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COMAR 10.47.07.02, 04, 05
Proposed Actions on Regulations
January 17, 2020
Maryland Department of Health
FULL TEXT OF REGULATION(S)

Prescription Drug Monitoring Program

The purpose of this action is to enable the Maryland Prescription Drug Monitoring Program (PDMP) to implement recent expansion of the requirements and authorities of the PDMP to support the safe and effective use of controlled dangerous substance prescription in Maryland.

COMAR 10.47.07.02

COMAR 10.47.07.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) *“Authorized user” means a licensed prescriber, a prescriber delegate, a licensed pharmacist, a pharmacist delegate, or a licensed health care practitioner registered with another state’s prescription drug monitoring program.*

[(1)] (2)—[(3)] (4) (text unchanged)

(5) *“Existing bona fide individual investigation” means an active and good faith investigation of an identified prescriber, dispenser, or patient for possible violations falling under the jurisdiction of the requesting governmental unit or agency.*

(6) *“Existing bona fide investigation” means an active and good faith investigation of identified prescribers, dispensers, or patients for possible violations falling under the jurisdiction of the requesting governmental unit or agency.*

[(4)] (7)—[(5)] (8) (text unchanged)

(9) *“Medical director” means an individual who is:*

(a) *A prescriber; and*

(b) *Employed by or under contract with a health care facility and serves as that facility’s chief medical officer or in an equivalent role.*

[(6)] (10) (text unchanged)

(11) *“Office” means the Office of Controlled Substances Administration in the Department.*

[(7)] (12)—[(19)] (24) (text unchanged)

COMAR 10.47.07.04

COMAR 10.47.07.04 Review of Prescription Monitoring Data.

A. The Program [may] *shall* review prescription monitoring data for indications of possible [misuse or abuse of a monitored prescription drug.]:

(1) *Misuse or abuse of a monitored prescription drug; and*

(2) *Violations of law or possible breaches of professional standards by a prescriber or a dispenser.*

B. In determining whether its review indicates a possible violation of law or possible breach of professional standards by a prescriber or dispenser, the Program shall take into account to the extent practicable the particular specialty, circumstances, patient type, and location of the prescriber or dispenser.

COMAR 10.47.07.05

COMAR 10.47.07.05 Disclosure of Prescription Monitoring Data.

A. (text unchanged)

B. Disclosure of Prescription Monitoring Data to a Prescriber, a Prescriber Delegate, a Pharmacist, or a Pharmacist Delegate.

(1)—(4) (text unchanged)

(5) If the Program's review of prescription monitoring data under Regulation .04 of this chapter indicates possible misuse or abuse of a monitored prescription drug, *possible violation of law, or possible breach of professional standards by a prescriber or dispenser*, the Program [may report] *shall*:

(a) *Report* the possible misuse or abuse, *possible violation of law, or possible breach of professional standards* to the prescriber or dispenser of the monitored prescription drug in a manner and form determined by the Program[.]; *and*

(b) *Provide education to the prescriber or dispenser.*

C. (text unchanged)

D. Disclosure of Prescription Monitoring Data to a Licensing Entity.

(1) The Program shall disclose prescription monitoring data to[:

(a) A] *a licensing entity [other than the State Board of Physicians] upon receipt of an administrative subpoena [voted on by a quorum of the board; or*

(b) *The State Board of Physicians upon receipt of an administrative subpoena voted on by a quorum of a disciplinary panel, as defined in Health-General Article, §14-101, Annotated Code of Maryland].*

(2) The [Program shall disclose prescription monitoring data that] *licensing entity shall include in the administrative subpoena:*

[(3)] (a) [Includes information] *Information* sufficient to identify the unique prescriber or dispenser about whom prescription monitoring data is requested;

[(4)] (b) [Specifies the] *The* time frame for which (b) prescription monitoring data is requested, including the day, month, and year the report is to begin and end;

[(5)] (c) [Includes a] *A* case number or other identifier sufficient to identify an existing bona fide individual investigation;

and

[(6) Includes an attestation that the subpoena was approved by a quorum of the board of the licensing entity; and]

[(7)] (d) [Bears the] *The* name, title, and original signature of the official under whose authority the subpoena is issued.

