Electronic Case Reporting (eCR)

Implementation Guide

Version 30

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1. Introduction

1.1 Purpose of Data Exchange Solution

Bi-directional data exchange allowing clinicians to share complete disease-related data for birth defects, overdoses, environmental conditions, chronic diseases, and all other reportable conditions, while receiving feedback and staying better informed.

Infectious diseases result in more than 10.2 million physician office visits, and 4.7 million emergency department visits each year in the United States (https://www.cdc.gov/nchs/fastats/infectious-disease.htm). MiHIN's Electronic Case Reporting (eCR) Data Exchange Solution allows clinicians to share complete disease-related data for birth defects, overdoses, environmental conditions, chronic diseases, and all other reportable conditions. Coordinated data sharing between health care organizations, MiHIN, and the Michigan Department of Health and Human Services (MDHHS) is essential for early detection, quick response, and accurate monitoring of health threats to protect vulnerable communities. The eCR bi-directional exchange process lays the foundation so clinicians can be in alignment with their statutory duty to report to local and state public health, while receiving feedback and staying better informed.

Additionally, eCR is required to meet the Public Health and Clinical Data Exchange Objective measures for Hospitals and Critical Access Hospital participants under the Medicare Promoting Interoperability Program (PIP) and for Eligible Professionals participating in the Merit-based Incentive Payment System (MIPS). Eligible hospitals, critical access hospitals, and eligible professionals must register their intent to report eCR to MDHHS within the Michigan Health System Testing Repository (HSTR). Please see "Onboarding" for additional information on registering with HSTR.

The *Michigan "Brick Book"* is an official reference guide published by MDHHS' Bureau of Infectious Disease Prevention. Its primary purpose is to provide health care professionals, laboratories, schools, and local health departments with guidance on Michigan's communicable disease reporting requirements.

This document is limited to communicable disease surveillance and reporting requirements, and does not address provider payment programs, quality incentive measures, or health system transformation initiatives such as PIP, MIPS, or HSTR.

1.2 Message Information

1.2.1 Message Content

For this data exchange solution, Message Content means an electronic initial case report (eICR) or a Reportability Response (RR) about an eICR.

The eICR messages will first be evaluated for structural compliance, followed by a review of their content. The content requirements outlined in the MDHHS eCR specifications for HL7® CDA® R2 establish the minimum criteria for eCR validation. In addition to these baseline requirements, MDHHS defines supplemental content obligations that may designate specific sections and templates as required, strongly recommended, recommended, or optional.

Set the minimum requirements for eCR validation. MDHHS has additional content obligations that may change the section and template criteria to required, strongly recommended, recommended or optional.

1.2.2 Message Format

Currently, public health's primary focus for eCR remains on the clinical document architecture (CDA) eICR model, as most certified Electronic Health Record (EHR) vendors are already CDA-enabled. While FHIR®-based eCR is now recognized and increasingly supported, many organizations are not fully ready to implement it. Below is a brief description of each of these standards and their current use in public health reporting.

- CDA, also known as HL7 V3, is limited to "clinical" use cases and incorporates a vast and somewhat complex structural offering. CDA allows clinical concepts to be structured differently in different circumstances. The message includes a header with sections and templates requiring narrative text that may be presented in various ways, such as in a paragraph, list, table, textual content, and hyperlinks.

