

## **Memorandum of Understanding for Data Sharing and Use for Hemodialysis**

**Purpose:** This Memorandum of Understanding (“Agreement”) between the U.S. Department of Veterans Affairs (VA), Veterans Health Administration (VHA) and the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), as specified herein, establishes the basic terms and conditions for the sharing, protection, and use of certain health-related data for public health reporting and surveillance designed to:

1. Assist in the oversight activities and compare performance of dialysis sites to ensure the appropriateness of services and protection for patients with End Stage Renal Disease (ESRD).
2. Support VA public health, patient care and health care quality improvement programs.

**Background:** The End Stage Renal Disease (ESRD) Program was established in 1972 pursuant to the provisions of §29I, Public Law 92-603. The Program Management and Medical Information System (PMMIS) were created in response to the Centers for Medicare and Medicaid Services (CMS) requirement to provide information on ESRD patients. The ESRD PMMIS system of records was established by Federal Register notice on December 29, 1988. Data in this system are used primarily to meet and implement statutory requirements of Public Law 92-603, to meet other legislative requirements, support ESRD research, quality improvement projects, and public service programs. Information for this system is collected primarily through the ESRD Networks who were established to serve as liaisons between the federal government and the provider of ESRD services.

CMS contracts with eighteen ESRD Network Organizations throughout the United States to review and analyze the data. ESRD Networks perform oversight activities and compare performance of dialysis sites to ensure the appropriateness of services and protection for patients with ESRD. Adequate VHA reporting is critical to CMS efforts in this area. Reporting includes the completion of required forms consistent with the ESRD Instruction Manual for Renal Providers, and timely transmittal of all the completed, required forms provided by CMS according to the reporting schedule of the ESRD Network.

All VA Dialysis Program sites receive assistance and support from the ESRD Network, as well as, reports on their unit specific data and how it compares to the VA National, non-VA National and non-VA male data. These are performance measures dealing with adequacy of dialysis, anemia, vascular access, albumin levels and co morbid conditions. Particular emphasis is placed on the review and analysis of VA’s performance in the ESRD Clinical Performance Measures (CPM) Project, an initiative designed to provide information to all stakeholders and to conduct quality improvement initiatives and activities.

**Authorities:** Data being released by VHA pursuant to this Agreement do fall under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule [45 Code of Federal

Regulations Parts 160 and 164], Privacy Act of 1974, as amended, 5 U.S.C. 522a; Title 38 U.S.C. Sections 5701 and 7332. The CMS reports provided to VHA do fall under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule [45 Code of Federal Regulations Parts 160 and 164], Privacy Act of 1974, as amended, 5 U.S.C. 522a; and Section 1106(A) of the Social Security Act. Criteria for releasing confidential individually-identifiable data will be satisfied before the beginning of the project.

CMS is a “public health authority” as defined at 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). As a covered entity under HIPAA the Veterans Health Administration (VHA) is permitted to disclose Protected Health Information to CMS, without patient authorization, as a disclosure to a public health authority authorized by 45 CFR §164.512(b). CMS will work with VA to determine what data constitutes the minimum necessary to accomplish the purposes of this project. The parties agree to abide by all requirements of the HIPAA Privacy Rule with respect to Protected Health Information disclosed under this Agreement.

The information requested is protected in a Privacy Act System of Records (SOR) and shall be released from VHA in accordance with the Privacy Act (5 U.S.C. §552a) and VHA data release policies and procedures. VA is authorized upon the receipt of an appropriately executed written request from the CMS to disclose protected health information for the purpose of public health pursuant to the Privacy Act disclosure exception found in “Patient Medical Records-VA” (24VA19) system of records Routine Use 10. This Memorandum of Understanding meets the requirements of a written request from CMS. Data provided by VHA to CMS for the purposes stated in this Agreement is also protected by Title 38 United States Code (U.S.C). The authority for VHA to share this data with CMS is an appropriately executed written request that meets the requirements of 38 U.S.C. §5701(b)(3) and (e).

