Statewide Lab Orders-Results

Implementation Guide

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Document History

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Acronyms and Abbreviations Guide

ACRS®	Active Care Relationship Service®
CCD®	Continuity of Care Document
CDA®	Clinical Document Architecture
C-CDA	Consolidated Clinical Document Architecture
DQA	Data Quality Assurance
DSM	Direct Secure Messaging
EHR	Electronic Health Record
HIN	Health Information Network
HL7	Health Level Seven
LIS	Laboratory Information System
MDHHS	Michigan Department of Health and Human Services
MDSS	Michigan Disease Surveillance System
MiHIN	Michigan Health Information Network Shared Services
MUCA	Master Use Case Agreement
NwHIN	Nationwide Health Information Network
PO	Participating Organization
TDSO	Trusted Data Sharing Organization
UCA	Use Case Agreement
UCS	Use Case Summary
VPN	Virtual Private Network
XCA	Cross Community Access
XML	Extensible Markup Language

Definitions

Attribution. The connection between a consumer and their health care providers. One definition of attribution is "assigning a provider or providers, who will be held accountable for a member based on an analysis of that member's claim data." The attributed provider is deemed responsible for the patient's cost and quality of care, regardless of which providers actually deliver the service.

Active Care Relationship(ACR). (a) For health providers, a patient who has been seen by a provider within the past 24 months, or is considered part of the health provider's active patient population they are responsible for managing, unless notice of termination of that treatment relationship has been provided to MiHIN; (b) for payers, an eligible member of a health plan;(c) an active relationship between a patient and a health provider for the purpose of treatment, payment and/or healthcare operations consistent with the requirements set forth in HIPAA; (d) a relationship with a health provider asserted by a consumer and approved by the health provider; or (e) any person or TDSO authorized to receive message content under an exhibit which specifies that an ACR may be generated by sending or receiving message content under that exhibit. ACR records are stored by MiHIN in the ACRS.

Active Care Relationship Service (ACRS). The MiHIN infrastructure service that contains records for those TDSOs, their participating organizations participants or any health providers who have an active care relationship with a patient.

Applicable Laws and Standards. In addition to the definition set forth in the Data Sharing Agreement, 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.

Data Sharing Agreement. Any data sharing organization agreement signed by both MiHIN and a participating organization. Data sharing organization agreements include but are not limited to: Qualified Data Sharing Organization Agreement, Virtual Qualified Data Sharing Organization Agreement, Consumer Qualified Data Sharing Agreement, Sponsored Shared Organization Agreement, State Sponsored Sharing Organization Agreement, Direct Data Sharing Organization Agreement, Simple Data Sharing Organization Agreement, or other data sharing organization agreements developed by MiHIN.

Electronic Address. A string that identifies the transport protocol and end point address for communicating electronically with a recipient. A recipient may be a person, organization or other entity that has designated the electronic address as the point at which it will receive electronic messages. Examples of an electronic address include a secure email address (Direct via secure SMTP) or secure URL (SOAP / XDR / REST / FHIR). Communication with an electronic address may require a digital certificate or participation in a trust bundle.

Electronic CQM (eCQM). CQMs that are specified in a standard electronic format and are designed to use data from Health IT systems for measurement.

Electronic Medical Record or Electronic Health Record (EMR/EHR). A digital version of a patient's paper medical chart.

Electronic Service Information (ESI). All information reasonably necessary to define an electronic destination's ability to receive and use a specific type of information (e.g, discharge summary, patient summary, laboratory report, query for patient/provider/healthcare data). ESI may include the type of information (e.g. patient summary or query), the destination's electronic address, the messaging framework supported (e.g., SMTP, HTTP/SOAP, XDR, REST, FHIR), security information supported or required (e.g., digital certificate) and specific payload definitions (e.g., CCD C32 V2.5). In addition, ESI may include labels that help identify the type of recipient (e.g., medical records department).

End Point. An instance of an electronic address or ESI.

Exhibit. Collectively, a use case exhibit or a pilot activity exhibit.

Health Directory. The statewide shared service established by MiHIN that contains contact information on health providers, electronic addresses, end points, and ESI, as a resource for authorized users to obtain contact information and to securely exchange health information.

