

Title 10 MARYLAND DEPARTMENT OF HEALTH
Subtitle 25 MARYLAND HEALTH CARE COMMISSION
Chapter 05 Data Release
Draft Regulation

COMMISSION MEETING
6/17/2021

Background

COMAR 10.25.05 Regulations

- .01 Scope and Purpose
- .02 Definitions
- .03 Types of Data Available for Release
- .04 Requests of Medicaid Data
- .05 Requests for Data from Governmental Entities
- .06 Requests for Data from Non-Governmental Entities
- .07 Transparency of Data Request and Data Release Process
- .08 Data Release Advisory Committee
- .09 Data Release Advisory Committee Review
- .10 Executive Director Review and Decision on Requests for Data
- .11 Review of Decision on Requests for Data
- .12 Fees
- .13 Data Use Agreement
- .14 Compliance and Enforcement

.01 Scope and Purpose

The purpose of this action is to repeal the existing COMAR 10.25.05 governing Small Group Market Data Collection in its entirety and replace it with a new COMAR 10.25.05 governing data release. Specifically...

1. Broadens the scope of permissible uses of Maryland Medical Care Data Base (MCDB) data through an expanded and updated data release process managed by the Commission.
2. Allows the Commission to offer standard, limited, and custom data sets that can be linked to other data sources securely via an encrypted patient identifier.
3. Expands potential data recipients to include non-research entities.
4. Aligns the review standards for release of Medicaid data with release standards for privately insured data.
5. Provides for the implementation of a new data fee structure.
6. Increases the transparency and efficiency of the overall application review and approval process.

.03 Types of Data Available for Release

Types of files for release conform with best practices in other states and CMS

- 1. De-identified standard analytic file:** A data extract containing only data elements that are not considered PHI because the extract excludes direct and indirect individual identifiers as defined in the HIPAA Privacy Rule.
- 2. Limited data set:** A data extract containing a limited set of indirect individual identifiers as defined in the HIPAA Privacy Rule and excludes direct individual identifiers.
- 3. Custom data file:** A data extract created based on criteria provided by an applicant and deemed the minimum amount necessary for an applicant's proposed use of the data.

.08/.09 Data Release Advisory Committee and Review

- A. The Commission establishes a Data Release Advisory Committee (DRAC) that meets the membership composition requirements and performs the review functions of a privacy board as described in 45 CFR§164.512.
 - The number of DRAC members determined by of the Commission.
 - DRAC membership includes representatives of academic research organizations, consumer advocacy organizations, employers, health care providers, health maintenance organizations, insurers, and nonprofit health service plans.
- B. DRAC determines whether an application meets the appropriate criteria for approval including among other factors:
 - Data requested is the minimum amount necessary to achieve the intended purpose.
 - The data management plan documents how the data will be stored and used securely.
- C. If an applicant proposes developing and selling a product that contains de-identified data, an applicant must provide a written justification on how the proposed sale of the de-identified data will serve the public.
- D. The DRAC prepares a written report and recommendation for the Executive Director on each application.

.04 Requests of Medicaid Data

- A. An application that includes a request for Medicaid data will be transferred to Medicaid for review after MHCC staff has determined the application to be complete.
- B. Medicaid notifies the MHCC staff of their decision on their review process:
 - allow MHCC to conduct the review or
 - conduct their own independent review.

.05 Requests for Data from Governmental Entities

- A. A governmental entity requesting data must submit a written data request in the format specified by the Commission.
- B. Request must document the purpose and use of the requested data including:
 - possible linkage with other data sources, and
 - a complete data management plan.
- C. Executive Director may make a final decision to approve or disapprove a governmental entity's data request or refer the data request to the DRAC for review and a recommendation.
- D. After receiving a recommendation from the DRAC, the Executive Director may:
 - Make a final decision or
 - Refer to a panel of three Commission members or the full Commission for a final decision on a governmental entity's data request.

.06 Requests for Data from Non-Governmental Entities

- A. A non-governmental entity must submit a written data request in the form specified by the Commission.
- B. The written request must document:
 - the purpose and use of the requested data;
 - possible linkage with other data sources; and
 - complete data management plan.
- C. A non-government entity must submit an application fee of \$200.
- D. The DRAC will review the complete application.
- E. A non-government entity is not eligible for approval by Executive Director without DRAC review.

