Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Quality Measurement & Health Assessment Group
7500 Security Blvd
Baltimore, MD 21244-1850

Implementation Guide

For

Electronic Submission of Medical Documentation Project (esMD)

Version: **2.7 (Draft)**
Last Modified: 08/25/2011

Document Number: Release_1.1_Implementation_Guide
Contact Number: HHSM-500-2007-00024I

APPROVALS

Submitting Organization's Approving Authority:

	Manoj Chaganti		847 903 5432
Signature	Printed Name	Date	Phone Number

QSSI esMD – HIT Chief Architect

	Michael Finkel		301 977 7884 x443
Signature	Printed Name	Date	Phone Number

QSSI esMD – Project Director

	Ranjith Madhusoodanan	301 977 7884 x478	
Signature	Printed Name	Date	Phone Number

QSSI esMD – Project Manager

CMS' Approving Authority and Business Owner:

	Melanie Combs-Dyer		410-786-8370
Signature	Printed Name	Date	Phone Number

esMD Project Manager/GTL and Business Owner

	Daniel Kalwa		
Signature	Printed Name	Date	Phone Number

esMD Business Owner

40 # Contributors

Name	NHIO Represented	Organization
Melanie Combs-Dyer	CMS – esMD	CMS
Daniel Kalwa	CMS – esMD	CMS
Manoj Chaganti	CMS – esMD	CMS/QSSI
Ranjith Madhusoodanan	CMS – esMD	CMS/QSSI
Laura Higdon	CMS – esMD	CMS/QSSI
Sacchidanand Girde	CMS – esMD	CMS/QSSI

41

42 # Document Change History

Version	Date	Changed By	Items Changed Since Previous Version
0.1		Melanie Combs-Dyer	Initial Draft
0.2		Naresh Saharya	Second Draft
0.3		Melanie Combs-Dyer	Third Draft
0.4		Manoj Chaganti	Updated the Content and added Technical Details Added the Security Assertions, Metadata and Payload details.
0.5		Manoj Chaganti	Reviewed the draft.
0.6	10/27/2010	Melanie Combs-Dyer, Manoj Chaganti, Laura Higdon	Reviewed and updated the sentenced in various sections.
0.7	11/16/2010	Manoj Chaganti, Laura Higdon	Updated Section 1.1 Introduction and its diagram. Updated Section 1.2 – On boarding Processes • Certification processes. • Turning on the FIPS 140-2 Updated the Section 3.1 – CMS Validation Region Testing with HIH (thru esMD VAL CONNECT Gateway) • Clarified the Testing Process. • Add CMS esMD OID Updated the Section 3.2 – CMS Production Region Testing with HIH (thru esMD Prod CONNECT Gateway) • Clarified the Testing Process. • Add CMS esMD OID Updated Section 10 – Release Notification Table • Updated Release dates Updated Section 5.3.9 – Meta Data • Added CMS esMD Review Contractor OIDs
0.8	12/07/2010	Manoj Chaganti Laura Higdon	Changed SSL to TLS throughout the document Updated Section 1.1 • error payment figures Updated Section 1.3 • TIFF formats Updated Section 2.1 Updated Section 8 Release Notification Details • current dates Updated Glossary
0.9	12/20/2010	Manoj Chaganti	• Updated the XDR link in section 1.2 • Updated 5.3.5 SOAP Envelope diagram • Added Intended Recipient to SAML Assertions • Deleted an XDSRegistryDeprecatedDocumentError Error message in section 5.3.5.4 • Added acknowledgment diagram in acknowledgement section.

1.0	01/05/2010	Manoj Chaganti	• Section 8 – Status and Notification Acknowledgment Diagram and content update. • Added a table with Namespace url details. • Section 5.3.5.5 – Added esMD SAML Assertion Table • Section 5.3.7 Metadata fields – Added / Updated the XDR Document and Submission Set Meta Data details to achieve XDR interoperability. • Section 5.3.8 Added esMD Submission Set Table with example • esMD Affinity Values are added in various tables. • Section 10 Release Notification Updated the Release Details • Section Appendix A – Updated the sample Message with Assertions and Meta data tags.
1.1	01/19/2011	Melanie Combs-Dyer / Manoj Chaganti	• Section 5.3.5 SOAP Envelope Updated Soap Envelope Figure. • Section 5.3.8 Cleaned Up. Redundant – esMD specific attributes • Table 2 and 3 Updated the default value context from “Shall be NA” to “May be NA”. • Table 5 to 11 – Affinity Values Updated the affinity values in the following tables. • Section 7 – Error Messages Deleted irrelevant errors (XDSRegistryDuplicateUniqueIdInMessage, XDSRegistryBusy and XDSRegistryOutOfResources /XDSRepositoryOutOfResources)
1.2	02/01/2011	Manoj Chaganti	• Section 2.1 – Added the IP address and port number requirement. • Section 5.3.5 SOAP Envelope Updated Soap Envelope Figure. Section 5.3.8 • Updated XDR SubmissionSet Metadata Table Column Title. • Updated XDR Document Metadata Table Column Title. • URL description is updated • Affinity Values Tables is updated. • Section 7 – Error Message Added Virus scan failure error message. • Section 8.3 Claim Reviewer Delivery Notification is updated for virus scan • Section 5.3.9 – HITSP C62 (Construct on top of CDA) Document Constraints Added Clinical document wrapper details • Section 8.4 Service Level Agreement Added service level agreement for acknowledgment. • Section 11 Glossary- Added Electronic Submission of Medical Documentation and definition • Section 11 Glossary- Changed NHIN references to NwHIN • Section 12 Acronyms- Updated Table with ADR, esMD, and NwHIN • Section 14 – Added Codes.xml place holder