Health Level 7 (HL7). An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven organization and approved by the American National Standards Institute (ANSI). HL7 provides a method for disparate systems to communicate clinical and administrative information in a normalized format with acknowledgement of receipt

Health Information. Any information, including genetic information, whether oral or recorded in any form or medium, that (a) is created or received by a health provider, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and (b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health Information Network (HIN). An organization or group of organizations responsible for coordinating the exchange of protected health information (PHI) in a region, state, or nationally.

Health Provider means facilities/hospitals, health professionals, health plans, caregivers, pharmacists/other qualified professionals, or any other person or organization involved in providing healthcare.

Information Source. Any organization that provides information that is added to a MiHIN infrastructure service.

Master Use Case Agreement (MUCA). Legal document covering expected rules of engagement across all use cases. Trusted data sharing organizations sign master use case agreement one time, then sign use case exhibits for participation in specific use cases.

Message. A mechanism for exchanging message content between the participating organization to MiHIN services, including query and retrieve.

Message Content. Information, as further defined in an Exhibit, which is sent, received, found or used by a participating organization to or from MiHIN services. Message content includes the message content header.

Message Header ("MSH") or Message Content Header. The MSH segment present in every HL7 message type that defines the Message's source, purpose, destination, and certain syntax specifics such as delimiters (separator characters) and character sets. It is always the first segment in the HL7 message, with the only exception being HL7 batch messages.

Michigan Health Information Network Shared Services. The MiHIN for the State of Michigan.

MiHIN Infrastructure Service. Certain services that are shared by numerous use cases. MiHIN infrastructure services include, but are not limited to, Active Care Relationship Service (ACRS), Health Directory, Statewide Consumer Directory (SCD), and the Medical Information DIrect GATEway (MIDIGATE®).

MiHIN Services. The MiHIN infrastructure services and additional services and functionality provided by MiHIN allowing the participating organizations to send, receive, find, or use information to or from MiHIN as further set forth in an exhibit.

Negative Acknowledgment (NAK or NACK). "Not acknowledged" and is used to negatively acknowledge or to reject previously received message content or to indicate some kind of error.

Notice. A message transmission that is not message content and which may include an acknowledgement of receipt or error response, such as an ACK or NACK.

Patient Data. Any data about a patient or a consumer that is electronically filed in a participating organization or participating organization participant's systems or repositories. The data may contain protected health information (PHI), personal credit information (PCI), and/or personally identifiable information (PII).

Person Record. Any record in a MiHIN infrastructure service that primarily relates to a person.

Principal. A person or a system utilizing a federated identity through a federated organization.

Provider Community. A healthcare provider with an active care relationship with the applicable patient.

Query for Documents Message. A message specific to the Query for Documents Web Services Interface Specification that references the Integrating the Healthcare Enterprise's Cross-Community Access specification.

Service Interruption. A party is unable to send, receive or find message content for any reason, including the failure of network equipment or software, scheduled or unscheduled maintenance, general Internet outages, and events of force majeure.

Transactional Basis. The transmission of message content or a notice within a period of time of receiving message content or notice from a sending or receiving party as may be further set forth in a specific exhibit.

Transitions of Care. The movement of a patient from one setting of care (e.g. hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, rehabilitation facility) to another setting of care and can include transfers within a healthcare organization.

Trusted Data Sharing Organization (TDSO). An organization that has signed any form of agreement with MiHIN for data sharing.

Use Case. (a) A use case agreement previously executed by a participating organization; or (b) the use case summary, use case exhibit and a use case implementation guide that participating organization or TDSO must follow to share specific message content with the MiHIN.

Use Case Exhibit. The legal agreement attached as an exhibit to the master use case agreement that governs participation in any specific use case.

Use Case Implementation Guide (UCIG). The document providing technical specifications related to message content and transport of message content between participating organization, MiHIN, and other TDSOs. use case implementation guides are made available via URLs in exhibits.

Use Case Summary. The document providing the executive summary, business justification and value proposition of a use case. Use case summaries are provided by MiHIN upon request and via the MiHIN website at www.mihin.org.

1. Introduction

1.1 Purpose of Use Case

> *The Statewide Lab Orders-Results use case supports provider workflow improvements by helping to send, find, receive and use lab results for tests performed at the point of care.*

Clinical lab results can be used in primary care provider offices as well as health departments. Doctors, laboratories, and other healthcare professionals have a critical need to easily send and find clinical lab results to help with clinical decision support, trending analyses, population health management, medication management, and numerous other care activities.

