Electronic Case Reporting (eCR) Implementation Guide

Version 1.0

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1.0   Introduction

This Implementation Guide outlines policy, technical, and process requirements for Implementers of the Carequality Electronic Case Reporting Use Case, under the terms of the Carequality Connected Agreement (CCA), and their Carequality Connections (CCs), under the Carequality Connection Terms.

This Use Case addresses the need for Public Health Agencies (PHAs) to be notified when cases occur for reportable conditions. Such reporting is required in all US jurisdictions, although details of reporting criteria and the specific conditions may vary. The case reports are used by PHAs to support case management, contact tracing, isolation, and other response activities. The case reports also convey vital demographic and other information that may not be present in lab data feeds.

This Guide is being developed in an expedited fashion, and in its initial version will rely on the principle of cooperation among Carequality Implementers and CCs to address any gaps in a collaborative fashion, and to report solutions so that they can be included in a future version of this Guide.

Unless defined in this Guide with their first use or associated with a reference to an external definition, capitalized terms are defined as in the Carequality Connected Agreement.

The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD","SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in IETF RFC 2119.[1]

2.0   Definition of Roles

The concept of a role within the use case is central to this Implementation Guide and to defining the rights, obligations, and responsibilities of Carequality Implementers and CCs. Implementers and CCs play a declared role or roles, and Implementers must indicate to Carequality, during the application process for each use case, which role or roles the Implementer will fill, and which role or roles each of its CCs fill.

By default, any requirement specified in this Guide applies to any Implementer or CC regardless of role. Requirements that apply only to those Implementers or CCs with a particular role or roles will clearly indicate the role or roles to which they apply.

An Implementer may fill different roles than its CCs.

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[1] *Key words for use in RFCs to Indicate Requirement Levels* (IETF RFC 2119) - available at: https://tools.ietf.org/html/rfc2119

2.1. Report Submitter

An Implementer or CC with the declared role of a Report Submitter either directly generates an electronic Initial Case Report for submission or plays a role in facilitating the sending of such reports to their intended recipients.

Report Submitters, despite that title, will receive Reportability Response messages under this use case.

2.2. Report Recipient

An Implementer or CC with the declared role of a Report Recipient is an entity that receives electronic case reports and is a PHA or is an entity acting under a grant of authority from, or under a contract with a PHA.

Report Recipients, despite that title, may send messages under this use case. Specifically, Report Recipients MUST send a Reportability Response to the original Report Submitter, if a Submission Manager Service is not used to facilitate the transaction. If a Submission Manager Service is involved in the submission, either the Report Recipient or the Submission Manager Service MAY originate the Reportability Response, but a Reportability Response MUST be provided.

2.3. Submission Manager Service

An Implementer or CC with the declared role of a Submission Manager Service (SMS) is an entity to which Report Submitters can send electronic Initial Case Reports, and which provides services to assist the Report Submitter with properly reporting cases to the appropriate PHAs. These services may include, but need not be limited to, determining whether or not the case actually is reportable given the jurisdiction from which the report originated, the residence of the patient who is the subject of the report, and other factors that may be relevant to a specific situation. By declaring the role of SMS, an Implementer or CC agrees to comply with the following requirements. The SMS shall:

- Comply with the obligations of a business associate under the HIPAA Privacy Rule as set forth at 45 CFR 164.502(e) and as presented in this IG. SMS shall only use electronic Protected Health Information (ePHI), as defined at 45 CFR 160.103, to which SMS has access solely to perform the functions and services of an SMS and otherwise as permitted or required by law. SMS shall also comply with the requirements of the HIPAA Security Rule as set forth at 45 CFR Subpart C to the extent that those requirements are applicable to prevent use or disclosure of ePHI except as provided by this Guide.
- Only submit to PHAs those cases that are reportable under Applicable Law, and as determined by each PHA. This will prevent any "over-reporting" of case reports to a PHA when that particular case or test has been determined by that PHA not to be reportable.
- Have mechanisms in place to maintain up-to-date information regarding which conditions are currently reportable for each PHA.
- Have the ability to provide a Reportability Response, either by forwarding a Reportability Response originally created by a PHA that provides it to the SMS, or originating the Reportability

Response itself, so that the Report Submitter receives necessary feedback on the case report that was submitted.

- Retain PHI only for as long as is necessary to make a determination on a case's reportability, provide the case report (if applicable) to the appropriate PHAs, reliably recover from system delays and processing failures, and return a Reportability Response to the Report Submitter.
- Make available to Report Submitters information required by the Report Submitter so that it can provide an accounting of disclosures in accordance with 45 CFR 164.528.
- Report any unauthorized use or disclosure of unsecured ePHI of which it becomes aware as soon as is commercially reasonable, and in no case longer than sixty (60) days after the unauthorized use or disclosure occurred.
- If the SMS uses any subcontractors, as that term is defined at 45 CFR 160.103, to perform its services as an SMS, require those subcontractors that create, receive, maintain, or transmit ePHI on behalf of the SMS to comply with the requirements of this Section with respect to the ePHI.

