MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet

PROPOSED
OR REPROPOSED
Actions on Regulations

Date Filed with AELR
Committee

06/09/2021

Date Filed with AELR
Committee

Date Filed with Division of
State Documents

Document Number

Date of Publication in MD
Register

- 1. Desired date of publication in Maryland Register: 7/16/2021
- 2. COMAR Codification

Title Subtitle Chapter Regulation

10 25 06 01-.18

3. Name of Promulgating Authority

Maryland Health Care Commission

4. Name of Regulations CoordinatorJulie Deppe

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5. Name of Person to Call About this Document Sarah Pendley Telephone No. 410-764-3284

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- 6. Check applicable items:
- X- New Regulations
- X- Amendments to Existing Regulations Date when existing text was downloaded from COMAR online: April 1, 2021.
- X- Repeal of Existing Regulations
- _ Recodification

_ Inco	rporation by	Reference of Documen	ts Requiring DSD Approval			
_ Repi	oposal of S	Substantively Different Te	ext:			
:		Md. R				
(vol.)	(issue)	(page nos)	(date)			
Under Maryland Register docket no.:P.						
7. Is there emergency text which is identical to this proposal: _ Yes X- No						

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

X- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

X- OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Sarah Pendley, Assistant Attorney General, (telephone #410-764-3284) on May 20, 2021. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Andrew N. Pollak, MD

TitleTelephone No.Chair410-764-3460

Date

May 20, 2021

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

10.25.06 Maryland Medical Care Data Base and Data Collection

Authority: Health-General Article, §§19-101, 19-103(c)(3), (4), (7), and (8), 19-109(a)(1), (6), and (7), 19-133, 19-134, and [19-138] 19-137, Annotated Code of Maryland

Notice of Proposed Action

П

The Maryland Health Care Commission proposes to amend Regulations .01—.04, repeal and replace Regulations .05 and .06, and amend Regulations .07—.18 under COMAR 10.25.06 Maryland Medical Care Data Base and Data Collection.

This action was considered by the Commission at an open meeting held on May 20, 2021, a notice of which was given through publication in the Maryland Register, in accordance with General Provisions Article §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to amend the existing regulations governing the submission of healthcare data (claims, encounters, and eligibility) by reporting entities to the Maryland Health Care Commission (MHCC). The amended regulations will allow the Commission to increase data collection frequency from quarterly to more frequently than quarterly; expand the Non-Fee-For-Service data collection to include all services, not only medical; and update definitions of terms used throughout the regulations. This increase in the frequency of data reporting will allow MHCC to meet the demands from stakeholders such as the Maryland Department of Health, the Health Services Cost Review Commission, the Maryland Insurance Administration, the Maryland Health Benefit Exchange, the Maryland Prescription Drug Affordability Board, the Maryland Legislature, the Governor's Office, and the public to provide healthcare data requests faster and to respond quickly to global health challenges such as the COVID-19 pandemic in Maryland.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The proposed action has an economic impact. These regulations change the reporting requirements for reporting entities that submit healthcare encounters and claims data files to the Maryland Health Care Commission (MHCC). COMAR 10.25.06 applies to payors and third-party administrators whose total covered lives exceed 1,000 insured members, and to payors that participate in the Maryland Health Benefit Exchange (MHBE), regardless of the number of covered lives. Activities resulting from changes to the regulations will be completed within the MHCC budget, MHCC Special Funds, by existing MHCC staff, and through an MHCC contract with a future MHCC data contactor to be selected from the new Medical Care Data Base (MCDB) recompete RFP.