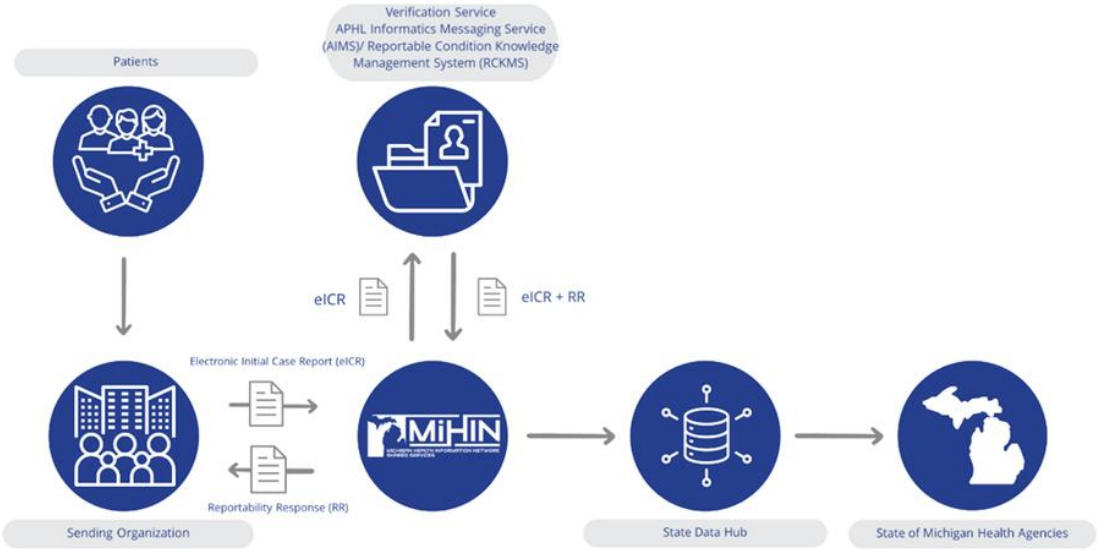
FHIR-based eCR follows the HL7 FHIR Implementation Guide for Electronic Case Reporting (eCR) – US Realm, leveraging US Core and United States Core Data for Interoperability (USCDI) aligned resources to represent patient, encounter, condition, observation, and related clinical information. FHIR-based eCR supports public health surveillance, case investigation, and response activities while providing a flexible, API-based foundation aligned with national

interoperability direction. No changes to required segments, data elements, or field usage are introduced because of the HTI-5 proposed rule at this time.

1.3 Data Flow

1.3.1 Functional Data Flow

The figure below illustrates the data flow involved when an EHR generates the eICR and subsequently sends it through the health provider.



Data Flow for eICR Created by EHR

1. The participating organization sends an eICR to MiHIN.
2. MiHIN sends the eICR to Association of Public Health Laboratories (APHL) Informatics Messaging Service (AIMS), where the clinical decision support service (RCKMS) determines reportability.
3. The reportability response (RR) message is created, indicating a "true" or "false" finding.
4. The AIMS platform then sends the eICR & RR to MiHIN. MiHIN only sends "true" reportable conditions to MDHHS.
5. Both true and false/non-reportable condition RRs are sent to the originating organization.

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 (UCEs) 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 visiting our portal https://mihinhelp.refined.site/portal/50

2.1.2 Technical Requirements Section

The following implementation dependencies and technical requirements must be completed for the Electronic Case Reporting (eCR) Data Exchange Solution to operate in a production environment.

2.1.2.1 Data Exchange Solution Requirements

There are no data exchange solution implementations required for data contributing organizations.

2.1.2.2 Other Requirements

EHR must have the capability to:

1. Produce an eICR,
2. Send an eICR via Direct Secure Message (DSM) and,
3. Receive a RR via Direct Secure Message and ingest it into their EHR.

2.1.2.3 Michigan Health System Testing Repository (HSTR) Registration

MDHHS has been charged with collecting and recording information on Eligible Professionals and Eligible Hospitals that test with one of the Public Health Promoting Interoperability measures for auditing purposes. This system will allow organizations to enter the required information and inform the public health system of your request to test for Promoting Interoperability, MIPS, and Meaningful Use (MU). For organizations to register their intent to submit eCR data to MDHHS, organizations will need to log into HSTR (https://mimu.michiganhealthit.org/) and check the box next to Michigan Disease Surveillance System – Electronic Case Reporting (MDSS-eCR).

On the HSTR site, organizations will verify that their hospital sites and physician practice sites are entered with the OID and Facility NPI. The sites may already be present; however, the identification used for the eiCR may be different than what is for electronic lab reporting or disease surveillance, syndromic reporting, etc.