.07 Transparency of Data Request and Data Release Process

- A. All completed applications are published on the Commission's website at the start of the review process, without those parts of the application that includes the data management plan.
- B. The public can submit written comments on the application for ten business days.

.10 Executive Director Review and Decision on Requests for Data

Remand of DRAC decision

- A. The Executive Director may refer an application back to the DRAC with a request that the DRAC:
- obtain more specific or additional information;
 - conduct a more detailed review and evaluation of the review criteria; and,
 - submit a revised written report and recommendation.

Rejection of DRAC decision

- B. If the Executive Director decides not to adopt the DRAC's recommendation, he prepares a proposed recommended decision and refers to Commission.
- C. The Commission affirms, reverses, or modifies the Executive's Director recommended decision.

Defer the decision to the Commission

- D. The Executive Director may refer the DRAC's written report and recommendation, and all public comment received on an application to a review panel of three (3) Commission members.
- Panel must include a consumer member of the Commission.
 - Panel may render a final written decision or refer the application to the full Commission for a decision.

.10 Executive Director Review and Decision on Requests for Data (continued)

- A. Limitation on the Executive Director's authority to Approve an Application**
 - Prohibited from approving an application that involves the sell of a product that contains requested de-identified data.
 - Must refer the application (involving sale of a product) and all materials to the full Commission for a decision.
- B. Notification of the Commission's Decision on a Data Request**
 - The Executive Director, the DRAC, or the full Commission, as applicable, must issue a written decision notifying an applicant that an application has been approved, approved with conditions, or disapproved.
 - The written decision must state the conditions imposed, if any, and, if an application is disapproved, state the reasons for disapproval.

.11 Review of Decision on Requests for Data

- 1. Request for Further Review of Executive Director/DRAC Decisions on Requests for Data.**
 - An applicant may submit a written request for Commission review of a written decision issued by the Executive Director or the DRAC within twenty (20) business days of the date the written decision is issued.
 - The Commission issues a written decision affirming, reversing, or modifying the decision Executive Director/DRAC's decision.
- 2. Request for Reconsideration of Commission Decisions on Requests for Data.**
 - If the full Commission, instead of the Executive Director or a review panel, issues a decision on an application, an applicant may submit, within twenty (20) business days of the date the Commission's written decision was issued, a written request for Commission reconsider its decision.
 - The Commission reviews an applicant's written request for reconsideration of its previous decision and issues a written decision affirming, reversing, or modifying its previous decision.

.12 Fees

- A. The Commission may charge fees to an applicant and data recipient to submit the application and the cost of accessing the data.
 - A list of fees is published on the Commission's website and
 - Reviewed and updated annually.
- B. An applicant may submit a written request for a full or partial fee waiver of the required fees:
 - Include detailed reasons for the fee waiver request
 - Document an applicant's inability to pay all or part of the required fees.
- C. The Executive Director may grant a fee waiver request if he determines a fee waiver is in the public interest.
- D. The Executive Director may consult with a panel of Commission members or the full Commission on the fee waiver.

.13 Data Use Agreement

- An approved applicant must enter data use agreement within thirty (30) days of the date of written notification of application approval and prior to receipt of requested data.
- An applicant must disclose any data sharing plan or agreement required by a funding source as a condition of an applicant's receipt of the funding.
- A data use agreement must cover all terms and conditions governing use, storage, destruction, and notifications to the Commission set out in this regulation.
- An approved applicant who requests additional data not requested in the recipient's approved application must submit a new application, pay required fees for receipt of additional data, and execute a revised data use agreement.
- A data recipient who wishes to re-use data released through an approved application and executed data use agreement must submit a written application, pay an application fee, and obtain approval prior to re-use of previously released data.
- The Executive Director may consider a request from a data recipient for an extension of time or a modification of a term or condition of an executed data use agreement.

.14 Compliance and Enforcement

- A. The Commission may take appropriate administrative and judicial enforcement actions, depending upon the facts, circumstances, and gravity of the acts of non-compliance if:
 - A data recipient does not comply with the terms and conditions of a data use agreement
 - Becomes known that a data recipient provided false information during the application process.
- B. Executive Director may refer an instance of unauthorized access, use, or disclosure of data to:
 - Office of the Attorney General of Maryland,
 - Maryland State's Attorney Office, or
 - An appropriate State or federal law enforcement authority.
- C. The Commission does not have the authority to impose fines for a data recipient's violation of data use agreement.
- D. Staff recommends that the Commission seek statutory authority to impose fines.