

**INFORMATION EXCHANGE AGREEMENT  
BETWEEN  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
AND  
THE PARTICIPATING STATE AGENCY  
FOR  
DISCLOSURE OF MEDICARE PART A, PART B, PART C, AND PART D DATA  
  
CMS AGREEMENT No. 2014-13**

**I. PURPOSE, LEGAL AUTHORITY, AND DEFINITIONS**

A. Purpose

This Information Exchange Agreement, hereinafter the “Agreement,” establishes the terms, conditions, safeguards, and procedures under which the Centers for Medicare & Medicaid Services (CMS) is willing (upon request and subject to the provisions of this Agreement and applicable law, including, but not limited to, the “minimum necessary” principles of the HIPAA Privacy Rule) to disclose Medicare Part A, Part B, and Part C claims data and/or Part D prescription drug event (PDE) data for dual eligible beneficiaries to the Participating State Agency, as defined below, for the State of \_\_\_\_\_ (also referred to herein as the “User”).

Furthermore, Participating State Agency is contractually limited to requesting CMS Data received under this agreement for performing Quality Improvement and Care Coordination, Program Integrity Activities and certain other Health Care Operations, as those terms are defined below. Any disclosure(s) of this CMS Data, or any derivative of this CMS Data, by the undersigned or its agents to a Downstream User, as defined below, shall be made in accordance with applicable law and the prior written approval of CMS, and must be preceded by the User’s execution of a Data Use Agreement, a copy of which is attached hereto as Attachment A.

Participating State Agencies may be required from time to time upon request from CMS to provide summary reports on the status of the activities listed above, and the findings, outcomes and/or recommendations that are obtained through the use of the CMS Data.

B. Legal Authority

This Agreement supports the responsibilities of the Federal Coordinated Health Care Office (“Medicare-Medicaid Coordination Office” or “MMCO”) as established by section 2602 of the Patient Protection and Affordable Care Act (ACA), which

specifically include providing States with the tools necessary to develop programs to align Medicare and Medicaid benefits for Dual Eligible Beneficiaries.

The disclosure of personally identifiable CMS Data under this agreement will only be made in accordance with applicable law, including the HIPAA Privacy Rule, and subject to the routine uses which are stated in the relevant System of Record Notices as required by the Privacy Act of 1974, as amended, and identified in Section III.A., below. The PDE Data, as defined below, which can be requested under this IEA is further limited to the requesting State Medicaid Program's Dual Eligible Beneficiaries' data that may be disclosed in accordance with applicable law for Medicare Part D data. Specific data elements in the PDE Data may be excluded or aggregated as indicated in 42 C.F.R. § 423.505(m) and as further described in MMCO-CMCS Informational Bulletin of May 11, 2011, as modified by any subsequent guidance.

This Agreement, and any data disclosures under this Agreement, does not constitute a "matching program" as defined by the Privacy Act (5 U.S.C. § 552a(a)(8)). The purpose of the disclosures described herein is not for establishing or verifying initial or continuing entitlement to or eligibility of individuals with respect to Federal benefit programs.

### C. Definitions

The following terms have the described meaning in this document:

1. "Attachment A" means the Data Use Agreement (DUA) Attachment A supplements CMS DUA forms for downstream users that are providers, specifying data terms of use specific to Medicare data requests for care coordination for Medicare-Medicaid enrollees.
2. "Attachment B" means the Data Use Agreement between CMS and the Participating State Agency. This agreement must be executed prior to the disclosure of data from CMS' Systems of Records to ensure that the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule and CMS data release policies. It must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.
3. "Attachment C" means the Data Use Agreement Addendum which supplements CMS DUA forms for downstream users that provide analytical support, specifying data terms of use specific to Medicare data requests for care coordination for Medicare-Medicaid enrollees.
4. "Breach" is defined by the Office of Management and Budget (OMB) Memorandum M-07-16, Safeguarding and Responding to the Breach of Personally Identifiable Information, May 22, 2007, and means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information, whether physical or electronic.

