

July 23, 2025

MEMORANDUM FOR: Advisory Board of Health and Liz King, Health Officer
St. Clair County Health Department

FROM: Dr. Remington Nevin, Medical Director, St. Clair County Health Department

SUBJECT: Conflicting Federal and State Guidance Regarding Vaccine Information Statements

The enclosed correspondence (Exhibit 1) has been sent to our county's congressional representative requesting their assistance in obtaining clarification from the U.S. Department of Health and Human Services (HHS) on conflicting guidance issued by the Michigan Department of Health and Human Services (MDHHS) regarding the use of Michigan-specific Vaccine Information Statements (VIS) (Exhibit 2). According to a Freedom of Information Act (FOIA) request (Exhibit 3), MDHHS has no current documentation of HHS coordination or authorization of this guidance. Accordingly, I am concerned that the St. Clair County Health Department's current use of Michigan-specific VIS, in accordance with MDHHS guidance, may conflict with federal law. As detailed in this correspondence, I am also concerned that this practice may unnecessarily delay the public's receipt of new and updated safety information in revised federal VIS that HHS may release in the future, such as in response to HHS efforts to better inform the public of matters of vaccine safety.

As we await a response from HHS to the requested congressional inquiry, I have determined that a related issue discussed in the correspondence requires more urgent action.

Although Michigan state law, namely MCL 333.9206(2) requires distribution of the designated MCIR opt-out form to parents prior to the child receiving an immunization, St. Clair County Health Department practices do not currently align with this statutory requirement.

MCL 333.9206(2) (Exhibit 4) requires distribution of "a form provided by the department." However, as noted in my correspondence, alternative documents such as Michigan-specific VIS that do not contain form elements, such as fields or prompts for specific information, do not meet the legal requirement of "form." Accordingly, I will be updating our standing immunization orders to require distribution of the designated MCIR opt-out form (Exhibit 5) prior to all childhood immunizations.



Remington Nevin, MD, MPH, DrPH
Medical Director

Enclosures as described



Elizabeth King, RN, BSN
Director/Health Officer

Greg Brown, BS
Administrator

Remington Nevin, MD, MPH, DrPH
Medical Director



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July 23, 2025

Congresswoman Lisa McClain
Washington DC Office
562 Cannon House Office Building
Washington, DC 20515

Dear Congresswoman McClain,

As Medical Director of the St. Clair County Health Department, I have responsibility to ensure that vaccines are administered within our county safely and in accordance with all pertinent laws and regulations.

In my role as Medical Director, and as your constituent, I am requesting the assistance of your office in clarifying with the Secretary of the U.S. Department of Health and Human Services (HHS) the validity of conflicting guidance from the Michigan Department of Health and Human Services (MDHHS) regarding the use of mandated Vaccine Information Statements (VIS).

The National Childhood Vaccine Injury Act (NCVIA, 42 U.S.C. § 300aa-26) requires that all vaccine providers give the appropriate federal VIS to the patient (or their parent or legal representative) prior to every dose of specific vaccines covered under the NCVIA. VIS are developed and distributed by the U.S. Centers for Disease Control and Prevention (CDC). Per current CDC website guidance, "Providers may add the name, address, and contact information of their practice to an existing VIS, **but may not make any substantive changes** [emphasis added]." (<https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>).

However, according to conflicting MDHHS guidance (<https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/immunizations/michiganvis>):

"In Michigan, vaccine recipients, their parents, or their legal representatives must be given the Michigan versions of VIS because they include information about the Michigan Care Improvement Registry (MCIR). **By state law in Michigan**, parents must be informed about MCIR. **Vaccine Information Statements that are obtained from other sources (e.g., from the CDC or IAC [Immunization Action Coalition] websites) do not contain information about MCIR** [emphasis in the original]."

I have several concerns with this MDHHS guidance. MDHHS makes what appear to be substantive and unauthorized modifications to the federal VIS, adding information related to the MCIR unrelated to vaccine safety. MDHHS directs the use of this modified Michigan VIS in place of the original federal VIS, potentially delaying dissemination of federal VIS changes. MDHHS also directs use of this modified federal document in place of other designated forms for state-specific MCIR-related purposes. These practices may conflict with federal and state law.



