

**INSTRUCTIONS FOR COMPLETING THE LIMITED DATA SET DATA USE
AGREEMENT (DUA)**

This Agreement is needed to ensure that the disclosure and use of Limited Data Sets derived from a CMS Privacy Act System of Records comply with the Privacy Act of 1974 (5 USC§522a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR Parts 160 and 164). Directions for the completion of the agreement follow:

Before completing the DUA, please note the language contained in this agreement cannot be altered in any form.

- A. First paragraph, enter the Requestor's/User's Organization Name.
- B. Item #1, enter the Requestor's/User's Organization Name.
- C. Item #3, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of the files (name and position/title) is defined as the person who will have actual possession of and responsibility for the limited data set files. This section should be completed even if the Custodian and Requestor/User are the same.
- D. Item #4 will be completed by a CMS representative.
- E. Item #5 should delineate the limited data set files and years of data the Requestor/User is requesting. Specific filenames should be specified. If these filenames are unknown, you may contact a CMS representative.
- F. Item #6 includes both a summary of the purpose and a detailed explanation of the research study or project. The detailed explanation describing your research purpose must be attached to the agreement. Attached to this Agreement are the Research Application Guidelines that should be followed in preparing your detailed explanation. CMS evaluates the purpose for which the limited data set file will be used to determine whether: 1) the purpose requires identifiable records; 2) the project is of sufficient importance to justify the risk on beneficiary privacy; 3) there is reasonable probability that the use of data will accomplish the purpose, i.e., the project is soundly designed; and 4) the purpose demonstrates the potential to improve the quality of life for Medicare beneficiaries or improve the administration of the Medicare program, including payment related projects. If the Research Application provided by the Requesting Organization contains proprietary information, a statement to that effect must be included in the Research Application submitted to CMS. Proprietary information is exempt from release under the Freedom of Information Act if it falls within the scope of Exemption 4, 5 U.S.C. § 552(b)(4).
- G. Item #8, complete by entering the completion date of the study or project.
- H. Item #16 is to be completed by the Requestor/User.
- I. Item #17 is to be completed by the Custodian.
- J. Item #18 will be completed by a CMS representative.

K. Item #19 will be completed by a CMS representative.

For assistance or questions in completing this Agreement, please contact Ned Burford at 410-786-3673.

DUA # _____

DATA USE AGREEMENT**AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) LIMITED DATA SETS**

In order to ensure that the disclosure and use of Limited Data Sets derived from a CMS Privacy Act System of Records comply with the Privacy Act of 1974 (5 USC §522a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR Parts 160 and 164), CMS and

_____ **enter into this Agreement:**

1. 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 _____, hereinafter termed "User."
2. The parties mutually agree that CMS retains all ownership rights to the limited data set 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. The parties further agree that CMS makes no representation or warranty, either implied or express, with respect to the accuracy of any data in the limited data set file(s),
3. The parties mutually agree that the following named individual is designated as Custodian of the limited data set file(s) on behalf of the User and the person shall oversee the observance of all conditions of use and the establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. 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.

(Name of Custodian and Position/Title)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

Phone No. - Including Area Code)

(E-Mail Address, If Applicable)

- 4. The parties mutually agree that the following named individual is designated as point-of-contact for the Agreement on behalf of CMS. (To be completed by CMS staff.)

 (Name of Contact)

 (Title/Component)

 (Street Address)

 (Mail Stop)

 (City/State/ZIP Code)

 (Phone No. - Including Area Code)

 E-Mail Address, If Applicable)

- 5. The following CMS limited data set file(s) is/are covered under this Agreement.

Filename(s)	Year(s)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

- 6. The User represents that the limited data set files in Section 5 above will be used solely for the following research purpose (provide a brief summary of the purpose below):

In addition to the summary above, the User must provide a detailed explanation of the research purpose which is incorporated by reference into this Agreement. The research 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. The User represents further that the facts and statements made in this explanation are complete and accurate. Research Application Guidelines are attached as 'Attachment A' and are incorporated by reference to this Agreement.

