an IEA allowing for the exchange, use, and distribution of USRDS data for operational and research uses within VHA.

c. CMS and USRDS data are distributed to approved-users within VHA, who have legal authority to access the data and have demonstrated their ability to safeguard the data through a documented request process. VHA's goal is to optimize the benefits realized from its investment in CMS and USRDS data while protecting the privacy of Veterans' personal healthcare data. CMS and USRDS data users within VHA must follow all laws and regulations applicable to VHA that pertain to privacy or security of highly sensitive information including any additional requirements enforced specifically for use of CMS and USRDS data.

3. DEFINITIONS

All definitions contained herein are implied to be specific to CMS data users and are not necessarily terms relating to general data use unless otherwise specified in this Handbook.

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 Information Technology (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 the 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. **The Centers for Medicare & Medicaid Services.** CMS is a Federal agency within of the Department of Health and Human Services (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 are maintained in VA system of records 97VA10P1.

(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 System of Records and are subject to CMS policies even after proper legal disclosure to VHA.

e. **Data Requestor.** An individual becomes a data requestor following submission of a request for CMS or USRDS data to an Information Custodian (IC). Hereinafter referred to as “requestor” in this document.

f. **Data Re-use.** Data re-use is the use of CMS or USRDS data for a use other than the originally approved use. The data to be re-used may be obtained directly from a source other than the IC, including from another user, such as a VA research or operations data repository.

g. **Data Use Agreement.** A data use agreement (DUA) is an agreement that describes the conditions under which data may be shared between two entities for use, the specific purposes and limitations for their use and the responsible parties and their required duties.

h. **De-Identified Data.** De-identified data is data that contains none of the 18 data elements defined in the Health Insurance Portability and Accountability Act as Protected Health Information.

i. **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 VHA data. VHA MAC is the IC for operational use and VIREC is the IC for research use of the CMS and USRDS data.

j. **Institutional Review Board.** The 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 Handbook, unless otherwise specified, references to IRB include any IRB that is responsible for approval and monitoring of a particular research project.***

k. **The National Institute of Diabetes and Digestive and Kidney Disease.** The NDDK 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).

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

m. **Operations/Research Partnership.** Operations/Research Partnership is a single project that includes both operational and IRB-approved research objectives and may involve both operational data use and research data use. Requests for use of data in partnerships are approved by both the MAC and the VIREC.

n. **VHA Privacy Compliance Assurance Office.** The VHA Privacy Compliance Assurance (PCA) Office is a division of the VHA Privacy Office that evaluates and monitors performance of privacy and records management programs within VHA facilities and conducts on-site data privacy assessments of VHA facilities.

o. **Project.** A project is a VA-approved research or operations study with a defined objective(s).

p. **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.

q. **Research and Development Committee.** The Research and Development (R&D) 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.

r. **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 appropriate IRB and a VA R&D Committee. Requests for research use are approved by the VIREC.

s. **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 system of records 97VA10P1 titled “Consolidated Data Information System-VA”.

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

t. **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 research project: VA/CMS Data for Research Project.

u. **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 titled “Consolidated Data Information System-VA” (97VA10P1).

4. SCOPE

This VHA Handbook is issued to describe the policies and procedures associated with management, distribution, use, and disposition of data obtained from the CMS and USRDS for healthcare operations and research. The MAC and VIReC oversee the implementation and any future modification of these policies and procedures.

5. OVERSIGHT

a. The MAC is overseen by the Office of the Assistant Deputy Under Secretary for Health for Policy and Planning, which provides oversight and guidance related to management, distribution, and disposition of CMS and USRDS data for operational use within VHA.

b. The VIReC is overseen by:

(1) The ORD Research Advisory Board (RAB), formed and sponsored by the VHA ORD, to provide oversight and guidance to the VIReC related to management, distribution, and disposition of CMS and USRDS data for research use within VHA. The RAB is comprised of stakeholders from a cross-section of VA and VHA organizations. The RAB is chaired by the Director of HSR&D Service.

(2) The Edward Hines, Jr. VA Hospital Research and Development Service and IRB oversee the VIREC in its role as IC for research use of CMS and USRDS data under a VA IRB approved research project, "VA/CMS Data for Research Project". This oversight focuses on compliance with research requirements and protection of human subjects.

6. CMS DATA ADVISORY COMMITTEE

a. The CMS Data Advisory Committee (CMS-DAC) provides guidance and recommendations to the MAC and the VIREC on issues related to managing access to, disclosure or receipt of CMS and USRDS data.

b. The CMS-DAC comprises stakeholders from a cross-section of VA and VHA organizations that are responsible for the use of data within VHA. This committee meets on an ad hoc basis.

c. The CMS-DAC is jointly managed by the MAC and the VIREC.

