

# Imaging Implementation Guide

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# **Table of Contents**

Acronyms and Abbreviations Guide1
Definitions2
1. Introduction71.1 Purpose of Use Case71.2 Message Content71.3 Data Flow and Actors71.3.1 Additional Information8
<ul> <li>2 Standard Overview</li></ul>
2.3 Administrative and Technical Requirements82.4 Configuration Steps92.5 Information for Laboratories92.6 Information for Electronic Health Record System Users102.7 Information for Health Information Exchanges10
3 Onboarding Process       10         3.1 Initial Onboarding       10         3.1.1 Initial Legal Process       10         3.1.2 Initial Technical Connectivity Process       Error! Bookmark not defined.
<ul> <li>4 Specifications</li></ul>
5 Troubleshooting



6 Legal Advisory Language 1	12
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# **Acronyms and Abbreviations Guide**

A CIZ			
ACK	Acknowledgement		
ACRS®	Active Care		
	Relationship Service®		
CCD®	Continuity of Care		
	Document®		
<b>CDA</b> <sup>®</sup>	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		
LR	Longitudinal Record		
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		
РО	Participating		
	Organization		
TDSO	Trusted Data Sharing		
	Organization		
UCA	Use Case Agreement		
UCS	Use Case Summary		
VPN	Virtual Private Network		
XCA	Cross Community		
лип	Access		
	11((5))		

XML	Extensible Markup	
	Language	



### Definitions

- **Acknowledge (ACK).** An acknowledgement (ACK) is a signal that is passed between communicating processes, computers, or devices to signify acknowledgement, or receipt of message, as part of a communications protocol.
- 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 Michigan Health Information Network Shared Services (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 Health Insurance Portability and Accountability Act (HIPAA); (d) a relationship with a health provider asserted by a consumer and approved by the health provider; or (e) any person or Trusted Data Sharing Organization 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 Active Care Relationship Service<sup>®</sup> (ACRS<sup>®</sup>).
- Active Care Relationship Service<sup>®</sup> (ACRS<sup>®</sup>). The Michigan Health Information Network Shared Services infrastructure service that contains records for those Trusted Data Sharing Organizations, 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.
- **Attribution**. The connection between a consumer and their healthcare 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 deliver the service.
- **Data Sharing Agreement.** Any data sharing organization agreement signed by both Michigan Health Information Network Shared Services (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.



- **Data Validity Questionnaire.** A data integrity check questionnaire to ensure matching of corresponding imaging studies.
- **DICOM QRU** is Digital Imaging and Communications in Medicine, Query and Retrieve. It is the international standard to transmit, store, retrieve, print, process, and display medical imaging information.
- **eHealth Gateways** are configured as hardware appliances and reside on the customer's network connected to the PACS using standard DICOM QRU.
- **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 Simple Mail Transfer Protocol (STMP)) or secure Uniform Resource Locator (URL) (SOAP/XDR/REST/FHIR). Communication with an electronic address may require a digital certificate or participation in a trust bundle.
- **Electronic CQM (eCQM).** Clinical Quality Measures (CQM) that are specified in a standard electronic format and are designed to use data from Health information technology (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 Electronic Service Information (ESI).
- Exhibit. Collectively, a use case exhibit or a pilot activity exhibit.
- **Health Directory**. The statewide shared service established by Michigan Health Information Network Shared Services (MiHIN) that contains contact information on health providers, electronic addresses, end points, and Electronic Service Information (ESI), as a resource for authorized users to obtain contact information and to securely exchange health information.
- **Health Level Seven® (HL7®)**. An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven (HL7) 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 healthcare to an individual; or the past, present, or future payment for the provision of healthcare 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.
- **Imaging** means high resolution images are available for viewing at the point of care without the need for additional storage and can be downloaded to a PO's PACS.
- **Information Source**. Any organization that provides information that is added to a Michigan Health Information Network Shared Services (MiHIN) infrastructure service.
- **Longitudinal Record**. A single comprehensive patient record comprised of message content from PO and/or TDSOs.
- **Master Use Case Agreement (MUCA).** Legal document covering expected rules of engagement across all use cases. Trusted Data Sharing Organizations (TDSOs) 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 Michigan Health Information Network Shared Services (MiHIN), 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 Michigan Health Information Network Shared Services (MiHIN). Message content includes the message content header.
- Message Header ("MSH") or Message Content Header. The Message Header (MSH) segment present in every Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) 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 health information network (HIN) 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<sup>®</sup> (ACRS<sup>®</sup>), Health Directory (HD), Statewide Consumer Directory (SCD), and the Medical Information Direct Gateway (MIDIGATE<sup>®</sup>).
- **MiHIN Services**. The Michigan Health Information Network Shared Services (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 "acknowledged" ACK or "not acknowledged" NACK.
- **PACS**. Picture archiving and communication system (PACS) is a modality of imaging technology which helps in image transmission from the site of image acquisition to multiple physically disparate locations. This technology not only is economical (film-less department), but also convenient to access multiple modalities (radiographs, CT, MR, ultrasound etc.).
- **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 Michigan Health Information Network Shared Services (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 (ACR) 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.
- **Site Survey Questionnaire.** A document your organization completes to provide information needed establish a connection with your PACS.



