Confidentiality Guidelines for the Michigan Childhood immunization Registry (MCIR)

Notice: These guidelines, any part or its entirety, are subject to revisions by the Michigan Department of Community Health (MDCH) at any time without advanced notice provided to all interested agencies and/or providers.

I. Introduction

In 1996, the 88th Legislature of the state of Michigan passed Public Act 540 (PA 540) (see attachment A). Section 9207 of the act sanctioned the Michigan Department of Community Health the right to establish an immunization registry, to be known as the "childhood immunization registry," to record information regarding immunizations performed by immunization providers. Subsection (2) of Section 9207 states The information contained in the childhood immunization registry is subject to the confidentiality and disclosure requirements of this section and sections 2637 and 2888 and to the rules promulgated under section 9227 (see those sections for additional information). Thus PA 540 requires that information contained in the MCIR be kept confidential. The following policy is intended to delineate and ensure this firm level of confidentiality. Section II. describes the levels of access granted to various immunization providers, states the Michigan MCIR usage agreement policy, and outlines the penalties in place for violating the confidential policy. Section III. Indicates how parents/guardians are notified of the registry. Section IV. provides information on how parents/guardians may choose to not participate in the MCIR. Section V. describes the purposes of collecting the immunization information and how the information will be used by specific providers. Information on the varying degrees of access to the registry by different providers is delineated in section VI. of this policy. Section VII. outlines the penalties for inappropriate use or disclosure of immunization information. Finally, Section VIII. explains the procedures in place for archival and deletion of immunization information.

II. Agreements to Protect Confidentiality

Access to the MCIR is permitted for the sole purpose of providing information and documentation needed for immunization purposes. This access is permitted under the provisions of MCL 540.9201, 9206, and 9227. Access to MCIR data is under the terms and conditions prescribed the MDCH, and stipulated below.

Users, defined as anyone with access to the MCIR, must register and sign a formal user/usage agreement (see attachment B). Users are categorized into one of the following user types:

- 1. Immunization providers (private and public)
- 2. Health care organizations
- 3. Public and private schools
- 4. Licensed day-care facilities and/or camps
- 5. Local health department (LHD) administrators

6. MDCH or its authorized agents (e.g., MPHI)

Providers, defined as those who can authorize the administration of any immunizing agent (as defined by Public Health Code MCL 333 9204), can be registered individually, or by organization. In the latter case, the organization assumes full responsibility and liability for the individual's usage of the MCIR, including any penalties associated with improper usage of the MCIR and/or any immunization data associated with the MCIR.

Any physicians who practice outside of the state of Michigan but regularly treat Michigan children (i.e., areas bordering Michigan) may be registered as MCIR users. Such providers need to enter demographic and immunization encounter data for their patients who are Michigan residents. The MCIR will not contain restrictions on entering data for children with out-of-state addresses.

Different user types will have varying degrees of access to MCIR data (see below). Anyone wishing to use the MCIR must first register with the MCIR as a user by reading and signing a user/usage agreement (see attachment B). In addition, regional coordinators and/or staff are responsible for re-verifying or re-certifying provider licenses or organizations every three years. The following process outlines an acceptable method for re-verification or recertification of provider licenses or organizational status to ensure that users of the MCIR are appropriately licensed providers or organizations in Michigan.

1. Every three years the provider licenses will be re-verified and every three years an organization or individual within the organization will be re-certified.

Provider licenses are re-verified as follows:

- A. Primary verification method is to use the Michigan Department of Consumer and Industry Services (MDCIS) license verification unit.
- B. Or, licenses can be compared to the list of VFC program providers;
- 2. If a provider license cannot be verified, the provider will be personally notified within one business day. The provider's User ID/password will then be immediately inactivated within one business day.
- 3. If a provider license cannot be re-verified, the provider will be personally notified, within one business day. The provider's User ID/password will then be inactivated within one business day.
- 4. It will be the provider's responsibility to investigate the issues related to the non-verification.

