STATE OF MARYLAND

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MEMORANDUM

To: Commissioners

From: Mahlet Nigatu, Chief of APCD Public Reporting and Data Release

Date: June 11, 2021

Subject: Staff Recommendation to: (1) Repeal the Existing Regulations in COMAR 10.25.05, *Small Market Group Market Data Collection*; and (2) Adopt as Proposed Permanent Regulations a New Replacement Chapter, COMAR 10.25.05, *Data Release*

Introduction and Overview

Maryland Health Care Commission (Commission) staff is recommending that the Commission repeal all of the existing regulations in COMAR 10.25.05, entitled, "*Small Group Market Data Collection*."[1] The Commission is no longer administering these regulations by collecting enrollment and premium information from participating carriers in Maryland's small group insurance market since the enactment of the Affordable Care Act and the establishment of the Maryland Health Benefit Exchange, which now regulates that market in Maryland.

Staff is recommending that the Commission adopt as proposed permanent regulations the attached all-new chapter of regulations governing data release to be inserted as a new chapter, COMAR 10.25.05, entitled, "*Data Release."* (For the full text of the proposed new Data Release regulations, see Attachment A). These new data release regulations will replace and occupy what will become a vacant COMAR 10.25.05 upon repeal of the existing *Small Group Market Data Collection* regulations.[2] The Commission is statutorily mandated to adopt regulations governing

[1] For the full text of the existing regulations at COMAR 10.25.05, *Small Group Market Data Collection*, that staff is recommending be repealed, see Appendix Item 1.

[2] Please note that the subject matter of the proposed new data release regulations is unrelated to the now obsolete *Small Group Market Data Collection* regulations currently occupying COMAR 10.25.05.

the access and retrieval of data by Maryland Code Annotated, Health-General Article § 19-133(d)(1), which provides:

> The Commission shall adopt regulations governing the access and retrieval of all medical claims data and other information collected and stored in the medical care data base and any claims clearinghouse licensed by the Commission and may set reasonable fees covering the costs of accessing and retrieving the stored data.

Staff began the process with a comprehensive assessment of data release policies and protocols in other states with All Payer Claim Data Bases to determine best practices and discovered that MHCC's approach was inconsistent with the more efficient practices employed by other states. Staff paid special attention to approaches employed by the New England states because these states had the most mature APCDs. Next, staff worked in consultation with the Commission's Assistant Attorneys General to draft an all new chapter, COMAR 10.25.05, containing regulations governing data release. It was important to ensure that the regulations were formulated and implemented fairly and transparently; hence a Workgroup of stakeholders was established that included the following stakeholders and interested parties: State agencies (MHCC, HSCRC, MIA, MHBE, Office of the Attorney General's Health Education and Advocacy Unit, Medicaid, and MBHA); payor representatives (CareFirst and Kaiser); provider representatives (Primary Care Coalition, MedChi, and MHA); one business representative, consumer advocacy groups; researchers (University of Maryland Medical System), Maryland's State-designated HIE (CRISP); one MHCC Commissioner (Commissioner O'Grady); and one member with expertise in CMS data release protocol.

In November 2020, staff released the first draft of the new data release regulations to the Workgroup for informal comments. Three virtual meetings with the Workgroup were held on November 13, 2020, December 1, 2020, and February 2, 2021 to obtain their comments and feedback. After the first and second meetings, staff further revised the draft regulations in response to the comments and feedback received from the Workgroup and released a revised draft for discussion at the third Workgroup meeting. Each of the three Workgroup meetings had approximately 20 - 25 attendees and lasted about 1 ½ hours.

I. The Need for New Data Release Regulations

The impetus for drafting all new data release regulations was staff's recognition that the existing regulations in COMAR 10.25.11 entitled, "*Institutional Review Board*" currently governing data release[3], which became effective in 1999, are outdated, limit release of data to traditional research uses, and require Institutional Review board (IRB) review of all data requests received by the Commission (either by an IRB appointed and convened by the Commission or by an external IRB designated by the Commission). Also, the existing regulations require that the full Commission review and approve or disapprove by a vote all requests for data. In sum, the current regulations are not aligned with the current needs to facilitate uses of Commission data in the public's current interests, such as to develop new public policy, promote improvement in public health outcomes, and advance the transparency of the health care system.

[3] For the full text of the existing regulations at COMAR 10.25.11, *Institutional Review Board*, see Appendix Item 2.