For additional questions related to HSTR, please visit:
https://mimu.michiganhealthit.org/Support

2.2 eCR Onboarding Process

2.2.1 Prerequisites

- Register intent to report electronic case reporting (eCR) to MDHHS in HSTR.
- Complete initial data quality validation with the Centers for Disease Control and Prevention (CDC).
- Receive CDC approval to enter soft go-live Public Health Agency (PHA) Validation.

2.2.2 MiHIN Engagement and Legal Onboarding

- Express interest in the eCR data exchange solution by contacting MiHIN's Help Desk. https://mihinhelp.refined.site/portal/50
- Meet with MiHIN staff to:

    - Review business needs
    - Discuss the data exchange solution
    - Complete required legal onboarding
- Upon completion of legal onboarding, MiHIN's onboarding team will initiate the technical onboarding process.

2.2.3 Technical Onboarding Activities

- At a high level, the following activities will occur during technical onboarding:
- Conduct a kickoff meeting to:
    - Review the eCR data exchange solution in detail
    - Clarify roles and responsibilities
    - Address outstanding questions
- Complete and return all required onboarding documentation.
- MiHIN, the EMR vendor, and the participating organization will:
    - Establish or confirm transport connectivity
    - Conduct message and data flow testing.

After successful connectivity to the MIHIN endpoint and data flow testing, the participating organization will enter Data Quality Assurance (DQA) with MDHHS.

- During DQA:
    - Test messages will continue to be sent to the MiHIN test DSM address.
    - Data will be routed to the MDHHS User Acceptance Testing (UAT) environment for review.
    - The participating organization will continue dual submission of messages.
- Dual submission will continue until MDHHS approves progression to Parallel Validation.
- Once Parallel Validation is complete and all message requirements are met:
    - MDHHS will notify MiHIN, the EMR vendor, and the participating organization that approval for production has been granted.
- MiHIN will then coordinate with all parties to schedule the production go-live.

2.3 Technical Connectivity Process

Currently, MiHIN supports the following transport method:

- **DSM:** Direct Secure Messaging
    - MiHIN accepts Direct Secure Messages from Health Internet Service Provider (HISPs) that have EHNAC-DTAAP (DirectTrust) accreditation. Test messages are sent to verify HISP connectivity ("ping pong"). The Message Header section in the test messages is verified for appropriate routing configuration.

- If the participating organization does not have a DSM address available, MiHIN may provision one.
  - Note: There may be a fee associated with the MiHIN-provisioned DSM address.

The following steps describe the technical onboarding process. However, MiHIN typically conducts "onboarding kickoff" meeting with new participating organizations to properly review each onboarding step in detail and address any questions.

1. The organization must first register in the Michigan Health System Testing Repository (HSTR).
2. Complete initial data quality validation with the Centers for Disease Control and Prevention (CDC)
3. The participating organization provides their test and prod DSM addresses(s) or goes through the onboarding process if the participating organization is seeking MiHIN to provision a DSM address.
   a. Direct Secure Messaging: The Message Header section in the test messages is verified for appropriate routing configuration.

After connectivity is successfully established, the participating organization must send a test message to the endpoint specified in **Section 3**.

MiHIN routes the initial message to APHL Informatics Messaging Services platform (AIMS) which performs message validation.

a. Once message validation is completed, the message is returned to MiHIN with a RR and routed to the Michigan Disease Surveillance System (MDSS) via the state data hub.
b. In addition to sending test messages to the MIHIN endpoint, the organization can also send test messages directly to AIMS for verification of message structure.
   i. AIMS also provides an online tool (https://validator.aimsplatform.org/) in which your test eICRs can be run through the AIMS Online Validator (no PII should be used with this tool). This tool will help identify issues with the messages. The AIMS team can also assist with interpreting the results, and work with you to resolve any schema violations, schematron severe warnings, and schematron errors.
   ii. If the organization would like direct validation from AIMs regarding test messages, please email the AIMS team (eCR-Info@aimsplatform.org) and put "EHR Content Review" in the subject

line. In the email, include the eICR and RR XMLs labeled for each test scenario in a zip file.

c. For more comprehensive information regarding the processes mentioned above and how AIMS can assist with your implementation, please visit the following link: https://ecr.aimsplatform.org/ehr-implementers/

2. After message structure verification, MDHHS will evaluate the message specifications to ensure all message instances align with public health requirements. This review includes validation of additional constraints such as:
    - Header requirements
    - Section requirements
    - Template requirements
    - Required narrative text
    - Coded data and value sets, including but not limited to:
        - ICD-10 diagnosis codes
        - LOINC laboratory test codes
        - SNOMED CT clinical findings

MDHHS will also assess content completeness to ensure that data elements critical to public health are at least mapped, even if they are not fully populated.