The coordination of lab results across organizations can be very challenging and have a negative impact on healthcare costs as well as patient care. Lab results must be presented in a timely manner and in a usable, actionable format so recipients can deliver efficient and effective patient care.

An electronic, statewide exchange of lab results through an interconnected network of trusted data-sharing organizations (TDSOs) can help improve the quality, efficiency, and cost of healthcare.

The Statewide Lab Orders-Results use case helps participating organizations electronically send and receive lab results via the statewide health information network (HIN) overseen by the Michigan Health Information Network Shared Services (MiHIN). Test results can be routed to all who require them, from public health agencies to healthcare providers, and other healthcare organizations.

The intended audience for this use case include all laboratories, hospitals, ambulatory clinics, health departments, physician offices, and medical practices that want to route electronic laboratory test results to healthcare providers.

1.2 Message Content

For this use case, message content could be in one of the following two message formats.

- HL7 2.x ORU^R01
- Continuity of Care Document (CCD) format

1.3 Data Flow and Actors

Multiple actors can participate in this use case, each with a specific role in the process.

- **Actor:** Sending organization (hospital lab, commercial lab, state lab)
- **Role:** Completes laboratory order and sends message containing results to MiHIN.

- **Actor:** Sending organization (healthcare provider)
- **Role:** Performs point-of-care testing and enters reportable results into an electronic health record (EHR). The lab result message is then sent from the EHR to MiHIN for routing.

- **Actor:** Routing organization
- **Role:** Receives laboratory result message from sending organization and routes it to MiHIN based on instructions in the message.

- **Actor:** MIHIN
- **Role:** Receives lab result message from sending organization and routes the message to the receiving organization(s) as indicated by the Active Care Relationship Service® (ACRS®).

- **Actor:** Routing organization
- **Role:** Receives laboratory results message from MiHIN and routes it to the receiving organization based on the instructions in the message.

- **Actor:** Receiving organization (healthcare provider)
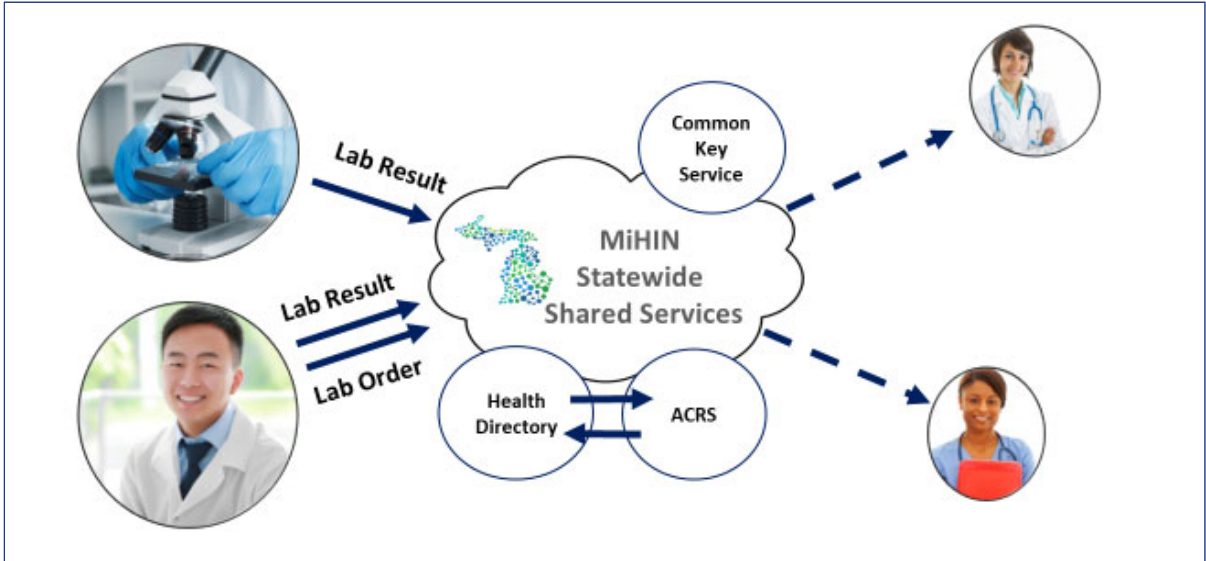- **Role:** Receives laboratory results routed from MiHIN and uses information for patient care.