Staff is not recommending that the existing regulations in COMAR 10.25.11, *Institutional Review Board*, governing data release be repealed at this time. Rather, staff recommends that existing COMAR 10.25.11 remain in effect for a period of time after the new COMAR 10.25.05 *Data Release* regulations become final, to allow time for start-up work to prepare to operationalize the new COMAR 10.25.05 regulations so that staff is able to apply the new data release regulations to new incoming requests for data. When the operationalization of COMAR 10.25.05 has been accomplished, staff plans to come back to the Commission with a recommendation to repeal the existing regulations at COMAR 10.25.11, *Institutional Review Board*.

II. Key Components of the Proposed New Data Release Regulations

The key components of the proposed new data release regulations are summarized below.

- **Scope of data**
  Allows the Commission to offer standard, limited, and custom data sets with the capabilities for linkage to other data sources safely and securely.

- **Data recipients**
  Broadens the range of potential data recipients to include individual researchers, non-governmental entities, and governmental entities.

- **Permissible data uses**
  Eliminates the requirement that data can only be released for traditional research uses.

- **Establishes a Data Release Advisory Committee (DRAC) to review data requests**
  - Eliminates the requirement that all data requests be reviewed by an Institutional Review Board (IRB) and authorizes the establishment of a Data Release Advisory Committee (DRAC) to review data requests and make written recommendations on approval or disapproval of data requests.

  - **Configuration and expertise of the DRAC**:
    - The DRAC will be comprised of individuals with relevant subject matter expertise including professional competency and subject matter expertise in the areas of consumer privacy and advocacy, data analytics, data privacy, data security, health policy research, individual privacy issues, information technology, public health, and the use and analysis of health care claims data.
    - The DRAC will include representatives of various stakeholder groups, including academic research organizations, consumer advocacy groups, employers, health care providers, health maintenance organizations, insurers, and non-profit health service plans, that possess the relevant experience, professional competency and subject matter expertise described above.
    - The Executive Director may remove a member of the DRAC for neglect of duty or misconduct by providing written notification to the DRAC member stating the reason for the removal.

- **Transparency of data request and data release process**
  - All completed applications except for data submitted by governmental entities pursuant to an express state or federal statutory or regulatory mandate shall be published on the Commission's website during the pendency of the review process.

  - Members of the public may submit written comment on an application for a period of ten (10) business days following the date on which an application is published on the Commission's website.

  - The Data Release Advisory Committee shall consider all public comments received on an application before making a recommendation to the Commission.

- **Sale of products that contain data**
  - If a data applicant proposes to develop and sell a product that contains de-identified data, the applicant has to meet its burden of providing satisfactory written justification of how the proposed sale of the de-identified data will serve in the public interest.

  - The Executive Director is prohibited from making a final decision on a request for data that proposes to develop and sell a product that contains requested de-identified data and shall refer the application, the DRAC's written report and recommendation, and all public comment received on the application to the full Commission for a decision.

- **Medicaid data requests and release**
  - Any application submitted to the Commission that includes a request for Medicaid data shall be transferred to Medicaid for review after Commission staff has reviewed the application and determined the application to be complete.

  - After Medicaid has reviewed an application, Medicaid shall notify Commission staff in a written response of its decision on each referred request to:
    1. Conduct an independent, parallel review.
    2. Decline to conduct an independent, parallel review and direct the Commission to release the requested Medicaid data if the request for non-Medicaid data is approved.
    3. Disapprove the request for Medicaid data.

- **Authority of Executive Director to make final decisions on data requests and refer to a panel of three Commissioners or to the full Commission under certain circumstances**
  - The Executive Director is authorized to make final decisions on data requests if the Executive Director reviews and considers the DRAC's written report and recommendation and all public comment; however, the Executive Director may

exercise the discretion not to make a final decision on an application and refer to a review panel of three (3) Commission members for a decision. The review panel may render a final written decision on the application or elect not to make a decision and refer the application to the full Commission for a decision.

- The Executive Director is not authorized to make a final decision on data requests and shall refer to the full Commission for a final decision in the following circumstances:
  - The Executive Director decides not to adopt the DRAC's recommendation.
  - The request for data proposes the development and sale of a product that contains requested de-identified data.

- **Fee Waivers: Authority of Executive Director to grant if in public interest**
  - After considering a written request and required supporting documentation submitted by an applicant in support of a request for a full or partial fee waiver, the Executive Director may determine if a full or partial waiver of fees is in the public interest and grant a full or partial fee waiver.