5. “Care Coordination” means uses of the data (e.g., analysis, monitoring, or feedback) to support interventions—and/or the design of interventions—at the individual dual eligible beneficiary level that have the potential to improve the care of dual eligible beneficiaries and includes the activities described in the first and second paragraphs of the definition of “Health Care Operations” in the HIPAA Privacy Rule at 45 C.F.R. § 164.501.
6. “CMS” means the Centers for Medicare & Medicaid Services.
7. “CMS Data” means any of the following types of data: Medicare Part A, Part B, and Part C claims data and/or PDE data, including, but not limited to, Minimum Data Set (MDS) data, Outcome and Assessment Information Set (OASIS) data, Medicare Integrated Data from the Integrated Data Repository (IDR), Chronic Condition Data from the Chronic Condition Data Repository (CCDR), and encounter data from Encounter Data System (EDS). CMS Data includes derivative files built by or for the undersigned out of CMS data that is subject to this IEA.
8. “Custodian” means the individual or entity that is tasked by the Participating State Agency with primary responsibility for ensuring that the data received under this Agreement is used, disclosed and maintained in accordance with the terms, conditions, safeguards and procedures laid out in this Agreement and applicable law.
9. “Downstream User” means any person or entity (e.g., a Treating Provider, contractor, business associate or subcontractor of the Participating State) that has signed a Data Use Agreement Addendum to receive CMS data or derivative data from the undersigned in accordance with the terms of this agreement; a template of which is attached as Attachment C and/or an Attachment A, if that downstream user is a provider of health care services, prior to receiving CMS data.
10. “DUA” means the Data Use Agreement attached hereto as Attachment B that has been approved by CMS. The DUA reflects the relationship between the Participating State Agency and a Downstream User as prescribed by CMS.
11. “Dual Eligible Beneficiary” means an individual who is entitled to both Medicare benefits under Title XVIII of the Social Security Act and medical assistance under a State plan under Title XIX of the Social Security Act.
12. “Encounter Data” means the record submitted to CMS about an Enrollee receiving any item(s) or service(s) provided through Medicaid or Medicare under a prepaid, capitated, or any other risk basis payment methodology. Encounter Data is the record of a Medicare Enrollee that is maintained in the CMS Encounter Data System (EDS).
13. “Health Care Operations” means those activities described in the first and second paragraph of the HIPAA Privacy Rule at 45 C.F.R. § 164.501, or the fraud and abuse activities described in section 164.506(c)(4).

14. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.
15. "Incident" means the act of violating an explicit or implied security policy, which includes attempts (either failed or successful) to gain unauthorized access to a system or its data, unwanted disruption or denial of service, the unauthorized use of a system for the processing or storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or consent. Incidents include the loss of data through theft or device misplacement, loss or misplacement of hardcopy documents, and misrouting of mail, all of which may have the potential to put the data at risk of unauthorized access, use, disclosure, modification or destruction. While certain adverse events, (e.g., floods, fires, electrical outages, excessive heat) can cause system crashes, they are not considered Incidents. An Incident becomes a Breach when there is the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information or personal health information, whether physical or electronic.
16. "Medicaid" means the health coverage program established under Title XIX of the Social Security Act.
17. "Medicare" means the health coverage program established under Title XVIII of the Social Security Act.
18. "Medicare-Medicaid Coordination Office" or "MMCO" means the Federal Coordinated Health Care Office
19. "Participating State Agency" means a State Medicaid Agency or other agency, including contractors, subcontractors, and agents of that agency, of the State that provides for or oversees health coverage programs, also referred to herein as the "User".
20. "PDE Data" means Medicare Part D Prescription Drug Event data that are reported to CMS by Part D prescription drug plan sponsors and maintained by CMS in the Privacy Act System of Records, Medicare Integrated Data Repository (IDR), System No. 09-70-0571, 71 *Fed. Reg.* 74915 (December 13, 2006). Personally Identifiable Information or Personal Health Information.
21. "Personally Identifiable Information" (or "PII") refers to information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc., alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc. (*Office of Management and Budget Memorandum M-07-16, May 22, 2007*)

22. “Program Integrity” refers to activities designed to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat health care fraud, waste, or abuse, as defined in the Social Security Act at 18 USC § 1347, to include the improper payments in the Participating State’s Medicaid program. When done by a HIPAA Covered Entity these are the “health care fraud and abuse detection or compliance” activities described in the fourth paragraph of the HIPAA Privacy Rule’s definition of “Health Care Operations,” and at 45 C.F.R. 164.506(c)(4). When done by a government actor under a legal mandate, these activities may qualify as “Health Care Oversight” under the HIPAA Privacy Rule.
23. “Protected Health Information” (or “PHI”) has the same meaning as provided in the definition of “Protected Health Information” in the HIPAA Privacy Rule at 45 C.F.R. § 160.103.
24. “Quality Improvement and Care Coordination” means uses of the data (e.g., analysis, monitoring, or feedback) to support interventions—and/or the design of interventions—at the individual dual eligible beneficiary level that have the potential to improve the quality of care of dual eligible beneficiaries and include the activities described in the first and second paragraphs of the definition of “Health Care Operations” in the HIPAA Privacy Rule at 45 C.F.R. § 164.501.
25. “Treating Provider” is a health care practitioner who is currently providing care to, or coordinating care for, one or more Dual Eligible Beneficiaries.

