



IN THE MATTER OF MARYLAND MEDICAL CARE DATA BASE DATA REQUEST APPLICATION SUBMITTED BY THE CHESAPEAKE REGIONAL INFORMATION SYSTEM FOR OUR PATIENTS (CRISP) BEFORE THE MARYLAND HEALTH CARE COMMISSION

STAFF REPORT AND RECOMMENDATION

June 17, 2021

TABLE OF CONTENTS

I. INTRODUCTION2

II. APPLICATION AND PROPOSED PROJECT DETAILS2

III. STAFF REVIEW AND ANALYSIS OF APPROVAL CRITERIA.....4

IV. SUMMARY AND STAFF RECOMMENDATION5

Appendix:

- Application submitted by Chesapeake Regional Information System for Our Patients (CRISP), June 10, 2021. Including three data management plans.
- Advarra IRB exemption determination, May 19th, 2021.
- Chesapeake Regional Information System for Our Patients (CRISP), Fee waiver request, June 8, 2021.

I. INTRODUCTION

A. The Maryland Medical Care Data Base

The Maryland Health Care Commission (the Commission or MHCC) is required by law to maintain the Maryland Medical Care Data Base (MCDB). The MCDB is a large-scale database that contains healthcare data (claims and enrollment) submitted by private payers. MHCC also collects healthcare data from public payers (Maryland Medicaid program, and Medicare). MCDB data is at the patient level and contain protected health and personally identifiable information.

Under current statutes and regulations governing access to MCDB data, the Commission must approve an Application for MCDB data prior to release of MCDB data to the an applicant. The required prerequisites for release of MCDB data are:

1. Approval or exemption by an Institutional Review Board (IRB) recognized by the Commission;
2. The proposed use of MCDB data must be in the public interest;
3. Submission of a complete Application including a data management plan that provides adequate data security safeguards and protections to prevent inappropriate and unauthorized disclosures of MCDB data; and
4. Entry into a Data Use Agreement with the Commission that includes required terms and conditions set out in the Commission's regulations.

The Commission may charge an applicant reasonable fees that cover the costs of accessing and retrieving MCDB data.

B. The Applicant

The Applicant requesting MCDB data is the Chesapeake Regional Information System for Our Patients (CRISP) , 7160 Columbia Gateway Drive, Suite 100, Maryland 21046. The individuals who are named on the Application are:

1. Jessica Heslop, Program Manager (primary applicant and researcher)
2. Megan Priolo, Senior Director of Population Health - Maryland | CRISP (Contact Person)
3. George Chalissery, Chief Executive Officer (data custodian)
4. Richard Jones, Executive Director (data custodian)
5. Ricky Ip, Data Security Officer (data custodian)

II. APPLICATION AND PROPOSED PROJECT DETAILS

A. Project Purpose

The Application submitted by CRISP describes the purpose and significance of its proposed project as follows:

1. Compare Maryland Medicare and Commercial spending in Ambulatory Surgery by Maryland region and in comparison to national averages. The study addresses the following specific research questions:
 - Changes in the market for the ambulatory surgery settings frequency

- Changes in the market for the ambulatory surgery settings cost
 - Changes in the market for the ambulatory surgery settings outcomes-related quality of care
 - Connect the outcomes in the state to the Maryland regulatory environment
2. Investigate the impact of Maryland's efforts to improve care delivery and outcomes related to first episode psychosis (FEP) through implementing evidence-based treatment. The study addresses the following specific research questions:
- What percentage of individual with FEP receive coordinated specialty care (CSC)
 - How does use of CSC vary by geographic location; race and ethnicity; and other characteristics such as comorbidities with substance use disorder?
 - How frequently is telehealth used to access treatment for FEP?

Application , page 4. (The entire Application is attached to this Staff Report.)

B. Project Methodology:

The Application submitted by CRISP describes the methodology of its proposed project as follows:

Ambulatory Surgery

Project Methodology:

- Medicare fee-for-service (FFS), Medicaid, and commercial claims data will be used identify surgical procedures performed in hospital outpatient or ASC settings
- Assesses the differences in the patient populations by demographic characteristics, ZIP Code sociodemographic characteristics, primary payer, chronic comorbidities, surgery type, and surgery volume
- Capture a 90-day pre-surgery time-period to assess the medical, surgical, and testing visits that patients encounter prior to ambulatory surgery by location and type of surgery
- Assesses the 90-day experience following ambulatory surgery

(Application , page 4.)