	Revenue (R+/R-)	
II. Types of Economic Impact.	Expenditure (E+/E-)	Magnitude
A. On issuing agency:		
Maryland Health Care Commission (MHCC)	(E+)	Within Budget
B. On other State agencies:	NONE	No Impact
C. On local governments:	NONE	No Impact
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		_
Reporting Entities - Payors (34)	(-)	Moderate
E. On other industries or trade groups:		
(1) Employers	(+)	Moderate
(2) Healthcare Practitioners	NONE	No Impact
F. Direct and indirect effects on public:	(+)	Moderate

- III. Assumptions. (Identified by Impact Letter and Number from Section II.)
- A. MHCC will not require additional State funds to execute the expended data collection in this regulation. MHCC has budgeted for the anticipated changes to these regulations in the new MCDB recompete RFP.
- B. The proposed regulations have no impact because the data collection activities of MHCC are not duplicative of any other State data collection effort.
- C. The proposed regulations have no impact on local governments because local governments do not have any requirements relating to the regulation.
- D. MHCC estimates that COMAR 10.25.06 will affect 34 reporting entities. All 34 reporting entities are already submitting data to the MCDB. There will be an increase in the ongoing extraction of all reports. MHCC expects the economic impact due to the rise to be moderate per reporting entity.
- E(1). Employers: Faster availability of healthcare costs for treatment will enable fully insured employers to swiftly identify variations in costs among providers and compare fully insured payments among private payors. Such information can be helpful to assist fully insured employers in identifying cost-effective care, which can lead to lower healthcare premiums. Employers with self-insured ERISA health plans are excluded from the MCDB due to the Gobeille ruling by the Supreme Court of the United States on March 1, 2016.
- E(2). Healthcare Practitioners: No Impact
- F. The increased frequency of information will allow MHCC to present information more quickly on the cost and quality of almost all healthcare services reimbursed by private payors and to respond more quickly to global health challenges such as the

COVID-19 pandemic. This quicker availability of healthcare data from the MCDB allows MHCC to provide accelerated data support to the Health Services Cost Review Commission in monitoring the Maryland Total Cost of Care Model. This healthcare data and resulting analytics also support the Maryland Insurance Administration's premium rate review process.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Janet Ennis, Chief, Special Projects, Maryland Health Care Commission, 4160 Patterson Avenue, or call 410-764-3779, or email to janet.ennis@maryland.gov, or fax to (410) 358-1236. Comments will be accepted through August 16, 2021. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Maryland Health Care Commission during a public meeting to be held on September 16, 2021, at 1:00 p.m., at 4160 Patterson Avenue, Baltimore, MD 21215.

Economic Impact Statement Part C

- A. Fiscal Year in which regulations will become effective: FY 2022
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Ves

C. If 'yes', state whether general, special (exact name), or federal funds will be used: Maryland Health Care Commission Special Funds

- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly:
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The regulations have no economic impact on small businesses as they are not reporting entities of healthcare data to the MCDB.

Attached Document:

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 06 Maryland Medical Care Data Base and Data Collection

Authority: Health-General Article, §§19-101, 19-103(c)(3), (4), (7), and (8), 19-109(a)(1), (6), and (7), 19-133, 19-134, and [19-138] 19-137, Annotated Code of Maryland

.01 Scope and Purpose.

These regulations establish appropriate methods for collecting and compiling Statewide data on selected health care services provided either under a Maryland contract or to Maryland residents by health care practitioners and facilities:

- A. (text unchanged)
- B. From third party administrators; [and]
- C. From managed behavioral health care organizations;
- D. From pharmacy benefit managers; and
- [C.] E. Regarding providers for whom the Maryland Health Care Commission otherwise receives data.

.02 Definitions.