  - Before making a final decision on a request for a full or partial fee waiver the Executive Director may but is not required to consult with a review panel or the full Commission.

III. Summary and Analysis of Major Issues Raised by Informal Comments

A. Regulation .01: Scope and Purpose

Comment #1: The term "public interest" used in various places in the regulations is very broad and undefined in the Commission's statutes and should be defined in the regulations.

Staff Response: Examples of uses that are in the public interest are described in COMAR 10.25.05.01B as follows:

> *B. The Commission releases data pursuant to this chapter to facilitate uses of data that are **in the public interest**, such as to develop public policy, promote improvement in health care access, delivery, efficiency, quality, safety, public health outcomes, and contain costs and advance the transparency of the health care system.*
> (emphasis added).

In addition, legal research of other Maryland statutes and regulations governing other State agencies revealed that the term, "public interest," is not defined in statutes and regulations governing other State agencies. Research of Maryland case law supports not including a definition of public interest:

> The ultimate determination of what constitutes the public interest must be made considering the totality of the circumstances of any given case against the backdrop of current societal expectations.

BJ's Wholesale Club v. Rosen, 435 Md. 714, 743 (2013).

Comment #2: There was a concern that cost was not expressly mentioned in the Scope and Purpose.

Staff Response: Regulation .01B was revised to add cost containment as a purpose as follows:

> *B. The Commission releases data pursuant to this chapter to facilitate uses of data that are in the public interest, such as to develop public policy, promote improvement in health care access, delivery, efficiency, quality, safety, public health outcomes, and* ***contain costs a****nd advance the transparency of the health care system.*

(emphasis added)

Comment #3: Another comment expressed that MHCC should be concerned, "[t]hat anti-competitive consequences are foreseeable and should probably be evaluated by subject matter experts who may also advise about how to eliminate that potential."

The staff disagrees. To elaborate on the commenter's point: Some anti-trust experts have argued that when markets are highly concentrated, as is often the case in many health care markets, the posting of negotiated prices (allowed amounts) between health systems and payors could lead to higher rather than lower prices.[4] These experts contend that posting of contracted prices has the potential for facilitating collusion. The thinking goes that even where there is no collusion, posting of contracted prices could change providers' assumptions about how competitors will behave if they reduce prices for a payor. The opportunities for competitors to offer secret discounts to some of their customers tend to hold prices down. For example, if a hospital can offer a secret discount to payor A, it can gain extra patients without sacrificing revenue from payor B. If its competitors see the discount and match it, then the hospital would not have gained any patients.

This thinking is less relevant in Maryland because hospital prices are known by all competitors due to the Maryland hospital rating setting system. The requirement that all payors pay the same rate at a given hospital is a central tenet of the hospital rate setting system. All hospitals already know competitors' prices, but patients do not have access to detailed hospital charge masters unless information held in data systems, such as the MCDB, are made public.

Allowed amounts negotiated between physician groups and payors are not subject to state rate setting. Anti-trust experts concerns about data disclosure leading to higher prices are more relevant, but not persuasive given payors strong negotiating position. The market power of any

[4] Federal Trade Commission, "Competitive Effects of California Assembly Bill no. 1960," Doc. no. V040027 (Washington: FTC, 7 September 2004), 9.

practice group mitigates its ability to set prices, except when the practice does not participate in a payor's network. Physician groups, even those owned by large health systems, are unlikely to exert sufficient market power to dictate a contracted price. MHCC has found little variation in what a payor pays one practice versus another practice for the same service in a geographic area.

To be mindful of the commenter's concern about the need to protect the public against non-competitive behavior, MHCC is cautious about the release of contracted prices by payor. A data requester would have to demonstrate to the satisfaction of the Data Release Advisory Committee and to the Commissioners that a payor identifier is required in an MCDB data release.

Comment #4: "[P}atients do not choose to have their health information in these databases and privacy and security protections exist under federal and State law, and should be honored, in light of that fact. Where those protections may be ambiguous or not clearly adequate, we ask, on behalf of patients, that the regulations clearly state that the protection of patient privacy and security interests supersedes other interests served by nonconsensual patient data releases."