1.3	2/07/11	Manoj Chaganti/Laura Higdon	• Section 3.1- Updated the validation region OID to 0.2 • Section 3.2- Updated the production region OID to 0.1 • Section 8- updated the image • Section 8.4- Claim Reviewer virus scan failure Notification • Section 8.5.2-Syntax and Semantics Validation Status Acknowledgment (Second Acknowledgment) • Section 8.5.3-Claim Review Delivery Notification (Third Notification) • Section 8.5.4-Claim Reviewer virus scan failure Notification (Fourth/final Notification) • Section 12- added OID to acronyms
1.4	02/16/2011	Manoj Chaganti/ Laura Higdon	• Section 5.3.1 Updated the Diagram • Section 5.3.5.5 • Added Source and Connect Software Assertion allowed Fields • Added a note about Intended Receipient and NPI assertion fields • Added about the esMD Connect patch. • Section Metadata Fields • Table 2 – Updated sample message to reflect CDA document • Table 2 – Updated the availability Status description. • Table 3 – Updated sample message to reflect CDA document • Table 3 – Updated the Class Code and its display Name description. • Table 3 – Update the Format Code description and possible values column. • Updated all the esMD affinity tables with CMS OID schema value. • Section Validation Added affinity value validation. • Section Error Messages Updated the Error Messages. • Section 8 Status and Notification Messages Updated the diagram • Section 8.4- Updated the Virus Scan Notification schedule and service level agreement. • Section 8.5.4- Updated claim reviewer Virus Scan Failure Details • Section 9 Updated Response Messages • Release Notification Details Updated the esMD Production Go-Live date. • Section Appendix A Updated Sample SOAP Message.

1.5	03/09/2011	Manoj Chaganti/ Laura Higdon	• Section 2.1- DURSA language amended in CMS On-boarding process • 5.3.5.5 esMD SAML Assertions details • Intended Recipient Format changed to HL7 XON Format • samlAuthzDecisionStatement – Added Unique ID and message details. • Updated the AssertionType proposed changes in CONNECT Software. • 5.3.6 Target System (changed to Target System 8/24/11) • CMS Response Message details were added. • 5.3.7 Metadata Fields • CDA document shall be encoded. • 5.3.8 esMD Functional Specific Submission Set Metadata Attributes • Deleted the optional SubmissionSet Metadata attributes. • Table 3: esMD specific Document Metadata Attributes • Deleted the optional Document Metadata attributes. • Table 4: Intended Recipient (Review Contractor) OIDs • Updated Table heading and OID values. • Table 6: Type Codes and corresponding Type Code Display Names • Disable the Unsolicited Claim Attachment Paperwork. • Table 10: Document Format Code – Payload Type • Added some of the new values. • Table 11: Over All mapping of Document submission with the Class and Type Codes. • Updated the description • Table 12: CDA Document Constraints Specification • Optional attributes were deleted • 9 Response Message • Added response Message description • 13 Appendix A Added the requirement for CDA Clinical Message attachments encoding.
1.6	03/16/2011	Manoj Chaganti/ Sacchidanand Girde/ Laura Higdon	• Section 5.3.8: esMD Functional Specific Submission Set Metadata Attributes - ClaimId and CaseId attributes were changed to esMDClaimId and esMDCaseId. - NPI was removed and populated into the Author attribute. - Removed the duplicate esMD specific Home Community ID. - Removed esMD specific Organization ID. - Removed all the optional and system generated attributes. • Table 3: esMD specific Document Metadata Attributes - Author details were updated to have individual Document Provider NPI. - Removed all the optional and system generated attributes. • Corrected ZPIC OIDs • Table 11: Over All mapping of Document submission with the Class and Type Codes. - Disabled Unsolicited Documentation.

43

44

1.7	3/23/2011	Manoj Chaganti/Sacchidanand Girde/Laura Higdon	Section 15: Appendix B • Added Test Cases
1.8	4/28/11	Manoj Chaganti/Sacchidanand Girde/Laura Higdon	Section 9: Response Message • Updated
1.9	5/02/11	Laura Higdon	• Section 2.4: Annual Review of HIH Accounts • Section 2.5: HIH Off-Boarding • updated Table 4: Intended Recipient OIDs • updated Section 10: Release Notification Details
2.0	5/19/11	Laura Higdon	**Section 3.1** • updated with note for quarterly induction of HIHs • Table 4: Intended Recipient (Review Contractor) OIDs: updated ZPIC OIDs
2.1	06/07/2011	Manoj Chaganti / Sacchidanand Girde	**Section 5.3.3.5** • Updated esMD SAML Assertions details **Section 5.3.8** • **Updated** esMD Functional Specific Submission Set Metadata Attributes: Tables 2 & 3: refined definitions and examples • Updated Table 5: Class Codes & corresponding Class Code Display Names- coding schema/code system • Updated Table 6: Type Codes & corresponding Type Code Display Names- coding schema/code system • Updated Table 8: Health Care Facility Type Code- coding schema/code system Updated Table 10: Document Format Code- Payload Type
2.2	06/14/2011	Manoj Chaganti / Sacchidanand Girde / Laura Higdon	Section 8 – • Updated the Response diagram. Section 9 – • Updated the Response Messages**.** • Update the assertion NPI username field • Removed the '0' before the affinity values. (i.e., instead of 01 to 1). • Update the sample message as per last week changes**.**
2.3	06/22/2011	Laura Higdon/Manoj Chaganti	Section 9 – • Updated the Response Messages to Response Types table Section 10- • Updated the Release Schedule
2.4	06/30/2011	Manoj Chaganti/Sumit Kapoor/S. Girde/Sathees Naicker	• Appendix A –Updated the sample SOAP message • Added data type and length column to Tables 2 and 3
2.5	7/12/2011	Manoj Chaganti/S. Girde/Sumit Kapoor/L. Higdon	• Added Appendix C • Added Appendix D