Elizabeth King, RN, BSN
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Medical Director

1. MDHHS guidance risks delays in the public's receipt of new safety information in updated versions of federal VIS.

As noted by the CDC in their Frequently Asked Questions on VIS (<https://www.cdc.gov/vaccines/hcp/about-vis/faq.html>):

“The date for a new VIS's required use is announced when the final draft is published in the Federal Register. **Ideally, providers will begin using a new VIS immediately....** As a general rule, **when changes to a VIS concern the safety of the vaccine** (e.g., contraindications or precautions, or adverse events), **it is essential that the new edition be used immediately upon publication** [emphasis added].”

However, as currently noted on the Vaccine Information Statements for Michigan webpage (<https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/immunizations/michiganvis>):

“CDC recently posted revisions of 17 VISs, dated January 31, 2025, on its Current VISs web page. The revisions comply with the January 20, 2025, Presidential Executive Order. Federal law allows up to 6 months for a new VIS to be used. MDHHS is in the process of printing these new versions, **however they will be unavailable for approximately 4-6 weeks.**”

The delays introduced by MDHHS in directing providers to use Michigan VIS in place of current federal VIS run contrary to federal guidance to immediately use updated VIS. Such delays may result in Michigan residents receiving outdated VIS that differ substantively from updated versions, potentially undermining current and future HHS efforts to improve safety guidance in federal VIS.

2. No current formal coordination or authorization exists between MDHHS and HHS for use of Michigan VIS.

In response to a Michigan Freedom of Information Act (FOIA) request (H028900-062625), MDHHS confirmed that it had no records of federal approval from HHS or CDC for use of a Michigan VIS. Although MDHHS responded that “Michigan worked with CDC several years ago to obtain permission to add a MCIR statement on the VIS,” MDHHS was unable to provide any records of formal coordination or authorization and merely stated in response to the FOIA request that “The approval took place in 1995, and the Department [MDHHS] no longer has those records.”

The absence of any apparent current formal coordination or authorization suggests the possibility that whatever temporary approvals, if any, may have been granted MDHHS for this modification three decades earlier may no longer be valid, nor reflect current HHS or CDC policy regarding use of federal VIS.

3. No Michigan state law or regulation specifically mandates that adult patients be provided a document regarding the MCIR.

Although Michigan Compiled Laws (MCL) 333.9207(3) provides that adult patients be permitted to opt-out of the MCIR, the law does not require that adults be informed of this through distribution of a Michigan VIS. Specifically, the law reads:

“Upon receipt of a written request from an individual who is 20 years of age or older, the department shall make any immunization information in the registry pertaining to that individual inaccessible. **The written request shall be in a form prescribed or otherwise authorized by the department** [emphasis added].”

To the extent that MDHHS may properly wish to inform adult patients of their statutory right, under MCL 333.9207(3), to opt-out of MCIR, this may be accomplished more directly through distribution of the designated MCIR opt-out form developed by MDHHS for this purpose (<https://mcir.org/wp-content/uploads/2014/09/OptOutForm.pdf>), than through the unnecessary modification of a federal VIS. Accordingly, the substitution of federally approved VIS for a Michigan VIS is wholly without justification for adult patients.

4. No Michigan state law or regulation specifically authorizes a Michigan version of the VIS for childhood immunization.

The cited rationale for mandating use of a Michigan VIS for childhood immunization, namely that parents “must be informed about MCIR,” appears to be a reference to MCL 333.9206(2) and (3), which read:

“(2) Before administering an immunizing agent to a child, a health care provider shall notify the parent, guardian, or person in loco parentis of the child, **on a form provided by the department**, of the right to object to the reporting requirement described in subsection (3) [emphasis added].