7. The User shall not attempt to identify or contact any specific individual whose record is included in the limited data set file(s) specified in section 5. Absent written authorization from CMS, the User shall not attempt to link records included in the file(s) specified in section 5 to any other beneficiary-specific source of information.
8. The parties mutually agree that the limited data set files specified in section 5 (and/or any derivative file(s) that include individually identifiable data) may be retained by the User until _____, hereinafter known as the “retention date.”
9. The User shall not use, disclose, release, show, sell, rent, lease, loan, or otherwise grant access to the limited data set files specified in section 5 of this Agreement, except as expressly permitted by this Agreement or otherwise required by law.
- 10 a. On approval of this Agreement, the User may disclose and/or publish any summary of aggregated data files that conforms to the description set forth by the user in the research application in response to number 5 of Attachment A “Research Application Guidelines.”
 - b. The User may not disclose the limited data set file(s) specified in Section 5 of this Agreement to a Secondary User until and unless the Secondary User enters into a DUA with CMS. CMS will only enter into a DUA with a Secondary User if the purpose for which the secondary use of the limited data set file(s) is consistent with the purpose specified in Section 6 of this Agreement.
11. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the limited data set file(s) and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security 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/a130.html>), which sets forth guidelines for security plans for automated information systems in Federal agencies. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the limited data set file(s) specified in section 5 is prohibited. Further, the User agrees that the limited data set file(s) must not be physically moved or electronically transmitted in any way from the site indicated in section 3 without prior written approval from CMS.
12. For each limited data set file, the User shall reimburse CMS for all associated processing fees.

13. The User shall promptly report to CMS any use or disclosure of the information not provided for by this Data Use Agreement of which it becomes aware. CMS in its sole discretion may require the User to: (a) promptly investigate and respond to CMS concerns regarding any alleged disclosure; (b) promptly resolve any problems identified by the investigation; (c) submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and/or (d) require that all limited data set files be immediately returned.
14. The User acknowledges that penalties under § 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including possible imprisonment, may apply with respect to any disclosure of information in the file(s) that is inconsistent with the terms of the Agreement. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i)(3)) apply if it is determined that the User, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. The User also acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641.
15. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the limited data set file(s) specified in section 5, and acknowledges having received notice of potential criminal, civil, and/or administrative penalties for violation of the terms of the Agreement.
16. The undersigned individual hereby attests that he or she is authorized to enter into this Agreement on behalf of the User and agrees to all the terms specified herein.

(Name and Title of Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code)

(E-Mail Address, If Applicable)

(Signature)

(Date)

- 17. The Custodian, as named in section 3, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with his/her obligations identified in this Agreement.

(Typed or Printed Name and Title of Custodian of File(s))

(Signature) (Date)

- 18. The disclosure provision(s) that allow(s) the discretionary release of CMS data for the purpose(s) stated in section 6 follow(s). (To be completed by CMS staff.)

- 19. The undersigned individual hereby attests that he or she is authorized to enter into this Agreement on behalf of CMS and agrees to all the terms specified herein.

(Typed or Printed Name and Title of CMS Representative)

(Signature) (Date)

ATTACHMENT A**Centers for Medicare & Medicaid Services (CMS)
Research Application Guidelines for Requesting Limited Data Sets****1. Introduction**

- Title.
- Purpose:
 - Provide a detailed explanation of the research purpose of the 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.
 - What are 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.
- Statement of 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, how will the privacy of information of beneficiaries in the files be safeguarded and guaranteed?
- Describe safeguards that would be followed for permitted disclosures of data, if applicable.

4. Key personnel

- List staff that will have access to the limited data set file(s) 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.

6. Proprietary Information

- If the Research Application provided by the Requesting Organization contains

proprietary information, a statement to that effect must be included in the Research Application submitted to CMS. Proprietary information is exempt from release under the Freedom of Information Act if it falls within the scope of Exemption 4, 5 U.S.C. § 552(b)(4).