Newborn Screening Critical Congenital Heart Disease (CCHD) Data Exchange Solution

Implementation Guide

Version 17

June 30th, 2026

Table of Contents

1. Introduction

1.1 Purpose

Enables healthcare organizations to electronically submit pulse oximetry screening results for newborns to the State of Michigan. This solution supports early identification of critical congenital heart disease (CCHD) through real-time data exchange with the State registry

Babies diagnosed with critical congenital heart disease (CCHD) are at high risk for serious complications within the first days or weeks of life and may require emergency intervention. CCHDs remain one of the most significant causes of infant death in the United States.

Early detection is essential, and receiving CCHD screening results from birthing hospitals in near real time helps the state improve health outcomes and reduce healthcare costs.

1.1.1 Michigan CCHD Screening Mandate:

- CCHD screening became mandatory in Michigan effective April 1, 2014.
- Michigan law requires all newborns to be screened for CCHD using pulse oximetry.
- As of January 5, 2026, MDHHS implemented a new updated algorithm for CCHD screening.
- The screening is performed at or around 24 hours of age, or before hospital discharge.

1.1.2 Current Workflow Challenge:

Currently, hospitals enter CCHD screening results into their electronic health record (EHR) system and then re-enter the same information into the Michigan Department of Health and Human Services (MDHHS) newborn screening system through a web-based application. Because CCHD screening often requires multiple readings, this double entry creates additional burden and increases the risk of data entry errors.

By enabling real-time electronic notifications, hospitals can send multiple-sequence CCHD test results directly from their EHR systems to MDHHS through the Michigan Health Information Network (MiHIN). This process reduces hospital workload and minimizes the chance for errors by eliminating the need for duplicate data entry.

1.1.3 Meaningful Use Compliance:

Eligible hospitals enrolled in the Medicare and Medicaid EHR Incentive Program may elect to report electronic HL7® pulse oximetry reports on screening for CCHD to the MDHHS Newborn Screening Program, fulfilling the Public Health Objective Specialized Registry Measure.

1.2 Message Content

Message Content means an HL7 2.5.1 conforming message containing information regarding newborn screening.

1.3 CCHD Background and Requirements

1.3.1 Target Conditions:

The seven primary target CCHD lesions screened for are:

1. Hypoplastic left heart syndrome
2. Pulmonary atresia (with intact septum)
3. Tetralogy of Fallot
4. Total anomalous pulmonary venous return
5. Transposition of the great arteries
6. Tricuspid atresia
7. Truncus arteriosus

Additional conditions that may be detected include: coarctation of the aorta, double outlet right ventricle, Ebstein's anomaly, interrupted aortic arch, single ventricle, and other critical non-cardiac conditions.

1.3.2 MDHHS Newborn Screening Program Contact Information:

- General Email: newbornscreening@michigan.gov
- Toll-Free Phone: 866-673-9939
- Direct Phone: 517-335-4181
- Follow-up Program: 517-335-4181
- Fax: 517-335-9419
- Alternative Fax: 517-763-0183
- Mailing Address: P.O. Box 30195, Lansing, MI 48909
- Website: Michigan.gov/NewbornScreening
- CCHD-Specific Website: Michigan.gov/CCHD

1.3.3 MDHHS Key Personnel:

- Newborn Screening Section Manager: Shawn Moloney, MPH, MLS (ASCP)CM - Phone: 517-335-5097
- Chemistry and Toxicology Division Director: Matthew Geiger, DrPH, M.S. - Phone: 517-335-8344

For more information about this data exchange solution, refer to the following link: https://mihin.org/wp-content/uploads/2024/05/MiHIN-UCIG-Newborn-Screening.pdf

You can contact MiHIN at www.mihin.org/requesthelp for more information.

2. Onboarding

2.1 Prerequisites

Participating organizations must complete legal onboarding prior to beginning the technical onboarding process. Once all required legal agreements are fully executed, the participating organization will proceed to the technical onboarding phase.