First Episode Psychosis (FEP)

Project Methodology:

- Define the services that constitute coordinated specialty care (CSC)
- Select individuals with FEP and define an FEP episode of care beginning with an initial healthcare encounter with a diagnosis code for psychosis
- Classify episodes of care by receipt of coordinated specialty care (CSC)
- Analyze the outcomes in relation to receipt of CSC, which is compare the frequency of each outcome for beneficiaries/ enrollees with FEP who received CSC compared to those who did not.

(Application , page 4.)

C. Data Sources to be Used

The Application states that the proposed project will use the following four main data sources:

1. Maryland Medicaid Management Information System (MMIS2);
2. Maryland Medical Care Database (MCDB); and

3. Maryland Medicare

D. Funding Source

No external funding. The project will be funded internally.

E. Data Requested

The Applicant is requesting the following MCDB data for the years 2015 till 2020:

- (1) MCDB Eligibility (medical and pharmacy)
- (2) Professional Services Claims
- (3) Institutional Services Claims
- (4) Pharmacy Services Claims

(Application , page 7.)

G. Anticipated Distribution of the Report or Product

The Application states that the plan is to disseminate the project's findings through two independent white papers that will be published on the CRISPHealth.Org website. The draft white papers will be sent to MHCC prior to publication.

(Application , page 5.)

H. Fees

The total non-profit/academic fees for the requested MCDB data would be \$16,000 per year of data x 6 years of data = \$96,000. The Applicant stated the reason for requesting a fee waiver as follows:

We request a waiver of these fees due to the scope and funding of the study. The scope of these projects will be to enable CRISP to more deeply understand key questions related to TCOC and care transformation and thus improve capabilities available to support those efforts across the State. Additionally, these projects are funded through CRISP via state funds and in direct coordination with The Maryland Health Services Cost Review Commission (HSCRC). These studies are meant to enhance understanding of specific aspects of care delivery to guide the state, hospitals and other constituents in developing and refining interventions. Therefore, the findings of these reports will be part of CRISP's efforts to support a State Learning System to support stakeholders under the Maryland Total Cost of Care Model.

III. STAFF REVIEW AND ANALYSIS OF APPROVAL CRITERIA

A. Requirement that Project be for Research Use in the Public Interest

Staff has considered the applicant's proposed project details as described in the Application and concludes that it meets the regulatory requirement of research use because the projects compares Maryland Medicare and Commercial spending in Ambulatory Surgery by Maryland region an in

comparison to national averages and investigate the impact of Maryland's efforts to improve care delivery and outcomes related to first episode psychosis (FEP) through implementing evidence-based treatment.

Staff also concludes that the proposed project meets the regulatory requirement of being in the public interest as the project will enable the understanding of key questions related to TCOC and care transformation and thus improve capabilities available to support those efforts across the State.

B. Requirement of Institutional Review Board Review and Approval

The Applicant has submitted documentation of IRB exempt determination from Advarra. The exemption provides the justification as follows:

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(4), the IRB determined that your research project is exempt from IRB oversight.

C. Requirement of Implementation of Data Management Plan for Adequate Safeguards

The Applicant submitted three Data Management Plans along with its Application. These Data Management Plans were reviewed by Levene Ward Chief of Network Operation and Administrative Systems who determined that the Applicant's Plan provides for the implementation of safeguards adequate to prevent inappropriate disclosure of the requested MCDB data.

Staff concludes that the Applicant has satisfied the requirement for an adequate Data Management Plan that will safeguard against inappropriate disclosures of MCDB data.

D. Requirement that Applicant enter into a Data Use Agreement with the Commission

Staff concludes that the attached Data Use Agreement contains the minimum regulatory terms and conditions listed above and additional terms and conditions that are necessary to provide further essential data protections.

IV. SUMMARY AND STAFF RECOMMENDATION

Staff has evaluated the Application and proposed project and concludes that the statutory and regulatory requirements for access to the requested MCDB data are met, specifically, that:

1. The proposed project constitutes research that is in the public interest;
2. An exempt for IRB approval has been obtained on 19 May 2021;
3. The Applicant has submitted three Data Management Plans for the three contractors involved in the project including adequate safeguards for preventing the inappropriate disclosure of MCDB data;
4. The Applicant will enter a Data Use Agreement with the Commission.

Staff recommends that the Commission vote to approve the MCDB Data Request Application submitted by the Applicant, Chesapeake Regional Information System for Our Patients (CRISP) contingent upon the data use agreement, and provide access to the Applicant to the MCDB Eligibility (medical and pharmacy), Professional Services Claims, Institutional Services Claims, and Pharmacy Services Claims data files for the years 2015 till 2020 to be used solely for the Project, "*Maryland Model Analytics*" as described in the Application submitted to the Commission, dated June 10, 2021.