MARYLAND
Department of Health

Requesting Maryland Medical Assistance Data—Frequently-Asked Questions

Step 1: Beginning your Data Request

Who do I contact at Maryland Medicaid for assistance with Data Requests?
John Parrish, Regulatory Economist III, is the point person at MDH for starting the Data Request process. Mr. Parrish can be contacted via email at mdh.medcaiddatarequests@maryland.gov or via phone at (410) 767-5808. We encourage the principal investigator or study coordinator to schedule a teleconference with Mr. Parrish early in the process, as an opportunity for her/him to pose questions, comments and concerns (e.g., tight timelines for deliverables) at the very front end of the process. During such a teleconference, Mr. Parrish will provide an overview of Medicaid's processes and procedures.

Pooja Regmi, Lead Analyst, is the point person for any and all Data Use Agreement (DUA) concerns after the beginning of the generation of the DUA. Ms. Regmi can be contacted via email at pooja.regmi@maryland.gov or via phone at (410) 767-5943.

What happens after I submit a Maryland Medicaid data request form to the Maryland Medicaid Planning Administration team?
The form is reviewed for completeness and clarity. A teleconference is scheduled, during which the purpose, scope and specifications of the proposed data pull are discussed and further defined. Once the specifications are refined, the request is forwarded to the team at the Hilltop Institute at UMBC responsible for providing the requested data. This team independently reviews the specified data request for feasibility and cost as well as clarity, and schedules a teleconference with the principal investigator to discuss perspectives and recommendations for optimization of the pending data pull.

What happens after the parameters of the data request and relevant data mining criteria, such as diagnostic codes, revenue codes, etc., are fully defined?
A statement (i.e., narrative description) of the agreed upon parameters, referred to as the Scope of Work statement, is drafted and reviewed by all involved parties. Relevant data mining criteria (such as codes and other identifiers) are appended to this statement. Upon request, the Hilltop team can provide a sample statement of the Scope of Work to serve as guidance when the research team takes next steps to draft such a narrative. To the extent necessary, the Hilltop team provides technical assistance to the research team during the drafting of this statement. After undergoing a rigorous review, this statement is finalized.

Is there a cost associated with the fulfillment of my data request?
Yes. This cost is estimated based upon the finalized statement of the Scope of Work.

What must I submit along with my data request?
As soon as feasible, the principal investigator submits the following to the Maryland Medicaid Planning administration team (John Parrish, Regulatory Economist III is the point person at MDH for starting the Data Request process. Mr. Parrish can be contacted via email at mdh.medicaiddatarequests@maryland.gov. or via phone at (410) 767-5808): (1) finalized statement of the scope of work; (2) that information needed from the principal investigator to customize templates for the Inter-Agency Agreement (IA) and the Data Use Agreement (DUA); and (3) a drafted MDH IRB application. MDH IRB Form 2124, available *here*.

Step 2: The Data Use Agreement and InterAgency Agreement Process

A. Definitions

What is Personally Identifiable Information (PII)?
PII shall mean personally identifiable information as defined by OMB Memorandum M-07-16 (May 22, 2007) ("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."). PII includes, but is not limited to, information that would be considered Protected Health Information (PHI) if held by a Covered Entity or Business Associate under Health Insurance Portability and Accountability Act (HIPAA). PII also includes, but is not limited to Medical Records protected by the Maryland Confidentiality of Medical Records Act (Health-General § 4-301 *et seq,* Ann. Code of MD*).*

What is Protected Health Information (PHI)? See above
PHI shall have the meaning set forth for "Protected Health Information" at 45 C.F.R. § 160.103.

What is Covered Data?
The data to be disclosed as defined in Attachment 1 of your DUA, almost always consisting of data extracted from Medicaid data files.

What is a Derivative Product?
These products include, but are not limited to, reports, studies, manuscripts, tables, and charts created from Medicaid data files.

What is incoming data?
The term incoming data references the data that is to be received by the Data Recipient(s).

What is outgoing data?
The term outgoing data references the data that is disclosed by the Data Provider(s).

What is a Limited Data Set (LDS)?
A LDS is information with facial identifiers, such as PHI and PII, which have been removed. Examples of facial identifiers can be, but are not limited to, information relating to the individual or his or her relatives, employers or household members. For more information on LDS, please see the informational link, available *here*.

What is Sanitization?
Sanitization refers to the general process of removing Covered Data from storage media and cloud services, such that there is reasonable assurance that the data may not be easily retrieved and reconstructed. There are several methods of sanitization, including, but not limited to, disposal, clearing (in a fashion that is resistant to keystroke recovery attempts), purging, and physical destruction.