E.—F. (text unchanged)

G. Disclosure of Prescription Monitoring Data to the Office of the Attorney General. The Program shall disclose prescription monitoring data to the Office of the Attorney General, for the purpose of furthering an existing bona fide investigation, on receipt of a subpoena that:

(1) Includes information sufficient to identify the prescribers, dispensers, or patients about whom prescription monitoring data is requested;

(2) Specifies the time frame for which prescription monitoring data is requested, including the day, month, and year the report is to begin and end;

(3) Includes an agency case number or other identifier sufficient to identify an existing bona fide investigation; and

(4) Bears the name, title, and signature of the official under whose authority the subpoena is issued.

[G.] *H. Disclosure of Prescription Monitoring Data to an Authorized User of Another State's Prescription Drug Monitoring Program or of any Other Authorized Agency.*

(1) Upon request, the Program [may] *shall* disclose prescription monitoring data to *an authorized user of another state's prescription drug monitoring program or an authorized user with any other authorized local, state, territorial, or federal agency in connection with the provision of medical care*, provided that the request:

(a) Is submitted [on a form or] in a manner approved by the Department;

(b) Is under the authority of the authorized administrator of that state's program *or authorized agency*; [and]

(c) Includes an attestation that prescription monitoring data will only be used or redisclosed in a manner consistent with the provisions of Health-General Article, §21-2A-06, Annotated Code of Maryland, and Regulation .08D of this chapter[.]; *and*

(d) Relates to a patient to whom the authorized user anticipates providing, is providing, or has provided medical care.

(2) The Program may develop and implement interoperability with another state's prescription drug monitoring program *or authorized agency* to facilitate the automated exchange of prescription monitoring data provided that a written agreement has been established with the other state's program *or authorized agency* specifying that the information technology employed will:

(a) Only disclose prescription monitoring data to [registered] *authorized* users [of the other state's program] in a manner consistent with the provisions of Health-General Article, §21-2A-06, Annotated Code of Maryland, and this regulation; and

(b) (text unchanged)

[H.] *I. Disclosure of Prescription Monitoring Data to Units of the Department. Upon request, the Program may disclose prescription monitoring data to [the Office of the Chief Medical Examiner,] the Maryland Medical Assistance Program, the Office of the Inspector General of the Department, the Office of Health Care Quality, and the [Division of Drug Control] Office, provided that the request:*

(1)—(4) (text unchanged)

J. Disclosure of Prescription Monitoring Data to a Medical Director of a Health Care Facility. The Program may disclose prescription monitoring data to the medical director of a health care facility, as defined in Health-General Article, §19-114, Annotated Code of Maryland, or the medical director's designee for the purpose of providing health care practitioners employed or contractually employed at the health care facility access to the prescription monitoring data in connection with the provision of medical care or the dispensing of a monitored prescription drug to an individual who receives health care at the health care facility and on whom a medical record is maintained at the health care facility, provided that the health care facility:

- (1) Is licensed by the Department of Health or is operated by the federal government or a federally recognized Indian tribe;*
- (2) Has an active participation agreement with the State's Health Information Exchange;*
- (3) Operates in accordance with all other State and federal laws and regulations governing the security and confidentiality of protected health information and personal medical records; and*
- (4) Can provide an audit trail of the facility's staff access to the prescription monitoring data to the Department upon request.*

K. Disclosure of Prescription Monitoring Data to the Office of the Chief Medical Examiner.

- (1) Upon request from the Office of Chief Medical Examiner, the Program shall disclose decedent-specific prescription monitoring data, provided that the request is made solely for the purpose of carrying out duties authorized under Health-General Article, §5-309, Annotated Code of Maryland.*
- (2) The Program shall determine the electronic means by which the Office of the Chief Medical Examiner may request disclosure of or otherwise access decedent-specific prescription monitoring data.*

[I.] *L.* (text unchanged)

[J.] *M.* Disclosure of Prescription Monitoring Data for Research, Analysis, Education, and Public Reporting.