2.6	8/19/2011 08/24/2011	L. Higdon Manoj Chaganti / Sumit Kapoor / Laura Higdon	• Updated language throughout (e.g., referenced acronyms and introductions for tables & figures) • Updated acronyms • Updated Glossary • Updated claim/case ID to 32 alphanumeric characters • Updated the Release Notification Details • Updated Table 1: esMD Profile Specifications • Adjusted headings • 5.3.6 Section: changed 'nhinTargetSystem' to 'nhinTargetCommunities' • Updated the SAML (Section 5.3.5.4), SubmissionSet (5.3.6 Table 6) and Document (Section 5.3.6 Table 7) Metadata attributes sample to align with sample message. • Section 13 sample message is updated. • Section 14 was added as separate section for C62.
2.7	8/25/11	L. Higdon	Section 2.1: CMS On-Boarding Process for organizations that have not completed the NHIN Exchange • Updated item C, obtaining an OID from HL7

Table of Contents

List of Tables

List of Figures

1 Introduction

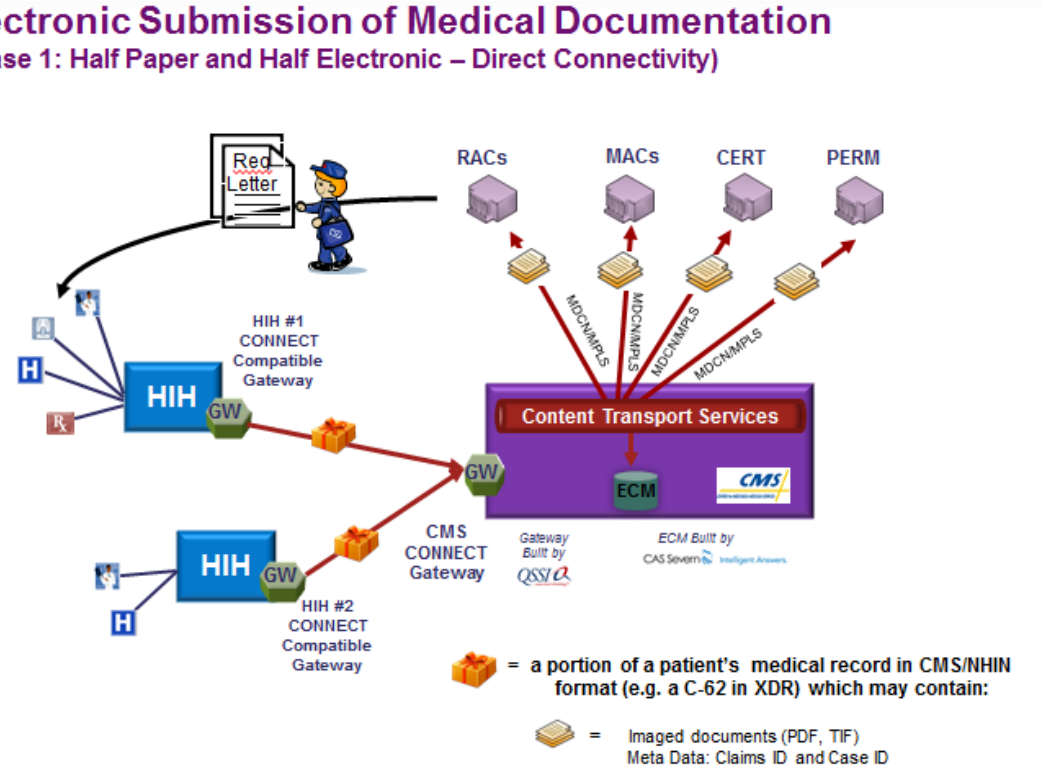
In 2009 the Medicare fee-for-service (FFS) program made an estimated $34.3 billion in improper payments. The Medicaid program made an estimated $22.5 billion in improper payments. Review contractors compare the claims submitted by providers (e.g., physicians and hospitals) against entries in medical records to measure, prevent, and correct improper payments.

- **CERT and PERM contractors measure improper payments.** The Comprehensive Error Rate Testing (CERT) contractor measures improper payments in the Medicare program. The Program Error Rate Measurement (PERM) contractor measures improper payments in the Medicaid program. CERT and PERM request thousands of medical records each year.

- **MACs prevent improper payments.** Medicare Administrative Contractors (MACs) conduct pre-payment and post-payment reviews of Medicare FFS claims. The Centers for Medicare & Medicaid Services (CMS) estimates that MACs will request several thousand medical records per year.

- **RACs identify and correct improper payments.** Medicare Recovery Audit Contractors (RACs) conduct post-payment review by comparing information from medical records to Medicare claims. CMS estimates that RACs will request over 1 million medical records from providers each year.

