

Introduction

The Centers for Medicare & Medicaid Services (CMS) is committed to better care, better health, and lower costs. As trusted partners in achieving these goals, we believe states should have access to Medicare data for research that is directed and partially funded by the state.

This request process will only cover the release of Medicare data to states for research activities. Under the new request process, a single state agency will request Medicare data from CMS to fulfill their research purposes for a broad range of activities and programs. The new request process will require applicants to provide the detail needed for the CMS Privacy Board to conclude that the request meets the criteria listed at 45 CFR 164.512(i)(2)(ii) (see below for additional detail on the criteria). The requesting agency will be able to reuse the data for additional research, and will be able to further disseminate the data to other state agencies or entities conducting research that is directed and funded by the state.

The requesting state agency will sign a single Data Use Agreement (DUA) for the data, eliminating the need for the state to sign a DUA for each distinct research-related use of the data. Instead, the requesting agency will be required to contractually bind all recipients of CMS' protected health information to the terms of the DUA related to use, re-use, and re-disclosure of the data.

This memo provides more specific details on several aspects of the new process:

- Defining research,
- Data disclosure and re-use,
- The request process,
- Data release,
- Technical assistance, and
- Cost of the data.

Defining research

Under this process, in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule definition of the same term, CMS plans to interpret research broadly in order to include numerous state data analytics activities. We believe that research goes beyond traditional academic research to include activities that help a state identify patterns and variations in the delivery of healthcare. This broad definition comports with the HIPAA Privacy Rule definition of the term, which defines research as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 C.F.R. § 164.501).

CMS has assembled a list of activities that could qualify as research. This is not a comprehensive list, but meant as an example of the range of activities that could be considered research.

Example Research Activities

- Identify characteristics of the top 1% Medicare beneficiaries with the highest spending
- Characterize the clinical determinants of health outcomes across the state

- Gain insight into health delivery systems by identifying statewide variation in care
- Identify communities that provide cost-effective care and learn from their successes
- Identify disparities in health care access, utilization, disease status and quality of care
- Study patient migration between health care service areas
- Multi-payer analyses, potentially using an all-payer claims database

Data disclosure and re-use

As described above, states may re-use the CMS data they receive under this new process for additional research projects. In doing so, the agency that requests the data may re-disclose the data to other state agencies and/or entities conducting qualified research activities under the direction and partial funding of the state. CMS uses the phrase “on behalf of the state” to describe any research performed under the direction of a state agency or official that is partially funded by the state. States may apply this definition narrowly or broadly based on the state’s internal operations.

Privacy Board Approval: As required by HIPAA, all CMS data disclosures for research must be approved by the CMS Privacy Board. For the Privacy Board to approve any data release, it must conclude that several criteria laid out at 45 CFR 164.512(i)(2)(ii) are met. Specifically, the requesting agency must provide:

1. A plan to protect the data from improper use or disclosure and assurances that the data will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research for which the data was requested, or for other research for which the use or disclosure of PHI would be permitted under 45 CFR 164.512(i)(2)(ii);
2. A plan to destroy the identifiers when the research is completed, unless there is a research justification for retaining the identifiers; and
3. An assertion that the research could not practicably be conducted without access to and use of protected health information.

Data Management Plan: CMS will require the requesting state agency to submit a data management plan for the primary location where it will house the Medicare data. However, the state will not need to submit a data management plan for all additional locations that will house the Medicare data. Instead, CMS will require the requesting state agency to describe how the data will be transferred to and secured at the additional storage locations. The requesting agency may determine its own procedures to ensure that any data stored at an additional location is sufficiently secure. CMS will also require the requesting agency to contractually bind all recipients of CMS’ protected health information to the terms of the DUA related to use, re-use, and re-disclosure of the data. The contract must require all recipients of CMS’ protected health information to: 1) immediately report any breach of personally identifiable information to the User; 2) return or destroy the data in the event the agreement with the User is terminated unless CMS determines the data may be retained; 3) take corrective actions for minor violations; and 4) return or destroy the data for major violations.

DUA Signature Addendum: States will not be required to submit a DUA signature addendum for each new user of the Medicare data. Instead, as stated above, the requesting agency will be

required to contractually bind all users of the data to the terms that they are subject to on use, re-use, and re-disclosure of the data.

