

**INSTRUCTIONS FOR COMPLETING THE LIMITED DATA SET (LDS) DATA USE AGREEMENT (DUA) FORM
CMS-R-0235L**

FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS

This agreement must be executed prior to the disclosure of data from a CMS Systems of Records containing personally identifiable information (PII) to ensure that the disclosure will comply and the data will be protected in accordance with the requirements of the Privacy Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, the Federal Information Security Management Act of 2002 (FISMA) and CMS data release policies.

Note:

- 1) **The language contained in this agreement may not be altered in any form.**
- 2) **Researchers must contact the CMS contractor, Research Data Assistance Center (ResDAC), on the web at www.resdac.org, via e-mail at resdac@umn.edu, or by calling 1-888-973-7322 for assistance in completing and submitting this form. CMS will not accept forms directly from researchers. CMS will only accept researcher forms that have been processed through ResDAC.**
- 3) **Federal contractors/grantees and State representative should contact their CMS representative for assistance.**

Section #1, enter the Requestor's Organization Name.

Section #4, enter the Project/Study Name and Federal contract/grant number if applicable.

Section #5, enter the file(s) and year(s) the User is requesting. (see note 2 and 3 above)

Section #6, enter the Project/Study's anticipated date of completion.

Section #16, is to be completed by the Requestor.

Section #17, is to be completed by the Custodian, defined as that person who will have actual possession of and responsibility for the data files. **This section must be completed even if the Custodian and Requestor are the same individual.**

Section #18, shall be completed by the CMS Privacy staff representative.

Section #19, for federally funded (other than CMS) projects only, enter the Federal Agency name. The Federal Project Officer shall complete and sign the remaining portions of this section.

Section #20 shall be completed by a CMS representative(s).

Attachment A Research Application Summary, must be completed by all Users. Attachment A generally should be between 1 and 4 pages in length.

Addendum, CMS-R-0235A, shall be completed when additional custodians will be accessing CMS PII data.

Once the DUA is received and reviewed for privacy and policy issues, a completed and signed copy will be sent to the Requestor and CMS or Federal Project Officer, if applicable, for their files.

LIMITED DATA SET (LDS) DATA USE AGREEMENT
for the use of Centers for Medicare & Medicaid Services (CMS) Data Containing Individual Identifiers

DUA #

1. **PURPOSE:** In order to secure data that resides in a CMS Privacy Act System of Records (SOR), and to ensure the confidentiality, integrity and availability of information maintained by CMS, and to permit appropriate disclosure and use of such data as permitted by law, this Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (DHHS), and _____ (Requestor's Organization) _____, hereinafter termed "User." CMS agrees to provide the User with data that reside in a CMS Privacy Act SOR as identified in this Agreement. In exchange, the User agrees to:

- a) use the data only for purposes that support the User's project or study referenced in this Agreement, which has been determined by CMS to provide assistance to CMS in monitoring, managing and improving the Medicare and Medicaid programs or the services provided to beneficiaries;
- b) ensure the integrity and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Federal Information Security Management Act of 2002 (FISMA); and
- c) pay any applicable fees.

2. **CONDITIONS:** This Agreement addresses the conditions under which CMS will disclose and the User will obtain, use, reuse and disclose the CMS data file(s) specified herein, and/or any derivative file(s) that contain direct individual identifiers or elements that could be used in concert with other information to identify individuals. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the file(s) specified herein and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services (DHHS) or any of its components with respect to the data specified herein. Further, the terms of this Agreement may be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS signatory in section 20 below. The parties agree further that CMS makes no representation or warranty, either implied or expressed, with respect to the accuracy of any data in the file(s).

3. **OWNERSHIP RIGHTS:** The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.

4. **PROJECT IDENTIFICATION:** The User represents, and in furnishing the data file(s) specified in section 5 below, CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

_____ Project/Study Name _____
_____ Federal Contract/Grant Number (if applicable) _____

Research Users must provide a summary explanation of the research project using the template in Attachment A which is incorporated by reference into this Agreement. Only direct CMS contractors and States are exempt from the Attachment A requirement to this Agreement.

The User represents further that, except as specified in an Enclosure to this Agreement or except as CMS shall authorize in writing, the User shall not reuse, disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person(s) or organization(s). The User affirms that the requested data is the minimum necessary to achieve the purposes stated in this section. The User agrees that, within the User’s organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and only to those individuals on a need-to-know basis. Disclosure of this data is made pursuant to:

- Privacy Act of 1974 5 U.S.C. Section 552a as amended;
- Computer Matching and Privacy Protection Act of 1988 (P.L. 100-503);
- Freedom of Information Act 5 U.S.C. Section 552 as amended by P.L. 104-231, 110 Stat. 3048;
- Section 1106 of the Social Security Act (42 U.S.C. Section 1306);
- Section 1843 of the Social Security Act (42 U.S.C. Section 1395v); and
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 C.F.R. Parts 160 and 164).