Figure 1: esMD Phase One



Review contractors notify providers that they have been selected for review and request medical documentation by sending a documentation request letter. Prior to the Electronic Submission of Medical Documentation (esMD) pilot, the provider had three choices when responding to these documentation requests: mail paper, mail a CD containing a Portable Document Format (PDF) or Tagged Image File Format (TIFF) file, or transmit a fax. The esMD system will give providers an additional option for responding to these requests for medical documentation: electronic transmission through a CMS "gateway" to the review contractor that requested it.

It should be noted that,

1. **The provider decides what to submit**. In both the current paper process and the new esMD process, the review contractor does not specify which documents the provider must send. It is up to the provider to decide which documents to send. The documents that a provider may submit include discharge summaries, progress notes, orders, radiology reports, lab results, etc.
2. **The initial phase esMD system will allow only unstructured documents**. The esMD system will only accept unstructured documents in PDF files in its initial phase of operation.
3. **One Way Transmission: Provider to Review Contractor.** Phase 1 of esMD will be unidirectional electronic document submission (from provider to review contractor).
4. **Each package must contain documentation about a single claim of a beneficiary.** Throughout this profile, the term "package" will be used to refer to one or more documents associated with a single beneficiary. Each package can contain multiple documents as long as all documents relate to the same claim of a beneficiary. The technical term for a package is a Simple Object Access Protocol (SOAP) message.
5. **More details about esMD data exchange can be found in the esMD Profile.** See http://www.connectopensource.org/product/connect-nhin-specs and click the esMD link.
6. **CMS is not involved in the business relationship between the Health Information Handler and the provider.** This document does not describe how HIHs should collect or store medical documentation from the providers. The HIH and provider must comply with all applicable Health Information Portability and Accountability Act (HIPAA) provisions.

1.1 Intended Audience

The primary audience for this document includes Health Information Handlers (HIHs) such as Regional Health Information Organizations (RHIOs), Health Information Exchanges (HIEs), Release of Information (ROI) vendors, claim clearinghouses, and other organizations that securely submit medical documentation on behalf of providers via CONNECT compatible gateways to review contractors.

> This document will refer to RHIOs, HIEs, ROI vendors, claim clearinghouses, and other entities that move health information over secure CONNECT compatible gateways on behalf of health care providers as **"Health Information Handlers** (HIHs)".

HIHs who have built a CONNECT compatible gateway and wish to participate in Phase 1 (Release 1.1-1.3) of esMD, should contact the esMD Team at esMDTeam@qssinc.com. For more information about CONNECT gateways, see www.connectopensource.org. **For a list of HIHs that intend to participate in Phase 1 (Release 1.1-1.3) of the esMD Pilot, see www.cms.gov/esMD.**

The secondary audience for this document includes:

- Software developers that aim to assist review contractors in viewing and more efficiently processing documents received in the esMD format.
- Software developers that may develop products to assist HIHs to receive data more easily from a provider's electronic health record (EHR) in the esMD format

Related Documents

- Nationwide Health Information Network (NHIN) approved CMS esMD External Data Representation (XDR) Profile Definition Version 1.0 (see http://standards-and-interoperabilty-specifications.wikispaces.com/CMS+esMD)
- Integrating the Healthcare Enterprise (IHE) Deferred Cross-Enterprise Document Reliable Messaging (XDR) (see v1.1.0.6 http://developer.connectopensource.org/download/attachments/32768185/NHIN+Document+Submission+Emergence+Pilot+Specification+v1.1.0.6.doc?version=1&modificationDate=1276195896000)
- NHIN Trial Implementations Document Submission Interface Specification Version 1.1.0 (See http://developer.connectopensource.org/download/attachments/30212307/ Document_Submission_Service_Interface_Specification_v1_1_0_FINAL.docx
- NHIN Trial Implementations Message Platform Service Interface Specification Version 1.9.8 (see http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_909196_0_0_18/MessagingPlatformSpecification.pdf)
- NHIN Authorization Framework Specification Version 2.0 (See - http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910545_0_0_18/NHIN_AuthorizationFrameworkProductionSpecification_v2.0.pdf)
- IHE TF3 Cross-Transaction Specifications and Content Specifications Version 6.0 (See - http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol3_FT_2009-08-10-2.pdf)

1.2 Business Needs Supported

This Implementation Guide defines how esMD program data may be submitted by healthcare providers to review contractors under contract with the CMS. The esMD Implementation Guide also describes how the status of these submissions will be conveyed to providers (e.g., transmission receipt, detailed validation status with errors or success, and delivery confirmation messages).

Phase 1 (Release 1.1-1.3) of the esMD system will support the submission of documentation by healthcare providers to a limited number of review contractors. (To see a list of participating **review contractors, see section 4.3.9 below and www.cms.gov/esMD).**

The purpose of this implementation guide is to supplement the esMD Profile and assist providers and their HIHs in submitting esMD transactions to review contractors. The esMD profile can be found at http://www.connectopensource.org/product/connect-nhin-spec.

The esMD system will accept medical documentation only in the following format.

Table 1: esMD Profile Specifications

Name of Specification	Purpose	Structured or Unstructured	Release or Time Period
esMD XDR	For submitting documentation in PDF format using HITSP's XDR standard	Unstructured	September 2011
esMD x12	For submitting documentation in PDF format using ASC X12 with HL7standard	Unstructured	TBD
TBD	For submitting an extract of progress notes from a	Structured	TBD

	medical record in a TBD format		

2 On-Boarding Process

The NHIN is a set of standards, protocols, legal agreements, and specifications that a consortium of health information organizations have agreed are necessary for secure and private exchange of health information over the internet. The NHIN is overseen by the Office of the National Coordinator (ONC) for Health IT.

