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## EXECUTIVE SUMMARY

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1. Study Overview *Please describe your study objectives and aims.*

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2. How have you ensured that your data request includes the minimum amount of data necessary to achieve your research objectives?

2.1. Please describe how this cohort will meet minimum data necessary. (Include estimated cohort size. Refer to your cost invoice.)

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2.2. List the CMS data files and years being requested at this time and provide justification for how each will be used in the analysis. If requesting reuse of data, include the DUA #5 to be reused. The list of files should match Item #5 of DUA.

2.2.1. List the Medicare (claims and enrollment) or Medicaid (claims and enrollment) being requested as this time and provide justification for how each file will be used in the analysis. If requesting reuse of data, include the DUA # to be reused. The list of files should match item #5 of DUA.

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2.2.2. List the Part D event data (if using in study) being requested as this time and provide justification for how each file will be used in the analysis. If requesting reuse of data, include the DUA # to be reused. The list of files should match item #5 of DUA.

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2.2.3. List the Part D characteristics files (if using in study) being requested as this time and provide justification for how each file will be used in the analysis. If requesting reuse of data, include the DUA # to be reused. The list of files should match item #5 of DUA.

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2.2.4. List the Assessment data (if using in study) being requested as this time and provide justification for how each file will be used in the analysis. If requesting reuse of data, include the DUA # to be reused. The list of files should match item #5 of DUA.

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2.3. If this study will require further years of CMS data that are not yet available for request, please list those CMS data files and years that will be required for the entire scope of your study (Note: Approval of data files for years that are not yet available will NOT be granted at this time, the information included here will simply provide CMS with an overview of your study).

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2.4. Please list any non-identifiable or non-CMS files you are planning to use in conjunction with the above files for your analysis. (e.g. Provider of Services (POS) file, AMA Physician Master file, etc.)

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3. You are requesting identifiable files. Why can't Limited Data Set (LDS) files be used for this study?

Please check all that are applicable to this request.

- I'm requesting data that are only available as identifiable data (Medicaid, Assessments, Medicare Part D event)
- My research requires personal beneficiary identifiers (in order to link to other datasets or to contact Medicare beneficiaries)
- My research requires beneficiary DOB, zip code, or physician identifiers.
- Other (please explain): \_\_\_\_\_

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4. Is it feasible to obtain individual level authorization from Medicare/Medicaid beneficiaries for your research? Explain.

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5. If you intend on requesting the National Death Index segment of the Master Beneficiary Summary File, please complete the [NDI Supplement](#).

- YES, I've included the NDI Supplement       NO, I'm not requesting the NDI

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6. If this research project is funded by a commercial entity, the (primary) lead investigator attests that they will limit data sharing with the funding entity to aggregated analytic results and will retain the right to independently prepare publications of the study results.

- I attest

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Signature of (Primary) Lead Investigator

Date

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### **DISSEMINATION AND REPORTING OF FINDINGS**

From the CMS DUA, "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."

- I agree.

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Please describe your plans for disseminating the findings from your analysis, including specific media through which you will report results.

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## DATA MANAGEMENT PLAN

Please reference the [Data Management Plan Guidelines](#), [Data Management Plan Review Checklist Evaluation Guide](#), [Collaborator Checklist](#), and/or the [FAQ document](#) for more information on completing this section. These materials are found under the Executive Summary section of the New Study Requesting Data page of the website.

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### 1. PHYSICAL POSSESSION AND STORAGE OF CMS DATA FILES

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1.1. Who will have the main responsibility for organizing, storing, and archiving the data? Please provide name(s) and job title(s).

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1.2. Explain the infrastructure (facilities, hardware, software, other) that will secure the CMS data files.

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### 2. DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION

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2.1. Describe your organization's policies and procedures\* regarding the sharing, transmission, and distribution of CMS data files.

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2.2. Please indicate how you will allow other state agencies (and/or contractors) to access the data files:

VPN connection

Will travel to physical location of data files at requesting organization

Request that a copy of the data files be housed at second location

Other: \_\_\_\_\_

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2.3. If an additional copy of the data will be housed in a separate location, please describe how the data will be transferred to this location. (Also, please ensure you have included information on this organization's data management under the appropriate subsections of the data management plan.)

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2.4. Who will have the main responsibility for notifying CMS of any suspected incidents wherein the security and privacy of the CMS data may have been compromised? Please describe and identify your organization's policies and procedures\* for responding to potential breaches in the security and privacy of the CMS data.

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\* Note that CMS is specifically asking for references to written policies and procedures related to your organization's administrative, technical and physical safeguards. If policies and procedures have not been developed, please explain any ongoing activities your organization is taking to document policies and procedures and make them available to staff. Organizations selected for DPSP reviews will be asked to provide copies of written policies and procedures. Please note that an explanation of the process is not sufficient.

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### 3. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION

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3.1. In the event that the state is required by CMS to stop all research activities with CMS data, describe your organization's process to complete the [Certificate of Disposition](#) form and policies and procedures\* to destroy data files.

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3.2. In the event that the state is required by CMS to stop all research activities with CMS data, describe your organization's policies and procedures\* to ensure original data files are not used following notice from CMS.

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\* Note that CMS is specifically asking for references to written policies and procedures related to your organization's administrative, technical and physical safeguards. If policies and procedures have not been developed, please explain any ongoing activities your organization is taking to document policies and procedures and make them available to staff. Organizations selected for DPSP reviews will be asked to provide copies of written policies and procedures. Please note that an explanation of the process is not sufficient.

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