These requirements are in addition to the general requirements of the Carequality Elements to which the SMS is subject by virtue of being an Implementer or a CC.

The use of an SMS is optional under this Use Case but may greatly allay concerns about disclosing information inappropriately to public health authorities. Management of multi-jurisdictional reporting requirements is complex, and an SMS can assist healthcare providers in their compliance.

By submitting a case report to an SMS, an Implementer or CC acknowledges that the SMS will serve as its agent with respect to releasing information about the case, if appropriate, to relevant public health agencies in accordance with HIPAA. This means that the SMS will function as a business associate, as that term is defined by HIPAA, since it will have access to ePHI while performing a service on behalf of a HIPAA covered entity.

2.4. Role Overlap

Some combinations of the defined roles for this Use Case will not make sense for individual organizations. Specifically, an individual Carequality Connection can have only one role. An Implementer may support CCs in any combination of roles, as long as each CC has a single role.

3.0 Customizable Principles of Trust

3.1. Permitted Purposes

Unlike other Carequality Use Cases, this Use Case has only one Permitted Purpose: Public Health.

This term is defined as in the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing regulations, 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E, *Standards for Privacy of Individually Identifiable Health Information*, and 45 C.F.R. Part 164, Subpart C, *Security*

Standards for the Protection of Electronic Protected Health Information. Public Health activities, specifically, are those permitted pursuant to 45 C.F.R. Part 164.512(b).

By submitting a report under this Use Case, a Report Submitter asserts that the conditions for doing so under HIPAA's Public Health provisions have been met, or, in the case of a report submitted via an SMS, that the Report Submitter reasonably believes the case may be reportable and is relying on the Submission Manager Service to make a final determination. Report Submitters must use the value PUBLICHEALTH to indicate the purpose for their submissions, when submitting according to the Electronic Submission of Medical Documentation XDR Production Specification V1.0.

3.2.   Full Participation

No specific Full Participation requirements have been defined for this Use Case at this time.

3.3.   Permitted Users

No specific Permitted Users have been defined for this Use Case at this time.

3.4.   Data Sufficiency and Integrity

Report Submitters should ensure that sufficient information is conveyed in their reports to meet the needs of relevant public health authorities. See HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2: the Electronic Initial Case Report (eICR), Release 1, STU Release 1.1 - US Realm for additional information on the format in which content is to be provided. Carequality requires only that those elements required by the referenced specification be present in the submitted reports; optional elements are not required at this time.

3.5.   Service Level Agreements

No Service Level Agreements (SLAs) have been identified for this Use Case at this time.

3.6.   Customizable Flow-downs

No additional customizable flow-downs have been identified for this Use Case at this time.

4.0   Non-Discrimination

Non-Discrimination is a significant consideration in most healthcare IT interoperability scenarios. In this Use Case, however, healthcare providers generally are required by law to submit case reports to public health authorities, so relatively few non-discrimination considerations exist. At this time, Carequality has identified one non-discrimination consideration, specific to Submission Manager Services.

The requirements for an SMS relevant to non-discrimination differ under a "Declared Emergency", which for purposes of this Guide is defined as a Public Health Emergency declared by the Health and Human Services Secretary under the Public Health Service Act.

During a Declared Emergency, an Implementer or CC in the declared role of a Submission Manager Service MUST accept report submissions from any Implementer or CC participating in this Use Case in the role of Report Submitter, as long as those submissions are consistent with the Carequality Elements, including the terms of this Guide. No additional requirements may be enforced by a Submission Manager Service during such a Declared Emergency, other than those outlined in this Guide or otherwise in the Carequality Elements.

Outside the context of a Declared Emergency, an Implementer or CC in the declared role of a Submission Manager Service MAY enforce additional conditions on its processing of submissions, including the payment of fees. Any such additional conditions must be imposed consistently on all Implementers and CCs who wish to make submissions through the Submission Manager Service. A Submission Manager Service MAY impose different fees on different Implementers and CCs, but the differences must be based on a consistently applied set of objective, economically relevant criteria and the fees must conform to Applicable Law. A Submission Manager Service is not required to refund fees already paid for its services during a particular time period, if a Declared Emergency becomes active during that time period.

5.0   Performance Measures

Because it is not, itself, a party to interoperability transactions, Carequality relies on Implementers to report statistics in order to gauge Carequality's success in advancing this Use Case.

Implementers of this Use Case are required to provide, on a monthly basis, information on the following measures. This information shall be correct to the best of the Implementers' knowledge. Implementers are encouraged to make reasonable efforts to provide automated reports of this information, to the extent possible under their technical architectures. Such automated reports are not required, however, if Implementers are providing the requested information for each month manually, within eight (8) weeks after that month ends.

The required measures are:

1. For Report Submitters: a count of the number of unique case reports submitted.
2. For Report Recipients: a count of the number of unique case reports received.

Report Recipients who receive their reports from a Submission Manager Service may delegate this reporting responsibility to the Submission Manager Service.