Staff response: The MHCC's enabling statute, MD Code, Health - General, § 19-133(d), provides that:

> *(d) (1) The Commission shall adopt regulations governing the access and retrieval of all medical claims data and other information collected and stored in the medical care data base and any claims clearinghouse licensed by the Commission and may set reasonable fees covering the costs of accessing and retrieving the stored data.*
>
> *(2) These regulations shall ensure that confidential or privileged patient information is kept confidential.*
>
> *(3) Records or information protected by the privilege between a health care practitioner and a patient, or otherwise required by law to be held confidential, shall be filed in a manner that does not disclose the identity of the person protected.*

This section presumes personally identified data are collected but access and retrieval of these data are constrained to ensure that confidential or privileged patient information is kept confidential. In developing the MCDB, MHCC limited data collection below what was permitted in Health -General, § 19-133(d). The MHCC enabling statute and data collection regulations at COMAR 10.25.06 define the broad scope of information collected in the MCDB, and the MCDB Data Submission Manual specifies the data elements payors must submit. The MCDB data collection is more limited than permitted in the enabling statute: MHCC does not collect any of the data elements defined under HIPAA as personally identifiable except for month and year of birth and ZIP code. Month and year of birth is converted to patient age, and ZIP code is converted to a three-digit ZIP code prior to any release unless an applicant can demonstrate a need for month

and year of birth and full ZIP code. Moreover, personally identifiable data elements flagged in HIPAA are not collected in the MCDB, such as:

- Street address – ***not collected, except for ZIP code***,
- Month,day, year of birth --- ***month and year only***,
- Telephone numbers – ***not collecte***d,
- Fax number – ***not collected***,
- Email address – ***not collected***,
- Social Security Number – ***not collected***,
- Medical record number – ***not collected***,
- Health plan beneficiary number – ***encrypted by submitter***,
- Account number – ***not collected***,
- Certificate or license number **– *not collected***,
- Vehicle identifiers and serial numbers, including license plate numbers – ***not collected,***
- Device identifiers and serial numbers – ***not collected***,
- Web URL – ***not collected***,
- Internet Protocol (IP) Address – ***not collected***,
- Finger or voice print – ***not collected***,
- Photographic image - Photographic images are not limited to images of the face – ***not collected,***
- Any other characteristic that could uniquely identify the individual such as genomic information– ***no other unique identifier collected,***

The MCDB and data collection regulations (COMAR 10.25.06) conform to the more restrictive requirements in the statute pertaining to "access and retrieval" of the data from the MCDB. It is not possible to release personally identifiable data elements, other than the encrypted patient identifier, patient age and ZIP code, because they are not collected from the payors.

B. Regulation .02: Definitions; and Regulation .06: Requests for Data from Non-Governmental Entities

Comment #5: Applicants should be required to disclose any data sharing requirements imposed by a funding source as a condition of receipt of funding so that fact can be taken into account in determining whether any required data sharing as a condition of receipt of funding is permissible under the Commission's data release regulations.

Staff Response: A definition of funding source was added at COMAR 10.25.05.02B(15) as follows:

(15) "Funding Source" means any federal or state governmental entity, public or private corporation or organization, educational or research institution or organization,

foundation, person, individual, or any other entity that has committed to give or grant, or has already given or granted, monetary funds to an applicant to cover all or part of the costs of the proposed use of the data described in an application submitted to the Commission.

Also, in response to this comment, staff added the requirement under Regulation .06A(2) and (3) that applicants disclose any data sharing requirements required by a funding source as a condition of a receipt of funding as follows:

A. Submission of Applications.
(1) An applicant shall complete and submit a written application in the form and manner specified by the Commission.
(2) If applicable, an applicant shall disclose on an application all potential or approved funding sources at the time of submission of an application.
(3) If applicable, an applicant shall disclose any data sharing or other requirements imposed by a funding source as a condition of receipt of funding.
(emphasis added).

C. Regulation .04: Requests for Medicaid Data

MHCC staff-initiated comments to Medicaid staff: MHCC staff initiated proposed language to Medicaid staff to streamline the process for referring to and obtaining Medicaid approval of data requests that contained a request for Medicaid data. Medicaid staff agreed to the proposed language streamlining and expediting Medicaid review.

Based on discussions and collaboration between MHCC and Medicaid staff, the current process for obtaining Medicaid approval of data requests submitted to MHCC that include a request for Medicaid data has been streamlined by authorizing MHCC staff to refer the data request for Medicaid data to the Data Release Advisory Committee for review within 15 days of referring a data request to Medicaid if Medicaid does not notify MHCC staff that Medicaid has disapproved the request for Medicaid data.

D. Regulation .07: Transparency of Data Request and Data Release Process

Comment #6: "It is not in the public's interest to allow an entity to claim a proprietary interest that is not subject to full transparency and accountability."