In its initial release, the esMD gateway will accept transmissions only from organizations that have successfully completed the CMS esMD On-boarding Process. In about April 2013, ONC plans to allow HIHs without government contracts to on-board the NHIN. Six months after that, CMS plans to phase out the CMS On-boarding Process and only accept esMD transmissions from organizations that have successfully on-boarded to the NHIN.

2.1 CMS On-Boarding Process for organizations that have not completed the NHIN Exchange

A. The HIHs will be required to sign an attestation indicating they intend to sign the Data Use and Reciprocal Support Agreement (DURSA) when ONC allows nonfederal agencies and contractors to on-board the NHIN.

B. The HIH sends an email to esMDTeam@qssinc.com. Email should include:

i. Company name
ii. Contact person email, phone
iii. Number of providers, a count of unique National Provider Identifiers (NPIs), supported by the HIH
iv. List of review contractors to which this HIH's providers submit medical documentation

C. The HIH acquires Organizational Identification (OID) from Health Level 7 (HL7), www.hl7.org, and submits the OID to QSSI via email to esMDTeam@qssinc.com. The HIH can get the OID registered from HL7: http://www.hl7.org/oid/index.cfm. Click the link in the top right corner: ***Obtain or Register an OID***.

All HL7 OIDs will have a prefix "**2.16.840.1.113883." [joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883).]** and are followed by an OID Type (e.g., 2.16.840.1.113883.3.xxx.x).

The HIH should pick the OID Type based on their type of Organization and purpose of use. Most of the HIHs registered their OIDs with OID Type = **3 - Root to be a Registration Authority** (External groups that have been issued an HL7 OID root for their own use).

D. The HIH submits their HIH Gateway Internet Protocol (IP) address, response Uniform Response Locator (URL) and port number to QSSI.

E. The HIH obtains a certificate from a certificate authority (CA)

All CAs used to generate certificates for use in the esMD project must adhere to the following guidelines:

1. Level 2 Identity Proofing as described in section 7 of this National Institute of Standards and Technology (NIST) publication: http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf. (Specifically, see Table 1 on pages 22 through 24.)
2. 1024 bit RSA keys
3. Advance Encryption Standard (AES) 128 bit encryption
4. Secure Hash Algorithm-1 (SHA-1) certificate signing algorithm
5. All cryptographic modules used by HIH NHIN instances (typically CONNECT) must adhere to Federal Information Processing Standards (FIPS) 140-2 Compliance criteria and utilize Transport Layer Security (TLS).

   For reference:

   - http://www.cms.gov/informationsecurity/downloads/ARS_App_B_CMSR_Moderate.pdf (See section Appendix B, SC13-1)
   - http://csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf

F. Turn on the FIPS 140-2 (For cryptographic modules)

The FIPS 140-2 is a government standard that provides a benchmark for how to implement cryptographic software (http://technet.microsoft.com/en-us/library/cc180745.aspx). For the CONNECT Solution, this standard is being met to ensure that the CONNECT Gateway is FIPS 140-2 compliant.

Any HIH that needs to communicate with the esMD gateway needs to have the FIPS mode enabled.

The CONNECT published the following instructions on how to configure CONNECT to be FIPS 140-2 compliant:

http://developer.connectopensource.org/download/attachments/32768208/CONNECT_Release_3_0_FIPS_060810.pdf?version=3&modificationDate=1276204228000

G. Upon successful CMS On-boarding, the HIH will receive a communication from the esMD team that they have completed the on-boarding process. The HIH will then be involved in integration and interoperability testing. This testing will be first done by sending the claim documentation through the CMS esMD Gateway in the validation region and later in the production region.

2.2 CMS On-Boarding Process with already NHIN On-Boarded HIHs

This will be addressed in later releases.

2.3 NHIN On-Boarding Process

This will be addressed in later January 2012 releases.

2.4 Annual Review of HIH Accounts

Eleven months after QSSI receives a certificated from an HIH, QSSI will send the HIH a certification status email. This notification will include a 30 day certificate expiration date and request for HIHs to submit an updated certificate within 2 weeks of this initial notification. Failure to comply with this request will result in being locked out of the esMD system.

If the 2 week period expires before QSSI receives an updated certificate from the HIH, daily email reminders will be sent warning HIHs of possible suspension of esMD access. Following 14 days from the 2 week warning notice, QSSI will manually remove the HIH's OID from the chart of acceptable HIHs.

2.5 HIH Off-boarding Process

2.5.1 HIHs who have not yet fully on-boarded

HIHs, who suspend participation before they fully complete the on-boarding process, will receive an esMD Exit Letter from QSSI staff. Their SharePoint access will be active for 90 days.

2.5.2 HIHs who have fully on-boarded

If an HIH informs QSSI they no longer want to participate in esMD, QSSI will ask them to specify an effective date. Following the specified date, QSSI will remove the HIH's OID from the approved chart of acceptable HIHs.

3 Integration and esMD Interoperability Testing

Before submitting the claim documentation in esMD production, all the on-boarded HIHs will complete the integration and esMD interoperability testing by sending the claim documentation through the CMS esMD Gateway in the Validation region. Upon successful completion of the testing in the validation region, HIHs will get a certificate of approval from the esMD team to operate in the esMD production region.

