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

(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.

Form Approved
OMB No. 0938-0734

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
Medicare Shared Savings Program Accountable Care Organization

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).

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

File	Years(s)	System of Record
HIGLAS - Payment Data	2010-2013	N/A
NLR - Meaningful Use	2010-2013	NCH
RAS - Risk Adjustment Data	2010-2013	IDR
CAHPS - Beneficiary Survey Data	2010-2013	IDR
GPRO - Quality Measurement Data	2010-2013	NCH
NPIXW - NPI Crosswalk	2010-2013	NPESS
PECOS - Provider Enrollment Data	2010-2013	PECOS
EDB - Beneficiary Enrollment Data	2010-2013	CMS
IDR - Parts A, B, and D Claims	2010-2013	IDR
Receipt of ACO Applications (HPMS or Portal)	2010-2013	ACO

6. The parties mutually agree that the aforesaid files(s) (and/or any derivative file(s)), including those files that directly identify individuals or that directly identify bidding firms and/or such firms' proprietary, confidential or specific bidding information, and those files that can be used in concert with other information to identify individuals, may be retained by the User until One Year, hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User agrees to destroy such data. The User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days. The User agrees not to retain CMS files or any parts thereof, after the aforementioned file(s) are destroyed unless the appropriate Systems Manager or the person designated in section 20 of this Agreement grants written authorization. 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. Upon notice of termination by 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. The User agrees 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 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)** as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" **(http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf);** and, Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" **(http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf)**. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable, bidder identifiable or deducible information derived from the file(s) specified in section 5 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 without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The User agrees to grant access to the data to the authorized representatives of CMS or DHHS Office of the Inspector General at the site indicated in section 17 for the purpose of inspecting to confirm compliance with the terms of this agreement.

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:

    See Attachment A

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** 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.

Name and Title of User *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature		Date

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.

Name of Custodian *(typed or printed)*		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
Signature		Date

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.) PA3-ACO

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)*		
Frederick T Ensor Jr.		
Title/Component		
Technical Advisor - Performanced Based Payment Policy Staff		
Street Address		Mail Stop
7500 Security Boulevard		
City	State	ZIP Code
Baltimore	Maryland	21244
Office Telephone *(Include Area Code)*	E-Mail Address *(If applicable)*	
(410) 786-5617	rick.ensor@cms.hhs.gov	

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 A

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

USE OF THE INFORMATION

A-1. Users are the Accountable Care Organization ("ACO"), a legal entity recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), that has entered into a signed agreement with CMS, is comprised of an eligible group of ACO Participants that work together to manage and coordinate care for Medicare Fee-for-Service beneficiaries and has established a mechanism for shared governance that provides all ACO Participants with an appropriate proportionate control over the ACO's decision making process. An ACO Participant, as identified by a TIN, is a Medicare-enrolled provider of services and/or a supplier that bills for items and services it furnishes to Medicare Fee-for-Service beneficiaries under a Medicare billing number assigned to the TIN of an ACO Participant in accordance with applicable Medicare rules and regulations. The ACO and its ACO Participants, including all ACO providers/suppliers (collectively "Users") intend to use the requested information as a tool to deliver seamless, coordinated care for patients with Original Medicare (that is, who are not in Medicare Advantage private health plans) to promote better care, better health, and lower growth in expenditures. 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 ACO and its ACO Participants in a manner consistent with Section A-2 to enable the ACO to improve care integration and be a patient-centered organization.

A-2. Users may reuse original or derivative data without prior written authorization from CMS for clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation, but shall not disseminate original or derived information from the files specified in Section 5 of the Data Use Agreement, with or without direct identifiers, to anyone who is not an ACO Participant or an ACO provider/supplier in an ACO that has entered into a signed agreement with CMS. Users may disseminate and link information derived from the files specified in Section 5 of the Data Use Agreement to other sources of individually-identifiable (patient-specific) health information, such as medical records, available to the ACO and its ACO Participants unless expressly prohibited by the Medicare beneficiary. 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 to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request. Users shall limit disclosure of information to the established Privacy Act "routine uses," which are categories established by the Privacy Act which dictate the types of uses under which data can be disclosed.

A-3. Nothing in the Data Use Agreement, including but not limited to Section 9, prohibits Users from discussing or reporting on specific individuals or incidents in a manner consistent with Section A-2.

A-4. Nothing in the Data Use Agreement, including but not limited to Section 9, prohibits the Users from obtaining and disseminating any information whatsoever that is obtained independent of the Data Use Agreement, whether or not the information also could be derived from the files specified in Section 5 of the Data Use Agreement.

A-5. 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.

A-6. Nothing in the Data Use Agreement grants CMS, or any other person or entity, any authority to review or restrain any report or communication by a User before its dissemination to an ACO Participant or an ACO provider/supplier in the same CMS-approved ACO.

POTENTIAL PENALTIES

A-7. Users acknowledge having received notice of potential criminal or administrative penalties for violation of the terms of the Data Use Agreement and this attachment.

_____

For: Centers for Medicare & Medicaid Services

_____

For: Accountable Care Organization