- **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 Michigan Health Information Network Shared Services 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 Trusted Data Sharing Organization must follow to share specific message content with Michigan Health Information Network Shared Services.
- **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, Michigan Health Information Network Shared Services, and other Trusted Data Sharing Organizations. 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 Michigan Health Information Network Shared Services (MiHIN) upon request and via the MiHIN website at <u>www.mihin.org</u>.



# **1. Introduction**

#### 1.1 Purpose of Use Case

The Imaging use case supports provider workflow improvements by providing access to a patient's images in a central location. Images shared can help improve the quality, efficiency, and cost of healthcare.

Coordination of care across the healthcare continuum can be very challenging and can have a negative impact on healthcare costs as well as patient care if data is unavailable. This is especially true for radiology imaging because duplicating certain radiology studies will expose patients to unnecessary doses of radiation and should be avoided, whenever possible.

These images are gathered from disparate sources and available in a single patient record. These images are also available to download to a participating organization's Picture Archiving and Communication System (PACS). This feature presents data in a timely manner and in a usable, actionable format so recipients can deliver efficient and effective patient care.

This use case leverages the image view based on a radiology report and historical source system images from the organization's PACS. This feature offers high resolution images available for viewing at the point of care without the need for additional storage.

The intended audience for this use case includes organizations that allow viewing and/or download to PACS of electronic radiology images to healthcare entities. These may include but are not limited to hospitals, ambulatory clinics, health departments, physician offices, and medical practices.

#### 1.2 Message Content

Participation in the LR Use Case is a prerequisite for participation in the Imaging Use Case. Message delivery and content is covered during LR Use Case onboarding. No additional messages are required for participation in the Imaging Use Case

#### 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, diagnostic radiology center)
- **Role:** Makes image available to the HIN.
- Actor: Receiving organization
- **Role:** accesses image through the HIN.





Figure 1. Data Flow for Imaging Use Case

- 1. The PO/DF makes radiology results available to HIN
- 2. HIN presents list of available images
- 3. PO/DF views and/or downloads images through HIN
- 4. PO views images through HIN

#### 1.3.1 Additional Information

For more information about this use case, all documents related to this use case can be found at <a href="https://mihin.org/imaging-use-case/">https://mihin.org/imaging-use-case/</a>

### **2 Standard Overview**

#### 2.1 Administrative and Technical Requirements

All participating organizations intending to participate in this use case must:

1. Execute the MiHIN Master Use Case Agreement and are required to onboard to the following use cases: Health Directory, Active Care Relationship Service, Common Key Service, and Radiology Document Delivery. (The Radiology Document Delivery use case is a prerequisite to sharing images via the Imaging Use Case.)