## **II. RESPONSIBILITIES OF CMS AND THE PARTICIPATING STATE AGENCY**

The Participating State Agency must submit a request to CMS/MMCO that includes the following: (1) an acknowledgement that the Participating State Agency is a HIPAA covered entity; (2) that the Participating State Agency is requesting the CMS Data for its Medicaid Program’s Quality Improvement and Care Coordination purposes and/or Program Integrity purposes; (3) provide a list of the requested data elements; (4) assert that the CMS Data that is being requested is the “minimum necessary” to carry out the stated use of the data, as defined in the HIPAA Privacy Rule at 45 C.F.R. § 164.502(b) and as currently approved by CMS; and (5) that the requested CMS Data pertains to the Participating State Agency’s relationship with such beneficiaries for Quality Improvement and Care Coordination activities or for Program Integrity purposes.

The Participating State Agency will also provide CMS/MMCO with a data management plan that will include, but not be limited to, a description of the planned uses and/or disclosures and will specify the data elements needed. The data management plan should include a list of any Downstream Users to whom the Participating State Agency anticipates making disclosures of the CMS data. Upon CMS’s receipt and approval of a Participating State Agency’s request and data management plan, CMS will disclose the appropriate CMS Data to the Participating State Agency.

The DUA shall be signed and returned to CMS to track disclosures of CMS Data and to ensure that the Downstream User only uses the CMS Data and any derivative data for the purposes provided under the terms of this Agreement and/or the DUA.

The Participating State Agency must have a signed DUA on file with CMS before sharing these data with any Downstream Users.

The Participating State Agency must confirm that CMS Data or derivative therefrom disclosed to a Downstream User shall only be used pursuant to the terms of this Agreement, for use in Quality Improvement and Care Coordination activities conducted on behalf of the Participating State Agency, or for Program Integrity purposes related to the activities conducted on behalf of Participating State Agency. CMS Data obtained under this Agreement may not be used for any other purposes that are not indicated in this Agreement. The Participating State Agency will be required to contractually bind Downstream Users by executing the DUA that is attached hereto as Attachment A to ensure that the same terms that Participating State Agency has agreed to under this Agreement will be required of all Downstream Users.

### **III. DESCRIPTION OF THE DATA TO BE DISCLOSED**

#### **A. Systems of Records**

CMS will provide CMS Data from the following systems of records:

1. Medicare Integrated Data Repository (IDR), System No. 09-70-0571, published at 71 Fed. Reg. 74915 (December 13, 2006). Data maintained in the IDR will be released pursuant to routine use number 2 and number 11 as set forth in the system of record notice. The IDR system of records notice can be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0571-IDR.pdf>.
2. CMS Encounter Data System (EDS), System No. 09-70-0506, published at 79 Fed. Reg. 34539 (June 17, 2014). Data maintained in the EDS will be released pursuant to routine use number 2 and number 7 as set forth in the system of record notice. The EDS system of records notice can be found at <http://www.gpo.gov/fdsys/pkg/FR-2014-06-17/pdf/2014-14038.pdf>.
3. Long-term Care Minimum Data Set (MDS), System No. 09-70-0528, published at 72 Fed. Reg. 12801 (March 19, 2007). Data maintained in the MDS will be released pursuant to routine use number 2 and number 9 as set forth in the system of record notice. The MDS system of records notice can be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0528-LTC-MDS.pdf>.
4. HHA Outcome and Assessment Information Set (OASIS), System No. 09-70-0522, published at 72 Fed. Reg. 63906 (November 13, 2007). Data maintained in the OASIS will be released pursuant to routine use number 2 and number 8 as set forth in the system of record notice. The most recently modified OASIS system of records

notice can be found at <http://www.gpo.gov/fdsys/pkg/FR-2007-11-13/pdf/E7-22083.pdf>.

5. Chronic Condition Warehouse (CCW), System No. 09-70-0573, published at 71 Fed. Reg. 54495 (September 15, 2006). Data maintained in the CCW will be released pursuant to routine use number 2 and number 11 as set forth in the system of record notice. The CCW system of records notice can be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0573-CCDR.pdf>. Note that the Chronic Condition Data Repository (CCDR) and was renamed to CCW and notice of this modified system of record was published at 79 Fed. 64802 (October 31, 2014).

