Michigan Health Information Network

Cancer Notifications

Implementation Guide

Version 23

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Acronyms and Abbreviations Guide

CCD	Continuity of Care Document
CDA	Clinical Document Architecture
DQA	Data Quality Assurance
DSM	Direct Secure Messaging
EHR	Electronic Health Record
HIN	Health Information Network
HIPAA	Health Insurance Portability and Accountability Act of 1996
HISP	Health Internet Service Provider
HL7	Health Level Seven
MDHHS	Michigan Department of Health and Human Services
MiHIN	Michigan Health Information Network Shared Services
MU	Meaningful Use
MUCA	Master Use Case Agreement
OID	Object Identifier
TDSO	Trusted Data Sharing Organization
VPN	Virtual Private Network

Definitions

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.

Caregiver. An individual such as a health professional or social worker who assists in the identification, prevention or treatment of an illness or disability.

Common Gateway. The method by which data is sent and received by HIN using different national standard protocols (e.g. NwHIN SOAP, IHE XCA, IHE XDS.b).

Conforming Message. A message that is in a standard format that strictly adheres to the implementation guide for this use case.

Data Sharing Agreement. Any data sharing organization agreement signed by both HIN and participating organization

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.

Electronic Medical Record or Electronic Health Record. A digital version of a patient's paper medical chart.

Electronic Service Information. 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).

Exhibit. A use case exhibit or a pilot activity exhibit.

Health Level 7 (HL7). An interface standard and specifications for clinical and administrative healthcare data developed by the American National Standards Institute. 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 professional, health plan, public health authority, employer, life insurer, school or university, or health care 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 Plan. An individual or group plan that provides, or pays the cost of medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)). Health Plan further includes those entities defined as a health plan under HIPAA, 45 CFR 160.103.

Health Professional or Health Provider. (a) Any individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services; (b) any person holding a non-clinical position within or associated with an organization that provides healthcare or healthcare related services; and (c) people who contribute to the gathering, recording, processing, analysis or communication of Health Information.

HIN Infrastructure Service. Certain services that are shared by numerous use cases. HIN Infrastructure Services include, but are not limited to, ACRS, HPD, Statewide Consumer Directory (SCD), and the Medical Information DIrect GATEway (MIDIGATE®).

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

Master Use Case Agreement. 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.

Meaningful Use. Using certified EHR technology to improve quality, safety and efficiency of healthcare, and to reduce health disparities.

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

Message Content. Information which is sent, received, found or used by a participating organization to or from HIN Services, including, but not limited to, PHI, common keys, de-identified data, metadata, Digital Credentials, and data schema. Message Content includes the Message Content Header.

Message 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 HIN for the State of Michigan.

Negative Acknowledgment. "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 but not be limited to an acknowledgement of receipt or error response.

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

Person Record. Any record in a HIN Infrastructure Service that primarily relates to an individual person.

Send / Receive / Find / Use. Means sending, receiving, finding, or using message content. Sending involves transport of message content. Receiving involves accepting and possibly consuming/storing message content. Finding means querying to locate message content. Using means any use of the message content other than sending, receiving and finding.

Service Interruption. A party is unable to send, receive or find message content for any reason, including but not limited to 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.

Trusted Data Sharing Organization. An organization that has signed any form of agreement with HIN for data sharing.

Use Case. A specific scenario or group of scenarios for sharing patient health information.

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. The document providing technical specifications related to Message Content and transport of Message Content between participating organizations, HIN, 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 HIN upon request and are available via www.mihin.org.

1 Introduction

1.1 Purpose of Use Case

> ***The Cancer Notifications use case scenario allows for ambulatory or eligible professionals within physician offices, hospitals, clinical laboratories, and dentist offices to electronically send cancer information to the cancer registry without interrupting normal workflow.***

Cancer is the second-leading cause of death in the United States.[1] Population-based surveillance is critical to support control activities aimed at reducing cancer morbidity and mortality.

Cancer registries throughout the United States are required to collect complete and timely cancer diagnostic, treatment, and outcome data. This data comes from healthcare providers including hospitals, physician offices, treatment centers, clinics, laboratories, and other facilities.

Sending cancer notifications to a central statewide registry:

- Allows an initial evaluation of cancer incidence within various regions
- Provides a source to baseline incidence data.
- Enables an evaluation of cancer frequency by demographic characteristics such as age, race, and sex
- Generates significant value for researchers in epidemiological case control studies

Cancer notifications are also helpful in planning health education and addressing public health concerns within regions of interest.