What is the Health Insurance Portability and Accountability Act (HIPAA)?
HIPAA shall mean the Health Insurance Portability and Accountability Act of 1996 including all pertinent privacy regulations (45 C.F.R. Parts 160 and 164) and security regulations (45 C.F.R. Parts 160, 162, and 164), as amended from time to time, issued by the U.S. Department of Health and Human Services as either have been amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5). The latter directly affects Medicaid data requests. MDH is required to generate and execute DUAs to comply with HIPAA. For more information on HIPAA, please see the following website, available *here*.

What is a Covered Entity?
Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

What is 45 CFR Part 2 – Substance Use Disorder Data?
Part 2 applies to federally-assisted programs that hold themselves out as providing, and do provide alcohol or drug use treatment, diagnosis or referral for treatment. Includes information that would identify a patient as an abuser directly or by reference to other public information except in certain

situations, including scientific research.

B. The DUA and BAA

What are the different roles in the DUA process?
MDH is the "Data Provider." Your organization or individual interest is the "Data Recipient." The Hilltop Institute at UMBC (in the majority of the cases) is the "Data Warehouse." In rare cases, Hilltop will not be a party to the DUA. It is also possible that other parties - such as contractors hired to study the Covered Data for the Data Recipient - will be added to the DUA to ensure compliance with HIPAA.

What happens after the statement of the Scope of Work is finalized?
If Hilltop is providing the Covered Data, the Hilltop team estimates the cost of providing the agreed upon deliverables, and submits a proposed budget to the principal investigator and her/his research administrator for review and negotiation. Once the budget has been tentatively negotiated with the principal investigator and her/his employer, the Hilltop team submits the draft budget to the Office of Sponsored Programs at UMBC for its administrative review and approval. A contract for payment by the principal investigator's employer to UMBC is then established and executed.
Once the Scope of Work statement and the corollary budget have been finalized, what happens next?

As soon as feasible, the principal investigator submits the following to the Maryland Medicaid Planning administration team: (1) finalized statement of the Scope of Work; (2) that information needed from the principal investigator to customize templates for the Inter-Agency Agreement (IA) and the Data Use Agreement (DUA) and (3) a drafted MDH IRB application (MDH IRB Form 2124, available *here*) or a MDH IRB Approval Letter.

What is a Data Use Agreement (DUA)?

Because Maryland Medicaid owns the requested data, an agreement must be formed for other parties to receive and use this data. The DUA allows the transfer of Medicaid data, while protecting all parties involved and allowing parties to be within federal and State regulations.

Typically, the DUA includes, but is not limited to, the following attachments comprised of information submitted to Medicaid Planning by the data requestor: Covered Data & Period of Use; Scope of Work; Additional Data Sources; Data Management Plan and Data Storage Location; Project Managers and Notice; Certificate of Data Destruction; and Documentation of IRB approval or a pending IRB application.

When is a DUA necessary?
A DUA is necessary whenever MDH is a provider of Medicaid Data, including LDS, with the requesting Data Recipient before use or disclosure of data if an authorization waiver for use of individual's health data was not obtained. The DUA is required by the HIPAA Privacy Rule.

Who is responsible for drafting the Data Use Agreement (DUA)?
The Maryland Medicaid Planning Administration team is responsible for drafting the DUA, using pre-approved templates. Hilltop and the Data Recipient will work together to customize the attachment to fit the needs of the request in accordance with rules and regulations. Templates are available upon request.

Once the DUA is fully drafted, what happens next?
The drafted DUA is provided to the principal investigator and representatives of the Hilltop Institute and UMBC for review and revision. Once the terms of the DUA are agreed upon by all named parties, the DUA is finalized and circulated for required, dated signatures. Each named party is provided a signed copy of the executed DUA.

When is a Business Associate Agreement (BAA) necessary?
The HIPAA rules apply to Covered Entities and Business Associates and any time MDH transfers data that contains PII and/or PHI with a Business Associate. A BAA is required whenever Part 2 data is requested and subsequently shared, and at any time a Covered Entity engages a Business Associate to help it carry out its healthcare activities and functions. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of the HIPAA Rules.

Who is a Business Associate?
A business associate is any organization or person working in association with or providing services to MDH who handles or discloses PHI and/or PII.