Figure 1. Data Flow for Statewide Lab Orders-Results

1. A physician orders a test on a patient.
2. The testing facility obtains the sample for testing.

3. The lab processes the lab and produces a result.
4. The testing facility forwards the results back to the provider organization.
5. The provider organization send the results to MiHIN.
6. Using the Active Care Relationship Service, Common Key Service and Health Directory, the lab result is matched to the patient's electronic health record and can simultaneously be sent to any other of the patient's care team members (dotted lines above).

1.3.1 Additional Information

For more information about this use case, all documents related to this use case can be found at:

https://mihin.org/statewide-lab-orders-results/

2 Standard Overview

2.1 Message Format

MiHIN supports HL7 2.x messaging standards. For sending lab results, HL7 v2.5.1 or newer version is preferred, however v2.3.1 is allowable.

2.2.1 HL7 2.x Reportable Lab Result Message Example

Below is an HL7 2.X Statewide Lab message example for blood lead results.[1]

> MSH|^~\&||MediLabCo-Seattle^45D0470381^CLIA|WADOH|WA|200112171830|
> |ORU^R01|200112170897|P|2.3.1
> PID|1||10006579^^^1^MRN^1~==afeuwdsvolwrdzu6dufn3ivbn4ixnl7uptbyxur7==^^^^C
> KS ||FRANKLIN^TRICIA^L||19860122|F|||770 SE PECAN
> STREET^^PONTIAC^MI^48341||839-555-9557|118-555-5271|||||000-00-1103|
> <hex 0D0A>
> NK1|1|Doe^Jane^Lee^^^^L|MTH^Mother^HL70063|2166 Wells Dr^Apt
> B^Seattle^WA^98109^ USA^M^^King^^A|^PRN^PH^^^206^6793240|<hex 0D0A>
>
> ORC||||||||||||||||||||||||MediLabCo - Northwest Pathology Ltd., Central
> Campus^^45D0470381^^^CLIA|2217 Rainier Way^^Renton^WA^98002^USA^M^^Black
> Hawk^A|^WPN^PH^helpline@medilab.com^^206^5549097|115 Pike Plaza^Suite
> 2100^Seattle^WA^98122^USA^^^^A|<hex0D0A>
> OBR|1||CHEM9700122|^^^3456543^Blood lead test^L|||200111270930||||||||BLDC^Blood
> capillary
> |^Welby^M^J^Jr^Dr^MD|^WPN^PH^^^206^4884144|||||||||F <hex 0D0A>
> OBX||SN|10368-9^Quantitative Blood Lead^LN||^45|µg/dL|||||F|||200111300800|
> 45D0480381<hex0D0A>

==*Green-highlighted area above is common key insertion area if your organization is participating in the Common Key Service.==

2.2.2 HL7 2.5.1 Reportable Lab Result Message Example

Below is an HL7 2.5.1 Statewide Lab message example for reportable lab results.[2]

MSH|^~\&|Lab1^1234^CLIA|^1234^CLIA|ELR^2.16.840.1.113883.19.3.2^ISO|SPH^2.16.840.1.113883.19.3.2^ISO|20080818183002.1-0700||ORU^R01^ORU_R01|1234567890|P^T|2.5.1|||NE|NE|USA||||USELR1.0^^2.16.840.1.114222.4.10.3^ISO

SFT|1|Level Seven Healthcare Software, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1.2|An Lab System|56734||20080817

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[1] *Implementation Guide for Transmission of Laboratory-Based Reporting using HL7 2.3.1,* Centers for Disease Control (2005), 68.

[2] *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm),* HL7 (2010), 193-229.