#### B. Number of Records Involved and Operational Time Factors

CMS PDE, Medicare claims, and Encounter Data records include data for approximately 10 million Dual Eligible Beneficiaries. Medicare records disclosed to the Participating State Agency under this Agreement may include approved PDE data elements and assessments data for approved timeframes for all Dual Eligible Beneficiaries residing in the Participating State Agency. CMS may provide the Participating State Agency with the CMS Data requested through a single disclosure of the applicable historical CMS Data in a one-time file of historical data followed by periodic subsequent data files for subsequent relevant data.

As needed, State Medicaid Agencies may request standard sets of Medicare Part A, Part B, and Part C data elements for approved timeframes for all Dual Eligible Beneficiaries residing in the Participating State Agency.

#### C. Data Elements Involved

The CMS Data that may be made available in accordance with applicable law upon the request of the Participating State Agency to support Quality Improvement and Care Coordination and/or Program Integrity activities are listed by the Participating State Agency and approved by MMCO and/or Center for Program Integrity (CPI).

### **IV. RETENTION AND DISPOSITION OF IDENTIFIABLE RECORDS**

The parties acknowledge that CMS retains all ownership rights to the CMS Data that Participating State Agency obtains under the terms of this Agreement, and that Participating State Agency does not obtain any right, title, or interest in any of the data furnished by CMS. The Participating State Agency will only retain the CMS data and any derivative of the CMS data for the period of time required for any processing or purpose related to the Quality Improvement and Care Coordination and/or Program Integrity activity purposes for which the data were received. After such time, the Participating State Agency will dispose of the records in accordance with section 6 of the DUA.

## V. PROCEDURES FOR SECURITY

- A. Participating State Agency agrees to safeguard the CMS Data received under this Agreement, and any derivative data or files, as follows:
1. Participating State Agency shall, in accordance with the requirements of the DUA, comply with all applicable statutes and regulations regarding the privacy and security of PII and PHI, and shall in all other respects maintain the privacy and security of PII and PHI at a level and scope that is not less than the level and scope of requirements applicable to federal agencies, including, but not limited to, provisions of the Privacy Act of 1974 (5 U.S.C. § 552a), DHHS Privacy Act Regulations (45 C.F.R. §5b), HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164) that govern protections for individually identifiable health information, the Federal Information Security Management Act (FISMA) of 2002, OMB Circular A-130 and the CMS Minimum Security Requirements.
  2. Participating State Agency must maintain a level of security in any automated information system in accordance with the requirements of the DUA.
  3. Participating State Agency shall restrict access to the CMS Data obtained under this Agreement to only those authorized Participating State Agency employees, contractors, and agents who need such CMS Data to perform their official duties in connection with purposes identified in this Agreement.
  4. The Participating State Agency shall ensure that its employees, contractors, and agents:
    - a. comply with such safeguards as referenced in Section 7 of the DUA implemented to protect PII and PHI that is furnished by CMS under this Agreement from loss, theft or inadvertent disclosure.
    - b. safeguard this information at all times.
    - c. ensure that laptops and other electronic devices/media containing PII are encrypted and password-protected.
    - d. send emails containing PII or PHI only if encrypted and being sent to and being received by email addresses of persons authorized to receive such information.
    - e. generally limit disclosure of the information and details relating to a PII or PHI loss to the extent permitted by law.
    - f. individually identifiable information received under this Agreement, or individually identifiable data derived from CMS Data, shall be stored in an area that is physically and technologically secure from access by unauthorized persons during duty hours as well as non-duty hours (e.g., door locks, card keys, biometric identifiers, etc.).
    - g. only authorized Participating State Agency personnel shall transmit the CMS Data, including any derivative files containing personally identifiable information, and in all cases, such data shall be encrypted at all times when in transit or when stored on portable media as required in section V.A.4.c. above.
    - h. in all other instances CMS Data shall be maintained, used and disclosed using

appropriate safeguards, as determined by a risk-based assessment of the circumstances involved.

Both CMS and the Participating State Agency are responsible for oversight and compliance of their respective contractors and agents. CMS reserves the right to conduct onsite inspections to monitor compliance with this IEA, including the privacy and security requirements provided in this Agreement, HIPAA, and other applicable laws and Federal regulations until such time CMS data is destroyed in accordance with the DUA.

## **VI. LOSS REPORTING**

Incidents and/or Breaches that implicate PHI must be addressed and reported, as applicable, in accordance with the HIPAA Breach Notification Rule, 45 C.F.R. §§ 164.400 - 414.