Staff Response: In response to this comment, staff revised Regulation .07D(4) to delete "subject to a proprietary interest" and add the new underlined language as follows:

> *(4) A summary description of a product derived in whole or part from data released to an applicant pursuant to this chapter, subject to any prohibition on public disclosure under applicable federal or State law, including the Maryland Public Information Act. ~~unless the product is not publicly available or subject to a proprietary interest.~~*

Comment #7: [r]eleased data [not] should be subject to a claim of proprietary interest or privilege. Applicants are not entitled to this data and an applicant who is unwilling to be fully transparent and accountable should not be approved to receive data. The public should have cost-free access to products.

Staff Response: Requiring that all products developed from the MCDB be available cost-free to the public would deter certain users from attempting to access the MCDB, even when the proposed application is in the public interest. Over the last decade, federal agencies and many state agencies have sought to make government data available to serve the public interest, inform consumers, or aid patients using care.[5] MHCC aims in making the MCDB align with those goals. Staff believes it unlikely that an innovator's program could have gained interest if the innovators had to make products available to the public at no cost. Making products available to the public at no cost would constrain development, especially by private organizations large and small that lack access to public funds. Requiring a data requestor to make any product available to the public at no cost would limit development of products to publicly funded organizations and powerful private sector companies. Staff believes it is appropriate that the public be informed of any reports and products developed through use of the MCDB data. Regulation 07.D(4) requires that product descriptions be posted on the MHCC website:

> *D. After a decision has been made on an application, the following information shall be published on the Commission's website:*
> *(1) The disposition of an application; that is, whether the application has been approved, approved with conditions, disapproved, or withdrawn;*
> *(2) For approved applications:*
> *(a) the amount of fees charged for requested data;*
> *(b) a statement that all fees were waived; or*
> *(c) in the case of a partial waiver of fees, the amount of fees waived;*
> *(3) If applicable, notice that further review of a decision on the application is pending under Regulation .11 of this chapter and a description of the final decision when the further review process is completed; and*
> ***(4) A summary description of a product derived in whole or part from data released to an applicant pursuant to this chapter, subject to any prohibition on***

[5] From 2011 through 2016, the Chief Information Officer at HHS sponsored a public meeting (DataPalooza) that focused on raising awareness and promoting use of government health data systems. In 2017, responsibility for convening the meeting was transferred to Academy Health, the national health services research organization dedicated to bringing together stakeholders to address the current and future needs of an evolving health system, inform health policy and practice, and translate evidence into action. One key program of this national meeting was the Data Innovators Program that highlighted small entrepreneurs innovative use of health data. Some of those applications involved use of sensitive information. For several years prior to 2014, the Maryland Department of Health offered a similar data innovators program aimed at small organizations.

> ***public disclosure under applicable federal or State law, including the Maryland Public Information Act.***

(emphasis added)

E. Regulation .08: Data Release Advisory Committee (DRAC)

Comment #8: The qualifications, experience and expertise required to serve as a Data Release Advisory Committee (DRAC) member should be specified in more detail; *e.g*., data privacy and security expertise should be required.

Staff Response: Staff revised Regulation .08C(2) in response to this comment to add more specificity regarding required DRAC expertise as follows:

> *(2) Provide relevant experience, professional competency, and subject matter expertise in the areas of consumer privacy and advocacy, data analytics,* ***data privacy, data security,*** *health policy research, individual privacy issues, information technology, public health, and the use and analysis of health care claims data.*

(emphasis added)

F. Regulation .09: Data Release Advisory Committee Review

Comment #9: re Regulation .09C(7) and (8): Allowing approval of data requests that propose to develop and sell a product containing data if determined to be in the public interest goes too far and should be expressly prohibited. Also, allowing for sale based on a "public interest" criteria is too broad and "public health" should replace "public interest."

The language of Regulation .09C (7) and (8) that is the subject of these comments provides:

> *(7) An applicant who proposes to develop and sell a product that contains de-identified data has provided satisfactory written justification of how the* ***proposed sale of the product using the de-identified data will serve the public interest****.*
>
> (*8) The proposed use of the data is in the public interest. Examples of uses of data that serve the public interest include:*
>
> *(a) Health care cost and utilization analysis to guide and develop public policy;*
> *(b) Studies that* ***promote improvement in public health****, health care quality, and health care access;*
> *(c) Health planning and resource allocation studies;*
> *(d) Making information on cost and quality accessible to the public; and*
> *(e) Studies directly tied to evaluation and improvement of federal and State government initiatives.*

