

---

## DATA USE AGREEMENT (DUA) LIMITED DATA SET (LDS) TERMS AND CONDITIONS

---

This Agreement governs the requesting organization's ("you/your") receipt and use of data from the Centers for Medicare & Medicaid Services ("CMS"), a component of the U.S. Department of Health and Human Services ("HHS"). This Agreement covers the CMS data files you requested and the corresponding purposes for their use, as specified in the Enterprise Privacy Policy Engine ("EPPE") system.

CMS agrees to provide you with the data files specified in the DUA Request, which reside in a CMS Privacy Act System of Records ("SOR"). In exchange, you agree to: (a) pay any applicable fees; (b) use the data only for purposes that support your study, research, or project, as specified in the DUA Request, which CMS has determined to be valuable in helping CMS monitor, manage, and improve the Medicare and Medicaid programs and/or services provided to beneficiaries; and (c) to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and any applicable law(s), including the Privacy Act (5 U.S.C. §552a) and Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA [45 C.F.R. Subpart C, Parts 160 and Part 164, Subparts A and E]). This Agreement is intended to: (a) secure data that reside in a CMS Privacy Act SOR; (b) ensure the integrity, security, and confidentiality of information maintained by CMS; and (c) permit appropriate disclosure and use of such data as permitted by law.

1. This Agreement addresses the conditions under which CMS will release and you will obtain, use, reuse, and disclose the CMS data files specified in the DUA Request. This Agreement also pertains to and covers any derivative files which may contain direct individual identifiers or elements that can be used in concert with other information to identify individuals. For all data released under this Agreement, the legal clauses contained herein supersede any and all agreements between you and CMS, and preempts and overrides any instructions, directions, agreements, or other understandings pertaining to any grant award or prior communication with HHS (or any of its components).

The terms of this Agreement can be changed only by a written modification to this Agreement or through adoption of a new agreement. Any instructions or interpretations issued to you concerning this Agreement or the data specified in the DUA Request are not considered valid unless issued in writing by the appropriate CMS representative associated with the project (e.g. Contracting Officer's Representative/Government Task Leader, Program Office, System Manager, etc.).

2. You agree that CMS retains all ownership rights to the data files specified in the DUA Request, and that you do not obtain any right, title, or interest in any of the data released by CMS.
3. You represent that the data files covered by this Agreement will be used solely for the purposes described in the DUA Request. In releasing the data files, CMS relies upon such representation.

You represent that the facts and statements made in any study, research protocols, or project plans listed in the DUA Request are complete and accurate. You also represent that said study protocols or project plans, which have been approved by CMS or another appropriate entity as CMS may determine, represent the total uses for which you will use the released data files.

You agree not to disclose, use, or reuse the data covered by this Agreement, except: (a) as specified in an Attachment uploaded to the DUA Request; (b) as authorized by CMS; or (c) as otherwise required by law. You also agree not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement, unless you receive express permission from CMS.

You affirm that the requested data is the minimum necessary to achieve the purposes covered by this Agreement. You agree that, within your organization and the organization of your agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the specified purposes (i.e., individual's access to the data will be on a need-to-know basis).

4. You agree that you may retain the files covered by this Agreement as well as any derivative files—including those that directly identify individuals, or that directly identify bidding firms and/or such firms' proprietary, confidential, or specific bidding information, which in concert with other information can be used to identify individuals—until the End Date specified in the DUA Request. If the purposes covered by this Agreement are completed before the specified End Date, you agree to notify CMS within 30 days of completion of those purposes. Upon such notice or the End Date, whichever occurs sooner, you agree to destroy the data in your possession covered by this Agreement and provide certification of disposition of the files identified in the EPPE system within 30 days. You agree not to retain the files covered by this Agreement or any parts of the files after the notice of disposition, unless the appropriate CMS representative overseeing the project grants written authorization. You acknowledge that the End Date is not contingent on any action by CMS.

You understand that you, or CMS, may terminate this Agreement at any time, for any reason, upon 30 days written notice. Upon notice of termination, CMS will cease releasing the requested data files to you, and will notify you to destroy any data files in your possession. Sections 2, 3, 4, 6, 7, 8, 9, 11, 12, and 13 shall survive termination of this Agreement.

5. You agree to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data 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 requirements established by the following documents:

Office of Management and Budget (OMB), “OMB Circular No. A-130, Appendix III—Security of Federal Automated Information Resources,” available at [https://obamawhitehouse.archives.gov/omb/circulars\\_a130\\_a130appendix\\_iii](https://obamawhitehouse.archives.gov/omb/circulars_a130_a130appendix_iii) .

National Institute of Standards and Technology (NIST), “Federal Information Processing Standards Publication 200—Minimum Security Requirements for Federal Information and Information Systems,” available at <http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf> .

National Institute of Standards and Technology (NIST), “Special Publication 800-53—Security and Privacy Controls for Federal Information Systems and Organizations,” available at <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf> .

