DATA USE AGREEMENT BETWEEN THE

MARYLAND HEALTH CARE COMMISSION AND

[NAME OF RECIPIENT]

This Data Use Agreement ("Agreement") is made by and between the Maryland Health Care Commission ("MHCC"), located at 4160 Patterson Avenue, Baltimore, Maryland 21215, and [NAME OF RECIPIENT] (the "Data Recipient") located at [ADDRESS] (each a "Party" and, collectively, the "Parties").

WHEREAS, pursuant to a data use agreement entitled, "*DATA USE AGREEMENT AMONG THE HEALTH SERVICES COST REVIEW COMMISSION, THE MARYLAND HEALTH CARE COMMISSION, AND THE DISTRICT OF COLUMBIA HOSPITAL ASSOCIATION REGARDING ACCESS TO AND USE OF DISTRICT OF COLUMBIA HOSPITAL DISCHARGE DATA*," (hereinafter "D.C. Data Use Agreement"), executed August 9, 2021, the District of Columbia Hospital Association provides to MHCC hospital inpatient discharge data on Maryland residents who have inpatient stays in District of Columbia hospitals ("D.C. hospital discharge data");

WHEREAS, the D.C. Data Use Agreement was amended on January 5, 2023 ("Amendment");

WHEREAS, pursuant to the terms of the D.C. Data Use Agreement and Amendment, MHCC may disclose D.C. hospital discharge data, upon receipt of a written request from Certificate of Need ("CON") applicants, including prospective CON applicants who file letters of intent to file a CON application, and, if applicable, any attorneys and consultants for CON applicants or prospective CON applicants, provided that, prior to MHCC's release of the requested D.C. hospital discharge data, MHCC enters into a data use agreement with the requestor of the D.C. hospital discharge data;

WHEREAS, on [DATE], the Data Recipient filed with MHCC a [CON application/letter of intent to file a CON application/interested party comments];

OR

WHEREAS, on [DATE], Data Recipient submitted an affidavit attesting that the purpose of the Data Recipient's request is for project planning related to a potential CON application, exemption request, or interested party comments; that the Data Recipient will not use the data for any other purposes; and that the Data Recipient will not disclose any findings related to the D.C. Data except in furtherance of a future CON application, request for exemption from CON review, or interested party comments;

WHEREAS, the Data Recipient, by written application dated [DATE] submitted to MHCC, requested access to the following data sets: ; and

WHEREAS, the D.C. hospital discharge data is visit-specific data containing identifiable information, including sex and race of patient, zip code of residence, provider identification numbers, diagnosis codes, and insurance plan information; thus, the MHCC and Data Recipient consider the security and confidentiality of this data to be a matter of high priority.

NOW THEREFORE, in consideration of the mutual promises and covenants, the sufficiency of which is hereby acknowledged, MHCC and the Data Recipient agree as follows:

AGREEMENT

The above recitals and following attachments are fully incorporated into this Agreement:

Attachment A – Covered Data;
Attachment B – Scope of Work and Project Methodology
Attachment C – Additional Data Sources
Attachment D – Data Users Log;
Attachment E – Data Management Plan and Data Storage Location; and
Attachment F – Certificate of Data Destruction.

1. DATA TO BE RELEASED

1.1 MHCC will provide to Data Recipient the electronic files described in Attachment A ("Covered Data").

1.2 The Covered Data files will have a "SAS7BDAT" extension. MHCC will send the Covered Data to Data Recipient via a SSH File Transport Protocol (SFTP). Data Recipient agrees to set up an appropriate location to download the Covered Data in compliance with this Agreement and the Data Management Plan contained in Attachment E ("Data Management Plan and Data Storage Location").

1.3 MHCC and Data Recipient agrees that the D.C. Hospital Association retains all ownership rights to the Covered Data provided to Data Recipient and that Data Recipient does not obtain any right, title, or interest in any of the data furnished by MHCC.

2. PERMITTED USES OF THE COVERED DATA

2. 1 The Covered Data shall be used solely by Data Recipient for project planning purposes related to [a CON application *OR* potential CON application *OR* its participation as an interested party in a CON review] as described in Attachment B ("Scope of Work"). Any other uses of the

Covered Data outside of the Scope of Work described in Attachment B, including any commercial uses, are strictly prohibited unless prior written approval is obtained from MHCC.

2.1.1 Data Recipient in its application states a plan to use the Covered Data as follows:

2.1.2 Data Recipient agrees not to publish or disseminate the Covered Data or the results of its analysis of the Covered Data except in furtherance of a CON application, request for exemption from CON review, or interested party comments.