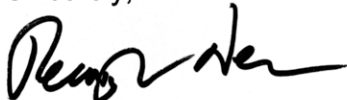
(3) Unless the parent, guardian, or person in loco parentis of the child who received the immunizing agent objects **by written notice** received by the health care provider prior to reporting, a health care provider shall report to the department each immunization administered by the health care provider, pursuant to rules promulgated under section 9227. If the parent, guardian, or person in loco parentis of the child who was immunized objects to the reporting requirement of this subsection **by written notice** received by the health care provider prior to notification, the health care provider shall not report the immunization [emphasis added].”

As noted above, MDHHS already produces a designated MCIR opt-out form (<https://mcir.org/wp-content/uploads/2014/09/OptOutForm.pdf>) which satisfies both the requirements of MCL 333.9206(2) and (3) and which meets the requirements of the MDHHS guidance above that parents “must be informed about MCIR.” However, contrary to the requirements of MCL 333.9206(2) for distribution of such a form, this specific MCIR opt-out form is not routinely distributed prior to childhood vaccination, with the Michigan VIS instead seemingly serving the role of the required “form” per MDHHS guidance.

As the Michigan VIS is a document, and does not contain any form elements, such as fields or prompts for specific information (e.g., name, date, checkboxes) to be filled out by the parent, the Michigan VIS cannot meet the legal requirements of “form” as required by MCL 333.9206(2). Likewise, unlike use of the designated MCIR opt-out form, distribution of the non-form Michigan VIS cannot facilitate the parent providing the appropriate written notice at the time of immunization to opt-out of MCIR reporting as required by MCL 333.9206(3).

I respectfully request that your office contact the HHS Secretary to obtain written clarification on whether the MDHHS guidance discussed above complies with federal law under the NCVIA, including confirmation of any current authorization for MDHHS modifications to federal VIS. Please provide this clarification to my office at your earliest convenience to ensure safe and lawful vaccine administration in St. Clair County.

Sincerely,



Remington Nevin, MD, MPH, DrPH
Medical Director
St. Clair County Health Department

Michigan's Vaccine Information Statement (VIS) Policy

A. Purpose

The purpose of this policy statement is to provide direction to state and local health department staff concerning the distribution and provision of copies of Vaccine Information Statements (VIS).

B. Definition and Background

1. As required under the *National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26)*, all health care providers in the United States who administer, **to any child or adult**, diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b, varicella, rotavirus, pneumococcal conjugate, influenza (inactivated and live), human papillomavirus, and meningococcal vaccines shall, **prior to administration of each dose of the vaccine**, provide a copy (to review and retain) of the relevant, current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC) to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and to any adult to whom the provider intends to administer such vaccine. (In the case of an incompetent adult, relevant VIS shall be provided to the individual's legal representative. If the incompetent adult is living in a long-term care facility, all relevant VIS may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each immunization.)
2. In the state of Michigan, it is important that vaccine recipients, their parents, or their legal representatives be given Michigan versions of VIS because these statements include information about the Michigan Care Improvement Registry (MCIR). Michigan law requires that parents be informed of the MCIR. VIS that are obtained from other sources (e.g., from the CDC or Immunization Action Coalition IAC websites) do not contain information about MCIR.
3. VIS with MCIR information is available at the Michigan Department of Health and Human Services (MDHHS) website www.michigan.gov/vis or at Local Health Departments (LHDs). End users can also acquire the VIS through a link from their MCIR site home page.

C. Policy

1. With the transition to centralized vaccine distribution in 2008, Michigan VIS are no longer shipped to LHDs with vaccine.
2. According to Minimum Program Requirements (MPRs), LHDs shall have protocols in place to ensure that all providers who administer vaccines (both VFC and non-VFC providers) are informed of requirements for use of VIS and changes to VIS versions.