Organizational status will be re-certified as follows:

- 1. Primary re-certification method is to use the licensing agency, the parent organization (e.g., school district office for a school).
- To re-certify an individual in a school district, such as the principal of a school
 who signed the Read Only User/Usage Agreement, the school district office can
 be contacted.
- 3. If an organization or an individual within the organization cannot be re-certified for any reason, the organization and/or individual will be notified personally within one business day. The organization or individual Password and User ID will then in inactivated within one business day.
- 4. It will be the responsibility of the organization or individual to investigate the issues related to non-verification.

As a registered user of the MCIR, users agree to the following stipulations:

- Users will handle information or documents obtained through the MCIR in a confidential manner.
- Users will restrict their use of the MCIR to accessing information and generating documentation only as necessary to properly conduct the administration and management of their duties as they relate to immunizations.
- Users understand that transactions on the MCIR are logged and are subject for review for overall usage.
- Users will not furnish information of documentation obtained through the MCIR to
 individuals for personal use nor to any individuals not directly involved with the conduct of
 the duties of the user as they related to the administration, recording, and reviewing
 immunizations.
- Users will not falsify any document or data obtained through the MCIR.
- Users will not attempt to or copy all or any part of the database or the software used to
 access the MCIR database for any unapproved purpose, nor attempt to falsify or otherwise
 alter data in the MCIR database, or otherwise violate all or any portion of the Michigan
 Computer Crime Law (MCL 333.791-333.797) or the Vital Records Law (MCL 333.2894)
 summarized on the back of the user/usage agreement.
- Users will carefully and deliberately safeguard their access privileges and password for the MCIR and will not permit the user of such access privileges by any other person, unless expressively authorized by MDCH to possess such use.
- Users agree to reports any threat to or violations of (whether real or perceived) to the appropriate MCIR security personnel.

Any improper use of the MCIR that violates the preceding stipulations will result in revocation of the user's access privileges and may include official penalties and/or sanctions as specified in Public Act 540 of the Public Acts of 1996 (see attachment A), the Vital Records Law (MCL 333.2898), or the Michigan Computer Crime Law (Sec 752.797).

III. Notification

Pursuant to Section 2828 (3) of Public Act 540, upon receipt of a vital record consisting of a birth registration transmitted by a local registrar pursuant to section 2815(2), the state registrar shall transmit the information contained in the birth registration to the childhood immunization registry created in section 9207. Thus, state laws do not require that parents receive any verbal and/or written notification that their child's immunization records will be loaded into and become part of the MCIR database. All Vaccine Information Statements (VIS) provided by the MDCH contain a paragraph informing parents that all immunizations administered to their children will be entered into the MCIR unless the parent signs an opt-out form. Immunization provider offices are given small posters from regional staff that informs patients that their provider participates in reporting all vaccines to the Michigan Childhood Immunization Registry.

Participation

The MCIR was authorized by the legislature to permit parents to "opt-out" if they so choose. Parents who do not want immunization information about their children in the MCIR are required to sign an Opt-out form which may be obtained from the local health department, immunization provider or the Regional Immunization Coordinator.

Immunization and demographic information on any child whose parent has chosen to opt-out is then no longer accessible by users and no reminder or recalls are generated. However, the child's basic demographic information - date of birth, gender and name remain within the MCIR for purposes of accurately determining the population of children for the sole purpose of calculating community and state immunization rates.

Parents may choose not to receive Reminder/Recall notices. If a parent chooses not to receive these notices any authorized user with write capacity can check the appropriate box on the MCIR screen. Written notice from the parent is not required.

Use of Immunization Registry Data

The purpose of the MCIR is to increase the number of Michigan children who are properly immunized. Access to the data in the MCIR is governed by P.A.368 333.9207 and the associated rules R 325.162. The MCIR assists providers in keeping a child's immunization status up-to-date, decreases over immunizing children, and gives the provider an efficient means by which to track a child's immunization history. More succinctly, the MCIR:

Maintains immunization histories of children between birth and age 20. Gives providers and other interested parties the ability to quickly and efficiently look up a child's immunization status.

Provides a report of immunizations that are due.

Evaluates immunization status and recommends future dose dates.