PID|1||10006579^^^1^MRN^1~afeuwdsvolwrdzu6dufn3ivbn4ixnl7uptbyxur7^^^^CKS
||FRANKLIN^TRICIA^L||19860122|F|||770 SE PECAN
STREET^^PONTIAC^MI^48341||839-555-9557|118-555-5271|||||000-00-1103|

PV1|1|O|4E^234^A^Good Health
Hospital&2.16.840.1.113883.19.3.2.3&ISO^N^N^Building 1^4^Nursing unit 4
East^1234&&2.16.840.1.113883.19.3.2.3&ISO^&2.16.840.1.113883.19.3.2.3&ISO|R||||||||||
||||||||||||||||||||||||||||200808151000-0700|200808151200-0700

PV2|||1^Sick^99AdmitReason|||||||||||||N|||||||||Level Seven Healthcare,
Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|||20010603|||19990603

ORC|RE|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.1
9.3.1.6^ISO|||||||||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^EI
^&2.16.840.1.113883.19.4.6^ISO^^^^^^^MD||^WPN^PH^^1^555^5551005|||||||Level
Seven Healthcare, Inc.^L^^^^&2.16.840.1.113883.19.4.6^ISO^XX^^^1234|1005
Healthcare Drive^^Ann Arbor^MI^99999^USA^B|^WPN^PH^^1^555^5553001|4444
Healthcare Drive^Suite 123^Ann Arbor^MI^99999^USA^B

OBR|1|23456^EHR^2.16.840.1.113883.19.3.2.3^ISO|9700123^Lab^2.16.840.1.113883.19.
3.1.6^ISO|625-4^Bacteria identified^LN^3456543^ CULTURE,
STOOL^99USI^2.26|||200808151030-
0700||||||diarrhea|||1234^Admit^Alan^A^III^Dr^^^&2.16.840.1.113883.19.4.6^ISO^L^^^
EI^&2.16.840.1.113883.19.4.6^ISO^^^^^^^MD|^WPN^PH^^1^555^5551005|||||200808
1830-
0700|||F|||||||787.91^DIARRHEA^I9CDX^^^^07/09/2008|1235&Slide&Stan&S&&Dr&MD
&&DOC&2.16.840.1.113883.19.4.6&ISO

OBX|1|CWE|625-4^Bacteria
identified:Prid:Pt:Stool:Nom:Culture^LN^^^^2.26|1|66543000^Campylobacter
jejuni^SCT^^^^January 2007||||||P|||200906041458|||0086^Bacterial
identification^OBSMETHOD^^^^501-20080815||200906051700||||GHH
Lab^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434 Industrial Loop^^Ann
Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.840.1.113883.19.4.6
&ISO^L^^^NPI

SPM|1|23456&EHR&2.16.840.1.113883.19.3.2.3&ISO^9700122&Lab&2.16.840.1.113883.
19.3.1.6&ISO||119339001^Stool
specimen^SCT^^^^20080131|||||||P^Patient^HL60369^^^^2.5.1|10^g&gram&UCUM&&&
&1.6|||||200808151030-0700|200808151100-0700

2.3 Administrative and Technical Requirements

All participating organizations intending to send, receive, find or use electronic lab results via MiHIN must:

1. Execute the MiHIN Master Use Case Agreement and Statewide Lab Orders-Results Use Case Exhibit.
2. Utilize an EHR or Laboratory Information System (LIS) that can report lab results electronically. The preferred format for sending results to MIHIN is HL7 v2.5.1 or v2.X, however some EHR systems may not be able to generate an outbound HL7 result message "out of the box."
3. Establish electronic connectivity with MiHIN via a supported transport protocol.

The required legal agreements are available by contacting legal@mihin.org.

2.4 Configuration Steps

Lab result messages routing to MiHIN require three independent process configurations:

1. Create EHR message
2. Construct HL7 message format
3. Transport message

This implementation guide assumes that the LIS or EHR message production process has already been implemented, and contains instructions and specifications for construction and transport of the message.

2.5 Information for Laboratories

Laboratories wishing to utilize MiHIN to route test results to their final destination need to set up and implement an outbound HL7 data feed from their LIS using HL7 v2.x ORU format. Laboratories should contact their LIS system vendor if this interface is not already implemented.

2.6 Information for Electronic Health Record System Users

Healthcare providers wishing to send electronic test results from their EHR through MiHIN should inquire with their EHR vendor whether this can be accomplished via HL7 messaging, and if not, what other options are supported.

The only additional option described in this document is to use Direct Secure Messaging to send a message with a CCD attachment containing structured results that have been captured in the EHR.

In this additional option, when required, MiHIN will transform results from the structured CCD attachment into HL7 messages, version 2 format prior to routing them.

2.7 Information for Health Information Exchanges

Health information exchanges will need to work with their integration vendor to ensure they can receive and send HL7 2.x ORU messages.