What do I do if there is a substantial change in my research project after my IRB protocol has been approved and/or the DUA has been signed?
These changes should be reported directly to the contract monitor at MDH and through the Quarterly reporting requirement. Each substantial change/deviation from the Scope of Work laid out in the DUA between the parties must be reported to the assigned Project Manager(s) in the DUA. Solutions include an amendment to the DUA, an extension of DUA timeframe, and/or closing out of the project. Any substantive change to the study protocol, as previously submitted to and reviewed by the MDH IRB, will warrant submission of a completed Request for Protocol Modification form, along with a revised Abstract Summary (with proposed changes highlighted in the text) before the MDH IRB.

What is the Quarterly reporting requirement?
MDH requires Data Recipients to submit a Quarterly report summarizing any analyses or reports for which Covered Data was used. These reports must be sent to John Parrish at mdh.medicaiddatarequests@maryland.gov.

If I already have a contractual relationship with Medicaid, are there limitations on access to shared Medicaid data?
No. Access and usage is limited to the terms of the Scope of Work. A DUA may be amended and/or a new DUA may be required for the new request.

Is our organization and/or (individual researcher) required to protect and/or encrypt the E-Medicaid data received?
Yes. Prior to receipt of E-Medicaid data, Data Requestors are required to complete a Data Management Plan (DMP) Google Form survey. MDH requires Data Requestors to have a sound DMP in compliance with NIST and DoIT guidelines to receive Maryland Medicaid data. MDH's Google Form survey to access a Data Requestors DMP, available *here*.

What is a Data Management Plan (DMP) and is it required for a DUA?
A DMP is a written document that describes the data you expect to acquire or generate during the course of a research project, how you will manage, describe, analyze, and store those data, and what mechanisms you will use at the end of your project to share and preserve your data. Completion of the DMP is a requirement to fulfill provisions in the DUA between the Data Recipient and the Maryland Department of Health. Access to the DMP Google Form is available *here*. The Google Form assists Planning Staff access your DMP, as well as providing valuable information regarding minimum requirements for a valid DMP.

Who at the organization/LHD can access the shared data?
Data Recipients agree, that within its contractors and subcontractors, access to the Covered Data, the Covered Data documentation, and any file derived from the Covered Data shall be limited to the minimum number of individuals necessary, as determined within the sole discretion of Medicaid, to achieve the purposes set out in the Scope of Work (Attachment A2 of the DUA), and access to the data shall be granted only on a need-to-know basis. Data Recipients shall keep and maintain a log of the identity of each employee, contractor, and/or subcontractor who is authorized to access the data disclosed under the DUA and shall provide the log to Medicaid on demand.

C. In Certain Circumstances, A Third Party Researcher May Need To Enter Into A Separate Agreement Governing Payment Of Costs With The Planning Admin. and/or Its Data Warehouse Provider.

What is an IA?
An Interagency Agreement (IA) is an agreement between government agencies and MDH that contains a brief description of the research project and data to be shared, as well as specific duties of each party to the Agreement and requirements to submit quarterly reports and updates. Please note there may be costs associated with research projects that are outside of the scope of the IA.

When is an IA necessary?
An IA is necessary when an exchange of funds occurs with MDH. Link to OPASS website – OPASS templates are *here*. This link is only relevant if an IA is necessary.

Step 3: MDH Institutional Review Board (IRB) Process

Is there a link to the MDH IRB?
The link to the MDH IRB is available *here*.

Who do I contact at Maryland Medicaid for assistance with the IRB process and approval?
John Parrish, Regulatory Economist III, is the point person at the MDH Planning Administration for starting the IRB application. Mr. Parrish can be contacted via email at mdh.medcaiddatarequests@maryland.gov or via phone at (410) 767-5808. Moreover, questions may be submitted to Ms. Gay Hutchen, IRB Administrator, gay.hutchen@maryland.gov.

What are the links to State policy and federal regulations governing IRB review policies and procedures?
At the home page of the MDH IRB, click on "Related Links." The next web page provides links to relevant federal agencies, federal regulations and the MDH's policy (01.03.02) on research involving human subjects. An overview of protocol submission and review procedures, approval criteria and board decisions is included in this policy statement.

Is my planned project likely to be deemed to be "research" or not? Does my research protocol qualify for expedited IRB review? Does my research protocol qualify for exemption from IRB review? Under what circumstances can the requirement for informed consent and/or HIPAA be waived?
To begin to address these questions, read the relevant sections of the MDH IRB policy statement located *here*. All projects must be reviewed by the MDH IRB. The MDH IRB will make a determination if a project is deemed research and/or deemed exempt from further review or not. These waivers or lack of waivers will affect the Covered Data able to be provided to you by Maryland Medicaid for your project.