6.0   Evidence of Compliance

Applicants wishing to become Implementers of this Use Case must show evidence that they are able to comply with the requirements of the Use Case. These requirements can be summarized as follows, with additional detail provided in sub-sections below:

1. The Carequality Application Process as defined for all Implementers, regardless of Use Case.

2. If the Applicant is in the role of Report Submitter, evidence that the Applicant is able to deliver content that is compliant with the standard specified in HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2: the Electronic Initial Case Report (eICR), Release 1, STU Release 1.1 - US Realm.
3. If the Applicant is in the role of Report Submitter, evidence that the Applicant is able to send and receive messages in compliance with the transport standard specified in Electronic Submission of Medical Documentation XDR Production Specification V1.0 or the Applicability Statement for Secure Health Transport Version 1.2
4. If the Applicant is in the role of Report Recipient or Submission Manager Service, evidence that the Applicant is able to receive messages in compliance with the transport standard specified in Electronic Submission of Medical Documentation XDR Production Specification V1.0and/or the Applicability Statement for Secure Health Transport Version 1.2
5. If the Applicant is in the role of Submission Manager Service, evidence that the Applicant is able to send messages in compliance with the transport standard specified in Electronic Submission of Medical Documentation XDR Production Specification V1. and/or Applicability Statement for Secure Health Transport Version 1.2, and that Reportability Response messages provided by the Applicant contain appropriate content.
6. If the Applicant is in the role of the Submission Manager Service, evidence that the Applicant has the ability to make appropriate reportability decisions.

6.1. Application Process

This Guide does not add any requirements or additional steps beyond the Carequality Application Process defined for all Implementers and enforced by the Carequality Connected Agreement.

Note that during a Declared Emergency, Carequality may waive the Carequality Application Process for those organizations who are Implementers of another Carequality Use Case. Notwithstanding anything else in this paragraph, Applicants must still complete the Content Compliance and Transport Compliance steps outlined below.

6.2. Content Compliance

Applicants must provide Carequality with a sample case report, for a test patient. Carequality may, in its sole discretion, choose to consult with appropriate organizations to validate the sample's compliance. Carequality will inform the Applicant of any issues with the case report format that are identified. The Applicant may submit a new sample when it believes in good faith that all identified issues have been corrected.

Similarly, Applicants in the role of Submission Manager Service must provide Carequality with a sample Reportability Response message, including any attachments or other content that would be provided to a Report Submitter. Carequality will inform the Applicant of any issues with the message and its content that are identified. The Applicant may submit a new sample when it believes in good faith that all identified issues have been corrected.

6.3. Transport Compliance

Each Applicant must submit to Carequality a statement outlining evidence of its ability to send and/or receive messages, depending on its role, using the transport standard specified in Electronic Submission of Medical Documentation XDR Production Specification V1.0 and/or the Applicability Statement for Secure Health Transport Version 1.2. Note that Applicants who wish to fill the Report Submitter role are required to be able to both send and receive messages. The requirement accommodates the need to receive a Reportability Response from the Report Recipient or SMS.

This statement should be submitted by email to admin@carequality.org, and include any supporting material that the Applicant deems necessary, as an attachment to the email.

In the interests of ensuring that this Use Case is not unnecessarily delayed in its development, Carequality will not publish specific expectations for these statements or the potential for supplemental evidence. Carequality may publish a more detailed process document in order to provide more guidance to Applicants, once real-world experience is sufficient to identify patterns, problem areas, and common questions.

7.0 Actors and Flows

7.1. Background

This Section describes the actors, transactions, and requirements to enable electronic case reporting. In its initial version, this Section may not enumerate all possible alternate flows. Other alternate flows are permitted, if they do not violate any provision of the Carequality Elements, including this Guide.

7.2. Use Case: Submit Electronic Case Reports

In this use case, a user (acting through an Initiating Gateway) submits a case report to Responding Gateways, using the IHE XDR as profiled for Electronic Submission of Medical Documentation (esMD) or Applicability Statement for Secure Health Transport Version 1.2.

7.2.1. Actors

1. Report Submitter (multiplicity of 1)
2. Report Recipient (multiplicity of 0..*).
3. Submission Manager Service (multiplicity of 0..*). Note that if there are no Report Recipients participating directly, there must be at least one Submission Manager Service.
4. Carequality Directory Service (multiplicity of 1)

7.2.2. Assumptions

1. The Report Submitter and any Submission Manager Service(s) are all Carequality Implementers or CCs, with entries in the Carequality Directory indicating their participation in this Use Case.

2. Report Recipients may be Carequality Implementers or CCs, with entries in the Carequality Directory indicating their participation in this Use Case but are not required to be if they expect to receive submissions only via a Submission Manager Service.

7.2.3. Pre-conditions

1. The Report Submitter has a list of currently reportable conditions and makes reasonable efforts to keep it up to date.
2. Triggers exist in the Report Submitter's relevant system(s), resulting in the creation of case reports when a reportable condition is documented for a patient.