3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data via MiHIN under this use case, the organization will need to undergo two onboarding processes simultaneously. The two onboarding processes are legal onboarding and technical connectivity onboarding. These may occur in parallel – i.e. the organization can review and complete legal agreements with MiHIN while simultaneously establishing and testing technical connectivity.

To initiate these two parallel onboarding processes, notify MiHIN via http://mihin.org/requesthelp/.

3.1.1 Initial Legal Process

The first time an organization undergoes the legal onboarding process with MiHIN, the organization negotiates and enters into a data sharing agreement which then allows the Participating Organization (PO)to enter into one or more use cases via Use Case Exhibits (UCEs) or Pilot Activity Exhibits (PAEs).

Once an organization has entered into a data sharing agreement, the organization must sign the Master Use Case Agreement (MUCA) which then allows the PO to enter an unlimited number of UCEs or PAEs with MiHIN. A listing MiHIN's use cases are available upon request.

3.1.2 Initial Technical Connectivity Process

MiHIN considers itself "transport agnostic" and offers multiple options for organizations to establish technical connectivity to transport data to MiHIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities, and put in a service request at www.mihin.org/requesthelp. Currently MiHIN accepts the following transport methods:

- LLP over IPsec VPN – Lower-Layer Protocol over Internet Protocol Security Virtual Private Network
- DSM – Direct Secure Messaging

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

Additional transport methods may be added in the future. These can include NwHIN, XCA, REST/RESTFUL APIs, FHIR, and others.

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

1. The organization selects one or more supported transport methods and establishes connectivity with MiHIN. This step varies based on the method selected:

a. **LLP over 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. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.
b. **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.

4 Specifications

4.1 Communication Setup

This implementation guide assumes that a secure connection between MiHIN and an organization has been established. Organizations should confirm this with their network administrator.

4.2 Laboratory Test Result HL7 Message Production

An ORU^R01 message formatted to HL7 v2.x is generated by an LIS or by an interface engine when new results are posted. Each HL7 message sent by MiHIN will conform to the standard HL7 2.x ORU definitions (HL7 v2.X).

4.3 Options for Laboratory Systems

The LIS should have the functionality to generate the HL7 ORU^R01 message. Hospital LIS applications may already be sending result interface messages to a central hub or interface engine used at a hospital.

If this is the case, please discuss these implementation guidelines with your IT Department, and involve them in generating and testing the data feed to MiHIN from that hub or engine.

4.4 Message Segment/Field Dynamic Definition

The following guidelines describe the way in which segment and field requirements apply to correctly formatted messages.

4.4.1 Segment Usage Requirements for Sending Organization

Correctly formatted messages (ORU) will adhere to the following usage requirements for message segments:

- Segments with usage code R will always be sent.
- Segments with usage code C will be sent conditionally, based upon fulfillment of the condition contained in the "Comments" column.
- Segments with usage code RE will be sent if information corresponding to the segment definition exists on the sending system.
- Segments with usage code CE will be sent conditionally, based upon fulfillment of the condition contained in the "Comments" column, if information corresponding to the segment definition exists on the sending system.
- Segments with usage code X, or whose segment ID does not appear in the static definition corresponding to the trigger event of the message, will be ignored.

4.4.2 Segment Cardinality Requirements for Sending Organization

Correctly formatted messages sent by organizations will adhere to the following cardinality requirements for message segments:

- No fewer occurrences of each segment will be sent than the number indicated by the minimum cardinality of the segment in the message-level static definition corresponding to the trigger event of the message.
- Occurrences of each segment exceeding the number indicated by the maximum cardinality of the segment in the message-level static definition corresponding to the trigger event of the message will be ignored.

4.4.3 Field and Subfield Requirements for Sending Organization

An ORU^R01 message formatted to HL7 v2.x is generated by an LIS or by an interface engine when new results are posted. Each HL7 message sent by MiHIN will conform to the standard HL7 2.x ORU definitions (HL7 v2.X).