The CMS Privacy Act Systems of Records from which the reports will be released to VHA is End Stage Renal Disease Program Management and Medical Information System (PMMIS) No. 09-70-0520. The legal authorization for the release of the data is Condition of Disclosure 1 of the Privacy Act of 1974, as amended.

**Safeguarding & Limiting Access to Shared Data:** CMS agree to establish and implement proper safeguards against unauthorized use and disclosure of the data provided under this Agreement. Proper safeguards shall include the adoption of policies and procedures to ensure that the data obtained under this Agreement shall be used solely in accordance with §§226A, 1875 and 1881 of the Social Security Act [42 U.S.C. §§426-1, 1395l and 1395rr], Privacy Act of 1974, as amended [5 U.S.C. § 552a] and the HIPAA Privacy Rule [45 C.F.R. Parts 160 and 164]. Proper safeguards shall also include the use of policies and procedures consistent with guidance and standards issued by the Office of Management and Budget and the National Institute of Standards and Technology under the Federal Information Security Management Act of 2002, 44 U.S.C. §§3541-49, 40 U.S.C. § 11131, and 15 U.S.C. § 278g-3. CMS also agrees to comply with security requirements for VHA data promulgated by VA under 38 U.S.C. § 5723.

CMS shall establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized access to the data provided by VHA. VA sensitive information must not be transmitted by remote access unless VA-approved protection mechanisms are used. All encryption modules used to protect VA data must be validated by NIST to meet the currently applicable version of Federal Information Processing Standards (FIPS) 140 (See <http://csrc.nist.gov/cryptval/140-1/1401val.htm> for a complete list of validated cryptographic modules). Only approved encryption solutions using validated modules may be used when protecting data during transmission. Additional security controls are required to guard VA sensitive information stored on computers used outside VA facilities. All VA data must be stored in an encrypted partition on the hard drive and must be encrypted with FIPS 140 validated software. The application must be capable of key recovery and a copy of the encryption key(s) must be stored in multiple secure locations. Further, CMS agrees that the data must not be physically moved or transmitted in any way from the site s agreed upon without first being encrypted and obtaining prior written approval from the data owner.

If a CMS employee, agent or contractor becomes aware of the theft, loss or compromise of any device used to transport, access or store VA information, or of the theft, loss or compromise of any VA data, the user must immediately report the incident to his or her supervisor. That supervisor must within one hour inform the VHA Point of Contact listed in paragraph 10 under the Agreement Principles section. The VAH Point of Contact will promptly make the appropriate contacts within VHA to determine whether the incident warrants escalation, and comply with the escalation requirements for responding to security incidents.

The authorized representatives of VHA and the VA Inspector General will be granted access to premises where the data are kept by CMS for the purpose of confirming that CMS is in compliance with the security requirements.

Access to the records shall be restricted to authorized CMS employees, agents and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this Agreement. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws. CMS agrees to limit access to, disclosure of and use of all data provided under this Agreement. CMS agrees that, access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to VHA's data to perform this Agreement.

**Restriction on Use of Data:** The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement. If CMS wishes to use the data and information provided by VHA under this Agreement for any purpose other than those outlined in this Agreement, CMS shall make a written request to VHA describing the additional purposes for which it seeks to use the data. If VHA determines that CMS's request to use the data and information provided hereunder is acceptable, VHA shall provide CMS with written approval of the additional use of the data.

Except as outlined in this Agreement and as VHA shall authorize in writing, CMS shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA data covered by this Agreement to any person outside CMS with the exception of CMS agents and contractors.

## **Agreement Principles:**

**1. Intended Use:** CMS collects information related to individuals with ESRD who are entitled to or may be entitled to Medicare benefits or who are treated by VHA. The data includes information taken from the beneficiary/patient medical records, claims data, and payment data collected from several non-reimbursement data collection instruments and Medicare bills. Data collected by CMS is covered by a system of records, which sets forth the uses and disclosure policies for the data.

