

STATE OF MICHIGAN JOCELYN BENSON, SECRETARY OF STATE DEPARTMENT OF STATE LANSING

May 1, 2024

NOTICE OF FILING

ADMINISTRATIVE RULES

To: Secretary of the Senate

Clerk of the House of Representatives Joint Committee on Administrative Rules Michigan Office of Administrative Hearings and Rules (Administrative Rule #22-024-HS) Legislative Service Bureau (Secretary of State Filing #24-05-01) Department of Health and Human Services

In accordance with the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6, this is to advise you that the Michigan Office of Administrative Hearings and Rules filed Administrative Rule #2022-024-HS (Secretary of State Filing #24-05-01) on this date at 11:01 A.M. for the Department of Health and Human Services entitled, "Chronic Disease Reporting".

These rules become effective immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(9) 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.

Sincerely,

Jocelyn Benson Secretary of State

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Lashana Threlkeld, Departmental Supervisor Office of the Great Seal

Enclosure

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GRETCHEN WHITMER GOVERNOR

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STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES SUZANNE SONNEBORN EXECUTIVE DIRECTOR

MARLON I. BROWN, DPA DIRECTOR

May 1, 2024

The Honorable Jocelyn Benson Secretary of State Office of the Great Seal Richard H. Austin Building – 1st Floor 430 W. Allegan Lansing, MI 48909

Dear Secretary Benson:

Re: Administrative Rules – Michigan Office of Administrative Hearings and Rules Administrative Rules #: 2022-24 HS

The Michigan Office of Administrative Hearings and Rules received administrative rules, dated March 27, 2023 for the Department of Health and Human Services "Chronic Disease **Reporting**". We are transmitting these rules to you pursuant to the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6.

Sincerely,

Michigan Office of Administrative Hearings and Rules



STATE OF MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES LANSING

ELIZABETH HERTEL DIRECTOR

CERTIFICATE OF ADOPTION

By authority conferred on the Director of the Department of Health and Human Services by sections 2221, 2226, 2233, and 5111 of the Public Health Code, 1978 PA 368, MCL 333.2221, 333.2226, 333.2233, 333.5111, and section 8 of the critical health problems reporting act, 1978 PA 312, MCL 325.78, the Director formally adopts the rules, "Mandatory Reporting of Chronic Diseases".

R 330.131, R 330.132, R 330.133, R 330.134, R 330.135, and R 330.136 are added to the Michigan Administrative Code.

Date: February ______, 2024

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GRETCHEN WHITMER GOVERNOR STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES SUZANNE SONNEBORN EXECUTIVE DIRECTOR

MARLON I. BROWN, DPA ACTING DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated March 27, 2023, in which the Department of Health and Human Services proposes to modify a portion of the Michigan Administrative Code entitled "Mandatory Reporting of Chronic Diseases" by:

• Adding R 330.131, R 330.132, R 330.133, R 330.134, R 330.135, and R 330.136.

The Legislative Service Bureau has approved the proposed rules as to form, classification, and arrangement.

I approve the rules as to legality pursuant to the Administrative Procedures Act, MCL 24.201 <u>et seq.</u> and Executive Order No. 2019-6. In certifying the rules as to legality, I have determined that they are within the scope of the authority of the agency, do not violate constitutional rights, and are in conformity with the requirements of the Administrative Procedures Act.

Dated: February 9, 2024

Michigan Office of Administrative Hearings and Rules

By:

Emily Leik

Emily Leik, Attorney



Legal Division

Kevin H. Studebaker, Director

CERTIFICATE OF APPROVAL

On behalf of the Legislative Service Bureau, and as required by section 45 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.245, I have examined the proposed rules of the Department of Health and Human Services dated March 27, 2023, adding R 330.131, R 330.132, R 330.133, R 330.134, R 330.135, and R 330.136 of the Department's rules entitled "Mandatory Reporting of Chronic Diseases." I approve the rules as to form, classification, and arrangement.

Dated: February 8, 2024

LEGISLATIVE SERVICE BUREAU

By

Rachel M. Hughart, Legal Counsel

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUREAU OF EPIDEMIOLOGY

DIVISION OF LIFECOURSE EPIDEMIOLOGY AND GENOMICS

MANDATORY REPORTING OF CHRONIC DISEASES

Filed with the secretary of state on May 1, 2024

These rules become effective immediately after filing with the secretary of state unless adopted under section 33, 44, or 45a(9) 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 director of the department of health and human services by sections 2221, 2226, 2233, and 5111 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, 333.2233, 333.5111, and section 8 of the critical health problems reporting act, 1978 PA 312, MCL 325.78)

R 330.131, R 330.132, R 330.133, R 330.134, R 330.135, and R 330.136 are added to the Michigan Administrative Code, as follows:

R 330.131 Definitions.

Rule 131. (1) As used in these rules:

(a) "Chronic disease registry" means the database maintained by the department that contains patient-level health information about individuals with a diagnosed chronic disease, including, but not limited to, diagnostic and demographic information.

(b) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(c) "Department" means the department of health and human services.

(d) "Director" means the director of the department.

(e) "Health information" means information about an individual, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental health or condition of an individual, and the provision of health care to an individual. Health information includes aggregate information if, in the opinion of the department, it could potentially lead to reidentification of an individual.

(f) "Health professional" means an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, to work as a physician, a physician's assistant, or a nurse practitioner.

(g) "Local health department" means a health department established under the provisions of part 24 of the code, MCL 333.2401 to 333.2498.