- A. (text unchanged)
- B. Terms Defined.
 - (1) (text unchanged)
- (2) "Behavioral health care services" means procedures or services rendered by a health care practitioner for the treatment of mental health [services or alcohol and] or substance [abuse services.] use disorders.
 - (3)–(6) (text unchanged)
- (7) "Fee-for-service encounter" means a [medical] *health* care visit in which a health care practitioner or office facility provided a health care service for which a claim was submitted to a reporting entity for payment, and payment was made on a per service basis.
 - (8) "General health benefit plan" means:
- (a) A hospital or [medical] *health care* policy, contract, or certificate issued by a [carrier;] *payor as defined in* §(20)(a) and (b) of this regulation;
 - (b)—(e) (text unchanged)
- (9) "Health Benefit Exchange" or "Exchange" means the Maryland Health Benefit Exchange established as a public corporation under §31-102 of this title and includes the Individual Exchange and the Small Business Health Operations Program (SHOP) Exchange.
- (10) "Health care service" means a health or medical care procedure or service rendered by a health care practitioner that:
 - (a)—(b) (text unchanged)
- [(10) "Health Benefit Exchange" or "Exchange" means the Maryland Health Benefit Exchange established as a public corporation under §31-102 of this title and includes the Individual Exchange and the Small Business Health Options Program (SHOP) Exchange.]
 - (11) (text unchanged)
- (12) "HIPAA" means the U.S. Health Insurance Portability and Accountability Act of 1996, P.L.104-191, as implemented and amended in federal regulations, including the HIPAA Privacy and Security rules, 45 CFR §§160 and 164, as may be amended, modified, or renumbered and including as amended by *the* Health Information Technology for Economic and Clinical Health (HITECH) Act.
- (13) ["Institutional Review Board" has the meaning stated in the federal regulations on the protection of human subjects.] "Managed behavioral health care organization" means a company, organization, private review agent, or subsidiary that:
- (a) Contracts with a payor as defined in §(20)(a) and (b) of this regulation to provide, undertake to arrange, or administer behavioral health care services to members; or
- (b) Otherwise makes behavioral health care services available to members through contracts with health care providers.

- [(14) "MCDB Submission Manual" or "Manual" means the composition of data reporting requirements with guidelines of technical specifications, layouts, and definitions necessary for filing the reports required by this chapter.] [(15)] (14)—[16] (15) (text unchanged)
- [(17)] (16) "Medical Care Data Base" or ["MDCB"] "MCDB" means the [Maryland Medical Care Data Base.] data base established and maintained by the Commission pursuant to Health-General Article, §19-133, Annotated Code of Maryland, that collects eligibility data, professional services claims, institutional services claims, pharmacy claims, and provider data for Maryland residents enrolled in private insurance, Medicaid, or Medicare. The MCDB is Maryland's All Payer Claims Data Base.
- (17) "MCDB Submission Manual" or "Manual" means the composition of data reporting requirements with guidelines of technical specifications, layouts, and definitions necessary for filing the reports required by this chapter.
 - (18) ["Office facility" means a freestanding facility providing:
 - (a) Ambulatory surgery;
 - (b) Radiologic or diagnostic imagery; or
 - (c) Laboratory services.
- (19)] "Non-Fee-for-Service [Medical] Expenses Report" means a report with information on lump sum payments made by [carriers] *a reporting entity* to providers as part of the [carriers'] *reporting entity's* compensation to the providers for [non-claim-based] *non-claims-based* services.
 - (19) "Office facility" means a freestanding facility providing:
 - (a) Ambulatory surgery;
 - (b) Radiologic or diagnostic imagery; or
 - (c) Laboratory services.
 - (20) "Payor" means:
 - (a)—(b) (text unchanged)
 - (c) For Medical Care Data Base [purposes, a] purposes:
- (i) A third party administrator registered under Insurance Article, Title 8, Subtitle 3, Annotated Code of [Maryland.] Maryland;
 - (ii) A managed behavioral health care organization as defined in §(13) of this regulation; or
 - (iii) A pharmacy benefit manager.
 - (21)–(22) (text unchanged)
- (23) "Pharmacy Benefit Manager" means a person who performs pharmacy benefit management services and is registered as a pharmacy benefit manager under Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland. [(23)] (24)–[27] (28) (text unchanged)
- [(28) "Reporting entity" means a payor or a third party administrator that is designated by the Commission to provide reports consistent with this chapter to be collected and compiled into the Medical Care Data Base.
- (29) "State-designated health information exchange" or "State-designated HIE" means an HIE designated by the Maryland Health Care Commission and the Health Services Cost Review Commission pursuant to the statutory authority set forth in Health-General Article, §19-143, Annotated Code of Maryland.
- (30) "Supplier" means a person or entity, including a health care practitioner, which supplies medical goods or services.
- (31) "Third party administrator" means a person that is registered as an administrator under Insurance Article, Title 8, Subtitle 3, Annotated Code of Maryland.
- (32) "Qualified dental plan" means a dental plan certified by the Maryland Health Benefit Exchange that provides limited scope dental benefits, as described in §1311(c) of the Affordable Care Act and Insurance Article, §31-115, Annotated Code of Maryland.
- (33) "Qualified health plan" means a general health benefit plan that has been certified by the Maryland Health Benefit Exchange to meet the criteria for certification described in §1311(c) of the Affordable Care Act and Insurance Article, §31-115, Annotated Code of Maryland.
- (34) "Qualified vision plan" means a vision plan certified by the Maryland Health Benefit Exchange that provides limited scope vision benefits, as described in the Insurance Article, §31-108(b)(3), Annotated Code of Maryland.]
- (29) "Qualified dental plan" means a dental plan certified by the Maryland Health Benefit Exchange that provides limited scope dental benefits, as described in §1311(c) of the Affordable Care Act and Insurance Article, §31-115, Annotated Code of Maryland.
- (30) "Qualified health plan" means a general health benefit plan that has been certified by the Maryland Health Benefit Exchange to meet the criteria for certification described in §1311(c) of the Affordable Care Act and Insurance Article, §31-115, Annotated Code of Maryland.
- (31) "Qualified vision plan" means a vision plan certified by the Maryland Health Benefit Exchange that provides limited scope vision benefits, as described in the Insurance Article, §31-108(b)(3), Annotated Code of Maryland.
- (32) "Reporting entity" means a payor, third party administrator, managed behavioral health care organization, or pharmacy benefit manager that is designated by the Commission to provide reports consistent with this chapter to be collected and compiled into the Medical Care Data Base.