7. MANAGEMENT OF CMS and USRDS DATA IN VHA

a. Obtaining CMS and USRDS Data in VHA.

(1) The Office of the Assistant Deputy Under Secretary for Health for Policy and Planning provides funding, and MAC serves as the VHA procuring agent, for annual and intermittent orders of CMS and USRDS data.

(2) MAC and VIREC collaborate to create an annual 'finder' file consisting of Veteran identifiers which are sent to CMS and USRDS for the purpose of matching and extracting associated CMS and USRDS data.

(3) In order to limit VHA expenses and to avoid the dissemination of inconsistent conclusions across VHA by analysis of different versions of the same datasets, end of year adjudicated CMS and USRDS data are obtained for VHA use. Additional datasets may be obtained under special circumstances at the discretion of the MAC and the VIREC.

(4) The MAC or the VIREC may request data directly from CMS or NIDDK on behalf of VHA projects in special circumstances, including requests for data not covered by the IEA or for data to be used for only one VHA project.

(5) No other VHA office, program or individual is permitted to request data directly from CMS or NIDDK without express written permission from the MAC or the VIREC.

b. Receiving, Managing, and Validating CMS and USRDS Data.

(1) The ICs:

(a) Receive data directly from CMS and USRDS.

(b) Maintain shipment and tracking information on all CMS and USRDS data received and warehoused.

(c) Perform quality checks on the CMS and USRDS data.

(d) Add CMS and USRDS data to the data repositories maintained by each IC.

c. Transferring Data between the MAC and the VIREC.

(1) The ICs transfer CMS and USRDS data reciprocally as needed. The following types of data may be transferred between the MAC and the VIREC:

(a) Finder files and data used to develop finder files except where access is specifically limited to the MAC or the VIREC by the data provider.

(b) CMS data that is included in both the MAC and the VIREC's DUAs with CMS.

(c) USRDS data.

d. **Data Disposition.** The ICs ensure proper disposition of both raw and merged data.

(1) Raw CMS data and raw USRDS data will be destroyed at the end of data use in accordance with requirements set forth in the CMS or NIDDK IEAs and CMS DUA.

(2) Merged CMS data and merged USRDS data will be dispositioned in accordance with VHA Records Control Schedule (RCS) 10-1 and for research data, also in accordance with VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

8. DISTRIBUTION OF CMS and USRDS DATA IN VHA

a. Types of Data Distributed.

(1) The ICs distribute merged CMS and merged USRDS data.

(2) The ICs distribute raw CMS and raw USRDS data with written approval for each use from CMS or NIDDK.

b. Management of Data Distribution.

(1) The requested use of the CMS and USRDS data determines which IC is responsible for oversight of data distribution. If the data is requested for research use, the IC is the VIREC. If the data is requested for operational use, the IC is the MAC.

(2) The ICs create policies, procedures, and standard processes for how prospective users may request access to CMS and USRDS data.

(3) No VHA personnel are allowed to purchase, receive, or transmit to VHA any CMS or USRDS data, without the knowledge and approval of the IC.

c. Request process and Data Use Agreements.

(1) The IC requires that data requestors submit specific documents in order to obtain access to CMS and USRDS data.

(2) Requests for CMS and USRDS data must include a determination that:

(a) The data requested comprise the minimum necessary data for the project

(b) The data provided to the project will be stored and maintained securely and will be dispositioned in accordance with the applicable RCS 10-1 authority.

(c) The project has legal authority to use any Protected Health Information (PHI) being requested.

(3) The IC reviews each request and determines whether the request will be approved.

(4) A DUA between the IC and the requestor (now referred to as the user), that sets out the conditions under which the data may be used, must be executed prior to release of data.

(a) If the user provides data to a secondary user within VHA an additional DUA between the user and the secondary user is required; this DUA must be approved by the IC.

(b) If the user provides data to an external contractor or sub-contractor, additional DUAs are required and must be approved by the IC:

1. An external DUA between the user and the contractor;

2. When applicable, an external DUA between the contractor and their subcontractor(s).

(5) Data are transferred to the user in accordance with VA and VHA data security policies as described in VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, and IC policy.

d. Data Storage Requirements for Users.

(1) CMS and USRDS data used by VA employees must be stored and used only on VA controlled systems.

(2) VA Contractors and sub-contractors must store and analyze data within the VA firewall and comply with VA data security requirements in VA Handbook 6500, unless the IC grants written approval for release of the data to a server outside the VA firewall

following a successful audit of the external server by VA and VHA Privacy and Security authorities.

e. Data Re-use.

(1) Re-use of merged CMS data or merged USRDS data is not permitted without prior written approval from the IC.

(2) Re-use of raw CMS data or raw USRDS data is not permitted without prior written approval from CMS or NIDDK, respectively, and the IC. The IC will contact CMS or NIDDK directly for this approval.