CMS may use and redistribute the data provided herein or analyses thereof to official governmental health agencies, including VA, or other agencies and entities conducting their public health responsibilities (collectively referred to as “recipients”) consistent with applicable federal law for the following purposes:

1. Develop analytic methods to identify possible events or concerns that warrant further follow-up research, investigation, or immediate public health intervention actions.
2. Share the data and derivative analyses with appropriate governmental health agency jurisdictions for local actions that may be warranted.
3. Enable authorized public health officials to query the source data repository for additional data or information as may be necessary to carry out critical public health functions.
4. Conduct research related to the analytic methods and public health threats described above.

**2. Data Content:** The specific data to be provided will be mutually agreed upon, including the format, coding, and periodicity. The data includes information taken from the beneficiary/patient medical records, claims data, and payment data collected from several non-reimbursement data collection instruments and Medicare bills. The data will be provided using the following CMS forms:

- CMS-2728-U3 (06/24), End Stage Renal Disease Medical Evidence Report, Medicare Entitlement and/or Patient Registration.
- CMS-2746-U3 (10/04), ESRD Death Notification
- CMS-2744 (A & B), ESRD Medical Information System ESRD Facility Survey
- CMS-820 (1/27/05), In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form
- CMS-821 (1/20/05), Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form

**3. Data Retention:** CMS will be designed as custodians of the VHA data for CMS and will be responsible for complying with all conditions of use and for establishment and maintenance of

security arrangements as specified in this Agreement to prevent unauthorized use and disclosure of the Owner's data provided under this agreement. The User agrees to notify the Owner within fifteen (15) days of any change of custodianship.

Technical Representative for VHA

James Kaufman, MD  
Div. of Nephrology  
VAMC  
150 S. Huntington Avenue  
Boston, MA 02130  
857-364-5613  
James.Kaufman@va.gov

Custodian for CMS

Director, Information Support Group  
Office of Clinical Standards and  
Quality, CMS, Room S3-02-01, 7500  
Security Boulevard,  
Baltimore, MD 21244-1850

**4. Asset Protection:** CMS will protect the privacy and confidentiality of any individually identifiable information contained in the data consistent with the Privacy Act of 1974, and, to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 38 U.S.C. 5701(f), and other applicable laws, regulations, and policies. CMS may provide data access to appropriate employees, contractors, and other authorized users. Except as may be required in a public health emergency to protect life and health of individuals and populations, and for authorized follow-up activities described in paragraph 1 above, CMS will not attempt to identify records contained in the data provided under this agreement or link these data with other data sources for identification purposes.

Without limitation to any other provision of this Agreement, CMS agrees not to disclose, display or otherwise make available any company proprietary information to any third party, in any form, except to public health officials in connection with the purposes established herein or as otherwise required under the Freedom of Information Act, or other Federal law. VA will clearly indicate in writing any information that is considered to be trade secret or confidential business information.

Transmission of the data from VA to CMS and other possible recipients shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents, as will transfer of data from CMS to VA. CMS shall maintain the data in confidence, using that same degree of care that CMS uses with its own confidential information and with the expectation that all Federal statutes relative and applicable to VA will be adhered to as well.

**4. Data Disposition:** Data that has been provided to CMS under this Agreement will be archived, stored, protected, or disposed of in accordance with relevant Federal records requirements and VA standards, if applicable.