4.4.3.1 Field and Subfield Usage Requirements for Sending TDSO

Correctly formatted messages sent by organizations will adhere to the following usage requirements for message fields, components, and subcomponents:

- Fields and subfields with usage code R will always be sent.
- Fields and subfields with usage code C will be sent conditionally, based upon fulfillment of the condition contained in the "Comments" column.
- Fields and subfields with usage code RE will be sent if information corresponding to the field or subfield definition exists on the sending system.
- Fields and subfields with usage code CE will be sent conditionally, based upon fulfillment of the condition contained in the "Comments" column, if information corresponding to the field or subfield definition exists on the sending system.
- Fields and subfields with usage code X, or whose field or subfield sequence number does not appear in the static definition of the field or subfield, will be ignored.

4.4.3.2 Field and Subfield Cardinality Requirements for Sending TDSO

Correctly formatted messages sent by organizations will adhere to the following cardinality requirements for message fields, components, and subcomponents:

- No fewer occurrences of each field or subfield will be sent than the number indicated by the minimum cardinality of the field in the static definition of the segment in which the field or subfield occurs.
- Occurrences of each field or subfield above the number indicated by the maximum cardinality of the field or subfield in the static definition of the segment in which the field or subfield occurs will be ignored.

4.4.4 Acknowledgement Message Requirements for Receiving TDSO

For each message received, a receiving organization will return an HL7 acknowledgment message formatted according to the requirements within this document.

An ERR segment will be returned for each usage and cardinality error recorded as a result of applying the rules in this section.

For a description on the format and structure of the HL7 2.X ORU Message, please visit HL7.org.

5 Troubleshooting

5.1 Production Support

	Severity Levels			
	1	*2*	*3*	*4*
Description	***Critical Impact/ System Down:*** Business critical software is down or critical interface has failed. The issue is impacting all production systems, causing all participating organizations' or other organizations' ability to function to be unusable.	***Significant Business Impact:*** Software component severely restricted. Entire organization is unable to continue business functions, causing all communications and transfer of messages to be halted.	**Partial Failure or Downtime:** Program is useable and less significant features unavailable. The service is online, though may not working as intended or may not currently working as intended or may not currently be accessible, though other systems are currently available.	**Minimal Business:** A non-critical software component is malfunctioning, causing minimal impact, or a test system is down.
Example	All messages to and from MiHIN are unable to be sent and received, let alone tracked	MiHIN cannot communication (send or receive) messages between single or multiple participating organizations, but can still successfully communicate with other organizations.	Messages are lost in transit; messages can be received but not sent.	Additional feature requested.
Primary Initiation Method	***Phone:*** (517) 336-1430	***Phone:*** (517) 336-1430	Web form at http://mihin.org/ requesthelp	Web form at http://mihin.org/ requesthelp
Secondary Initiation Method	Web form at http://mihin.org/ requesthelp	Web form at http://mihin.org/ requesthelp	Email to help@mihin.org	Email to help@mihin.org
Tertiary Initiation Method	Email to help@mihin.org	Email to help@mihin.org	N/A	N/A
Initial Response	Within 2 hours	Within 2 hours	1 business day	1 business day
Resolution Goal	24 hours	24 hours	3 business days	7 business days

A list of common questions regarding the Statewide Lab Orders-Results Use Case can be found at:

https://mihin.org/statewide-lab-orders-results/

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

- www.mihin.org/requesthelp
- Phone: (517) 336-1430
- Monday – Friday 8:00 AM – 5:00 PM (Eastern)

6 Legal Advisory Language

This reminder applies to all UCEs or PAEs covering the exchange of electronic health information:

The data sharing agreement establishes the legal framework under which PO can exchange messages through the HIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

a. By health care providers for Treatment, Payment and/or Health Care Operations consistent with the requirements set forth in HIPAA;
b. Public health activities and reporting as permitted by HIPAA and other Applicable Laws and Standards;
c. To facilitate the implementation of "meaningful use" criteria as specified in the American Recovery and Reinvestment Act of 2009 and as permitted by HIPAA;
d. 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;
e. 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; and
f. **For any additional purposes as specified in any UCE or PAE, provided that such purposes are consistent with Applicable Laws and Standards**.

Under these agreements, "*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 agency, including the State of Michigan, or the Michigan Health Information Technology Commission 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 which is enforceable against a Party. Without limiting the generality of the foregoing, "Applicable Laws and Standards" includes 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 PO'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 UCE is directed to the exchange of physical health information that may be exchanged without patient authorization under HIPAA, the PO 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 will apply 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.