7.2.4. Use Case Steps – "Nominal Flow"

Each of the following steps may be repeated for multiple Report Recipients or Submission Manager Services.

1. This use case begins when the Report Submitter recognizes that a case report should be sent to a Report Recipient. The Report Submitter queries the Carequality Directory Service for each Report Recipient, to determine the receiving endpoint(s) of the intended Report Recipient(s). Each query must include the name of the Report Recipient, and may also include its city, state, or zip code.
2. The Carequality Directory Service returns endpoint information for each Report Recipient.
3. The Report Submitter sends a case report to the desired endpoint for each Report Recipient, using the standards identified in 7.2 above.

7.2.5. Post-conditions

1. Each Report Recipient has received an electronic case report from the Report Submitter.

7.2.6. Alternate Flows

1. Report Recipient returns a Reportability Response
   a. After step 3, the Report Recipient processes the case report and determines if it was, in fact, reportable.
   b. The Report Recipient queries the Carequality Directory Service and retrieves the Report Submitter's return address.
   c. The Report Recipient generates a Reportability Response and sends it to the Report Submitter's return address.
   d. The use case ends.
2. Report Submitter uses a local copy of the Carequality Directory Service
   a. Prior to step 1, the Report Submitter has downloaded a local cache of the Carequality Directory Service.
   b. In step 1, rather than querying the Carequality Directory Service for endpoints, the Report Submitter queries its own local cache.
   c. The use case continues.
3. Report Submitter sends the case report to a Submission Manager Service

a. In step 1, rather than querying the Carequality Directory Service (or local cached copy, as in Alternate Flow 2) for one or more Report Recipients, the Report Submitter retrieves endpoints for one or more Submission Manager Services. Note that it is anticipated that only one Submission Manager Service would be used, but the use case does not rule out multiple Submission Manager Services.
b. The Report Submitter sends a case report to each desired Submission Manager Service.
c. The Submission Manager Service evaluates the reportability of the case with respect to relevant jurisdictional requirements.
d. If the case is deemed reportable for one or more jurisdictions served by the Submission Manager Service, the Submission Manager Service provides the case report to one or more Report Recipients. These Report Recipients need not be Implementers or CCs and may not have entries in the Carequality Directory Service.
e. The use case ends.

4. Submission Manager Service returns a Reportability Response.
a. After completing Alternate Flow 3, the Submission Manager Service generates a Reportability Response and sends it to the Report Submitter's return address.