2.2 Data Recipient may retain the Covered Data and utilize such data for the specific purposes described in Attachment B during the effective dates of this Agreement.

2.3 Data Recipient agrees to provide a list of any files from sources other than the Covered Data that it plans to use in conjunction with the Covered Data in its analysis. Attachment C ("Additional Data Sources") contains all additional data sources known to Data Recipient at the time of execution of this Agreement. Data Recipient shall update this list, and provide such update to MHCC, prior to the use of any new data source(s) in conjunction with the Covered Data. Data Recipient further agrees not to link patient-level data to any additional data source.

2.4 Data Recipient agrees that any use of the Covered Data in the creation of any document (report, study, manuscript, table, chart, etc.) must adhere to MHCC's cell size suppression policy unless MHCC approves the use of an alternate cell size. This policy requires that no cell of ten (10) or less may be displayed and that no use of percentages or other mathematical formulas may be used if they are based on a sample of ten (10) or fewer patients.

2.5 Data Recipient agrees not to disclose direct findings, listings, or information derived from the Covered Data, 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, geographic location, age (if > 89), sex, diagnosis and procedure, admission/discharge date(s), or date of death.

2.6 Data Recipient agrees not to attempt to re-identify individuals whose information is contained in the Covered Data. Data Recipient further agrees to not attempt to link any Covered Data to any other source of clinical or health service information.

3. PERMITTED USERS OF THE COVERED DATA

3.1 The Data Recipient shall limit access to the Covered Data, the Covered Data documentation, and any files derived from the Covered Data to the minimum number of individuals necessary, as determined within the sole discretion of Data Recipient to achieve the purposes set out in Attachment B, and access to the data shall be granted with minimal access and risk to PHI, in accordance with the Health Insurance Portability and Accountability Act ("HIPAA") of 1996, and the implementing regulations at 45 CFR Parts 160 and 164, specifically, 42 CFR § 164.512.

3.2 Data Recipient shall keep a log of the identity of each individual ("Data User") who is authorized to access the data provided under this Agreement. Attachment D ("Data Users Log") contains the log of authorized Data Users known to Data Recipient at the time of execution of this Agreement. After execution of this Agreement, Data Recipient will provide updates of the log to MHCC before authorizing any new individual to access the Covered Data.

3.3 Data Recipient shall be responsible for making all individuals who are permitted Data Users of the Covered Data under this Agreement, including any personnel of contractors and subcontractors, aware of the terms and conditions of this Agreement. Specifically, Data Recipient shall advise all Data Users of the confidential nature of the Covered Data and the safeguards required to protect the security of the data. In addition, Data Recipient shall provide a copy of this Agreement to all Data Users, inform them that they are required to comply with all terms and conditions of this Agreement, and obtain written acknowledgments from each Data User. Data Recipient shall provide documentation of Data Users' written acknowledgments to MHCC upon request.

4. DATA SECURITY AND CONFIDENTIALITY

4.1. Data Recipient agrees to comply with any applicable State and federal security requirements regarding collection, maintenance, and use of the Covered Data, including HIPAA and the implementing regulations at 45 CFR Parts 160 and 164, and the Maryland Confidentiality of Medical Records Act ("MCMRA"), Md. Code Ann., Health-Gen §§ 4-301 *et seq*.

4.2. The Covered Data is confidential and shall not be disclosed or transferred without written consent of MHCC to anyone or entity other than the authorized Data Users listed in Attachment D ("Data Users Log").

4.3. Data Recipient will maintain the electronic security of the Covered Data in accordance with the Data Management Plan ("DMP") submitted by Data Recipient (Attachment E) for each data custodian. Each DMP, which shall be consistent with the State of Maryland Information Security Policy, and relevant State and federal laws, must be approved by MHCC prior to the release of data to Data Recipient.

> 4.3.1. The Covered Data shall be stored and processed so as to protect the confidentiality of the data, and in such a way that unauthorized persons cannot retrieve such records by means of computer, remote terminal, or any other means. If the Covered Data is stored in a folder on a network drive, that folder shall be omitted from the

standard data back-up process utilized by Data Recipient. If the Covered Data is stored on a local hard drive, that computer must be in a secure location at all times.

4.3.2. Data Recipient will submit a revised DMP (Attachment E) to MHCC if there are any changes to the plan, including, but not limited to, storage location (in which case a revised Data Storage Location form must also be submitted) and security protocols. MHCC must review and approve any revised DMP (and Data Storage Location, if applicable) before such plan is implemented.