The Participating State Agency shall further handle and report Incidents and Breaches in accordance with the agency's documented Incident Handling and Breach Notification procedures and in accordance with 42 C.F.R. §§ 431.300 - 306. In addition to, and notwithstanding, Participating State Agency's compliance with all applicable obligations and procedures, Participating State Agency procedures must also address how the Participating State Agency will:

1. Identify Incidents;
2. Determine if personally identifiable information is involved in Incidents;
3. Report suspected or confirmed Incidents as required in the DUA;
4. Identify and convene a core response group within the Participating State Agency to determine the risk level of Incidents and determine risk-based responses to Incidents; and
5. Determine whether Breach notification is required, and, if so, identify appropriate Breach notification methods, timing, source, and contents from among different options, and bear costs associated with the Breach notice as well as any mitigation measures.

## **VII. RECORDS USAGE AND REDISCLOSURE RESTRICTIONS**

The Participating State Agency agrees that the CMS Data will be used and disclosed only as provided in this Agreement to the following limitations on the access to, and disclosure and use of, CMS Data provided under the terms of this Agreement and any derivative data created therefrom.

## **VIII. REIMBURSEMENT AND REPORTING**

No funds will be exchanged under this Agreement for any work to be performed by the Participating State Agency to carry out the requirements of this Agreement. CMS will provide data to the Participating State Agency at no cost.

## **IX. APPROVAL AND DURATION OF AGREEMENT**

- A. Effective Date: This Information Exchange Agreement will become effective when signed by authorized officials of both parties.

- B. Duration: The duration of this Agreement is 5 years. Parties to this Agreement may execute a new agreement prior to the close of a 5-year period.
- C. Modification and Extension: The parties may modify or extend this Agreement at any time by a written modification, agreed upon by both parties.
- D. Termination: Either party may unilaterally terminate this Agreement upon written notice to the other party, in which case the termination shall be effective 30 days after the date of that notice or at a later date specified in the notice. In no instance shall such a termination be effective prior to the return or destruction of all CMS Data that were provided to the Participating State Agency or derived from the CMS Data obtained under the terms of this Agreement, including any CMS Data or information disclosed to Downstream Users in accordance with this Agreement. Participating State Agency agrees that it has the duty to protect and maintain the privacy and security of CMS Data, and that duty shall continue in full force and effect until such CMS Data is returned and/or destroyed. For any CMS Data or derivative data that destruction is not feasible for, the privacy and security requirements of this Agreement shall survive the termination or expiration of this Agreement.
- E. Breach: If CMS determines that there may have been an Incident or Breach of the CMS Data or individually identifiable derivative data or information by the Participating State Agency, its contractors and/or agents, and/or any Downstream Users that violates the terms of this Agreement, CMS may, in its sole discretion, immediately and unilaterally terminate this Agreement upon notice to Participating State Agency. Participating State Agency covenants and agrees to cease using and return and/or destroy all CMS Data and derivatives therefrom in its possession, contractors'/agents' possession, or Downstream Users' possession immediately upon notice of termination for an Incident or Breach. Participating State Agency agrees that it has the duty to protect and maintain the privacy and security of CMS Data, and that duty shall continue in full force and effect until such data is returned and/or destroyed. For any such data that return/destruction is not feasible, the privacy and security requirements of this Agreement shall survive the termination or expiration of this Agreement.

## **X. PERSONS TO CONTACT**

- A. CMS program and policy contact:

Candace Anderson  
Medicare-Medicaid Coordination Office  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop: S3-13-05  
Baltimore, MD 21244-1850  
(410) 786-1553  
E-Mail: [Candace.Anderson@cms.hhs.gov](mailto:Candace.Anderson@cms.hhs.gov)

CMS contact for Privacy issues:

Mr. Walter Stone  
CMS Privacy Officer  
Division of Security, Privacy Policy, and Governance  
Information Security & Privacy Group  
Offices of Enterprise Information  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop: N1-24-08  
7500 Security Boulevard  
Baltimore, MD 21244-1849  
Telephone: 410-786-5357  
Facsimile: 410-786-1347  
E-Mail: [Walter.Stone@cms.hhs.gov](mailto:Walter.Stone@cms.hhs.gov)

- B. The contact person for the Participating State Agency can be found on the Participating State Agency's signature page.

**XI. APPROVALS**

A. Centers for Medicare & Medicaid Services Program Official

The authorized program official, whose signature appears below, accepts and expressly agrees to the terms and conditions expressed herein, and confirms that no verbal agreements of any kind shall be binding or recognized, and hereby commits their respective organization to the terms of this Agreement.

