A Guide to Obtain Permission to Use the Medicare Data Located at the UNC-CH Sheps Center

Background Information about the Data

The UNC Department of Epidemiology houses a sample of approximately 20% of all Medicare beneficiaries age 65 and older with fee-for-service coverage of Medicare Parts A, B, and D simultaneously for at least one calendar month in 2007-2010. Once a patient meets selection criteria, claims data (only available while enrolled in fee-for-service plans) and death data are available for all subsequent years through 2010. Medicare standard analytic files contain fully adjudicated paid claims and dates of service for all non-capitated ambulatory, emergency department, inpatient, and outpatient encounters (including administrative claims for laboratory tests), skilled nursing facility, hospice, home health, and durable medical equipment claims for patients at the time of service. Patient enrollment data, medical care, and health care utilization may be tracked for each individual in the database. Diagnoses and procedures are identified by the International Statistical Classification of Diseases and Related Health Problems (ICD-9); Current Procedural Terminology (CPT); and Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS) codes for both outpatient and inpatient visits/stays. Physician, specialist, and emergency room visits, as well as hospital stays, are captured in the database through CPT codes, revenue codes (e.g., room and board), used on billing forms such as the UB-92, and place of service codes. The Beneficiary Annual Summary File contains demographic information, including county of residence, dates of death, and comorbidity flags that can be used to identify patients with certain chronic conditions. Part D drug claims contain dates of dispensing, National Drug Codes (NDCs), strength, amount, and days supply. The Medicare data is administered by the Cecil G. Sheps Center for Health Services Research.

How Can I Obtain Permission to Use this Data?

There are a number of steps that you will need to complete in order to obtain access to the Medicare data.

Step 1: Obtain permission from the primary investigator in charge of Medicare data access, Til Sturmer, sturmer@unc.edu. Dr. Sturmer will assign the data supervisor role to Dr. Alan Brookhart, Dr. Michele Jonsson-Funk, or himself. Your data supervisor will be responsible for ensuring that the remaining steps are completed prior to data access.

Step 1a: If you are a Visiting Scholar at UNC, do not proceed past this step. Dr. Sturmer or the faculty hosting your visit will inform you about the paperwork to be completed by UNC Human Resources. After your paperwork is processed and approved, restart at step 1.

Step 2: Your data supervisor will be responsible for determining if your project is suitable for Medicare data use and in agreement with current Data Use Agreements (DUAs). If your project is determined to not fall under a current DUA, your data supervisor, or their designee, will discuss with you the steps and commitment involved to obtain from CMS a data re-use agreement for your specific research topic. Data cannot be accessed and the remaining steps in this document should not be completed until a DUA is granted by CMS through a reuse agreement or an existing DUA is determined to be applicable and associated paperwork is signed. A sample internal DUA that your data supervisor may use is located at the end of this document.

The remaining steps should not be completed until an appropriate DUA is obtained and signed.

Step 3: Discuss with your data supervisor IRB approval as it relates to your intended use of the Medicare data. Documentation of IRB approval is needed prior to obtaining access to the Medicare data. If you are a student and you intend to use your research involving the Medicare data as your dissertation or thesis, you will need to submit your own IRB application of your student-led project. More information concerning students and IRB processes can be found here,
https://research.unc.edu/offices/human-research-ethics/online-submission/
http://research.unc.edu/offices/human-research-ethics/researchers/faq/#whatstud
(see "what about student research or class projects?")

Step 4: Complete the UNC ITS Security Training located at this website:
https://itsapps.unc.edu/ITSSelfStudy/
Provide documentation of your training to your data supervisor and Diane Reams, diane.reams@unc.edu

Step 5: Complete the Collaborative Institutional Training Initiative (CITI) training located at this website: https://research.unc.edu/offices/human-research-ethics/researchers/training/
Notify your data supervisor and Diane Reams concerning the completion of your training, diane.reams@unc.edu

Step 6: After your data supervisor has determined that steps 1-5 have been successfully completed, your data supervisor will email Mark Whelan to inform Mark that you have permission to access the Medicare data.   Mark will instruct you on how to access the server at the Sheps Center through a UNC ITS portal system. When you first log into the portal, you will be required to read the following Sheps policies: "Sheps Policy for Handling Confidential Data," "Sheps Rules of Behavior," "Sheps Sanction Policy," and "Sheps Information Training Slides." After acknowledging that you have read and understand these policies, you will provide an electronic signature. **You will be expected to abide by all of these policies and the previous training that you completed to get to this step. Please read everything that you sign very carefully and understand your responsibilities as a Medicare data user.**

In order to ensure the security of data resources and to comply with data use agreements, you may not connect to the pharmacoepi server to work with the MarketScan data using a personal computer unless it meets both of the following criteria:
   • Security updates managed by UNC-IT *and*
   • PGP whole disk encryption

There are 4 options to choose among:

Option 1. Use the Virtual Computing Lab – you will connect to a virtual computer and then from there to the pharmacoepi server (instructions here: http://sdrv.ms/1fTE6Ic)

Option 2. Do your work from campus using computers in the computer labs.

Option 3. Use a UNC-issued laptop. The pharmacoepi group has a few available that you can checkout (first come, first serve).

Option 4. Get your personal computer put onto the active domain and have whole disk encryption implemented. Be warned: this will result in your personal computer being controlled / monitored by UNC-ITS, and that may have downstream consequences that will be undesirable. We strongly encourage you to use Option 1, 2, or 3.