5. Use of intermediary to assist in delivery of case reports
a. Prior to step 1, rather than determining appropriate endpoints and sending the case report directly to one or more Report Recipients or Submission Manager Services, the Report Submitter sends the report to an intermediary, who then either performs the steps outlined in the Nominal Flow or an Alternate Flow resulting in the delivery of the case report, or sends the report to a further intermediary. Note, for Carequality purposes, all such intermediaries are considered to play the role of Report Submitter.
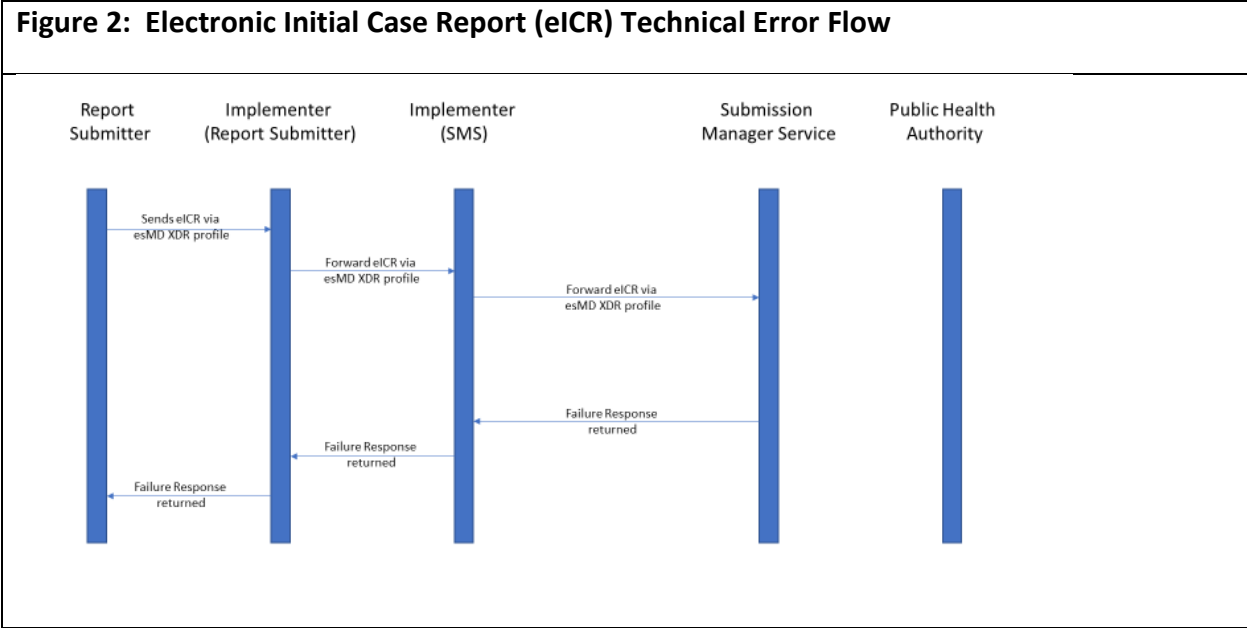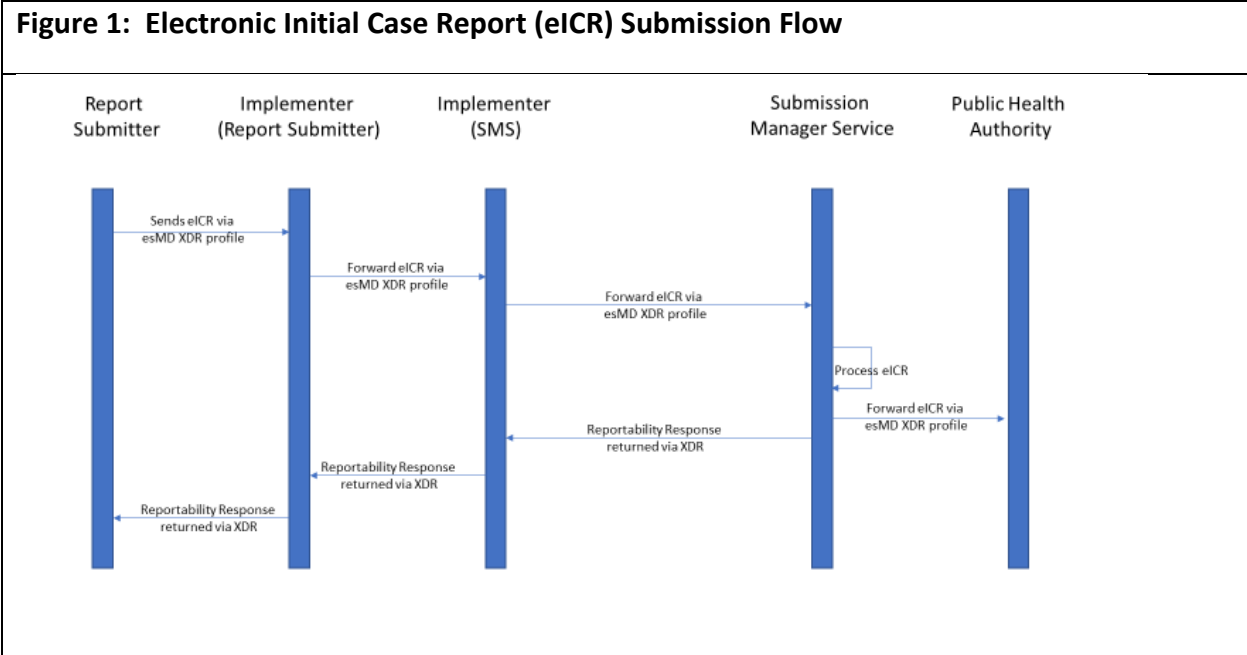b. The use case continues.

7.2.7. Error Flows

1. Case Report is not delivered
a. Following step 2, the Report Submitter fails to receive an acknowledgment of the message's receipt or receives an acknowledgment that indicates an error in receipt or delivery.
b. The Report Submitter should make a later attempt to resend the message, in order to account for transient failures, but should not make multiple attempts to resend in an automated fashion in a short timeframe. If attempts to resend are not successful, the Report Submitter may attempt to send the message in some other way, such as fax.
c. The use case ends.