Other Uses of the Data: CMS acknowledges that states may have other needs for Medicare data beyond research. However, the HIPAA Privacy Rule requires that protected health information (PHI) released for research only be re-used or re-disclosed for other qualifying research. As a result, states will still need to make a separate request for Medicare data for:

- Healthcare operations. Under HIPAA, states may only request data for dual eligible beneficiaries for healthcare operations. The Coordination of Benefits Agreement (COBA) Program run by the Medicare-Medicaid Coordination Office has processes in place for data sharing for this purpose.
- CMS Contractor Use. A State is allowed to receive any data that is necessary in order to fulfill the obligations of a contract with CMS. For example, there are currently 15 States that have contracted with CMS/MMCO to design models of integrated care.
- Program integrity activities. Some data analysis for program integrity may be considered research, for example, using predictive analytic models to identify fraudulent activity worth scrutiny. However, for those activities that are not research, HIPAA permits disclosure for fraud and abuse under two provisions. The first is under healthcare operations, which only allows for the disclosure of data on dual eligible beneficiaries. The second is if a state health oversight agency makes a fact-specific request for data that is key to a specific fraud and abuse investigation. The health oversight agency would only be able to request the minimum data necessary for their investigation.

Standard Research Requests: CMS does not intend this process to replace CMS's current research data request process for other researchers. Researchers that are not doing work under the direction of the state will need to request the data through the current CMS research request process. Additionally, researchers in states that receive data under this process for studies that are under the direction of, and are partially funded by a state, will still be required to request the data through the current CMS research request process for other studies that are conducted under different authorities or funding.

The state request process

1. A single state agency that is currently engaged in or intends to engage in research can request Medicare data from CMS for research purposes. This request can encompass a broad range of analytic activities that support multiple purposes and programs, avoiding the need to submit multiple individual research requests. States will need to submit a request letter and an executive summary containing:
 - a. Information on the overall intent and goals of the research that the state plans to perform using Medicare data;
 - b. A plan for disclosing the data to other state agencies and entities performing research on behalf of the state;
 - c. Details necessary to allow the CMS Privacy Board to approve the data release; and
 - d. A plan to identify and track additional research projects done by the state and on behalf of the state.

2. The requesting state agency signs a DUA with CMS for a year (rather than a separate DUA for each individual data release) that allows for multiple research uses of the data across any state agencies. The state agency that signs the DUA with CMS will:
 - a. Be able to reuse the data itself for additional research, or further disseminate the data to other state agencies and/or entities conducting research on behalf of state if such research projects would allow for a Privacy Board or an IRB to make the findings listed at 45 CFR 164.512(i)(2)(ii) if the anticipated data recipient were to apply for the data from CMS directly.
 - b. Agree to track the entities and organizations using the data and for what they are using it, as well as any sites where the data has been physically moved, transmitted, or disclosed, and then report this information to CMS quarterly as a condition of receiving the data.
3. On-going research protocols will have to be periodically renewed to ensure that, as time goes on, CMS is still only disclosing the minimum data necessary to carry out the activities taking place under that protocol.

Data release

CMS anticipates state research data needs encompass the following data files, but data applicants will need to supply a minimum necessary analysis that explains why the data is needed for the research described in the executive summary. HIPAA allows CMS to rely upon the minimum necessary assertions of other HIPAA Covered Entities when such reliance is reasonable, so, for ease of review, applicants should also indicate if they are a HIPAA Covered Entity.

- *Population*: Medicare beneficiaries residing in the requesting state, plus a 5% national file for benchmarking
- *Data Files*: As required by the submitted protocol:
 - Enrollment information
 - Main elements of Parts A and B claims
 - Part D PDE data
 - i. Must be released in accordance with the Part D data disclosure rule
 - ii. Executive summary must document a need for the PDE data and the specific PDE data elements
 - Assessment data, including:
 - i. Long Term Care Minimum Data Set (MDS)
 - ii. MDS Swing Bed
 - iii. Home Health Outcome and Assessment Information Set (OASIS)
 - iv. Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)
 - MedPAR
- *Timeframe*: Depending on the research protocol:
 - An initial set of historical data (e.g., 2 years)
 - Routine updates (e.g., quarterly for claims) for the duration of the DUA
- *Claims Run-out*: 6-9 months of run out time for Parts A and B (with longer run-out for Part D, if provided)
- *Linking*: CMS will permit data to be linked to permit easy tracking of beneficiaries across care settings, as well as inclusion in all-payer databases

Technical Assistance

CMS has a contract with the Research Data Assistance Center (ResDAC) to provide technical assistance to researchers, including states, interested in using Medicare and/or Medicaid data for their research. Additionally, CMS plans to provide periodic outreach on the use of Medicare data.

Cost of the Data

Where appropriate, CMS plans to provide state requestors with a standardized extract of the Medicare data. As states develop their research protocols, they should keep in mind that standardized extracts are significantly less expensive than customized data sets, so, where appropriate under HIPAA's minimum necessary principle, states should ask for standard extract files.

CMS defers to applicable state law as to whether the requesting state agency may recoup some of the costs of re-disclosing the data to downstream users. However, we do expect that in instances in which the requesting agency is permitted to recoup costs from downstream users, that the requesting agency would limit the total fees collected to the cost of making the data available.