

DEPARTMENT OF COMMUNITY HEALTH
COMMUNITY PUBLIC HEALTH AGENCY
MICHIGAN CARE IMPROVEMENT REGISTRY

(By authority conferred on the department of community health by section 9227 of 1978 PA 368, and Executive Reorganization Order No. 1996-1, being MCL 333.9227 and 330.3101)

R 325.161 Definitions.

Rule 1. As used in these rules:

- (a) "Act" means 1978 PA 368, MCL 333.1001.
- (b) "Department" means the Michigan department of community health or its authorized agent.
- (c) "MCIR" means the Michigan care improvement registry which is a registry of health information, including but not limited to; children's immunizations, immunization history, and identification information on children, adolescents, and adults.
- (d) "User" means any of the following entities:
 - (i) A health care provider as defined in section 9206(5) of the act.
 - (ii) Michigan schools.
 - (iii) Michigan day-care providers.
 - (iv) Healthcare organizations.
 - (v) Department personnel.
 - (vi) A person or organization otherwise authorized by the department.

History: 1997 AACCS; 2009 AACCS.

R 325.162 Users; access authorization; revocation of access privilege.

Rule 2. The department shall maintain a registry of all users. An eligible user may apply to the department to be authorized for MCIR access. The department may grant access and issue an authorization code only upon receipt and acceptance of a written agreement between the user and the department that stipulates the terms and conditions of obtaining information, including the data elements that may be obtained and how the user will maintain the confidentiality of the information. The department may revoke a user's access privileges for just cause.

History: 1997 AACCS.

R 325.163 Reportable information.

Rule 3. (1) A person who administers an immunization, as defined in section 5101(e) of the act for a disease identified in R 325.176 after the effective date of these rules to a child who was born after December 31, 1993, shall report the immunization to the department in a manner consistent with the rules and the procedures issued by the department, under either of the following circumstances, unless the immunization need not be reported under section 9206(2) and (3):

- (a) The individual was born after December 31, 1993.
 - (b) The individual is less than 20 years of age.
- (2) A person who administers an immunization may report any immunization administered to an individual under either of the following circumstances.
- (a) The individual was born before January 1, 1994.
 - (b) The immunization was not included in the list of vaccines in R 325.176.
- (3) Only a health care provider who is authorized to administer an immunizing agent under section 9204 of the act shall report an immunization.
- (4) A health care provider shall submit all of the information required by the department.

(5) A health care provider who receives written notification from a person requesting that his or her (or his or her child's) immunization data not be reported to the registry shall forward the request to the department in a manner prescribed by the department. The department shall not add any immunization information to that individual's or child's record after receipt of the request. This subrule does not apply to drugs, medications, chemicals, vaccines, or biological products being used in response to a public health emergency.

(6) A health care provider who is required to report an immunization shall submit the report within 72 hours of administering an immunization. The report shall be on a form prescribed or approved by the department, except for a report that is submitted by electronic transmission or on electronic media.

(7) A health care provider who submits an immunization report by electronic transmission or on electronic media shall ensure that the report meets the data quality, format, security, and timeliness standards prescribed by the department.

(8) In the event of a public health emergency, and at the discretion of the director of the department in consultation with the chief medical executive, health care providers and other persons as defined by the director shall report to the department information regarding administration or dispensing of certain drugs, medications, chemicals, vaccines, or biological products used in response to the public health emergency. The department shall add functionality to the MCIR so that such information can be reported using the MCIR.

History: 1997 AACS; 2009 AACS.

R 325.164 Quality assurance.

Rule 4. (1) For the purpose of assuring the quality of submitted data, a provider shall allow the department to inspect the parts of a patient's medical records as necessary to verify the accuracy of submitted data.

(2) A health care provider who meets the standards of quality and completeness of submitted data set by the department is subject to inspection not more than once every 3 years for the purpose of assessing the quality and completeness of reporting from the provider, unless summary data for the provider indicate a significant deviation from expectation.

(3) A health care provider shall, at the request of the department, supply missing information, if known, or clarify information submitted to the department.

(4) Upon mutual agreement between a health care provider and the department, the provider may elect to submit copies of medical records instead of submitting to an inspection. The department shall use a copy of a submitted medical record or part of a record only to verify corresponding reported data, shall not recopy the record, and shall keep the record in a locked file cabinet when the record is not being used. The department shall promptly destroy a copy of a medical record submitted under this rule after verifying corresponding reported data or, if the reported data appear to be inaccurate, after clarifying or correcting the reported data.

History: 1997 AACS.

R 325.165 Amendment, replacement, and removal of records.

Rule 5. (1) To protect the integrity and accuracy of the MCIR, information contained in the MCIR may only be amended, replaced, or removed as prescribed by these rules.

(2) A provider who submits health information or the department may amend the information in the MCIR by providing the minimum information needed to identify the record, a valid authorization code, and the replacement information on a form or in an electronic format prescribed by the department.

(3) A provider or the department may amend or update information in the MCIR by providing the minimum information needed to identify the record, a valid authorization code, and replacement or additional information on a form or in an electronic format prescribed by the department.

(4) A subject of a record, the subject's parents, a provider who did not submit the information to be amended, or a legal representative of either the subject or the subject's parents may apply to amend information contained in the MCIR. An application shall be in writing on a form prescribed by the

department and shall be accompanied by documentary evidence specified by the department to support the amendment. The department shall review the application and supporting evidence and either make the amendments or deny the request. An applicant shall be informed in writing of the denial and of the reason for the denial.