Gives interested parties the ability to enter immunization information into MCIR via paper or electronic transactions.

Provides immunization assessments.

Can assess immunization coverage of a population.

Assists in streamlining vaccination reports.

Provides different levels of data access (see below), and safeguards confidentiality. Allows a provider to manage their vaccine inventory.

Information contained in the MCIR is to be used for the sole purpose of providing information and documentation needed for immunization purposes. The use of data in the MCIR for research purposes is specifically authorized by rule R325.167. The MCIR is to be used only to track a child's immunization status and to ensure that s/he is up-to-date with respect to immunizations.

Access to and disclosure of Information

Access to the MCIR is restricted to Immunization Providers and others, such as schools and day care centers who have a need for such access, as well as technical and program staff at local and state health departments and the MCIR Regional Administrator. The following table outlines the different types of access to MCIR data that are allowed for each user group (type). Note that Add Child means that the provider has the ability to add a new child's demographic record into the MCIR database. Alter Child Info. Means the provider has the authority to alter demographic information already appearing as part of a specific child's record; Add Immunization Encounter grants the provider access to place another immunization (shot record) into a child's record; Alter Immunization Encounter means that the provider can change an immunization (shot record) they entered into the MCIR; View Immunization Status allows providers to assess whether a particular child is up-to-date, not up-to-date, or overdue with respect to their immunization status; and View Immunization History gives providers permission to examine the entire immunization history (immunization record) of a particular child in the MCIR.

User Type	Add Child	Alter Child Info.	Add Immunization Encounter	Alter Immunization Encounter	View Immunization Status	View Immunization History
Providers (public and private), including WIC	*	*	*	*	*	*
Health care organizations					*	*
Schools/day cares/camps					*	*
LHD administrators					*	*
MDCH or its authorized agents	*	*	*	*	*	*

^{* =} Has authorization.

Users are classified and provided a discrete level of access based on the information they need to obtain in order to carry out specific functions. That is, access is granted to users only on a "need-to-know" basis. Providers with read and write access can enter vaccine and demographic information into the MCIR, and can only edit vaccine information they specifically entered. If a provider finds that vaccine or a that a child's name was entered by another agency or provider is incorrect, the provider who finds the error must complete a petition for modification form that indicates what error(s) was made, requesting that it be corrected by their regional coordinator.

All authorized users must sign a User Agreement before they are provided with a unique Identification number and password to access the MCIR.

All requests for research use of the data should be directed to the Chief Medical Executive, Michigan Department of Community Health. The request will be reviewed by the State MCIR Review Committee and approved, refused or returned for additional information.

Disclosure of MCIR data on individuals by users to others, including law enforcement is specifically prohibited. All sub-pænas and other legal demands for MCIR data received by any authorized user of the MCIR should be referred to the Division of Immunization, Michigan Department of Community Health. They will be responded to in accordance with MDCH policy on sub-pænas, court orders and other legal documents by the Office of Legal Affairs.

Disclosure of community, regional and state immunization levels are permitted and encouraged.

Penalties for Unauthorized Disclosures

As previously indicated in Section II. of this policy, any breach or violation of any portion of the stipulations delineated in the User/Usage Agreement that the user signs will result in revocation of the user's access privileges and may include official penalties and/or sanctions as specified in Public Act 540 of the Public Acts of 1996 (see attachment A), the Vital Records Law (MCL 333.2898), or the Michigan Computer Crime Law (Sec. 752.797). Please see the appropriate statute for the specific penalties associated with violation of a particular mandate. For example, a person who is found to be in violation of the Vital Records Law is guilty of a misdemeanor punishable by imprisonment for not more than 1 year, or a fine of not more than \$1,000.00, or both. A departmental employee who violates this regulation shall be subject to immediate dismissal.

Data Retention and Disposal

All data in the MCIR, unless specifically excluded from access by parental request, will be accessible to all authorized users until a child reaches their 20th birthday. When a child reaches their 20th birthday, the data from the MCIR will be removed from the MCIR and archived in a secure location at the MDCH. It will no longer be accessible by users

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