Following successful testing and approval by MDHHS, MiHIN will work with the participating organization to initiate the transmission of production eCR messages.

3. Specifications

3.1 Overview

3.1.1 Environments

- MiHIN Pre-Production
- MiHIN Production

3.2 General Message Requirements

3.2.1 Submission via Direct Secure Messaging (DSM)

Consolidated Clinical Document Architecture (C-CDA) files that are sent to MiHIN via DSM as email attachments must adhere to the following specifications:

1. There can only be one CDA file attached per email when sending to MiHIN via DSM.
2. The appropriate MiHIN DSM email address must be in the "To" line. An error will occur if it is in the Carbon-Copy (Cc) line of the outgoing message.

3.2.2 Direct Addresses

Participants using DSM should use the following addresses:

- For test messages with no protected health information (PHI):
  - If using a PROD HISP account for testing
    - Diretto: ecr-foc@direct.mihin.net
  - If using a non-PROD HISP account for testing
    - ecr@direct-test.mihin.org
  - Production
    - ecr@direct.mihin.net

3.2.3 Receiving Reportability Response via Direct Secure Messaging

For eICR and RR receivers using DSM, MiHIN does not need an acknowledgment response message.

For more information on the Reportability Response, please view the update to latest release: HL7 CDA R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1.1 - US Realm located at:
http://www.HL7.org/implement/standards/product_brief.cfm?product_id=470

Response Characteristics

The exchange of eICR and RR functions differently based on the response status code returned by the server.

Status Code	Message Replay	Response Contents
None or 500	Yes	If available, the response will contain reasoning why the service failed
400	No	Used when the data cannot be handled by the receiving system, and the message should not be requeued. The response will contain reasoning why the document was rejected.
200	No	Successful response with a tracking Id

- All responses will be logged
- All responses will be in JSON (JavaScript Object Notation)
- All responses will contain a globally unique ID to track the response

A sample response body on a successful message will look like:


```
{
"trackingId": "047ee203-857c-46fb-835e-18b80bccc392"
}
```


A sample response body of an unsuccessful message will look like:


```
{
"trackingId": "32c051f3-ad91-4b77-8776-b931a9f99741",
"errors": [{
```

```
"title": "Invalid field detected",
"details": "//section/component/ssn must not be null"
}]
}
```


3.3 Specific Segment and Field Definitions

3.3.1 Message Trigger Events

Hospitals and ambulatory practices will provide the eICR document via a CDA upon discharge to MiHIN. An eICR should be sent for inpatient, ambulatory, and emergency department visits. Messages must be sent at least once, at a minimum, upon discharge. Specifications are outlined below:

- CDA must be sent in xml format.
- CDA message may be sent as an XDM.zip file. Note that this encoding occurs automatically with most HISP vendors upon sending.

3.3.2 C-CDA Required Fields

For information on the required fields, please view the HL7 CDA R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1.1 – US Realm– the Electronic Initial Case Report (eICR), located at: http://www.HL7.org/implement/standards/product_brief.cfm?product_id=436

4. 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)

5. 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.

6. Appendices

6.1 Appendix A – Message Examples

For an example of what a properly formatted message should look like for this data exchange, visit:

- https://www.HL7.org/implement/standards/product_brief.cfm?product_id=436
- https://www.HL7.org/fhir/us/ecr/2.1.2/MessageHeader-messageheader-ecr-requested-eicr.html

6.2 Appendix B – External Information

More complete information on the above processes and how AIMS can support your implementation can be found here: https://ecr.aimsplatform.org/ehr-implementers/