(3) Data transfer methods must be approved by the IC.

f. Special Requirements for Operations/Research Data Use Partnerships.

(1) Both aspects of the operations/research project must obtain approval from both ICs to use all of the CMS and USRDS data obtained for the project.

(2) Governance of CMS and USRDS data use for projects arising from operations/research partnerships is managed jointly by the ICs while the project is open for both operations and research. When operations use is concluded and research use continues, governance is assumed solely by the VIREC. When research use is concluded and operations use continues, governance for the operations use is assumed solely by the MAC and a copy of the data is dispositioned in accordance with RCS-10-1 and VHA 1200.05.

(3) Access to data for operations use is permitted only while the operations project is open. Access to data for research use is permitted only while the research project is open.

(4) On a case by case basis, the ICs collaborate on the development of appropriate data request processes, on-going oversight and data disposition.

g. Ongoing Oversight of Data Use. The IC continues oversight of approved data use by:

(1) Developing and managing a process for renewal of authorization for data use.

(2) Providing a list of locations where data are used or stored to the VHA Privacy Compliance Assurance (PCA) Office.

(3) All CMS and USRDS data users are subject to an assessment of their privacy and security practices by VHA PCA and must make their operations available to PCA for inspection within 15 days of a request for an assessment.

h. Maintaining Records. The IC maintains records for each data request, including:

(1) Documents submitted by the requestor;

(2) Documentation of the IC's review process, data preparation and release, oversight of data use, and disposition of data.

i. Suspension and Termination of Data Use for Cause.

(1) The IC may suspend use of the data:

(a) If there is a suspected or known violation of any provision of the DUA or of VA/VHA policy. The IC may seek advice from its Oversight Body or CMS-DAC as applicable.

(b) When data has been confiscated by an oversight or law enforcement office/body. The user must report the incident to the IC.

(2) The user's access to the data, including that of all project staff, must be removed during the suspension.

(3) The user, the user's approving officials, and the oversight body will be notified of the suspension, the reason for the suspension, and steps required for remediating the precipitating condition(s).

(4) The IC may approve resumption of data use when all conditions precipitating the suspension have been remediated.

(5) Data use may be terminated by the IC, in consultation with the oversight body, where conditions precipitating the suspension are not remediated.

(6) The user and the user's approving officials are notified of the termination.

(7) The user's access to the data, including that of all project staff, is removed permanently upon notification of termination.

j. Ending a Project's Data Use.

(1) Project data use ends when the project no longer needs the data, at the expiration of the DUA, or for research use, at the close of IRB approval for the project, whichever comes first.

(2) The user is responsible for managing disposition and notifying the IC of the final disposition of the data, in accordance with the requirements of the DUA and IC policies.

(3) Merged CMS Data and merged USRDS data will be dispositioned in accordance with VHA RCS 10-1, and for research data, also in accordance with VHA Handbook 1200.05.

(4) Raw data are dispositioned in accordance with the requirements of the CMS or NIDDK DUA.

k. **Re-opening a Project.** Once a project has closed, the user must submit a new request and receive approval from the IC prior to accessing the data.

9. PROVIDING DATA TO NON-VHA OFFICES WITHIN VA

Data use by VA offices external to VHA is not covered in the VHA-CMS IEA or the VHA- USRDS IEA. To avoid duplication of VA costs in purchasing data, the MAC may provide data to these VA organizations with prior written approval from CMS or NIDDK.

10. DATA PROVIDED DIRECTLY FROM CMS/NIDDK

VHA employees or contractors who previously received data directly from CMS or NIDDK for non-VHA purposes, may transfer and use the data within VHA only with prior approval from CMS or NIDDK and the IC. Data that is brought into VHA becomes VHA data once it is merged with VHA data.

11. DE-IDENTIFIED CMS OR USRDS DATA

a. Individual-level CMS or USRDS data that have been de-identified:

(1) Are sensitive VA data and remain subject to all VA policies regarding use and disclosure of VA sensitive data, and

(2) Will not be redistributed or used beyond the scope of the approved use without prior written approval from the IC.

b. The use of CMS or USRDS data in the creation of any document (manuscript, table, chart, study, report, etc.) must adhere to CMS's current cell size suppression policy.

12. DELEGATION OF ADDITIONAL INFORMATION CUSTODIANS

Projects may create new data sources that include CMS or USRDS data. These new data sources may not be redistributed or reused without prior written approval from the IC. The IC may delegate partial or complete IC authority to these projects to redistribute or reuse the CMS or USRDS data contained in the new data source.

13. REFERENCES

a. "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.

b. "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.

c. SORN 97VA10P1 - "Consolidated Data Information System-VA", 76 FR 25409 (May 4, 2001).

d. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

e. VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program.