2.1.1 Universal Legal Prerequisites

Upon a participating organization indicating interest in onboarding, MiHIN will review the organization's legal status to confirm whether the appropriate agreements are in place. If required legal agreements have not yet been executed, a MiHIN staff member will work with the participating organization to complete the necessary pre-onboarding legal steps.

Prior to initiating technical onboarding, the participating organization must have an executed Participation Agreement or the applicable legacy master data-sharing agreement plus applicable Use Case Exhibits executed. In some cases, execution of a Statement of Work (SOW) may also be required.

To initiate the pre-onboarding legal process, please contact MiHIN's Help Desk by emailing help@mihin.org or visiting our portal https://mihinhelp.refined.site/portal/50

2.1.2 Technical Requirements

The following data exchange solution implementations and technical requirements will need to be conducted for Newborn Screening-CCHD to function.

2.1.3 Data Exchange Solution Requirements

No other data exchange solution implementations are required for participation in the Newborn Screening-CCHD Data Exchange Solution.

2.1.4 Other Technical Requirements

- MiHIN supports an HL7 over Lower Layer Protocol (LLP) via IPsec Virtual Private Network (VPN) and HL7 2.x messaging standards. HL7 v2.5.1 or newer versions are preferred, but HL7 v2.3.1 is still allowable.
- If the participating organization has an established connection to our HIE Platform (Integrated Technology Platform) and will be a net-new participant in participating in this Data Exchange Solution, the customer will be required to support two VPN connections:
  - The first VPN connection to support their participation on the HIE Platform (ITP) and,
  - a second connection to Rhapsody specifically for Public Health Reporting data exchange solutions.
- Participating organizations will need the ability to generate ORU Messages that adhere to specifications listed in the MDHHS Implementation Guide https://michiganhealthit.org/wp-

content/uploads/MDHHS-Newborn-Screening-CCHD-IG.pdf and send them via one of the transport options listed in Section 2.3.
- Organizations will need to be able to receive response messages from MiHIN via one of the transport options listed in Section 2.3 and ingest it into their EHR where applicable.

2.1.5 Alternative Reporting Methods:

For specific instructions on setting up any of these reporting methods, contact the MDHHS Newborn Screening Program at newbornscreening@michigan.gov or 517-335-4181.

2.2 Newborn Screening-CCHD Onboarding Process

1. Express interest in participating in the Newborn Screening-CCHD Data Exchange Solution
2. Meet with Account Manager
3. Exchange contact information
4. Kickoff meeting with Customer Success Team
5. Exchange required documents:
    - Onboarding Contact Form (If not already collected)
    - Transport Document
        - VPN Request Form
6. Establish transport method/connectivity
7. Test ORU HL7 Messages
8. Complete Data Quality Assurance (DQA) with MDHHS
9. Go Live

2.3 Technical Connectivity Process

Currently MiHIN accepts:

- **HL7 over Lower Layer Protocol (LLP) via IPsec Virtual Private Network (VPN)**

Two VPNs are required. A primary VPN will facilitate regular traffic. A secondary will be established for fail-over purposes.

The following steps describe the technical onboarding process. MiHIN typically conducts "onboarding kickoff" meetings with new organizations to go through each of these steps in detail and answer any questions.

1. The Initial Sending Facility must register with the Michigan Department of Community Health OID Registry (MDCH). https://mimu.michiganhealthit.org/
2. The Initial Sending Facility must send their Object Identifier (OID) number to MiHIN at http://mihin.org/requesthelp.
3. The organization establishes connectivity with MiHIN.
    a. HL7 over LLP IPsec VPN – MiHIN's site-to-site VPN request form must be completed, sent and approved by MiHIN. Send a request via www.mihin.org/requesthelp to obtain the VPN request form. A pre-shared key is then exchanged between the organization and MiHIN to initialize the connection.
4. Test messages are sent by the organization to MiHIN.

a. All test messages must have a "T" in the Message Header – field 11
b. Test traffic is routed via MiHIN to the appropriate destination. For CCHD messages, the destination is the CCHD registry via the state data hub.
c. The end destination monitors for inbound test traffic and confirms receipt with MiHIN, which confirms with the organization.