It is mandatory in Michigan to report cancer notifications electronically to the state cancer registry. Under the Michigan Cancer Surveillance Program, facilities that diagnose or treat a cancer patient are required to report results to the cancer registry. All hospitals, clinical laboratories, physician offices, dentists and other healthcare providers who have knowledge of a case of cancer must report the case.

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[1] "Meaningful Use of Electronic Health Records," Centers for Disease Control and Prevention, accessed April 21, 2016, http://www.cdc.gov/cancer/npcr/meaningful_use.htm

Ambulatory care and eligible professionals that send cancer data electronically meet Meaningful Use requirements for Cancer Case Reporting by communicating with a public health agency on a transactional basis.[2] [3]

1.2 Message Content

For this use case scenario, Message Content means encapsulated CDA in HL7 2.xx, ORU^R01.

1.3 Data Flow and Actors

In this use case, the health information network (HIN) enables the transport of messages across trusted data sharing organizations (TDSOs) within HIN, called "Participating Organizations" in the diagram below.
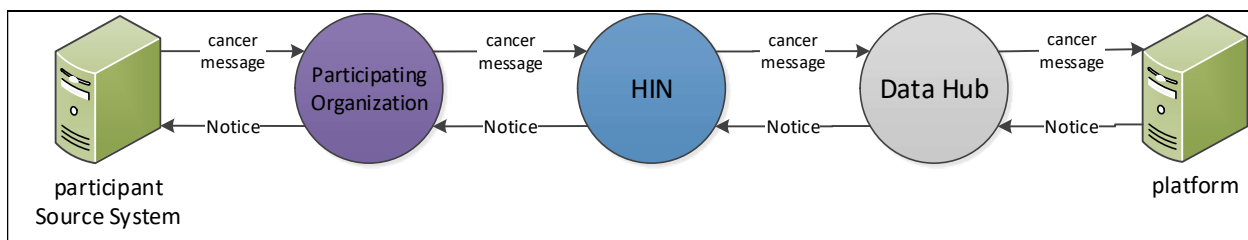
Figure 1: Workflow Between Participating Organization (TDSO), HIN, and State

For more information about this use case scenario, refer to the documents at the page below:

http://mihin.org/cancer-notifications/

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[2] "Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017," Federal Register, accessed January 20, 2017, https://www.federalregister.gov/documents/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

[3] Federal Register, *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule,* (Washington, D.C.: Department of Health and Human Services, 2015), accessed January 20, 2017, https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25597.pdf

2 Standard Overview

2.1 Message Format

Cancer Notification Clinical Document Architecture (CDA) documents must be encapsulated into HL7 messages before sending to the state. This is accomplished with an HL7 standard header and an observation segment with the CDA's Base64 encoding inserted.

HIN supports HL7 2.x messaging standards. For sending Public Health Reporting messages to state registries, HL7 v2.5.1 or newer version is preferred, however v2.3.1 is allowable.

2.2 Message Example

HIN is content agnostic and does not validate content for this use case scenario beyond the message header. To enter fully into production, however, messages must conform to the Michigan Cancer Surveillance Program Implementation Guide as well.

MSH|^~\&|||MCSR|MDCH|20160127084129.116||ORU^R01^ORU_R01|20160127084129.116||2.5.1|||||||||

PID|1||^~common key insertion area|||||F

OBR|1|12345^Encapsulation Placer ID|121212^Encapsulation Filler ID|ENDOC^EncapsulatedDocument^L|||20160127084129||||||||||||||||0000|||F|

OBX|1|ST|MD5^MD5 Message Digest^L||9a6fa2bccd687690b8c201a9f64b1f53||||||F |||20160127084129|||||||||||

OBX|2|NM|LEN^Message Length^L||2236||||||F |||20160127084129|||||||||||

OBX|3|ED|Content^Message Content^L||CDA Content^application^text/xml^Base64^PD94bWwg ..<more data>.. Rob3I+DQo=||||||F |||||||||||||

* Yellow-highlighted area above is CDA Base64 encoding insertion area

*Green-highlighted area above is common key insertion area

3 Onboarding Process

3.1 Initial Onboarding

For organizations to share data with HIN under this use case, the organization undergoes 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 the health information network (HIN) while simultaneously establishing and testing technical connectivity. To initiate these two parallel onboarding processes, notify HIN via http://mihin.org/requesthelp/.