<b>Approved by: (Signature of Authorized CMS Program Official)</b>	
<b>Sharon Donovan Group Director Program Alignment Group Medicare-Medicaid Coordination Office Centers for Medicare &amp; Medicaid Services</b>	<b>Date:</b>

B. Centers for Medicare & Medicaid Services Approving Official

The authorized approving official, whose signature appears below, accepts and expressly agrees to the terms and conditions expressed herein, and confirms that no verbal agreements of any kind shall be binding or recognized, and hereby commits their respective organization to the terms of this Agreement.

<b>Approved By: (Signature of Authorized CMS Approving Official)</b>	
<b>Emery Csulak Director Information Security and Privacy Group, and Senior Official for Privacy Office of Enterprise Information Centers for Medicare &amp; Medicaid Services</b>	<b>Date:</b>

C. Participating State Agency Program Official

The authorized Participating State Agency program official, whose signature appears below, accepts and expressly agrees to the terms and conditions expressed herein, and confirms that no verbal agreements of any kind shall be binding or recognized, and hereby commits their respective organization to the terms of this Agreement.

**NAME OF PARTICIPATING STATE AGENCY**

*State Name:*

*Medicaid Agency Name:*

<b>Approved By: (Signature of Authorized State Approving Official)</b>	
<b>Name:</b> <b>Title:</b> <b>Affiliation:</b>	<b>Date:</b>

Attachments:

1. Attachment A – Attachment for Downstream Users that are Providers
2. Attachment B – Data Use Agreement for Participating State Agency
3. Attachment C – Data Use Agreement Addendum for Downstream Users

# Attachment A

This is a Data Use Agreement (DUA) Attachment A is for use of Participating State Agencies that have executed the INFORMATION EXCHANGE AGREEMENT BETWEEN CENTERS FOR MEDICARE & MEDICAID SERVICES AND THE PARTICIPATING STATE MEDICAID AGENCY FOR DISCLOSURE OF MEDICARE PART A, PART B, PART C, AND PART D DATA (CMS AGREEMENT No. 2014-13), hereinafter referred to as “CMS IEA” for use when disclosing the CMS Data obtained under the terms of the CMS IEA with any Downstream Users that are Treating Providers.

This DUA Attachment A must be executed prior to the disclosure of CMS Data and any derivative data from Participating State Agency to a Downstream User to ensure that the disclosure will comply with the requirements of the CMS IEA, the Privacy Act, the DHHS Privacy Act Regulations and CMS data release policies. It must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.

This Attachment supplements the Data Use Agreement between the Centers for Medicare & Medicaid Services (“CMS”) and the Users. To the extent that the provisions of this Attachment are inconsistent with any terms in the Data Use Agreement, this Attachment modifies and overrides the Data Use Agreement.

## **I. Use of the Information**

### Section A-1

Users are defined as the State Medicaid Agencies and downstream entities that are Health Insurance Portability and Accountability Act (HIPAA) Covered Entities that are given individually identifiable data to carry out care coordination and quality improvement work, as well as the business associates of such entities and any sub-contractor Business Associates of such entities.

Users may include providers and care coordination organizations that wish to use individually identifiable data about beneficiaries of the Medicare and Medicaid programs (Medicare-Medicaid enrollees) to provide care coordination and quality improvement programs on behalf of the State Medicaid Agency and/or one or more HIPAA Covered Entity providers. Such work would need to be done subject to a HIPAA business associate agreement with that State Medicaid Agency and/or those HIPAA Covered Entity providers.

The Users must use any individually identifiable information that they receive under A-1 to further the delivery of seamless, coordinated care for individuals who are Medicare-Medicaid enrollees to promote better care, better health, and lower growth in expenditures.

### Section A-2

Subject to the limitations described below, users may reuse original or derivative data from the files specified in Section 5 of the Data Use Agreement, with or without direct identifiers, without prior written authorization from CMS, for clinical treatment, case management and care

coordination, and quality improvement activities. Information derived from the files specified in Section 5 of the Data Use Agreement may be shared and used within the legal confines of the Users authority in a manner consistent with this section to improve care integration. When using or disclosing protected health information (PHI) or personally identifiable information (PII), obtained under the Data Use Agreement, Users must make “reasonable efforts to limit” the information that is used or disclosed to the “minimum necessary” to accomplish the intended purpose of the use or disclosure. Users shall limit disclosure of information to that which CMS would be permitted to disclose under the established Privacy Act “routine uses,” which are categories of disclosures or uses permitted by CMS’s system of records notice available at [CMS’s Senior Agency Official for Privacy website \(http://www.cms.hhs.gov/privacy\)](http://www.cms.hhs.gov/privacy), as well as other permitted disclosures found in the Privacy Act at 5 U.S.C. § 552a(b)(1) through (b)(12).