(emphasis added)

Staff response: The staff wishes to clarify that the MCDB, like other All Payer Claims Databases (APCD), has been designed to meet a range of health information needs. Applications from APCDs have expanded as more than twenty states have or are now implementing APCDs and Maryland has learned from the states' shared experiences. APCDs are used for health system evaluation, payment model development, price transparency initiatives, cost effective studies, and health disparity research. Use of APCDs for what is narrowly defined as public health purposes would eliminate numerous classes of legitimate users. The federal government recognized the broad applicability of APCDs by incorporating grant funding for state APCD development in the No Surprises Act signed by President Trump on December 27, 2020 (No Surprises Act is part of the Consolidated Appropriations Act of 2021 (H.R. 133; Division BB – Private Health Insurance and Public Health Provisions)).[6]

In response to this comment, staff did revise the language of .09C(7) to specify that it is not the data that is being sold, but only products that contain de-identified data. Staff recommends not changing the "public interest" review criteria to "public health" because "public health" is too narrow and not consistent with the Commission's statutory mandate in Health-General Article § 19-909 (a)(7) to "[p]ublish and give out any information that relates to the financial aspects of health care and is considered desirable **in the public interest**." (emphasis added). In addition, staff notes that the phrase, "public health," does not appear anywhere in the Commission's governing statutes; however, the promotion of "public health outcomes" is named in the specific context of approving or disapproving a request for data as one example of a use of data that would be in the public interest (see Regulation .01B, section A *supra*) and Regulation .09C(8)(b) (quoted above in this section).

G. Regulation .10: Executive Director Review and Decision on Requests for Data

Comment #10: The Executive Director of the Commission should not have the authority to make a final decision approving an application that the Data Release Advisory Committee has e disapproved and vice versa. There should be Commission oversight if the Executive Director is making a final decision on a data request application that differs from the DRAC's recommendation.

Staff response: In response to this comment, staff added the following language as Regulation .10D requiring the Executive Director to refer data requests to the full Commission for a final decision as follows:

[6] See a summary of the No Surprises Act at: https://www.healthaffairs.org/do/10.1377/hblog20201217.247010/full/. The Act established grant funding for the establishment or further development of an APCD in Section 115.

D. If the Executive Director decides not to adopt the DRAC's recommendation, specifically to approve an application that the DRAC has recommended be disapproved, or disapprove an application that the DRAC has recommended be approved, then the Executive Director shall prepare a proposed recommended decision and refer to the full Commission for consideration and issuance of a final decision affirming, reversing, or modifying the Executive's Director recommended decision.

H. Regulation .14: Compliance and Enforcement

Comment #11: If the Commission learns after release of data to an approved data recipient and after entry into an executed data use agreement with the Commission, that the data recipient providing false information or documents during the application process, the data recipient should be subject to the compliance and enforcement actions specified in Regulation .14.

Staff Response: In response to this comment, staff added language in Regulation .14A as follows:

A. If a data recipient fails to comply with any of the terms and conditions of a data use agreement, ***or it becomes known after execution of a data use agreement that a data recipient provided false information during the application process****, the Commission, acting through the Executive Director, may take one or more of the following administrative and judicial enforcement actions, depending upon the facts, circumstances, and gravity of the acts of non-compliance:*
(emphasis added)

Comment #12: Meaningful monetary penalties or fines should be added in Regulation .14 as a compliance and enforcement option for noncompliance with a data use agreement or unauthorized use or release of data.

Staff Response: Staff agrees, but monetary penalties or fines cannot be added in the regulations without statutory authority. The Commission currently does not have statutory authority to impose monetary penalties or fines in the context of data release so an amendment to the Commission's statutes would be needed to give the Commission authority to impose monetary penalties or fines for data release noncompliance and violations. Staff recommends that MHCC pursue legislation in a future legislative session that provides authority to imposing monetary penalties for violation of a data use agreement.

Staff Recommendation

Staff recommends that the Commission repeal the existing regulations in COMAR 10.25.05, *Small Group Market Data Collection*, and adopt all new regulations, COMAR 10.25.05, *Data Release*, as proposed permanent regulations.

ATTACHMENT:
Attachment A: Proposed Permanent Regulations COMAR 10.25.05- *Data Release*

APPENDIX:
Appendix Item 1: COMAR 10.25.05 - *Small Group Market Data Collection*
Appendix Item 2: COMAR 10.25.11 - *Institutional Review Board*