5. For the CCHD use case, the registry deems the sending facility to have entered Data Quality Assurance Status (DQA) once they have successfully received a properly formatted message from the sending facility via the organization through MIHIN.
6. The CCHD registry declares the sending facility to be at Production Status after a period of successful testing and exiting DQA status.
   a. At this time, the sending facility may then send production messages through the organization to MiHIN. The sending facility now places a "P" (for production) value in the MSH-11 instead of the "T" used during testing.

2.3.1 Onboarding Additional Sending Facilities

When an organization wishes to onboard additional sending facilities, those facilities must first register with the CCHD registry. Once successful, the registration information from the registry, including the Facility OID, must be emailed to www.mihin.org/requesthelp. The new sending facility should then begin sending test messages to the CCHD registry in the same fashion as the initial facility as detailed in section 2.3, making sure to place a "T" value in MSH-11. The receiving system deems the sending facility to be in DQA and eventually Production Status.

For specific information regarding testing, refer to the MDHHS Newborn Screening CCHD Implementation Guide: https://michiganhealthit.org/wp-content/uploads/MDHHS-Newborn-Screening-CCHD-IG.pdf

3. Specifications

3.1 Overview

3.1.1 Environments

- **MiHIN Pre-Production**
  - Private: 172.16.5.95
  - Public: 23.20.140.197
- **MiHIN Production**
  - Private: 172.16.5.125
  - Public: 52.204.207.180

3.2 General Message Requirements

For general rules that apply to the entire message, refer to the MDHHS Newborn Screening CCHD Implementation Guide, located at: https://michiganhealthit.org/wp-content/uploads/MDHHS-Newborn-Screening-CCHD-IG.pdf

3.2.1 Message Trigger Events

The HL7 message type for CCHD messages are ORU and the trigger event is R01.

3.3 Specific Segment and Field Definitions

The definitions in the table below shall be conformed to by all HL7 messages communicating the message header (MSH) segment:

Sequence	Length	DT	Usage	Cardinality	TBL	Item	Element Name	Comments
1	1	ST	R	1..1		00001	Field Separator	
2	4	ST	R	1..1		00002	Encoding Characters	
3	180	HD	R	1..1	0361	00003	Sending Application	
4	180	HD	R	1..1	0362	00004	Sending Facility	Facility OID
5	180	HD	R	1..1	0361	00005	Receiving Application	CCHD
6	180	HD	R	1..1	0362	00006	Receiving Facility	MDHHS
7	26	TS	R	1..1		00007	Date/Time of Message	
8	40	ST	X	0..0		00008	Security	
9	7	CM	R	1..1	0076 0003	00009	Message Type	ORU
10	20	ST	R	1..1		00010	Message Control ID	Should be repopulated (rather than pass-through) for outbound message header
11	3	PT	R	1..1		00011	Processing ID	**P** when in production, **T**

								for testing
12	60	VID	R	1..1	0104	00012	Version ID	
13	15	NM	X	0..0		00013	Sequence Number	
14	180	ST	X	0..0		00014	Continuation Pointer	
15	2	ID	X	0..0	0155	00015	Accept Acknowledgment Type	
16	2	ID	X	0..0	0155	00016	Application Acknowledgment Type	
17	2	ID	X	0..0		00017	Country Code	
18	16	ID	X	0..0		00692	Character Set	
19	60	CE	X	0..0			Principal Language of Message	
20	20	ID	X	0..0		00356	Alternate Character Set Handling Scheme	

3.3.1 All Remaining Segments

The message header is the only segment which MiHIN requires to be formatted in a certain way. MiHIN does not evaluate or verify any other part of the message. For all remaining segments and fields, follow the CCHD standards, which can be found in the Newborn Screening CCHD Implementation Guide at: https://michiganhealthit.org/wp-content/uploads/MDHHS-Newborn-Screening-CCHD-IG.pdf