Section A-3

Nothing in the Data Use Agreement, including but not limited to Section 9, governs the use and/or disclosure of any information that is obtained independent of the Data Use Agreement, regardless of whether the information was also obtained or could also be derived from the files specified in Section 5 of the Data Use Agreement.

Section A-4

Users are expressly authorized to undertake further investigation into events and individuals related to the files specified in Section 5 in a manner consistent with Section A-2. This includes, but is not limited to, reviewing other records, interviewing individuals, and attempting to link the files specified in Section 5 to other files.

**II. Potential Penalties**

Section A-5

Users acknowledge having received notice of potential criminal or administrative penalties for violation of the terms of the Data Use Agreement and this attachment.

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a. Participating State Agency Signature

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b. Provider, Care Coordination Organization, or Administrative Contractor Signature

# **Attachment B**

## **Data Use Agreement**

### **INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA)**

This is a Data Use Agreement (DUA) for use of Participating State Agencies that have executed the INFORMATION EXCHANGE AGREEMENT BETWEEN CENTERS FOR MEDICARE & MEDICAID SERVICES AND THE PARTICIPATING STATE AGENCY FOR USE OF MEDICARE PART A, PART B, PART C, AND PART D DATA (CMS AGREEMENT No. 2014-13), hereinafter referred to as “CMS IEA” ,for use when disclosing the CMS Data obtained under the terms of the CMS IEA.

## INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA) FORM CMS-R-0235

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### (AGREEMENT 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 CMS' Systems of Records to ensure that the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule and CMS data release policies. It must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.

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.**

- First paragraph, enter the Requestor's Organization Name.
- Section #1, enter the Requestor's Organization Name.
- Section #4 enter the Study and/or Project Name and CMS contract number if applicable for which the file(s) will be used.
- Section #5 should delineate the files and years the Requestor is requesting. Specific file names should be completed. If these are unknown, you may contact a CMS representative to obtain the correct names. The System of Record (SOR) should be completed by the CMS contact or Project Officer. The SOR is the source system the data came from.
- Section #6, complete by entering the Study/Project's anticipated date of completion.
- Section #12 will be completed by the User.
- Section #16 is to be completed by Requestor.
- Section #17, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of files is defined as that person who will have actual possession of and responsibility for the data files. **This section should be completed even if the Custodian and Requestor are the same.** This section will be completed by Custodian.
- Section #18 will be completed by a CMS representative.
- Section #19 should be completed if your study is funded by one or more other Federal Agencies. The Federal Agency name (other than CMS) should be entered in the blank. The Federal Project Officer should complete and sign the remaining portions of this section. If this does not apply, leave blank.
- Sections #20a AND 20b will be completed by a CMS representative.
- Addendum, CMS-R-0235A, should be completed when additional custodians outside the requesting organization will be accessing CMS identifiable 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 Project Officer, if applicable, for their files.

## DATA USE AGREEMENT

DUA #

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

CMS agrees to provide the User with data that reside in a CMS Privacy Act System of Records as identified in this Agreement. In exchange, the User agrees to pay any applicable fees; the User agrees to use the data only for purposes that support the User's study, research or project 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; and the User agrees to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability and Accountability Act. In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and \_\_\_\_\_ enter into this agreement to comply with the following specific paragraphs. (Requestor)

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 (HHS), and \_\_\_\_\_, hereinafter termed "User." (Requestor)
2. 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 in section 5 and/or any derivative file(s) that contain direct individual identifiers or elements that can 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 files specified in section 5 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 or any of its components with respect to the data specified herein. Further, the terms of this Agreement can 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 point-of-contact or the CMS signatory to this Agreement shown in section 20.
3. 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. The User represents, and in furnishing the data file(s) specified in section 5 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

\_\_\_\_\_  
Name of Study/Project

\_\_\_\_\_  
CMS Contract No. (if applicable)

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, 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 will be put.

The User agrees not to disclose, use or reuse the data covered by this agreement except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing or as otherwise required by law, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement. 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 organization and the organizations of its 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 purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).



9. The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in section 5, with or without direct 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 date(s), or date of death.