(h) "Public health investigation" means the collection of medical, epidemiologic, exposure, and other information to determine the cause of illness or disability, which is used to determine appropriate actions to prevent or mitigate additional illness or disability.

(i) "Report" means documents or data containing health information provided to the department consistent with this ruleset.

(2) A term defined in the code has the same meaning when used in these rules.

R 330.132 Reportable information.

Rule 132. (1) Health professionals and health facilities must provide reports to the department in a format that ensures the inclusion of all patient information, if available and applicable, as follows:

(a) Last and first name and middle initial.

(b) Sex.

(c) Race.

(d) Ethnicity.

(e) Birth date or age.

(f) Current residential address.

(g) Telephone number.

(h) If the individual is a minor, the name of the individual's parent or guardian.

(i) Social security number.

(j) The date of symptom onset, if applicable.

(k) The date of diagnosis.

(l) The diagnosis, including diagnostic code.

(m) Prescribed medications, if they are available to the health professional or health facility, and the health professional or health facility is able to report them in the format prescribed by the department.

(n) Brief narrative of the patient's signs and symptoms, clinical findings, results of other diagnostic tests, and clinical outcome, if available to the health professional or health facility.

(2) The reporting health professional shall provide the name, address, telephone, and other contact information, including, but not limited to, email communication, for the ordering physician or physicians as directed by the department.

(3) The reporting health facility shall provide the facility's name, address, telephone, and other contact information, including, but not limited to, email communication, as directed by the department.

(4) Submitted reports must meet data quality, format, and timeliness standards prescribed by the department.

R 330.133 Reporting responsibilities.

Rule 133. (1) Health professionals and health facilities capable of reporting to the department via an electronic health record must do so on a real-time, ongoing basis.

(2) Health professionals and health facilities that do not submit reports consistent with subrule (1) of this rule shall provide reports to the department as follows:

(a) Reports must be made within 3 months following a request by the department or local health department.

(b) The department shall notify health professionals and health facilities when reports of a chronic disease must be submitted.

(3) Nothing in this rule should 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 section 5111 of the code, MCL 333.5111.

R 330.134 Chronic disease registry advisory board.

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Rule 134. (1) The department shall create a chronic disease registry advisory board that convenes at the time and place instructed by the director and considers proposals and requests for the addition or removal of new reportable chronic diseases.

(2) The chronic disease registry advisory board shall consist of not less than 12 members appointed by the director as follows:

(a) One individual representing the Michigan Health and Hospital Association.

(b) Two individuals representing the department's public health administration.

(c) One individual representing a chronic disease organization.

(d) One individual representing a local health department.

(e) One individual representing the Michigan State Medical Society.

(f) One individual representing emergency medical services.

(g) One individual representing the chronic disease academic community.

(h) One individual representing a minority-serving community-based organization.

(i) One individual representing a tribal health agency.

(j) One individual representing a health system or hospital in this state.

(k) One individual representing the general public.

(3) In addition to those representatives named in subrule (2), the director may appoint additional representatives to the board.

(4) As directed by the department, members of the board shall maintain and adhere to the chronic disease registry advisory board's bylaws, including member term limits, member nominations, subcommittee formation, and other policies and procedures relevant to the board's ongoing operations.

(5) The board shall examine the public health need for the collection of this information and may request assistance from the department to inform their recommendation regarding the addition or removal of a chronic disease as needed. This information may include requesting supplementary information from the individual or party proposing the chronic disease, convening subject-matter experts or individuals with knowledge of the particular condition, or assembling ad-hoc subcommittees.

(6) The board shall release its recommendations, including whether a chronic disease should be made reportable, to the director of the department. The board may review or modify their recommendation at any time prior to the director's review. The director shall then approve, modify, or reject the recommendations of the board.

R 330.135 Investigation and quality assurance.

Rule 135. (1) The department, upon receiving a report under R 330.133, may request more information from the reporting entity. The reporting entity must provide the information to the department no later than 30 days after the request is made.

(2) The department shall consult with local health departments in the development of procedures for processing chronic disease reports and conducting follow-up investigations to ensure efficient, non-duplicative, and effective public health response.

(3) Requests by the department or local health departments for individual medical and epidemiologic information to validate the completeness and accuracy of reporting are specifically authorized. Persons or organizations that receive such requests must provide the information sought to the requesting organization promptly and no later than 30 days after the request is made.

(4) Health information from reported chronic disease cases shall be stored in a reasonably secure manner by the department.

R 330.136 Confidentiality of reports.

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Rule 136. (1) To the maximum extent permitted by law, reports and health information collected under these rules are not public records and are exempt from disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(2) Reports and health information collected under this rule are medical records for the purpose of section 13(1)(1) of the freedom of information act, 1976 PA 442, MCL 15.243.

(3) Except as provided in subrule (5) of this rule, health information that is gathered in connection with an investigation is confidential and is not open to public inspection. All persons in possession of reports and health information collected under these rules shall maintain the confidentiality of reports and health information and shall not reveal the identity of any person.

(4) Records released to a legislative body must not contain information that identifies or could reasonably be expected to identify a specific individual.

(5) Information collected under these rules must be used for epidemiologic investigation and evaluation. The department and local health departments may release reports or information under any of the following conditions:

(a) The department receives written consent from the individual or consent from a minor's parent or legal guardian after requesting the release of information.

(b) As necessary for the department to carry out its duties designated by the code.

(c) If necessary for the purpose of research designed to contribute to generalizable knowledge, with documented approval by the department's institutional review board.

FILED WITH SECRETARY OF STATE

ON 5/1/24 AT 11:01 A.M