The User represents further that the facts and statements made in any study or research protocol or project plan(s) submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plan(s) that have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 5 below will be put.

5. **DATA DESCRIPTION:** The following CMS data file(s) is/are covered under this Agreement.

File	Years(s)	System of Record

6. **EXPIRATION DATE:** The parties mutually agree that the aforesaid files(s) and/or any derivative file(s), including those files that directly identify individuals or maintains continued identification of individuals, may be retained by the User until _____, hereinafter known as the “Expiration Date.” The User agrees to provide CMS, within 15 days of the completion of the purpose specified in section 4 above, but no later than the expiration date, as amended, in the method prescribed by CMS, a

certification of the disposition of all the data as specified in section 5 above and as applicable all derivative files. The User agrees that no data from CMS records, or any parts thereof, shall be retained when the aforementioned certification has been provided to CMS. The User acknowledges that stringent adherence to the aforementioned information outlined in this paragraph is required. The User acknowledges that the date is not contingent upon action by CMS.

The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Immediately, upon notice of termination by the User, CMS will cease releasing data from the file(s) to the User under this Agreement and will notify the User to destroy such data file(s). Sections 3, 4, 6, 8, 9, 10, 11, 13, 14 and 15 shall survive termination of this Agreement.

7. DATA PROTECTION: The User agrees to establish appropriate management, operation and technical controls to protect the confidentiality, integrity and availability of the data and to prevent unauthorized use or disclosure. The safeguards shall provide a level and scope of security that is not less than the level and scope of protection as established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems, http://www.whitehouse.gov/omb/circulars_a130, as well as Federal Information Processing Standard 200, "Minimum Security Requirements for Federal Information and Information Systems", <http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>, and National Institute of Science and Technology (NIST) Special Publication 800-53, "Recommended Security Controls for Federal Information Systems", <http://csrc.nist.gov/publications/nistpubs/800-53A/SP800-53A-final-sz.pdf>, including any revisions as applicable. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable, or deducible information derived from the file(s) specified in section 5 above is prohibited. Further, the User agrees that the data must not be physically moved, transmitted or disclosed in any way from or by the site indicated in section 17 below without written approval from CMS unless such movement, transmission or disclosure is required by law.

8. SECURITY COMPLIANCE OVERSIGHT: The User agrees that the authorized representatives of CMS, the DHHS Office of the Inspector General, or the Comptroller General, will be granted access to premises where the aforesaid file(s) is/are kept for the purpose of inspecting security arrangements confirming whether or not the User is in compliance with the security requirements specified in section 7 above.

9. MINIMUM CELL SIZE DISCLOSURE: The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in section 5 above, with or without direct identifiers, if such findings, listings, or information may, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death. The User agrees further that CMS shall be the sole judge as to whether any finding, listing, or information, or any combination of data extracted or derived from CMS' files identifies or would, with reasonable effort, permit one to identify an individual or to deduce the identity of an individual with a reasonable degree of certainty.

The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 above (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the file(s) specified in section 5 or any data derived from such file(s)) must adhere to CMS' current cell size suppression policy. **This policy stipulates that no cell size (e.g. admittances, discharges, patients, services) less than 11 may be**

displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell of less than 11. By signing this Agreement the User hereby agrees to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. If the User is unsure, they may submit their product to CMS for review prior to publication. CMS agrees to make a determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries.

10. RECORD LINKAGE: The User shall not attempt to identify or contact any specific individual whose record is included in the files listed in section 5 above. The User agrees that, absent express written authorization from the CMS signatory designated in section 20 below, the User shall not attempt to link records included in the file(s) specified in section 5 above to any other individually identifiable source of information. This includes attempts to link the data to other CMS data. A protocol that includes the linkage of specific files that has been approved in accordance with section 4 above constitutes expressed authorization from CMS to link files as described in the protocol.

11. DATA RE-USE: The User understands and agrees that they may not reuse original or derivative data files without prior written approval from the CMS signatory in section 20 below.

13. DATA BREACHES: The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the CMS signatory in section 20 below, CMS, at its sole discretion, may require the User to:

- (a) Promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized use, reuse or disclosure;
- (b) Promptly resolve any problems identified by the investigation;
- (c) Submit a formal response to an allegation of unauthorized use, reuse or disclosure;
- (d) Submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and
- (e) Return data files to CMS or destroy the data files it received from CMS under this agreement.

The User understands that as a result of CMS' determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

The User agrees to report within one (1) hour, any breach of personally identifiable information (PII) from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS IT Service Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined in section 3 above, the User shall bear the cost and liability for any breaches of PII from the data file(s), or as applicable any derivative file(s), while they are entrusted to the User. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the User agrees to carry out these remedies without cost to CMS.

