#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

# BUREAU OF EPIDEMIOLOGY AND POPULATION HEALTH DIVISION OF ENVIRONMENTAL HEALTH

## REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION OR ILLICIT DRUGS

### Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the department of health and human services by section 8 of the critical health problems reporting act, 1978 PA 312, MCL 325.78, sections 2221, 2226, 2233, and 5111 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, 333.2233, and 333.5111, and Executive Reorganization Order No. 2015-1, MCL 400.227)

R 325.76, R 325.77, R 325.78, and R 325.79 are added to the Michigan Administrative Code as follows:

#### R 325.76 Definitions.

Rule 6. As used in these rules:

- (a) "Department" means the department of health and human services.
- (b) "Drug" means any of the following as provided in section 17703 of the public health code, 1978 PA 368, MCL 333.17703:
- (i) A substance recognized or for which the standards or specifications are prescribed in the official compendium.
- (ii) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
- (iii) A substance, other than food, intended to affect the structure or a function of the body of human beings or other animals.
- (iv) A substance intended for use as a component of a substance specified in subdivision (i), (ii), or (iii), but not including a device or its components, parts, or accessories.
- (c) "Health facility" means any facility or agency licensed under article 17 of the public health code, 1978 PA 368, MCL 333.20101 to 333.22260, that provides health care services. "Health facility" includes a hospital, clinical laboratory, surgical outpatient facility, health maintenance organization, nursing home, home for the aged, rural health county medical care facility, and ambulance operation. "Health facility" does not include any facility or agency that is prohibited by law under 42 CFR part 2 from releasing records on substance abuse disorders.

- (d) "Health professional" means a person licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, in medicine, osteopathic medicine, as a physician's assistant, or nurse practitioner.
- (e) "Illicit drugs" means any Schedule 1 drug, new and emerging psychoactive substances, or Schedule 2-5 drugs that are not obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice.
- (f) "Local health department" means a public health department established under the provisions of part 24 of the public health code, 1978 PA 368, MCL 333.2401 to 333.2498, to protect the public health and prevent disease within a specific geographic area.
- (g) "Poison" means a substance which, when ingested, inhaled or absorbed, injected into, or developed within the body, causes damage to structure or disturbance of function in the body.
- (h) "Poisoning" means any morbid condition, including death, that is related to, characterized by, affected by, induced by, or a product of a poison as defined in subrule (g)."
- (i) "Public health investigation" means the collection of medical, epidemiologic, exposure, and other information to determine the magnitude and cause of illness or injury, which is used to determine appropriate actions to prevent or mitigate additional illness or injury.
- (j) "Substance use disorder services" means substance use disorder prevention, treatment, and rehabilitation services established under the provisions of article 6 of the public health code, 1978 PA 368, MCL 333.6230 to 333.6251, to reduce the consequences of substance use disorders in individuals and communities.
- R 325.77 Reporting requirement; timeframe; reports provided without request; electronic reporting.
- Rule 7. (1) Health professionals and health facilities shall provide reports when requested by the department or local health department for routine public health surveillance and/or investigation of specific events. The department or local health department shall notify health professionals and health facilities when reports of prescription or illicit drug poisonings shall be submitted. Both of the following apply:
- (a) Reports shall be made within 5 working days following request by the department or local health department.
- (b) Reports shall be provided to the department or local health department that makes the request.
- (2) Reports may be provided by health professionals and health facilities, without departmental or local health department request, when the reporting entity believes that public health investigation is needed to protect the public.
- (3) Nothing in this rule shall be construed to relieve a health professional or health facility from reporting to any other entity as required by state, federal, or local statutes or regulations or in accordance with accepted standard of practice, except that reporting in compliance with this rule satisfies the reporting requirements of the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