2. Reportability Response is not delivered
a. Following part c of Alternate Flow 1, the Report Recipient or SMS fails to receive an acknowledgment of the Reportability Response's delivery or receives an acknowledgment that indicates an error in receipt or delivery.
b. The Report Recipient or SMS should make a later attempt to resend the Reportability Response, in order to account for transient failures. Persistent failures will likely require cooperative troubleshooting with the Report Submitter, since there isn't a clear manual alternative to electronic delivery of the Reportability Response.
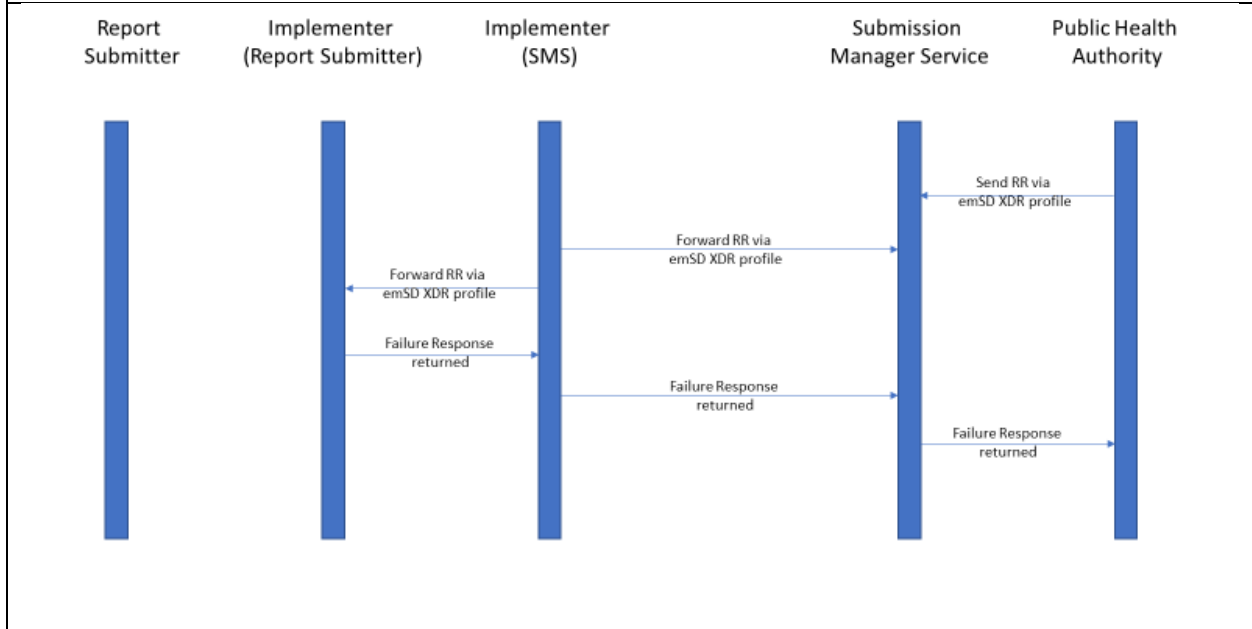c. The use case ends.

7.3. Flow Diagrams

7.3.1. esMD XDR Submission

The following two diagrams depict the submission and Reportability Response process, and an example error flow. The diagrams depict these flows with Implementer intermediaries serving both the Report Submitter and the Submission Manager Service. Other configurations are permitted, including ones that do not involve a Submission Manager Service at all.

Figure 1: Electronic Initial Case Report (eICR) Submission Flow

Figure 2: Electronic Initial Case Report (eICR) Technical Error Flow
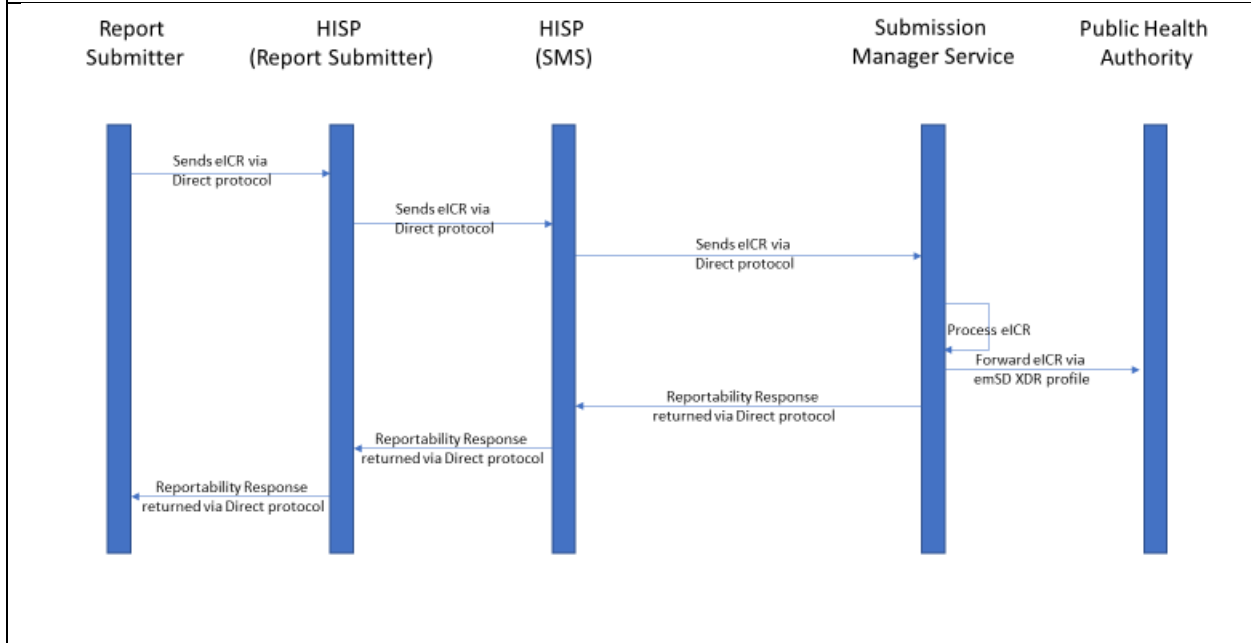
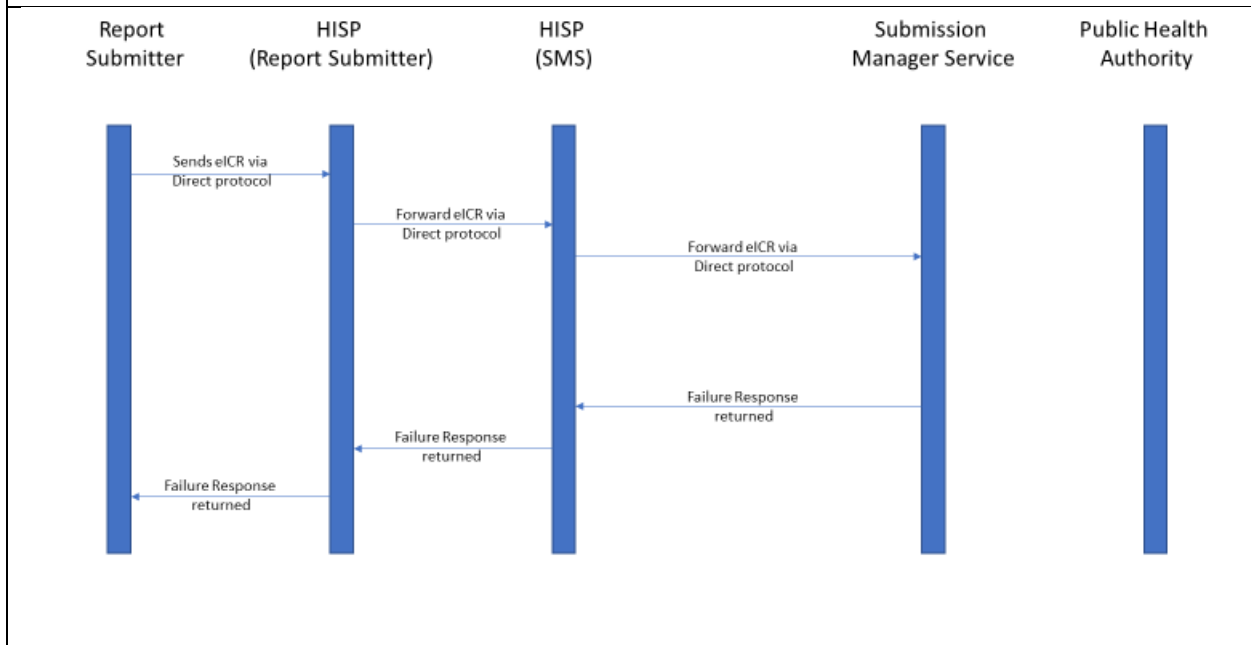**Figure 3: Reportability Response (RR) Technical Error Flow**