3.1.1 Initial Legal Process

The first time an organization undergoes the legal onboarding process with HIN, the organization negotiates and enters into a master participating organization agreement and master use case agreement which then allows the participating organization to enter into one or more use cases via use case exhibits.

Once an organization has entered into a master participating organization agreement, the organization can enter into an unlimited number of use cases with HIN. All of HIN's use cases are available at:

http://mihin.org/use-case-factory/

3.1.2 Initial Technical Connectivity and Transport Process

HIN considers itself "transport agnostic" and offers multiple options for organizations to establish technical connectivity to transport data to HIN. Organizations should select one or more connectivity methods for message transport based on their technical capabilities, and should communicate the selection(s) to http://mihin.org/requesthelp/ early in the onboarding process. Currently HIN 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.

Connectivity between Direct addresses require EHNAC-DTAAP accreditation of Direct HISPs. For more information regarding accreditation see http://www.directtrust.org.

Connectivity between HISPs can be confirmed with a sample message (that does not contain protected health information) sent to a non-production address at HIN.

CDA files can be sent via DIRECT as email attachments. Every email must adhere to the following specifications:

1. There shall be only one CDA file attached per email.
2. Emails shall not have any carbon copies (CCs)

Senders should have the ability to receive DIRECT email for the HIN's acknowledgment response in the form of an ACK message.

Participants using Direct Secure Messaging should use the following addresses:

■ For production: cancernotifications@direct.mihin.org

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, HIN typically conducts "onboarding kickoff" meetings with new participating organizations to go through each of these steps in detail and answer any questions.

1. The participating organization selects one or more supported transport methods and establishes connectivity with HIN. This step varies based on the method selected:
   a. LLP over IPsec VPN – HIN's site-to-site VPN request form must be completed, sent and approved by HIN. Send an email via www.mihin.org/requesthelp to obtain the VPN request form. A pre-shared key is then exchanged between the participating organization and HIN to initialize the connection. The LLP over IPsec VPN is the most efficient transport for very high volumes of messages.
   b. Direct Secure Messaging – HIN 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.
2. Test messages are sent by the participating organization to HIN.
   a. All test messages must have a "T" in the Message Header – field 11
   b. Test traffic is routed via HIN to the appropriate destination. For cancer notifications, the destination is the cancer registry via the state data hub.
   c. The end destination monitors for inbound test traffic and confirm receipt with HIN, which confirms with the participating organization.
3. The sending facility will enter into Data Quality Assurance (DQA) status once they have successfully received a properly formatted message from the sending facility via the participating organization through HIN.
   a. Until completion of the DQA process, sending facilities should continue to dually send through HIN as well as continuing to send using any current method.
4. HIN declares the sending facility to be at production status after another period of successful testing and exiting DQA status.
   a. At this time, the sending facility may then send production messages through the participating organization to HIN. The sending facility now places a "P" (for production) value in the MSH-11 instead of the "T" used during testing.

3.2 Onboarding Additional Sending Facilities

When a participating organization wishes to onboard additional sending facilities, those facilities must first register with the cancer registry. Once successful, the registration information from the cancer registry, including the Facility ID Number, must be emailed via www.mihin.org/requesthelp.

The new sending facility should then begin sending test messages to the cancer registry in the same fashion as the initial facility as detailed in section 3.1.2. Test messages may be required to contain "T" value in MSH-11. This requirement is decided by the receiving organization.

4 Specifications

4.1 Message Trigger Events

The HL7 message type for cancer notifications is ORU and the trigger event is R01.

4.2 General Message Requirements

For general rules that apply to the entire message, refer to the following:

- Michigan Cancer Surveillance Program Implementation Guide
- Michigan Cancer Surveillance Program Manual

4.3 Specific Segment and Field Definitions

4.3.1 Segment 1 – Message Header

The definitions in the table below will be conformed to by all HL7 messages communicating the message header 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	MCSR
6	180	HD	R	1..1	0362	00006	Receiving Facility	MDCH
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^R01^ORU _R01
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	

Sequence	Length	DT	Usage	Cardinality	TBL#	Item #	Element Name	Comments
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	

4.3.2 All Remaining Segments

The message header is the only segment that HIN requires to be formatted in a certain way. Please follow the registry specified standards for all remaining segment and field definitions:

- Michigan Cancer Surveillance Program Implementation Guide
- Michigan Cancer Surveillance Program Manual

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 HIN are unable to be sent and received, let alone tracked	HIN 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

If you are experiencing difficulties or have questions, please contact the HIN 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 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 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
f. For 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. HIN 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 HIN's control.