- (33) "State-designated health information exchange" or "State-designated HIE" means an HIE designated by the Maryland Health Care Commission and the Health Services Cost Review Commission pursuant to the statutory authority set forth in Health-General Article, §19-143, Annotated Code of Maryland.
- (34) "Supplier" means a person or entity, including a health care practitioner, which supplies medical goods or services.
- (35) "Third party administrator" means a person that is registered as an administrator under Insurance Article, Title 8, Subtitle 3, Annotated Code of Maryland.

.03 Persons Designated to Provide Data to the Commission.

- A. [Payors] *Reporting Entities*. By December 31 of each year, the Commission shall make available a list of each payor, *third party administrator*, *pharmacy benefit manager*, *and managed behavioral health care organization* meeting the criteria for designation as a reporting entity and who shall file the reports under this chapter in the following year.
- (1) The Commission shall designate as a reporting entity each payor *and third party administrator* whose total lives covered exceeds 1,000, as reported to the Maryland Insurance Administration.
- (2) The Commission shall designate as a reporting entity each payor offering a qualified health plan, qualified dental plan, or qualified vision plan certified by the Maryland Health Benefit Exchange, *under* Insurance Article, §31-115, Annotated Code of Maryland.
 - (3) (text unchanged)
 - (4) The Commission may conduct surveys as needed to fulfill the purposes of the [MCBD] MCDB.
- (a) The Commission may conduct a survey of any [payor] *reporting entity* to determine if the [payor] *reporting entity* is required to report data or for other purposes consistent with this chapter.
- (b) If necessary, the Commission may institute an annual survey to obtain information needed to determine and designate *a* third party [administrators] *administrator* whose annual covered lives report filed with the Maryland Insurance Administration does not delineate the number of covered lives for the following:
 - (i)—(ii) (text unchanged)
 - (c) A [payor] reporting entity shall timely report information sought by the Commission in a survey.
 - B. Data Otherwise Collected by the Commission from [Payors] Reporting Entities or Providers.
- (1) A [payor's] *reporting entity's* reports are considered submitted to the Commission if [they] *the reports* are contained within the submission of another [payor.] *reporting entity*.
- (2) For [the purpose] *purposes* of supplementing the MCDB, the Commission may include information that the Commission has otherwise received regarding providers and services.
 - C. (text unchanged)

.04 Process for Submitting Data.