DATA USE AGREEMENT FOR
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
PART D MEDICARE DATABASE

This agreement ("Agreement") establishes the terms and conditions under which *[insert legal name of individual user]* _____ ("User") will obtain and use data ("Data") in specified data sets ("File(s)") of the Medicare & Medicaid Services (CMS) Part D Medicare Database ("Database") maintained by the University of North Carolina at Chapel Hill's Cecil G. Sheps Center for Health Services Research ("Sheps Center").   The User's work with Data has been approved by *[insert legal name(s) of the individual(s) who will oversee the Users use of the Data]* _____ ("Supervisor(s)"), who has signed the Part D Data Use Agreement (DUA #_____) that has been dually executed between the University of North Carolina at Chapel Hill and the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS).

A.   DATA

1.   Pursuant to the terms and conditions of this Agreement, the User may obtain from Sheps Center the following extracts, subsets, or derivatives of the Database: [select one from ***each*** section]

        (a) DATASETS: __x__ All Available
                                  _____ MCBS only
                                  ____ Claims only (i.e., all except MCBS)
                                  _____ Only the following dataset(s) _____

        (b) YEARS: __x__ All Available
                                    _____ Only the following year(s): _____

        (c) SAMPLE: _____ Full Datasets
                                __x__ Random 1% Sample
                                _____ Otherwise specified cohort: _____

2.   User may retain the above-listed extracts, subsets, or derivatives of the Database until **_____**, hereinafter known as the "retention expiration date." User agrees that no later than the retention expiration date, User shall return to Sheps Center or destroy the above-listed extracts, subsets, or derivatives of the Database and shall not retain any of these data after the retention expiration date.

B.   DATA USE

1.   The User agrees to access data only on the Pharmacoepi secure server administered by the Sheps Center. The User acknowledges that copying or electronically transmitting the data to desktop computers, laptop computers, unsecure servers or other devices outside of the pre-specified server is prohibited.

2.	The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the File(s) is prohibited.

2.	The User represents that the File(s) will be used solely for the following purpose: "_____" (insert DUA title here). The User affirms that the requested data is the minimum necessary to achieve the stated purpose.

3.	The User understands and agrees that they may not reuse original or derivative data file(s).

4.	The User agrees not to attempt to link records included in the File(s) to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s).

5.	The User agrees not to disclose direct findings, listings, or information derived from the File(s), with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce and 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 must adhere to CMS' current cell size suppression policy. This policy stipulates that no cell less than 11 may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than 11.

6.	The User agrees that within thirty (30) minutes of any breach of personally identifiable information (PII) from the CMS File(s), loss of the File(s), or disclosure to any unauthorized persons, the User will report the unauthorized access, use or disclosure to the User's Supervisor and to the Custodian of the Data, Til Sturmer.

7.	The User agrees to abide by all other stipulations specified in the Part D Data Use Agreement (DUA #_____) that has been dually executed between the University of North Carolina at Chapel Hill and the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS). The User agrees to comply with applicable law, including the Privacy Act, Social Security Act, and the Health Insurance Portability and Accountability Act.

8.	The User agrees not to make any statement indicating or suggesting that interpretations drawn are those of the Sheps Center.

9.	For any published research material resulting from the User's use of the Data, the User shall provide an abstract and reference to the Sheps Center.

D.   OTHER TERMS AND CONDITIONS

1.   User agrees to indemnify, defend, and hold harmless the Sheps Center and CMS, from any or all claims and losses accruing to any person, organization, or other legal entity as a result of User's violation of this Agreement.

2.   This Agreement shall be governed in all respects by the laws of the State of North Carolina.

3.   The User understands and agrees that a violation of any of the terms and conditions of this Agreement may also be a violation of state and/or federal statutes and subject to the criminal, civil and administrative penalties associated with violations of those statutes, in addition to constituting a material breach of this Agreement with attendant legal liabilities.

4.   **All notices, contractual correspondence, and transmission of Data** under this Agreement shall be made in writing and delivered to the following:

To Sheps Center:	Roger Akers_____
	725 Martin L King Jr Blvd, CB 7590
	Chapel Hill, NC 27599-7590
	akers@unc.edu__919-966-7188
To Custodian of the Data:	Til Sturmer_____
	Department of Epidemiology
	UNC Gillings School of Global Public Health
	Chapel Hill, NC 27599-7435
	sturmer@unc.edu__919-966-7433
To Supervisor of the User:	_____
(address, phone number, fax, email)	_____
	_____
	_____
	_____
To User:	_____
(address, phone number, fax, email)	_____
	_____
	_____
	_____

5.   The term of this Agreement shall become effective upon final execution and shall continue in effect through the retention expiration date specified above or until earlier terminated.

6.   In the event of a material breach of this Agreement by User, Sheps Center may terminate this Agreement immediately by providing written notice to the User. Upon termination by Sheps Center, the User shall immediately either return to Sheps Center or destroy at Sheps Center's discretion and directive the above-listed File(s) and any derivative File(s) of Data and shall not retain any File(s) and/or any derivative File(s) of Data.

7.   This Agreement may be amended or modified only by mutual written consent of the authorized representatives of Sheps center and User. Both parties agree to amend this Agreement to the extent amendment is required by an applicable regulatory authority.

8.   This Agreement contains all the terms and conditions agreed upon by the parties regarding the subject matter of this Agreement and supersedes any prior agreements, oral or written, and all other communications between the parties relating to such subject matter.

The USER has executed this Agreement as set forth below.

BY: _____   DATE: _____
          (signature)

NAME: _____   TITLE: _____
          (printed)

The undersigned individual(s) agrees to allow the User to access the files and data specified in A.1 above, under the understanding that the User agrees to fully comply with the terms of this Agreement.

Name: _____   Phone Number: _____
          (printed)
Signature: _____   Email: _____

Date: _____