The required legal agreements are available by contacting <u>legal@mihin.org</u>. 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.



### 2.2 Configuration Steps

Imaging made available to the HIN for viewing and/or download will require:

- 1. An *eHealth Gateway* will need to be configured and installed at your facility for managing the image access and workflow with your PACS or image archive using standard DICOM QRU.
- 2. With the assistance of the facility's network team, the configuration of a secure VPN connection between the *eHealth Gateway* and the external data center, which will enable your imaging studies to be accessible by authorized LR users in the context of each patient's LR.
- 3. Image access is managed in accordance with the HIN's existing user authentication, consent, security and access controls.

#### 2.3 Implementation Steps

Imaging made available to the HIN for viewing and/or download will require the project team to complete the following:

1. MiHIN typically conducts "onboarding kickoff" meetings with new organizations to go through the project requirements in detail and answer any questions. Please include your Network/IT Administrator and PACS Administrator.

2. Complete Site Survey Questionnaire, which provides your organization and eHealth Technologies with the information needed establish a connection with your PACS.

3. Configure your PACS to support a new local QRU location, which will reside on the eHealth Gateway.

4. Complete a Data Validity Questionnaire, with the coordination of the MiHIN team. If there are Accession Number or MRN discrepancies between your results report feed and PACS, some corrective action may be required.

5. Rack and connect the eHealth Gateway and VPN appliance to your local network.

6. Assist the MiHIN team and your organization personnel with testing the connection to assure that the eHealth Gateway can be accessed through the VPN, imaging studies can be retrieved from your PACS, successfully cashed on the eHealth Gateway, and viewed by the HINs user community.

#### 2.4 Information for Radiology Departments

Authorized users of the LR can view imaging studies from the patient's record by launching the study of interest on eHealthViewer<sup>®</sup> ZF - a zero-footprint, web-based viewing platform that is also a fully diagnostic-quality FDA 510(k) Class II medical device.

Through the HIN, eHealth Connect® Image Exchange provides an automated solution for importing external prior imaging studies onto a local PACS. Authorized users of the LR with additional PACS authorization can initiate the transfer of imaging studies that reside on any connected external Imaging Provider PACS. These studies will be automatically reconciled prior to transfer, assuring that key image attributes in the DICOM header such as patient ID



(MRN) and accession number have been updated prior to transferring images into the destination PACS.

### 2.5 Information for Electronic Health Record System Users

Healthcare providers wishing to access images via their EHR may do so through Single Sign On(SSO). Providers should inquire with their EHR vendor whether this is supported.

#### 2.6 Information for Health Information Exchanges

N/A

### **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 <u>http://mihin.org/requesthelp/</u>.

### **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.



## **5** Troubleshooting

### **5.1 Production Support**

	Severity Levels					
	1	2	3	4		
Descripti on	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	<b>Phone:</b> 517-336-1430	Web form at https://mihin.org/request help/	Web form at https://mihin.org/request help/		
Secondar y Initiation Method	Web form at https://mihin.org/request help/	Web form at https://mihin.org/request help/	Email to <u>help@mihin.org</u>	Email to <u>help@mihin.org</u>		
Tertiary Initiation Method	Email to <u>help@mihin.org</u>	Email to <u>help@mihin.org</u>	N/A	N/A		
Initial Response	Within 2 hours	Within 2 hours	1 business day	1 business day		
Resolutio n Goal	24 hours	24 hours	3 business days	7 business days		

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

- <u>https://mihin.org/requesthelp/</u>
- Phone: 517-336-1430
- Monday Friday 8:00 AM 5:00 PM (Eastern Standard Time)



# 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 MiHIN Platform, and sets forth the following approved reasons for which messages may be exchanged:

- a. By health care providers for Treatment, Payment and/or Healthcare 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 "promoting interoperability" 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.



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