- (1) (text unchanged)
- (2) The Secretary may waive the requirement of [§J(1)(b)] §M(1)(b) of this regulation for requests from units of the Department.

[K.] *N.* Technical Advisory Committee Review.

(1) Before the Program discloses prescription monitoring data under [§§C—E, G, and H] §§C—E, H, and I of this regulation, the Technical Advisory Committee [shall] *may*:

(a)—(b) (text unchanged)

(2) Notwithstanding [§K(1)] §N(1) of this regulation, the Program may disclose prescription monitoring data to the authorized administrator of another state's prescription drug monitoring program *or authorized agency* for disclosure to [a prescriber, a prescriber delegate, a pharmacist, a pharmacist delegate, a licensed health care practitioner authorized by a prescriber or a dispenser, or a patient] *an authorized user* in a manner consistent with [§§B(1)—(4) and F] §H of this regulation.

(3) Before the Program discloses prescription monitoring data to a prescriber or dispenser under §B(5) of this regulation, the Technical Advisory Committee [shall]:

[(a) Review any prescription monitoring data upon which the Program's report to a prescriber or dispenser is based; and

(b) Within 10 business days of submission of the data to the Technical Advisory Committee for review, submit to the Program:

(i) Clinical guidance regarding indications of possible misuse or abuse; and

(ii) Interpretation of the prescription monitoring data that indicates possible misuse or abuse.]

(a) For indications of possible misuse or abuse, may provide clinical guidance and interpretation of the prescription monitoring data that indicates possible misuse or abuse; and

(b) For indications of possible violations of law or breach of professional standards, shall provide clinical guidance regarding the method used and advise whether the method identifies possible violations of law or breach of professional standards.

(4) If the Technical Advisory Committee has not provided clinical guidance and interpretation in accordance with [§K(1) or (3)] §N(1) or (3) of this regulation within 10 business days of submission of the request or data to the Technical Advisory Committee for review, the [Department] Program may[:

(a) Proceed] *proceed* as if the Technical Advisory Committee does not have clinical guidance or interpretation to provide regarding the request, [or] data, *or method* at issue[; and].

[(b) Respond to the original request for disclosure under §§C—E, G, and H of this regulation, or report potential misuse or abuse of a monitored prescription drug to a prescriber or dispenser under §B(5) of this regulation.]

(5) Before making a referral to the Office in accordance with Regulation .05O of this chapter, the Program shall provide to the Technical Advisory Committee notice and an opportunity to make recommendations within 10 business days on the referral.

(6) If the Technical Advisory Committee has not provided recommendations within 10 business days under §N(5) of this regulation, the Program may proceed as if the Technical Advisory Committee does not have clinical guidance or interpretation to provide.

[(5)] (7)—[(6)] (8) (text unchanged)

O. Disclosure of Prescription Monitoring Data to the Office. The Program may disclose prescription monitoring data and make a referral to the Office about a possible violation of law or possible breach of professional standards by a prescriber or dispenser as identified under Regulation .04 of this chapter, if the Program:

(1) Determines the:

(a) Outreach and education provided was inadequate to address the possible breach or violation; or

(b) Outreach and education would be inadequate to address the possible violations of law or a possible breach of professional standards;

(2) Provides notice and an opportunity to the Technical Advisory Committee to make recommendations within 10 business days regarding interpretation of the prescription monitoring data;

(3) Provides the recommendations, if any, of the Technical Advisory Committee to the Office; and

(4) Notifies the prescriber or the dispenser that the prescription monitoring data will be provided to the Office for further investigation.

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