- A. The Commission shall provide each reporting entity with an annual update to the MCDB [Data] Submission Manual, and each current [submission] *Manual* update available, as specified in Regulation .15 of this chapter.
 - B. Each reporting entity shall provide each of the following reports, if applicable:
 - (1)–(6) (text unchanged)
 - (7) Dental Services Data Report; and
 - (8) Non-Fee-for-Service [Medical] Expenses Report.
 - C. (text unchanged)

.05 Time Period for Submitting Data Reports.

- A. Unless a different reporting time period is specified in the MCDB Submission Manual pursuant to §B of this regulation, each reporting entity shall submit to the Commission a complete set of the entity's data for claims paid during each quarter of a calendar year in the form and manner described in Regulations .07—.14 of this chapter within two months of the last day in the applicable quarter.
- B. Each reporting entity shall submit at least quarterly to the Commission a complete set of the reporting entity's data for claims paid during the specific time period in the form and manner described in Regulations .07—.14 of this chapter and within the time period specified in the MCDB Submission Manual, unless a more frequent submission schedule is instituted by the Commission pursuant to §C of this regulation.
- C. Before instituting a requirement that a reporting entity submit data for claims paid more frequently than quarterly, as required in §§A and B of this regulation, the Commission shall:
- (1) Establish a multi-stakeholder group consisting of representatives of reporting entities, involved State agencies, and other stakeholders, as appropriate, to discuss the benefits and costs of expanding data collection; and
 - (2) Include a transition period for reporting entities to adjust to the new data submission schedule and process.

.06 Protection of Confidential Information in Submissions.

- A. To assure that confidential records or information are protected, each reporting entity shall encrypt each of the following data elements in such a manner that each unique value for a data element produces an identical unique encrypted data element:
 - (1) Patient or enrollee identifier; and

- (2) Internal subscriber contract number.
- B. In order to maintain a consistent and unique identifier for each patient across providers, payors, and services, the Commission shall:
- (1) Provide selected data to the State-designed HIE for the creation and encryption of a Master Patient Index; and
- (2) Include Master Patient Index identifiers received from the State-designated HIE in each eligibility data report submitted under Regulation .11 of this chapter.
 - C. Each reporting entity shall maintain the security and preserve the confidentiality of the encrypted data.

.07 Professional Services Data Report Submission.

A. Each reporting entity shall submit a professional services data report that provides the data for each fee-for-service and capitated encounter, *including fee-for-service equivalents prices for capitated services*, provided by a health care practitioner or office facility. This report shall include all health care services provided:

(1)—(2) (text unchanged)

B. Each professional services data report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.08 Pharmacy Data Report Submission.

A. (text unchanged)

B. Each pharmacy data report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.09 Provider Directory Report Submission.

A. Each reporting entity shall submit a provider directory report detailing each health care practitioner or supplier that provided services to any enrollee of that reporting entity during the reporting period. This report shall contain information for each in-State Maryland practitioner or supplier, and for each out-of-State practitioner or supplier[,] that has served a Maryland resident or a non-Maryland resident under a Maryland contract.

B. (text unchanged)

C. Each provider directory report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.10 Institutional Services Data Report Submission.

A. (text unchanged)

B. Each institutional services data report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.11 Eligibility Data Report Submission.

A. Each reporting entity shall submit an eligibility data report that provides information on the characteristics of each enrollee that is a Maryland resident insured under a fully insured contract or a self-insured contract, and *each enrollee* that is a non-Maryland resident insured under a Maryland contract, for services covered under each policy or contract issued by the reporting entity that are subject to this chapter.