7.3.2. Direct Submission Example

The following two diagrams depict the submission and Reportability Response process and an example error flow. The diagrams depict these flows with Implementer intermediaries serving both the Report Submitter and the Submission Manager Service using a potential combination of Applicability Statement and/or esMD XDR. Other configurations are permitted, including ones that do not involve a Submission Manager Service at all.
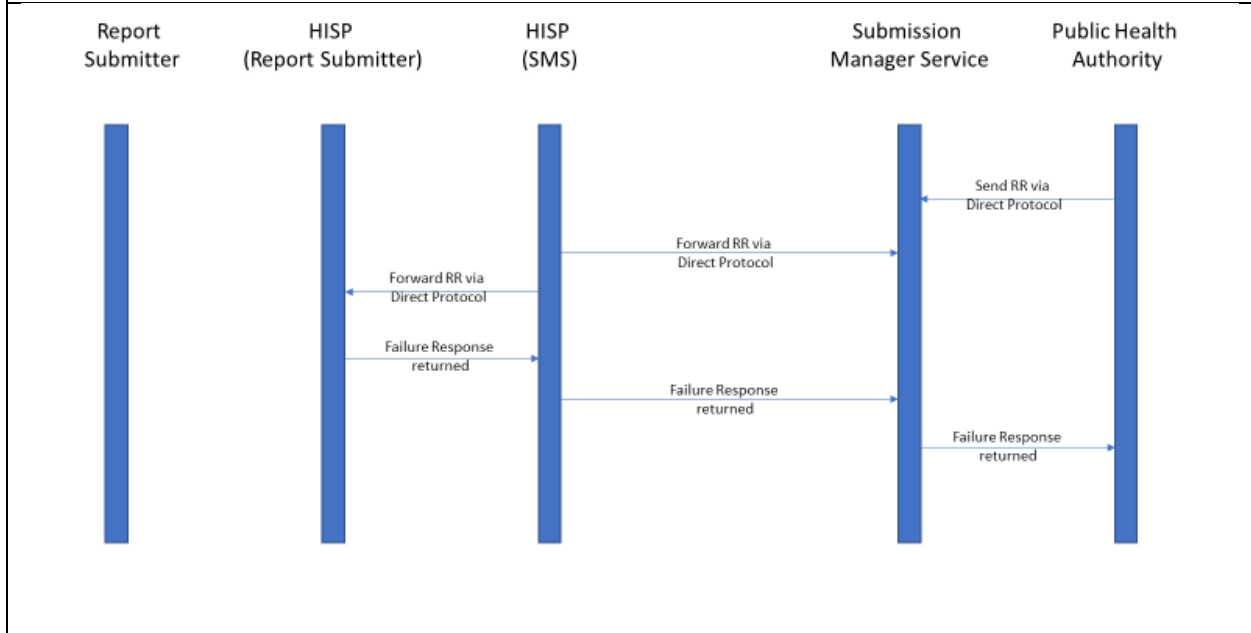
Figure 4: Electronic Initial Case Report (eICR) Submission Flow