14. DISCLOSURE PENALTIES

a. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not to exceed \$10,000 or imprisonment not exceeding 5 years,

or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law.

b. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000.

c. The User also acknowledges under HIPAA, “General Penalty for Failure to Comply with Requirements and Standards” Section 1176, that the DHHS Secretary may impose fines for noncompliance as high as \$100 per offense, with a maximum of \$25,000 per year on any person who violates a provision of this part; “Wrongful Disclosure of Individually Identifiable Health Information” Section 1177, that a person who knowingly:

- (A) uses or caused to be used a unique health identifier;
 - (B) obtains individually identifiable health information relating to an individual;
 - or
 - (C) discloses individually identifiable health information to another person,
- shall be fined not more than \$50,000, imprisoned not more than 1 year, or both;
 - if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and
 - if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

d. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641, Protection of Government Property, if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to their own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of \$1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.

15. **USER AGREEMENT:** By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

16. **REQUESTOR:** The parties mutually agree that the individual identified in this section is designated as “Requestor” of the file(s) on behalf of the User and hereby attests that he or she is authorized to legally bind the User to the terms of this Agreement and agrees to all the terms specified herein. The User agrees to notify CMS, in the method prescribed by CMS, within fifteen (15) days of any change of Requestor.

Name (<i>typed or printed</i>)		Title	
Company/Organization			
Street Address City		State	ZIP Code
Office Telephone (<i>Include Area Code</i>) extension (if applicable)		E-Mail Address	
Signature		Date	

17. **CUSTODIAN:** The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and will be the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use or disclosure. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

The Custodian hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

Name (<i>typed or printed</i>)		Title	
Company/Organization			
Street Address City		State	ZIP Code
Office Telephone (<i>Include Area Code</i>) extension (if applicable)		E-Mail Address	
Signature		Date	

18. **PRIVACY ACT DISCLOSURE PROVISION:** The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in section 4 above is: (To be completed by CMS Privacy staff) _____.

19. **FEDERAL (NON-CMS) REPRESENTATIVE:** On behalf of _____ (Federal Agency name) _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS' data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all questions of such interpretation or compliance with the terms of this Agreement to the CMS official named in section 20 below (or to his or her successor).

Typed or Printed Name		Title of Federal Representative	
Street Address		Mail Stop	
City		State	ZIP Code
Office Telephone (<i>Include Area Code</i>)		E-Mail Address	
Signature		Date	

20. **CMS REPRESENTATIVE:** The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name of CMS Representative (*typed or printed*)

A. Title/Component Street Address		Mail Stop
City	State	ZIP Code
Office Telephone (<i>Include Area Code</i>)		E-Mail Address
Signature of CMS Representative		Date
B. Concur/Nonconcur — Printed Name and component		Date
Signature of CMS Business Owner		
C. Concur/Nonconcur — Printed Name and component		Date
Signature of CMS Business Owner		
D. Concur/Nonconcur — Printed Name and component		Date
Signature of CMS Business Owner		

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0734. The time required to complete this information collection is estimated to average 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: Reports Clearance Officer, Baltimore, Maryland 21244-1850.

ATTACHMENT A
Research Application Summary
to
LIMITED DATA SET (LDS) DATA USE AGREEMENT
for the use of Centers for Medicare & Medicaid Services (CMS) Data Containing Individual Identifiers

1. Introduction

- Title
- Purpose
 - Provide a summary explanation of the research project. The purpose must demonstrate the potential to improve the quality of life for Medicare beneficiaries or improve the administration of the Medicare program, including payment related projects. Under the Privacy Rule, permitted purposes include research, public health and/or health care operations.
 - Describe the potential uses of this project to Medicare providers of service.

2. Project Issues and Methods

- List and describe the key issues to be studied.
- Describe the plan to analyze the data for the project, including the methodology and procedures that will be used.
- Provide an outline of project reports, including types of tabulations, aggregations, and other data presentations.
- State whether any of the methodology or tools contain proprietary information [proprietary information is exempt from release requirements under the Freedom of Information Act if it falls within the scope of Exemption 4, 5 U.S.C. § 552(b)(4)].

3. Data Management Safeguards

Describe the procedures that will be used to protect the privacy and identity of an individual. For example, explain how the privacy of information of beneficiaries in the files will be safeguarded and guaranteed.

4. Key personnel

List the staff that will have access to the data and their role in the project.

5. Dissemination/Implementation

- Describe how the findings will be used.
- Briefly describe any data dissemination plan that includes how the findings and any reported data elements will be aggregated to a level that does not permit the identification of the individual.
- Describe the type of data that will be disseminated, if applicable.