(5) The department shall delete or replace birth registration information transmitted to the MCIR when original birth registration information is deleted or replaced by the department.

(6) The department shall make immunization information inaccessible or reinstate immunization information from the MCIR upon receipt of a written request to make inaccessible or reinstate immunization information. The request shall be on a form prescribed or authorized by the department, be signed by the subject of the record, the subject's parents, or legal representative of the subject or the subject's parents and be witnessed as required in R 325.166(3).

(7) If a parent or legal guardian requests that the department terminate its notices regarding required immunization for the parent's child, then the department shall terminate the notices. A request shall be in writing and may be submitted to the department or to a provider.

(8) The department shall maintain a record of all changes to information in the MCIR, except for changes where the original birth information supplied by the department is deleted or replaced by the department. At a minimum, the record shall indicate the date of the change, the item changed, and the user who made the change.

History: 1997 AACS; 2009 AACS.

R 325.166 Confidentiality of reports.

Rule 6. (1) The department shall maintain the confidentiality of all health information submitted to the department and shall not release the reports, immunization assessments, or any information that, because of name, identifying number, mark, or description, can be readily associated with a particular individual, except in accordance with subrules (2), (3), (4), (5), and (6) of this rule. The department shall not release any information that would indicate whether or not the name of a particular person is listed in the registry, except in accordance with subrules (2), (3), (4), (5), and (6) of this rule.

(2) An immunization report submitted to the department concerning a particular individual, and any other information maintained in the MCIR that, because of name, identifying number, mark, or description, can be readily associated with a particular individual, shall be released by the department only as follows:

- (a) To the particular individual upon compliance with both of the following provisions:
 - (i) Receipt of a written request which is signed by the particular individual and which is witnessed or notarized as required by subrule (3) of this rule.
 - (ii) Presentation by the particular individual of suitable identification as required by subrule (4) of this rule.
- (b) If the particular individual is a minor, to a parent of the particular individual upon compliance with all of the following provisions:
 - (i) Receipt of a written request which is signed by the parent and which is witnessed or notarized as required by subrule (3) of this rule.
 - (ii) Receipt of a certified copy of the birth certificate of the particular individual.
 - (iii) Presentation by the parent of suitable identification as required by subrule (4) of this rule.
- (c) If the particular individual has a court-appointed guardian or if the particular individual is deceased, to the court-appointed guardian or to the executor or administrator of the particular individual's estate upon compliance with all the following provisions:
 - (i) Receipt of a written request which is signed by the particular individual's executor, administrator, or court-appointed guardian, and which is witnessed or notarized as required by subrule(3) of this rule.
 - (ii) Receipt of a certified copy of the order or decree that appoints the guardian, executor, or administrator.
 - (iii) Presentation by the guardian, executor, or administrator of suitable identification as required by subrule (4) of this rule.
- (d) To an attorney or other person designated by the particular individual upon compliance with both of the following provisions:

(i) Receipt of a written request which is signed by the particular individual, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(e) To an attorney or other person designated by the court appointed guardian of the particular individual or designated by the executor or administrator of the estate of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the court appointed guardian, executor, or administrator, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the order or decree that appoints the guardian, executor, or administrator.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(f) If the particular individual is a minor, to an attorney or other person designated by the parent of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the parent, is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the birth certificate of the particular individual.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(3) Every written request for the release of information submitted pursuant to subrule (2) of this rule shall be signed by the person making the written request. The signature shall either be witnessed by an employee or authorized agent of the department who has been designated to witness requests and to whom the person making the request presents suitable identification as required by subrule (4) of this rule or shall be notarized by a notary public or magistrate.

(4) A person who is required by subrules (2) or (3) of this rule to present suitable identification shall present an identification document, such as a driver's license, or other document that contains both a picture of the person and the signature or mark of the person.

(5) Information in the MCIR may be provided to any registered user of the MCIR upon presentation of a written, oral, or electronic request containing the minimum information necessary to identify the record requested and the user's authorization code.

(6) As specified in R 325.167, the director of the department may release information from the MCIR to an authorized representative of a study or research project reviewed by the scientific advisory panel and approved by the director. The department shall not release any part of a patient's medical record obtained under R 325.164.

History: 1997 AACS; 2009 AACS.

R 325.167 Scientific advisory panel; release of information for research.

Rule 7. (1) A research proposal that requires the release of information which identifies individuals in the MCIR shall be reviewed by the department's scientific advisory panel as established under R 325.9055.

(2) The panel shall advise the director in writing concerning the merits of the study.

(3) A release of information for research that identifies individuals in the MCIR is subject to the terms and conditions set by the department. A person who conducts a study or research project shall not publish the name of any individual who is or was in the MCIR and shall not release any identifying number, mark, or description that can be readily associated with an individual who is or was the subject of an immunization report submitted to the department.

History: 1997 AACS.

R 325.168 Exchange of records.

Rule 8. By written agreement, the department may transmit transcripts or copies of public health records or reports to state or national secure public health data systems or individuals responsible for the health care of a person if the records or reports relate to residents of other states or countries. The agreement shall require that the transcripts or records be used only for public health purposes and that the identity of a person who is subject to the report is confidential and shall only be released as specified in the agreement.

History: 1997 AACS; 2009 AACS.

R 325.169 Acceptance of immunization record as official record.

Rule 9. An immunization record obtained from the MCIR shall be accepted as the official immunization record of the person for the purposes of satisfying the requirements of sections 9208 and 9211 of the act.

History: 1997 AACS.