What do I need to do to put my protocol before the MDH IRB?
The initial IRB application packet, including both the application form and application instructions,

is available in PDF and MS Word formats available *here*.

To whom is the drafted MDH IRB application to be submitted?
The principal investigator submits the drafted MDH IRB application to John Parrish for review. Mr. Parrish can be contacted via email at john.parrish@maryland.gov or via phone at (410) 767-5808. Along with the completed initial MDH IRB application form MDH IRB Form 2124), the principal investigator must submit the required responses to the nine questions posed routinely by the MDH IRB; an executive summary (i.e., brief narrative description) of the study protocol; study instruments; and other required attachments (e.g., the most recent determination letter issued by the IRB of the principal investigator's employer).

When will I receive the requested data?
The timeline to receive E-Medicaid data varies for each individual data request. Generally, the process timeline varies for each projects individual requests and needs.

If the principal investigator has questions, comments and concerns to be discussed with the MDH IRB administrator, what steps should be taken?
Contact the MDH IRB Office at either MDH.OIG@maryland.gov or 410-767-5784.

Steps 4 and 5: Data Exchange, Maintenance and Closing out Process (Step 4 and 5)

How will the data be transferred?
Generally, a Secured File Transfer Program (SFTP) will be used to securely transfer the Medicaid data. If another secured method is preferred and meets the State's security requirements, it may be used.

What format will the data be in?
Data can be transferred in a variety of formats including, but not limited to, (SAS/SPSS/STATA/Excel/etc.)

Who is responsible for maintaining the data?
Each party to the DUA will name a Project Manager to ensure the data remains secured. The Project Managers' responsibilities shall include: serving as liaison in negotiating any procedures necessary for the implementation of this Agreement, including establishing the project plan and implementation strategy; coordinating requests for information and other cooperative activities between the Parties; and communicating and working with information technology staff to resolve logistical and technical problems related to accessing the Covered Data. As previously mentioned, each party must establish a DMP and the Covered Data must be maintained consistent according to the terms of the DMP. Maryland follows the data protection and technology guidelines published by National Institute of Standards and Technology (NIST). The NIST guidelines detailing the

minimum requirements for data maintenance, sanitization of covered data, and other data management guidelines are available *here*.

Am I required to notify the Maryland Medicaid Office of Planning Administration of the final disposition of the shared data file(s)?
When the principal investigator notifies the Maryland Medicaid Office of Planning Administration that the protocol is officially closed, the principal investigator is required to either return the previously shared data files to the data provider or to submit a completed Certificate of Data Destruction. The Certificate of Data Destruction form is available *here*.

How should I report an unanticipated problem, such as a breach of sensitive information?
The Project Manager, listed in an Attachment to the DUA, is required to report the occurrence or suspicion of any unanticipated problems as defined above immediately both to the Maryland Medicaid Office of Planning Administration and the IRB. One such unanticipated problem may be a breach of sensitive information, *e.g.*, the unauthorized sharing of PHI or PII.

Am I expected to share work products with the Maryland Medicaid Office of Planning Administration?
Yes. The principal investigator is expected to share in a timely manner with the Maryland Medicaid Planning Administration key work products resulting from an IRB-approved investigation. Such products may include a comprehensive final narrative project report and/or PowerPoint presentation; one or more published research articles, monographs, book chapters or books; etc. Products that provide key findings and implications related to prospective advances in health practices and policies are of particular interest.

Am I required to notify the Maryland Medicaid Office of Planning Administration when my protocol is closed; that is, is no longer open and active?
Yes. In all cases, whether the protocol has been deemed to be exempt or non-exempt from further review by the MDH IRB, when the protocol is no longer open and active, the PI is required to complete and submit a Certificate of Study Closure to MDH. In the case of a non-exempt MDH IRB-approved protocol (protocol for which an annual review by the IRB is required), such notification is indicated on the MDH IRB Continuing Review Form II (MDH 2125) when the final annual review packet is submitted to the IRB. As part of this notification, the principal investigator is to provide a Closing Summary of project-related activities and accomplishments, and is to clarify in writing as a required aspect of this Closing Summary whether released Medicaid data have been either (a) returned to the Medicaid Planning Administration, Office of Health Care Financing or to the data provider or (b) have been destroyed or sanitized. The Certificate of Study Closure form is available *here*, and Certificate of Data Destruction form is available *here*.