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 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 5 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) 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. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. If you are unsure if you meet the above criteria, you may submit your written products for CMS review. 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. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in section 5 to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol.
11. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 20 of this Agreement.
12. The parties mutually agree that the following specified Attachments are part of this Agreement:

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13. 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 appropriate System Manager or the person designated in section 20 of this Agreement, 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) if requested by CMS, submit a formal response to an allegation 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 (e) if requested by CMS, 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's 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 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 Action Desk by telephone at (410) 786-2580 or by e-mail notification at [cms\\_it\\_service\\_desk@cms.hhs.gov](mailto:cms_it_service_desk@cms.hhs.gov) within one hour and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the User shall bear the cost and liability for any breaches of PII from the data 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. 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 exceeding \$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. 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. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his 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. 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. On behalf of the User the undersigned individual hereby attests that he or she is authorized to legally bind the User to the terms this Agreement and agrees to all the terms specified herein.

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Name and Title of User *(typed or printed)*

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Company/Organization

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Street Address

City	State	ZIP Code
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Office Telephone <i>(Include Area Code)</i>	E-Mail Address <i>(If applicable)</i>
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Signature	Date
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17. 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. 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.

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Name of Custodian *(typed or printed)*

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Company/Organization

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Street Address

City	State	ZIP Code
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Office Telephone <i>(Include Area Code)</i>	E-Mail Address <i>(If applicable)</i>
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Signature	Date
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18. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in section 4 follow(s). (To be completed by CMS staff.) \_\_\_\_\_
19. On behalf of \_\_\_\_\_ 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's 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 (or to his or her successor).

Typed or Printed Name		Title of Federal Representative	
Signature			Date
Office Telephone (Include Area Code)		E-Mail Address (If applicable)	

20. 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)			
Title/Component			
Street Address			Mail Stop
City	State	ZIP Code	
Office Telephone (Include Area Code)		E-Mail Address (If applicable)	
A. Signature of CMS Representative			Date
B. Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date

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 30 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 C**

## **Data Use Agreement Addendum**

### **INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA) Addendum**

This is a Data Use Agreement (DUA) Addendum for use of Participating State Agencies that have executed the INFORMATION EXCHANGE AGREEMENT BETWEEN CENTERS FOR MEDICARE & MEDICAID SERVICES AND THE PARTICIPATING STATE MEDICAID AGENCY FOR DISCLOSURE OF MEDICARE PART A, PART B, PART C, AND PART D DATA (CMS AGREEMENT No. 2014-13), hereinafter referred to as “CMS IEA” for use when disclosing the CMS Data obtained under the terms of the CMS IEA with any Downstream Users. A Downstream User means any person or entity (e.g., a Treating Provider, contractor, business associate or subcontractor of the Participating State Agency).

This DUA Addendum must be executed prior to the disclosure of CMS Data and any derivative data from Participating State Agency to a Downstream User to ensure that the disclosure will comply with the requirements of the CMS IEA, the Privacy Act, the DHHS Privacy Act Regulations and CMS data release policies. It must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.

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## DATA USE AGREEMENT (DUA) ADDENDUM for Data Acquired from the CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

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The following individual(s) requests access to CMS data. Their signature(s) attest to their agreement with the terms and conditions defined in the original documentation for Data Use Agreement (DUA) \_\_\_\_\_ or for new DUA study/project name \_\_\_\_\_

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**Part A**      \_\_\_\_\_ **Requester**      \_\_\_\_\_ **Custodian**      \_\_\_\_\_ **Subcontractor**      \_\_\_\_\_ **Recipient**

Printed Name \_\_\_\_\_ Phone \_\_\_\_\_ Ext \_\_\_\_\_

Organization \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

E-mail \_\_\_\_\_

Signature \_\_\_\_\_

(if applicable) Courier name \_\_\_\_\_ Account number \_\_\_\_\_

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**Part B**      \_\_\_\_\_ **Requester**      \_\_\_\_\_ **Custodian**      \_\_\_\_\_ **Subcontractor**      \_\_\_\_\_ **Recipient**

Printed Name \_\_\_\_\_ Phone \_\_\_\_\_ Ext \_\_\_\_\_

Organization \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

E-mail \_\_\_\_\_

Signature \_\_\_\_\_

(if applicable) Courier name \_\_\_\_\_ Account number \_\_\_\_\_

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### **Contracting Officer Representative (COR)/Government Task Lead (GTL) or CMS Privacy Staff**

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

Organization \_\_\_\_\_

Please send as an email attachment to [DataUseAgreement@cms.hhs.gov](mailto:DataUseAgreement@cms.hhs.gov), and see our website at [www.cms.gov/privacy](http://www.cms.gov/privacy)

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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 10 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 comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Md. 21244-1850.