4.4. At the termination of this Agreement for any reason, Data Recipient agrees to destroy the Covered Data, any products created from the Covered Data, and all back-up and archived copies of the Covered Data. The destruction process shall ensure that the data is erased from all networks, drives or computers and could involve using software such as WipeDrive that is capable of destroying data on a drive in a manner that meets the data destruction standards specified by the National Institute of Standards and Technology ("NIST") Special Publication 800-88, Guidelines for Media Sanitation. Data Recipient will send a fully executed Certificate of Data Destruction (Attachment F) within thirty (30) days of the date of the termination of this Agreement to MHCC in accordance with section 8 of this Agreement.

4.5. The Parties agree to work together in a mutually agreeable fashion to address technical issues that may arise during project implementation and thereafter. Each Party also agrees to notify the other Party as soon as reasonably practicable if a significant technical issue arises.

5. REPORTING AND NOTIFICATION REQUIREMENTS

5.1. Data Recipient shall submit a semi-annual report to MHCC in the form and manner specified by MHCC, which shall include, but not be limited to, a description of the work performed and uses of the Covered Data; approved changes or expansions to the Scope of Work; approved changes to permitted Data Users; approved changes to data access and security methods; and any approved revisions to the data custodian's data management plan; and a summary of analyses, results, reports, publications, or any other work product derived in whole or part from use of the Covered Data.

5.2. Data Recipient agrees to notify MHCC in writing within 24 hours of receiving a request, subpoena, or order for disclosure relating to the Covered Data, whether for a judicial proceeding or matter, an administrative hearing, a request under Maryland's Public Information Act ("PIA") or the federal Freedom of Information Act ("FOIA"), or similar request. Data Recipient shall not disclose the Covered Data without either MHCC's prior written agreement or before affording the MHCC sufficient time to intervene in opposition to such a request, subpoena, or order.

6. BREACH OF AGREEMENT

6.1 Data Recipient shall give MHCC written notice immediately or as soon as reasonably practicable upon having reason to know that a potential or actual Data Breach, as defined in Section 6.2, has occurred.

6.2 "Data Breach" means the unauthorized acquisition, access, use, or disclosure of the Covered Data, or any unsecured PHI that compromises the security or privacy of such information, subject to the statutory exceptions specified at Section 13400 of the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") and the regulatory exclusions specified at 45 CFR §164.402 and any future amendments thereto.

6.3 Any breach of security or unauthorized use or disclosure of the Covered Data, including a Data Breach, shall constitute a breach of this Agreement. Any violation of State or federal law with respect to disclosure of the Covered Data, including but not limited to, the MCMRA or the HIPAA Privacy Rule, shall constitute a breach of this Agreement. Notwithstanding the breaches specifically enumerated above, any other failure by Data Recipient to comply with the terms and obligations of this Agreement shall constitute a breach of this Agreement.

6.4 Any alleged failure of MHCC to act upon a notice of a breach of this Agreement does not constitute a waiver of such breach, nor does it constitute a waiver of any subsequent breach(es).

6.5 The Data Recipient shall comply and assist in any audit of compliance with this Agreement if requested by MHCC. In the event that MHCC reasonably believes that the confidentiality of the Covered Data has been breached, MHCC may: investigate the matter, including an on-site inspection for which Data Recipient shall provide access; and require Data Recipient to develop a written plan of correction, acceptable to MHCC, to ameliorate or minimize the damage caused by the breach of confidentiality and to prevent future breaches of data confidentiality.

6.6 In the event of a breach of this Agreement, MHCC may seek all other appropriate remedies available under law, including termination of this Agreement, disqualification of Data Recipient from receiving PHI or PII from MHCC in the future, and referral of any inappropriate use or disclosure to the Consumer Protection Division of the Office of the Attorney General of Maryland, the Maryland State's Attorney Office, or any other appropriate state or federal law enforcement authority.

7. FEES

7.1 Data Recipient agrees to pay to MHCC a one-time fee in the amount [FEE] for the Covered Data. Data Recipient shall pay the one-time fee of [FEE] in full to MHCC before any of the Covered Data is provided to Data Recipient.

7.2 No reimbursement will be made to either Party by the other Party for expenses related to accessing, maintaining, or upgrading a Party's information technology infrastructure, or for any expenses related to extracting, using, or storing the Covered Data, or for any other expense otherwise arising out of this Agreement.