D. Procedure

1. MDHHS is responsible for updating the MDHHS VIS website, Important VIS Facts, Immunization Material Order Form, Important Information for Michigan Health Care Providers and for providing information to LHDs when VIS versions are updated.
2. MDHHS will send a memorandum of any new or interim VIS to each LHD. The LHD needs to share memorandum with providers in their area. The LHDs and providers should begin using the new VIS immediately.
3. LHDs shall place advance orders to MDHHS for any new or interim VIS. MDHHS will get the VIS printed; once the VIS have been printed, MDHHS will fill and ship orders directly to those LHDs that have placed advanced orders.
4. LHDs needs to print a small quantity of the new or interim VIS until shipment arrives from MDHHS. The estimated time frame is usually 4 to 6 weeks.
5. MDHHS will provide print versions of VIS. LHDs and hospitals may order bulk copies of interim VIS and other VIS from MDHHS. Quantities of the VIS may be ordered by faxing the *Immunization Materials* order form to 517-335-9855. For more information about this process – or to obtain the *Immunization Materials* order form – please contact Jacquelyn Jones at jonesj11@michigan.gov or 517-284-4883.
6. *Exceptions* to this procedure are foreign language VIS; these will not be printed by MDHHS. Foreign language VIS may be obtained at www.michigan.gov/VIS.
7. LHDs are encouraged to provide quantities of VIS to immunization practices within their jurisdiction. Providers shall be responsible for obtaining quantities of VIS from the LHD.

Policy Effective Date: 5/26/21

H028900-062625 - FOIA Request

Message History (4)

✉ On 7/8/2025 2:19:30 PM, MDHHS FOIA Records Center wrote:

Subject: MDHHS FOIA Request :: H028900-062625

Body:

RE: Public Records Request, Reference # H028900-062625.

Dear Medical Director Nevin,

This notice is issued in response to your request, legally received by the Michigan Department of Health and Human Services (Department) on June 27, 2025, requesting information under the Freedom of Information Act (FOIA), MCL 15.231 *et seq.*

Your request is denied.

To the best of the Department's knowledge, information, and belief, this Department does not possess or maintain records under the description you provided or by other names reasonably known to the Department. The approval took place in 1995, and the Department no longer has those records.

As to the denial, the Department is obligated to inform you that under MCL 15.240 the following remedies are available:

1. Appeal this decision in writing to the Legal Affairs Administration, Department of Health and Human Services, Suite 207, PO Box 30037, Lansing, MI 48909. The writing must specifically state the word "appeal" and must identify the reason or reasons you believe the denial should be reversed. The Department must respond to your appeal within ten days of receipt. Under unusual circumstances, the time for response to your appeal may be extended by ten business days.

2. File an action in the appropriate court within 180 days after the date of the final determination to deny the request. If you prevail in such an action, the court is to award reasonable attorney fees, costs, disbursements, and possible damages.

The Department's FOIA policies and procedures are available at [Policies and Procedures](#).

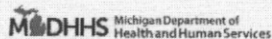
Sincerely,

Bureau of Legal Affairs

✉ On 6/27/2025 8:04:32 AM, MDHHS FOIA Records Center wrote:

Subject: Confirmation of FOIA Request:: H028900-062625

Body:



Dear Medical Director Nevin,

Thank you for your interest in public records of the Michigan Department of Health and Human Services (hereinafter "Department").

Records Requested: All records, including emails, correspondence, reports, memoranda, and agreements, pertaining to MDHHS obtaining federal approval, including from HHS or CDC, for the use of Michigan-specific Vaccine Information Statements (VIS), as referenced in MDHHS response H028881-062525 (enclosed), which stated "Michigan worked with CDC several years ago to obtain permission to add a MCIR statement on the VIS."

Your request has been assigned the following tracking number: H028900-062625. Your request has a legally received date of June 27, 2025. You will receive a response by the Department by July 07, 2025. Unfortunately, we are unable to expedite requests and the time permitted for response by the Department may be extended beyond July 07, 2025 by ten (10) business days.

In accordance with the Michigan Freedom of Information Act (FOIA), MCL 15.231 *et seq*, the Department provides copies of existing non-exempt records. Records which are exempt from disclosure under state or federal law will not be provided, or records may be redacted to separate exempt information. The FOIA does not require the Department to create new records or answer queries.

You can monitor the progress of your request at the [MDHHS Public Records Center](#) and you will receive an email when your request has been completed.