Production Support

	Severity 1	Severity 2	Severity 3	Severity 4
Description	A critical production system is down or does not function at all, and there is no circumvention or workaround for the problem; a significant number of users are affected, and a production business system is inoperable.	More than 90% of messages received and delivered successfully, but some messages are not delivered/received with required accuracy. Service component severely restricted in one of the following ways: • High impact risk or actual occurrence of patient care affected or operational impairment • Business critical service has a partial failure for multiple TDSOs • A critical service is online however, is operating in a degregated state and having a significant impact on multiple TDSOs	Service component restricted in one of the following ways: • A component is not performing as documented or there are unexpected results • Business critical service has failed for a two or more TDSOs • A critical service is usable however, a workaround is available, or less significant features are unavailable	No operational impact to MiHIN. A non-critical service component is malfunctioning, causing minimal impact, or a test system is down.
Initiation Method	**Call** (844) 454-2443 and **submit** a ticket online at www.mihin.org/requesthelp	**Call** (844) 454-2443 and **submit** a ticket online at www.mihin.org/requesthelp	**Submit** a ticket online at www.mihin.org/requesthelp	**Submit** a ticket online at www.mihin.org/requesthelp
Acknowledgement Communication	Within **30 minutes**	Within **30 minutes**	Within **3 business hours**	Within **6 business hours**
Resolution Goal	**<2** hours Restore Time from 8 am – 5 pm ET Monday-Friday and **<4** hours nights, weekends and holidays	**<4** hours Restore Time from 8 am - 5 pm ET Monday-Friday and **<8** hours nights, weekends and holidays	**<12** hours Restore Time from 8 am - 5 pm ET Monday-Friday and **<24** hours nights, weekends and holidays	Within **5 business days**

If you have questions, please contact the MiHIN Help Desk:

- www.mihin.org/requesthelp (preferred)
- Phone: 844-454-2443
- Monday – Friday 8:00 AM – 5:00 PM (Eastern Time)

Legal Advisory Language

This reminder applies to all use cases covering the exchange of electronic health information:

The Data Sharing Agreement (DSA) establishes the legal framework under which participating organizations can exchange messages through the MiHIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

1. By health care providers for Treatment, Payment and/or Health Care Operations consistent with the requirements set forth in HIPAA
2. Public health activities and reporting as permitted by HIPAA and other Applicable Laws and Standards
3. To facilitate the implementation of "Meaningful Use" criteria as specified in the American Recovery and Reinvestment Act of 2009 and as permitted by HIPAA
4. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual's personal representative in accordance with HIPAA
5. By Data Sharing Organizations for any and all purposes, including but not limited to pilot programs and testing, provided that such purposes are consistent with Applicable Laws and Standards
6. or any additional purposes as specified in any use case, provided that such purposes are consistent with Applicable Laws and Standards

Under the DSA, "***Applicable Laws and Standards***" means all applicable federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, regulations and judicial or administrative decisions promulgated by any governmental or self-regulatory agency, including the State of Michigan, the Michigan Health Information Technology Commission, or the Michigan Health and Hospital Association, as any of the foregoing may be amended, modified, codified, reenacted, promulgated or published, in whole or in part, and in effect from time to time. "Applicable Laws and Standards" includes but is not limited to HIPAA; the federal Confidentiality of Alcohol and Drug Abuse Patient Records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2; the Michigan Mental Health Code, at MCLA §§ 333.1748 and 333.1748a; and the Michigan Public Health Code, at MCL § 333.5131, 5114a.

It is each participating organization's obligation and responsibility to ensure that it is aware of Applicable Laws and Standards as they pertain to the content of each message sent, and that its delivery of each message complies with the Applicable Laws and Standards. This means, for example, that if a use case is directed to the exchange of physical health information that may be exchanged without patient authorization under HIPAA, the participating organization must not deliver any message containing health information for which an express patient authorization or consent is required (e.g., mental or behavioral health information).

Disclaimer: The information contained in this implementation guide was current as of the date of the latest revision in the Document History in this guide. However, Medicare and Medicaid policies are subject to change and do so frequently. HL7 versions and formatting are also subject to updates. Therefore, links to any source documents have been provided within this guide for reference. MiHIN applies its best efforts to keep all information in this guide up-to-date. It is ultimately the responsibility of the participating organization and sending facilities to be knowledgeable of changes outside of MiHIN's control.