8. NOTICE

Any notice given pursuant to this Agreement must be in writing and addressed to:

If to MHCC:
Mahlet Nigatu,
Chief of APCD Public Report and Data Release
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, MD 21215
Mahlet.Nigatu@maryland.gov
(410)-764-3779

If to Data Recipient:
[ADD]

9. GOVERNING LAW AND JURISDICTION

This Agreement shall be construed, interpreted, and enforced according to the laws of the State of Maryland without reference to its conflict of laws principles. Data Recipient acknowledges doing business in Maryland and agrees to submit to the jurisdiction of the courts in Maryland in the event of an action for an alleged breach of this Agreement.

10. EFFECTIVE DATE, AMENDMENTS, MODIFICATIONS, AND TERMINATION

10.1 This Agreement becomes effective on the date of its execution and shall remain in effect for a period of one (1) year from the date this Agreement is executed, or upon termination of the Agreement by either Party in accordance with section 10.3 below.

10.2 This Agreement may be amended or modified if mutually agreed to in writing by the Parties.

10.3 This Agreement may be terminated by either Party, with or without cause, provided that written notice is given to the non-terminating Party at least thirty (30) days before the determined termination date.

In acknowledgment of the foregoing, the Parties by their duly authorized officials do hereby indicate their consent to this Data Use Agreement.

Maryland Health Care Commission	[DATA RECIPIENT NAME]
Signed:	Signed:
_____	_____
Ben Steffen	Printed Name:
Executive Director	Title
Date:	Date:

ATTACHMENT A – Covered Data

This Data Use Agreement pertains to the D.C. hospital discharge data for the calendar years listed below:

ATTACHMENT B – Scope of Work and Project Methodology

ATTACHMENT A: SCOPE OF WORK FROM THE APPLICATION WILL BE INSERTED HERE.

ATTACHMENT C – Additional Data Sources

No additional data sources required

ATTACHMENT D – Data Users Log

DATE OF LAST UPDATE: _____

Data Recipient shall keep a log of the identity of each individual who is authorized to access the data provided under this Agreement. This Attachment contains the log of authorized data users known to Data Recipient at the time of execution of this Agreement. After execution of this Agreement, Data Recipient shall provide written updates of this log to MHCC before authorizing any new individual to access the Covered Data.

By signing my name below as a Data User, I certify that I have reviewed this *DATA USE AGREEMENT BETWEEN THE MARYLAND HEALTH CARE COMMISSION AND*

Data Recipient Name_____.

I understand the confidential nature of the Covered Data and I agree to abide by the required safeguards to protect the security of the data. I understand that the Covered Data can only be used for "Permitted Uses" identified in section 2 of this Agreement and can only be shared with individuals listed and approved in this Data Users Log.

Data Recipient Personnel with Access to MCDB Data:

Name of Data User	**Title**	**Unit**	**Signature**	**Date**

Name of Data User	**Title**	**Unit**	**Signature**	**Date**

Subcontractor Team(s) Personnel with Access to MCDB Data: (Insert one table per subcontractor, as needed):

Name of Data User	**Title**	**Unit**	**Signature**	**Date**

ATTACHMENT E – Data Management Plans and Data Storage Locations

ATTACHMENT E1 from the Application will be inserted here.

Attachment F: Certificate of Data Destruction

Maryland Health Care Commission (MHCC) Medical Claims Database
CERTIFICATE OF DATA DESTRUCTION

Data must be destroyed so that it cannot be recovered from electronic storage media in accordance with the methods established by the "Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals," as established by the U.S. Department of Health and Human Services (HHS).

The undersigned hereby certifies that all copies of the following data files provided to the Data Recipient Name_____ have been destroyed.

Project Title	
MHCC DUA Number	
Principal Investigator Name	
Title	
Organization	
Address	
Tel Number	
Fax Number:	
E-mail Address	
Data Custodian Name	
Title	
Organization	
Address	
Tel Number	
Fax Number	
E-mail Address	
Date the Data was Destroyed:	

Description of files provided:

Describe how the Data Custodian, System Owner/Maintainer has disposed of, destroyed, erased, and/or anonymized the file regardless of the method of storage. Use as much space as needed to provide a complete description.

Add description here: (fillable field)

Certification
I/we certify that we have destroyed all Data received from MHCC in connection with this project, in all media that were used during the research project. This includes, but is not limited to data maintained on hard drive(s), diskettes, CDs, etc.

SIGNATURES:

Principal Investigator
Organization:
_____
Signature
_____
Printed Name
_____
Title
_____
Date

Data Custodian
Organization:
_____
Signature
_____
Printed Name
_____
Title
_____
Date

Person Responsible for Destroying the Data
Organization
_____
Signature
_____
Printed Name
_____
Title
_____
Date

Signature Witness
Organization
_____
Signature
_____
Printed Name
_____
Title
_____
Date