3.1 CMS Validation Region Testing with HIH

This testing is performed through the esMD VAL CONNECT Gateway.

a) The HIH provides its testing gateway OID to QSSI.

b) The CMS esMD CONNECT Gateway configuration will hard code the HIH provided testing OID.

c) The HIH will configure its gateway with the CMS esMD CONNECT Gateway validation region OID 2.16.840.1.113883.13.34.110.2.

d) The HIH acquires a TLS certificate from any CA that conforms to the esMD security standards for the on-boarding process.

e) The esMD Team and the HIH perform the connectivity test.

f) The esMD Team will coordinate the manual interoperability and end-to-end integration testing between the esMD CONNECT Gateway system and the HIH by opening a conference call with the related stakeholders and sharing the results. A manual test will be performed, due to the lack of automated XDR Testing tools. For ASC X12 transmissions, exploration of possible X12 testing tools is necessary.

g) Upon successful completion of the interoperability and integration testing (i.e., transmission of 100% correctly formed payload and receipt of the two asynchronous responses back from the esMD gateway) between the HIH and the validation region esMD Gateway, the HIH will officially receive a communication from the esMD Team. The HIHs can then start production connectivity and integration testing with the CMS production esMD CONNECT Gateway.

In the event an HIH misses the testing preparation timeline of 4 weeks (i.e., sending statistics, attaining OIDs, building and configuring their gateway, and exchanging TLS certificates) OR actual integration test time lines of 2 Weeks, QSSI will work with the HIH to induct them in the **next quarterly Integration session**. Taking into consideration the esMD release timelines, QSSI plans to hold quarterly sessions to induct new HIHs. Information on the commencement of new integration testing sessions will be published and placed on the esMD SharePoint site.

3.2 CMS Production Region Testing with HIH

This testing is performed through esMD Prod CONNECT Gateway.

a) The HIH provides its production OID to QSSI.

b) The CMS esMD CONNECT Gateway configuration will hard code the HIH provided production OID.

c) The HIH will configure its gateway with the CMS esMD CONNECT Gateway production region OID 2.16.840.1.113883.13.34.110.1.

d) The HIH acquires a TLS certificate from any CA that conforms to the esMD security standards for the on-boarding process.

e) The esMD Team and the HIH perform the connectivity test.

f) The esMD Team will coordinate the manual interoperability and end-to-end integration testing between the esMD CONNECT Gateway system and the HIH by opening a conference call with the related stakeholders and sharing the results. A manual test will be performed, due to the lack of automated XDR Testing tools. For ASC X12 transmissions, exploration of possible X12 testing tools is necessary.

g) Upon successful connectivity and integration testing (i.e., transmission of 100% correctly formed payload and receipt of the two asynchronous responses back from the esMD gateway) between the HIH and the CMS Production esMD Gateway, the HIH will officially receive communication from the esMD Team that the HIH has passed the production testing and can officially transmit the claim documents through the CMS production esMD CONNECT Gateway.

4 Profiles

4.1 esMD XDR Profile

This esMD Implementation Guide provides more information about the transmissions sent using the esMD XDR (see http://standards-and-interoperabilty-specifications.wikispaces.com/CMS+esMD)

4.2 esMD X12 275 Profile (planned for Phase 2)

This esMD Implementation Guide will be revised in the future after the publication of the esMD X12 Profile. (See: http://standards-and-interoperabilty-specifications.wikispaces.com/CMS+esMD)

5 Interface Definition

5.1 Interface Descriptive Name

The HIH adopts the IHE Cross Enterprise Document Reliable Interchange (XDR) profile in a SOAP envelope with ITI – 41 Provide and Register Document set – b transaction metadata and C62 document payload attachment. Each SOAP message can contain multiple document attachments related to the same claim of a patient. The initial esMD Phase 1 Release 1 (R1.1) allows HIHs to submit messages **up to 19MB in size**. The esMD Gateway allows HIHs to submit multiple SOAP messages with different Unique IDs for a Claim Document Request of a patient.