- (4) The department shall develop procedures and systems to enable electronic laboratory and case reporting by health care providers and facilities to reduce reporting burden and ensure efficiency and security of information sharing.
- R 325.78 Patient information; diagnostic and clinical information to be reported.
- Rule 8. (1) Reportable information is information specifically related to patients with known or suspected poisonings due to use of prescription or illicit drugs, including fatal and nonfatal overdoses.
- (2) International Classification of Disease Codes (ICD) for medicinal and illicit drug poisonings and toxicological laboratory evidence shall be considered evidence of poisoning.
- (3) The health professional or health facility shall submit its report in a format that ensures the inclusion of the information listed under subdivisions (a) to (e) of this subrule as applicable.
  - (a) All of the following information with respect to the patient shall be provided:
  - (i) Last and first name and middle initial.
  - (ii) Sex.
  - (iii) Race, if available.
  - (iv) Ethnic group, if available.
  - (v) Birth date or age.
  - (vi) Residential address.
  - (vii) Telephone number.
  - (viii) If the individual is a minor, the name of a parent or guardian.
- (b) If the reporting entity is a health care provider or health facility other than a clinical laboratory, the following diagnostic information shall be provided, in addition to information specified in subdivision (a) of this subrule.
  - (i) The date of diagnosis.
  - (ii) The diagnosis, including ICD diagnostic code, if available.
- (iii) Brief narrative of the poisoning event, including date, location, and type of medicine or drug involved, and any other information considered by the health professional or health facility to be related to health of the public.
- (iv) Brief narrative of the patient's signs and symptoms, clinical findings, results of diagnostic tests, and clinical outcome.
- (c) If the reporting entity is a clinical laboratory, the following information shall be provided in addition to information specified in subdivision (a) of this subrule.
  - (i) Unique specimen ID or accession number, or both.
  - (ii) Name of the clinical test performed.
  - (iii) Test result, including units of measurement and LOINC and SNOMED codes.
  - (iv) Laboratory reference range including units of measurement.
  - (v) Date the laboratory test was ordered.
- (d) Name, address, telephone, and other contact information shall be provided for the reporting health professional. If the reporting entity is a health facility, contact information for the diagnosing, treating, and/or ordering physician shall be provided.
- (e) Name, address, telephone and other contact information for the health facility shall be provided if the reporting entity is the facility.

- R 325.79 Investigation and collaboration; storage of information; confidentiality.
- Rule 9. (1) The department or local public health department, upon receiving a report under subrule (2) of this rule, may investigate to determine the accuracy of the report, a patient's source of drug, and adverse health effects resulting from the poisoning due to drugs.
- (2) The department and local public health departments shall collaborate in the development of procedures for processing reports of poisonings and conducting follow-up investigations to ensure efficient, non-duplicative, and effective public health response.
- (3) Requests by the department or local public health departments for individual medical and epidemiologic information to validate the completeness and accuracy of reporting are specifically authorized.
- (4) Information from reported cases shall be kept in a secure manner when not in use. Information stored electronically shall be maintained in a secure manner, accessible only by department or local health department program staff through password protected user accounts.
- (5) Except as provided in subrule (6) of this rule, the department and local health departments shall maintain the confidentiality of all reports and other information received under these rules and shall not release reports or information that may be used to directly link the information to a particular individual.
- (6) The department and local health departments may release reports or information, otherwise protected under subrule (5) of this rule, under any of the following conditions:
- (a) If the department has received written consent from the individual, or from the individual's parent or legal guardian, requesting the release of information.
- (b) As necessary for the department to carry out its duties under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.
- (c) If necessary for the purpose of public health activities designed to prevent poisonings due to use of prescription or illicit drugs.
- (d) If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board.
- (e) If the director of the department determines that release of information is crucial to protect the public health against an imminent threat or danger.
- (7) Nothing in this rule shall be construed to relieve or preempt any other entities from investigating hazards associated with drug poisonings under state, federal, or local statutes or regulations.
- (8) Reports submitted to the department or local health department under Rule 7 are not public records and are exempt from disclosure pursuant to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.
- (9) Reports and information submitted to the legislature by the department as necessary to carry out its duties shall not contain any identifiable information. Aggregate information concerning public health that is released to the public shall not contain information that allows individuals to be identified.