Regards,

Bureau of Legal Affairs,

Michigan Department of Health and Human Services

 On 6/26/2025 4:23:17 PM, Remington Nevin wrote:

Request Created on Public Portal

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.9206 Certificate of immunization required; form; contents; right to object to reporting requirement; report to department; failure to comply with subsection (3); "health care provider" and "health professional" defined.

Sec. 9206. (1) A health care provider administering an immunizing agent to a child shall present the person accompanying the child with a written certificate of immunization, or make an entry of the immunization on a certificate in the person's possession. The certificate must be in a form prescribed by the department and indicate the diseases or infections for which the child has been immunized, the number of doses given, the dates when administered, and whether further immunizations are indicated. Beginning January 1, 2024, the certificate must also have a space to indicate whether the minor has been tested for lead poisoning.

(2) Before administering an immunizing agent to a child, a health care provider shall notify the parent, guardian, or person in loco parentis of the child, on a form provided by the department, of the right to object to the reporting requirement described in subsection (3).

(3) Unless the parent, guardian, or person in loco parentis of the child who received the immunizing agent objects by written notice received by the health care provider prior to reporting, a health care provider shall report to the department each immunization administered by the health care provider, pursuant to rules promulgated under section 9227. If the parent, guardian, or person in loco parentis of the child who was immunized objects to the reporting requirement of this subsection by written notice received by the health care provider prior to notification, the health care provider shall not report the immunization.

(4) A health care provider who complies or fails to comply in good faith with subsection (3) is not liable in a civil action for damages as a result of an act or omission during the compliance, except an act or omission constituting gross negligence or willful and wanton misconduct.

(5) As used in this section:

(a) "Health care provider" means a health professional, health facility, or local health department.

(b) "Health professional" means an individual who is licensed, registered, or otherwise authorized to engage in a health profession under article 15.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1996, Act 540, Imd. Eff. Jan. 15, 1997;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2023, Act 145, Imd. Eff. Oct. 3, 2023.

Popular name: Act 368

Michigan Care Improvement Registry (MCIR) Participation in the MCIR Reporting



In accordance with Public Act 540 of the Public Acts of 1996, Amended 2006, Act 91, the Michigan Department of Health and Human Services (MDHHS) has established the Michigan Care Improvement Registry (MCIR) to record information regarding childhood immunizations administered by health care providers. The information contained in the MCIR is subject to confidentiality and disclosure requirements. The information in the MCIR shall be used only for immunization purposes as authorized in state statutes and rules. Under the Public Act mentioned above, providers shall report each immunization they administer to children born after January 1, 1994. This reporting requirement is in effect unless the child's parent or guardian or individual objects by written notice in accordance with Sections 9206 and 9207 listed on the reverse side of this form.

Purpose -- Michigan Care Improvement Registry

The MCIR will collect standard, reliable information on the immunization status of individuals in Michigan. The MCIR will enable private and public providers of immunization services to assess a person's immunization status and administer age-appropriate vaccinations. The MCIR will allow for reminder and recall notifications for persons who are due or overdue for immunizations.

Statement -- Reporting Requirements of the MCIR

In accordance with Section 9206(3) of P.A. 540 of 1996 and Section 9207(3) of P.A. 91 of 2006:

☐ **I OBJECT** to the reporting requirements of the MCIR and issue this written notification to the MDHHS that immunization information for myself or my child not be reported to the MCIR. I understand that by signing and submitting this form, no MCIR user will be able to record immunization information for me or my child within the MCIR, nor will my or my child's immunization history be available through the MCIR.

☐ **I RESCIND THE PREVIOUS OBJECTION** to record immunization information for myself or my child in the MCIR. I understand that by signing and submitting this form, the MCIR will resume recording immunization information for my self or my child within the MCIR.

Person or Individual Information (this information is necessary to properly identify you or your child)

Name _____		
Last	First	Middle
MCIR ID _____ Date of Birth _____		
(MM/DD/YYYY)		

Parent/Guardian or Individual Contact Information

Name _____		
Last	First	Middle
Relationship to Child _____		Phone Number (____) _____
Signature _____		Date _____

Name of Submitter _____

Completed forms must be sent via email MDHHS-MCIRHelp@michigan.gov or via fax to 517-763-0370