5.2 Interface Level

From the HIH to the CMS esMD CONNECT Gateway

5.3 Definition

5.3.1 Interaction Behavior

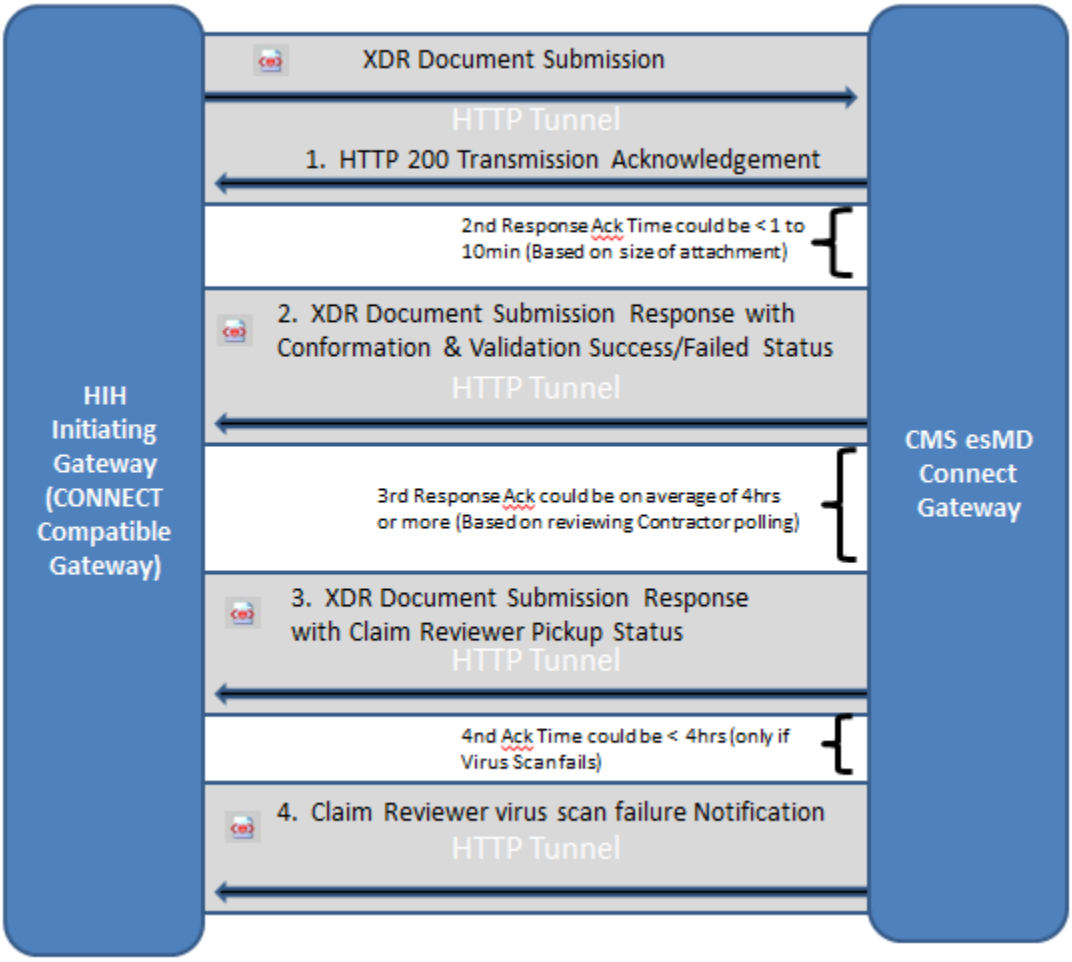
The following diagram illustrates the communication between the HIH and the CMS esMD CONNECT Gateway with asynchronous messaging with three HTTPS requests.

The HIH Gateway submits the electronic medical claim documentation based on the CMS on-boarded HIH and their gateway OID. The HIH submits the IHE Cross-Enterprise Document Reliable interchange (XDR) profile SOAP Messages to CMS with the ITI – 41 (Provide and Register Document Set – b) transaction, SAML Assertions, Document Submission Meta Data and C62 Payload in the SOAP body.

The CMS esMD CONNECT Gateway receives the request, with SAML Assertions, and consults its gateway Policy Enforcement Point (which could be a SAML authority) which, in turn, uses the esMD database to establish whether the submitted Home Community ID will be allowed to perform the esMD document submission function.

Assertions can convey information about the authentication and authorization acts that the HIH performed by subjects (the OID acts as a User ID), its attributes, and authorization decisions (to check whether the subject /OID is allowed to submit the claim supporting documents).

519 **Figure 2: Asynchronous Acknowledgments with multiple HTTP connections**



520
521

522 ### 5.3.2 Triggers

523
524 All requests issued by the HIH must implement the NHIN Messaging Platform Service Interface
525 Specification and the NHIN Authorization Framework Service Interface Specification.

526 ### 5.3.3 Transaction Standard

527
528 The authorization framework is based on the implementation of the OASIS WS-I Security Profile SAML
529 Token Profile as specified in the NHIN Messaging Platform Service Interface Specification. SAML 2.0 is
530 the base specification for expressing assertions in the NHIN.