Figure 5: Electronic Initial Case Report (eICR) Technical Error Flow

Figure 6: Reportability Response (RR) Technical Error Flow

8.0 Technical Requirements and Guidance

CONF-001: All XDR based transaction specifications pertain to the Electronic Submission of Medical Documentation (esMD) XDR Production Specification V1.0[2].

CONF-002: All Direct Messaging transaction specifications pertain to the Applicability Statement for Secure Health Transport Version 1. 2[3]

CONF-003: Content and submission requirements refer to HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2: the Electronic Initial Case Report (eICR), Release 1, STU Release 1.1 - US Realm[4].

CONF-004: Upon conversion of an eCR from SMTP to SOAP the requirements for XDR MUST follow CONF-001

CONF-005: All requirements specified by the documents in CONF-001 MUST be followed, except as specified below.

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[2] Nationwide Health Information Network (NHIN) Electronic Submission of Medical Documentation (esMD) esMD XDR Production Specification available at https://s3.amazonaws.com/seqprojectehex/wp-content/uploads/2018/09/28215041/esmd-xdr-production-specification-v1.0.pdf

[3]Applicability Statement for Secure Health Transport Version 1.2 available at http://wiki.directproject.org/w/images/e/e6/Applicability_Statement_for_Secure_Health_Transport_v1.2.pdf

[4]Available from: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436

8.1. Directory Services

The Carequality Directory Service is the expected method for resolution of Gateway endpoints including Direct addresses. Full details on interfacing with the Directory Service may be found in the Carequality Directory Implementation Guide. Carequality can provide guidance on the version of the document in force at any given time. At the time of this writing, the Directory Implementation Guide can be found in the Wiki portion of the Carequality website.

CONF-006: All endpoint discovery queries MUST use the Carequality Directory Service for endpoint discovery OR use a locally cached copy.

CONF-007: Users of the Carequality Directory Service SHOULD create a locally cached copy and SHOULD prioritize that copy for endpoint discovery queries.

CONF-008: Local cached copies of the Carequality Directory Service MUST validate their cached information no more often than once per hour and no less often than once per day

CONF-009: An Implementer or CC MUST discover the desired service endpoints for the selected Report Recipient's or Submission Manager Service's esMD Gateway via a Carequality Directory Service lookup or locally cached copy. This includes endpoints for:

- a Report Recipient
- a Submission Manager Service.

8.2. Security and Transport

CONF-010: Carequality participants MUST follow the requirements listed in the separate document: Carequality Technical Trust Policy[5].

CONF-011: Implementers and connections using the Electronic Submission of Medical Documentation (esMD) XDR Production Specification V1.0 MUST use the NHIN Exchange Authorization Framework and Messaging Platform specifications V3.0

CONF-012: For the TLS Security Certificate requirement as per esMD XDR Production Specification Section 3.1, a Carequality issued certificate MUST be used.

8.3. Gateway Transition Metadata Requirements

The following are requirements specific to eCR submission via Direct Messaging.

CONF-013: authorTelecommunication MUST be the Direct address of the originator of the Direct transmission or the originator of the conversion of RFC5322 to XDR.

CONF-014: During conversion of the Reportability Response transmission back to the Report Submitter, the authorTelecommunication metadata MUST be used for the Direct recipient information

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[5] Carequality Technical Trust Policy Version 2.0 -- available at https://s3.amazonaws.com/ceq-project/wp-content/uploads/2018/09/30162038/Carequality-Technical-Trust-Policy-v2-FINAL-7-31-18.pdf

CONF-015: The DocumentEntry sourcePatientId metadata MUST include the patient identifier, including AssigningAuthority for all DocumentEntries. This patient identifier MUST be the identifier necessary for the identification of the case patient.

8.4. Direct Applicability Statement Additional Requirements

CONF-016: Report Submitters, Submission Manager Services, and Report Recipients wishing to send or receive via the Direct Messaging protocols MUST add a Direct address to the Carequality Directory five days prior to first transmission.

CONF-017: Report Recipients and Submission Manager Services MUST allow messages to be received from Direct addresses within the same domain as those Direct addresses listed in the Carequality Directory, within five business days of a Direct address being added to the Carequality Directory.

CONF-018: Report Recipients and Submission Manager Services MUST NOT allow messages from Direct addresses whose domains do not match those of addresses that are in the Carequality Directory unless these addresses are submitting reports pursuant to a legal arrangement not affiliated with Carequality.