**5. Project Responsibilities**

a. VHA Responsibilities

- VHA will issue a VHA Directive instructing all VHA personnel who are responsible for reporting dialysis program data to the ESRD Networks to complete the forms outlined in paragraph 1 above.
- If VHA data is not being reported to the ESRD Networks, the VHA Central Office will assist the ESRD Networks with compliance.
- The Chief of the Dialysis Unit has the ultimate responsibility for assuring that reporting is performed when required by the ESRD Network and for correcting and resolving discrepancies in data before they are reported to the ESRD Network Office.
- VA sites may (but are not required to) participate in ESRD Network activities, e.g., meetings, quality improvement projects, Committee or Board members.
- VHA Central Office will provide its ESRD sites with a copy of the annual nationwide report received from CMS.

b. CMS Responsibilities

- CMS will provide a written notification of the continuation of this project every three years starting from the effective date of this Agreement to VHA.
- CMS will provide VHA Central Office with a negotiated annual nationwide report on how VA ESRD sites compare to non-VA ESRD sites.
- CMS will ensure that the below listed ESRD Network Responsibility are included in the ESRD Network contracts, as well as, provisions for the protections and confidentiality of the data received from VHA.

c. ESRD Network Responsibilities

- The ESRD Networks will train the VHA Dialysis Unit in completion of the forms.
- The ESRD Networks will send VA sites facility-specific reports that are comparable to reports sent to Medicare ESRD providers that will allow the VA sites to compare their medical care performance with the rest of the provider community.
- The ESRD Networks will place particular emphasis on review and analysis of VA's performance in the ESRD Clinical Performance Measures (CPM) Project to assist the VA in carrying out quality improvement projects.
- The ESRD Networks will invite VHA sites to participate in Network activities realizing that only data reporting is required.
- The ESRD Networks will collect CPM data on all VHA ESRD patients so a comparison of the populations may be made.

6. **Funding:** This MOU is not an obligation or a commitment of funds, or a basis for a transfer of funds, but rather a statement of understanding between the parties concerning the sharing and use of covered data. Expenditures by each party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies. Both agencies agree that the activities under this Agreement will benefit both agencies equally. Therefore, this Agreement will entail no transfer of funds between the two agencies.

7. **Settlement of Disputes:** Disagreements between the parties arising under or relating to this MOU will be resolved by consultation between the parties and referral of the dispute to appropriate management officials of the parties whenever possible.

8. **Applicable laws:** U.S. Federal law relevant to CMS and VA shall govern the construction, interpretation, and performance of this Agreement.

9. **Term of Agreement, Amendment, and Termination:**

a. This Agreement will become effective upon the date of final signature and will remain in effect until it is amended or rescinded as outlined in this agreement.

b. Except as otherwise expressly provided herein, this Agreement may be amended only by the mutual written consent of the authorized representatives for each party.

c. This MOU may otherwise be terminated with ninety days advance notice upon written notice by either party.

10. **Agency Representatives:** The following named individuals are designated as their agencies' Points of Contact for performance of the terms of the Agreement.

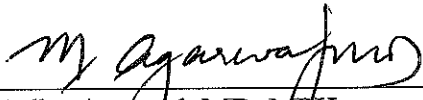
Point-of-contact on behalf of VHA

William E. Duncan, MD, PhD  
Chief Consultant, Medical-Surgical Services  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420  
202-461-7120  
[William.Duncan@va.gov](mailto:William.Duncan@va.gov)

Point-of-contact on behalf of CMS

Jacqueline Abt, RN, MS  
Centers for Medicare and Medicaid Services  
7500 Security Blvd. Mailstop S3-02-01  
Baltimore, MD 21244  
410-786-3676  
Jacqueline.Abt@cms.hhs.gov

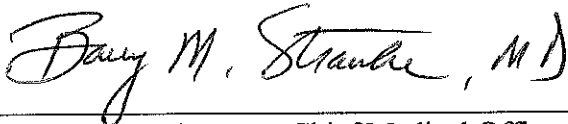
**Signatures**



7/24/07

---

Madhu Agarwal, MD, MPH  
Chief Patient Care Services Office  
Veterans Health Administration  
Department of Veterans Affairs



7/30/2007

---

Barry S. Straube, MD. Chief Medical Officer  
Director  
Office of Clinical Standards and Quality  
Centers for Medicare and Medicaid Services