CMS Office of Information Services, “Acceptable Risk Safeguards, Appendix B—CMSR Moderate Impact Level Data,” available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/ARS-31-Publication> .

You acknowledge that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable, bidder identifiable, or deducible information derived from the files covered by this Agreement is prohibited. You also agree that the data must not be physically moved, transmitted, or disclosed in any way from or by the site indicated in the DUA Request without written approval from CMS, unless such movement, transmission, or disclosure is required by law.

6. You agree to grant physical and/or electronic access to authorized representatives of CMS and/or HHS Office of the Inspector General (“OIG”) for inspection of the site indicated in the DUA Request to confirm compliance with the terms of this Agreement.
7. You agree not to disclose direct findings, listings, or information derived from the files covered by this Agreement with or without identifiers if such findings, listings, or information can 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 dates, or date of death.

You agree that any use of CMS data in the creation of any document (e.g. manuscript, table, chart, study, report, etc.) concerning the purposes covered by this Agreement—regardless of whether the written product expressly refers to those purposes, CMS, the requested data files, or any data derived from such files—must adhere to CMS’ current cell size suppression policy. This policy stipulates that no cell (e.g. admittances, discharges, patients, services, etc.) 10 or less may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less. You agree to abide by these rules, and therefore, will not be required to submit any written documents for CMS review. If you are unsure whether you meet the above criteria, you may submit your written products for CMS review. 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.

8. You agree that, absent express written authorization from the appropriate CMS representative associated with the project to do so, you shall not attempt to link records included in the files covered by this Agreement to any other individually identifiable source of information. This includes attempts to link the specified data to other CMS data files. CMS approval of study, research, or project protocols covered by this Agreement that include instruction for the linkage of specific files constitutes express authorization from CMS to link files, but only in the manner described in the protocols.
9. You understand and agree that you may not reuse original and/or derivative data files without prior written approval from the appropriate CMS representative associated with the project.
10. You agree that the Attachments uploaded electronically to the DUA Request are incorporated into this Agreement.
11. You agree that, in the event CMS determines or reasonably believes that you have made or may have made an unauthorized use, reuse, or disclosure of the files covered by this Agreement or another written authorization from the appropriate CMS representative associated with the project, then CMS—at its sole discretion—may require you to: (a) promptly investigate and report to CMS any of your determinations regarding all alleged or actual unauthorized use, reuse, or disclosure; (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to any allegations of unauthorized use, reuse, or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses, or disclosures; and/or (e) if requested by CMS, return or destroy the data files covered by this Agreement to CMS, as well as any derivative files containing information from the files released under this Agreement. You understand that as a result CMS' determination or reasonable belief that unauthorized uses, reuses, or disclosures have taken place, CMS may determine a period of time during which you are excluded from access to CMS data.

You agree to report any breach, loss, or unauthorized disclosure of protected health information (PHI) and/or personally identifiable information (PII) from the CMS data files covered by this Agreement to the CMS Action Desk by telephone at (410) 786-2850 or by e-mail notification at [cms\\_it\\_service\\_desk@cms.hhs.gov](mailto:cms_it_service_desk@cms.hhs.gov) within 1 hour and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data files, as outlined above, you agree to bear the cost and liability for any breaches of PHI and/or PII from the data files while they are entrusted to you. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons regarding the security breach and/or other remedies, you agree to carry out these actions without cost to CMS.

12. You acknowledge that criminal penalties under Section 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by Section 1106 and that are not authorized by regulation or by Federal law. You further acknowledge that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i)(3)) may apply if it is determined that the Requester, Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the files under false pretenses. Any person found to have violated the above-cited section of the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000. Finally, you acknowledge that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that you or any individual employed or affiliated therewith, has taken or converted the data files to their own use, or received the data knowing that the files had been 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.

You acknowledge that in the event of a breach of this Agreement, additional criminal, civil, and/or administrative penalties, assessments, or fines may be determined as applicable by law.

13. By clicking “Agree,” you attest that you are authorized to legally bind the requesting organization listed in the DUA Request, and agree to all the terms specified herein. Furthermore, you agree to abide by all provisions set out in this Agreement and acknowledge having received notice of potential criminal, civil, and/or administrative penalties for violation of the terms of this Agreement.

## **Attachment B**

This attachment supplements the above-referenced Data Use Agreement (DUA) between the Centers for Medicare and Medicaid Services and the User (as set forth in the DUA). Upon execution by both parties, to the extent this Attachment is inconsistent with any terms in the DUA, this Attachment modifies and overrides the DUA.

A-1. Use of Data: Users may disseminate research findings on providers or suppliers (including individual physicians) using original or derived information from the files specified in Section 5 of the DUA provided all findings are limited to patient de-identified data that conform with the HIPAA Privacy Rule’s definition of de-identified data at 45 CFR 164.514(b).

A-2. Disclosure of Findings: Nothing in the DUA, including but not limited to Section 8, prohibits Users from discussing or reporting on specific providers or suppliers (including individual physicians) in a manner consistent with A-1.