B. Each eligibility data report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.12 Plan Benefit Design Report.

Each plan benefit design report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.13 Dental Services Data Report.

Each dental *services* data report shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.14 Non-Fee-for-Service [Medical] Expenses Report.

Each [Non-Fee-for-Service Medical Expenses Report] *non-fee-for-service expenses report* shall contain the information specified by the Commission in its annual update to the MCDB [Data] Submission Manual and be filed in a form and manner specified in the Manual.

.15 Report Submission Methods.

A. When a reporting entity collects more granular information than required [by] *under* this chapter, [it] *the reporting entity* shall provide a conversion table that describes how internal values are mapped to each required category.

- B. The MCDB [Data] Submission Manual shall contain technical specifications, [encryption algorithms,] layouts, required reports, and definitions for each reporting entity.
 - (1) (text unchanged)

- (2) The Commission may correct incomplete or erroneous information in the MCDB Submission Manual[,] as [necessary] *necessary*, and provide notice of each correction on the Commission website and by email to the contact persons designated by [payors.] *the reporting entities*.
- (3) The Commission shall timely post the annual MCDB [Data] Submission Manual on the Commission website and provide notice in the Maryland Register.
- C. The Commission may require that each reporting entity electronically submit sufficient demographic information on each enrollee to create a Master Patient Index.
- (1) The Commission may require that the reporting entity provide this information to the State-designated [health information exchange] *HIE* solely for this purpose.
 - (2) (text unchanged)

.16 Request for an Extension of Time.

- A. (text unchanged)
- B. For a [30 day] 30-day extension request to be considered by Commission staff, the reporting entity shall submit a written request to the Executive Director at least 30 days before the [quarterly] required submission date that includes:
 - (1) (text unchanged)
- (2) A proposed date, which is no more than 30 days after the initial [quarterly] *required* submission date, when the reporting entity will provide the [quarterly] *required* data to the Commission.

.17 Request for an Annual Waiver or Format Modification.

- A. Annual Waiver Request. When a reporting entity is not able to submit a data report as set forth in this chapter, [it] *the reporting entity* shall file with the Commission by March 15 of the year for which a waiver is sought, a written request for an annual waiver that shall include:
 - (1) (text unchanged)
 - (2) Any Supporting Documentation Required.
 - (a)—(c) (text unchanged)
- (d) A behavioral health care services organization shall include an affidavit from an officer of the organization stating that its total lives covered does not exceed 1,000, as reported to the Maryland Insurance Administration.
- (e) A pharmacy benefit manager shall include an affidavit from an officer of the organization stating that its total lives covered does not exceed 1,000.
- B. Format Modification Request. When a reporting entity is not able to provide all the information required in Regulations .07—.14 of this chapter, [it] *the reporting entity* shall file with the Commission a written request for a format modification *at least* 30 days before the applicable submission date that shall include:
 - (1)—(2) (text unchanged)
- (3) A detailed description of the reporting entity's proposed layout or submission method, or [both] both, when applicable.
 - C. (text unchanged)
- D. Appeal of the Executive Director's Decision. The aggrieved party may file a written request for Commission review of the Executive Director's written decision [within14] within 14 days of the decision.
 - (1)—(3) (text unchanged)

.18 Failure to File Data Reports.

- A. A reporting entity that does not timely file a data report *in compliance with* the MCDB Submission Manual may be subject to monetary penalties as provided in COMAR 10.25.12.
- B. In accordance with COMAR 10.25.12.01C, a data report that is substantially incomplete or inaccurate is not timely filed within the meaning of §A of this regulation and may be subject to monetary penalties as provided in COMAR 10.25.12.

.19 Summaries and Compilations.

The Commission shall develop public-use data, summaries, and compilations for public disclosure, pursuant to Health-General Article, §§19-103(c)(3), 19-109(a)(6), and 19-134, Annotated Code of Maryland, in compliance with all applicable federal and State laws and regulations.