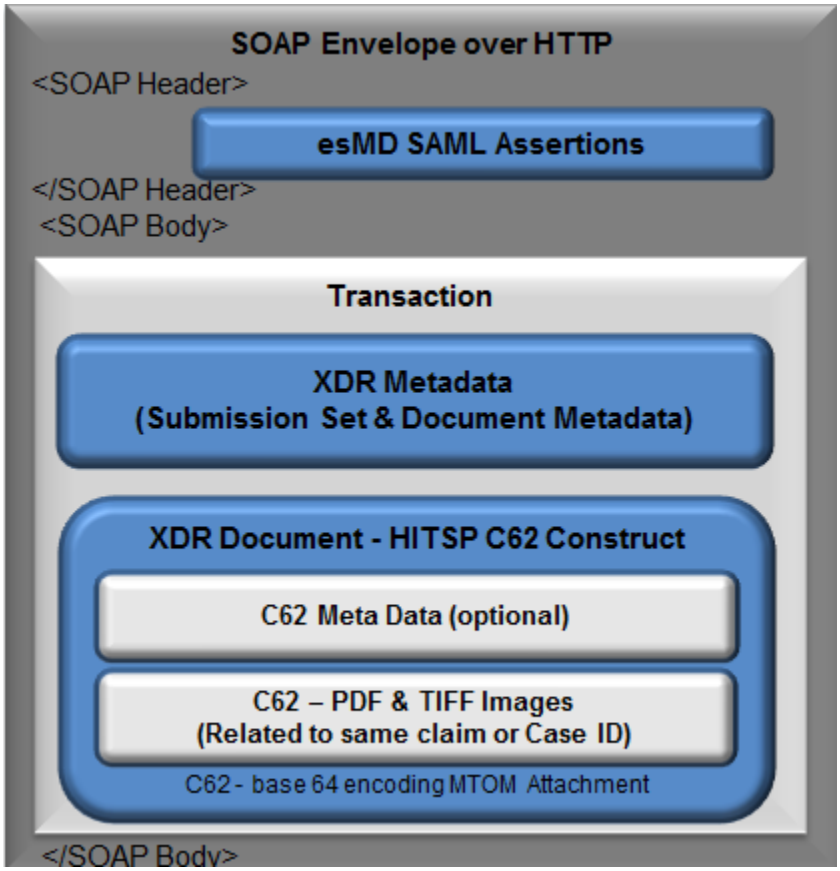
531 ### 5.3.4 Technical Pre-Conditions

532 • HIHs must conform to the interoperability standards:
533 ○ NHIN and CMS esMD Profile
534 ○ IHE CROSS-ENTERPRISE DOCUMENT RELIABLE MESSAGING (XDR)
535 ○ WS-I Basic Profile

    - WS-I Basic Security Profile
- HIHs must conform the Claim Medical Document to the Health Information Technology Standards Panel (HITSP) C62 Interoperability Specification.
- HIHs must conform to NHIN messaging platform and authorization framework for communication.
    - Messages: SOAP v2.0 with Message Transmission Optimization Mechanism (MTOM) attachments
    - Service Descriptions: WSDL
    - Addressing/Routing: WS-Addressing
    - Security: WS-Security, XML DSIG
    - Authorization: SAML Assertion
    - Authentication: X509 certificate, 2-way TLS with FIPS 140-2 enable mode, 128 bit encryption.
    - Base 64 encoding of the C62 payload
- The esMD Document Submission data is transmitted in the SOAP message with IHE Cross - Document Reliable XDR (in Phase1) and ASC X12 (in phase 2) transactions.
- There will be mutual authentication between the HIH gateway and the CMS CONNECT Gateway using a Non ONC TLS certificate for phase 1 and ONC issued entrust TLS certificates for Phase 2.
- The CMS CONNECT Gateway will authorize the requests based on the SAML Assertions with its Home Community ID and Organization IDs.
- The HIH will create digitally signed SAML Assertions.
- A globally unique identifier, assigned by HIH internal system and primarily intended for use as a unique identifier for each submission that can be used to correlate the request and responses of a particular submission, is generated (Note: The Gateway created message ID is different from this unique ID).
- The HIH will encode the attached C62 document in base 64 encoding and add its hash key to the XDR metadata.
- The HIHs have established CMS data use agreements to share claim supporting documentation data to CMS. A later release of esMD requires HIHs to be NHIN on-boarded as outlined in the data user agreement.
- Architectures of the HIHs are decoupled from, and are opaque to, the CMS esMD and other HIHs. The HIHs need not use the same CMS esMD security mechanisms or standards internally.
- We suggest the initiating HIH authenticate and authorize the gateway system by sending the document submission request to the esMD project, and it is required that they do so internally. The esMD is not responsible for this action.

5.3.5 SOAP Message Envelope

Figure 3: SOAP Envelope with XDR Interchange / HITSP C62 Construct




```
<soapenv:Envelope
        xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
        xmlns:urn="urn:gov:hhs:fha:nhinc:common:nhinccommonentity"
        xmlns:urn1="urn:gov:hhs:fha:nhinc:common:nhinccommon"
        xmlns:add="http://schemas.xmlsoap.org/ws/2004/08/addressing"
        xmlns:urn2="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0"
        xmlns:urn3="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
        xmlns:urn4="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
        xmlns:urn5="urn:ihe:iti:xds-b:2007">
        <soapenv:Header/>
        <soapenv:Body>
                <urn:RespondingGateway_ProvideAndRegisterDocumentSetRequest>
                        <urn:assertion>
                        <urn:nhinTargetCommunities>
                        <urn:ProvideAndRegisterDocumentSetRequest>
                </urn:RespondingGateway_ProvideAndRegisterDocumentSetRequest>
        </soapenv:Body>
</soapenv:Envelope>
```

The MTOM related tags are abstracted in above soap envelope.

Table 2 lists the Name space details associated with the CONNECT Software.

Table 2: Name Spaces Details with CONNECT Software

S.No	Name Space	Name Space URL
1	soapenv	http://schemas.xmlsoap.org/soap/envelope/
2	urn	urn:gov:hhs:fha:nhinc:common:nhinccommonentity"
3	urn1	urn:gov:hhs:fha:nhinc:common:nhinccommon
4	add	urn:http://schemas.xmlsoap.org/ws/2004/08/addressing
5	urn2	urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0
6	urn3	urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0
7	urn4	urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0
8	urn5	urn:ihe:iti:xds-b:2007

5.3.5.1 SAML Assertions

The SAML Assertions define the exchange of metadata used to characterize the initiator of an HIH request so that it may be evaluated by the CMS esMD CONNECT Gateway in local authorization decisions. The purpose of this SAML Assertion exchange is to provide the CMS esMD CONNECT Gateway with the information needed to make an authorization decision using the policy enforcement point for the requested esMD function. Each initiating SOAP message must convey information regarding the HIH attributes and authentication using SAML 2.0 Assertions.

5.3.5.2 Assertions Design Principals and Assumptions:

The esMD CONNECT Gateway uses the information conveyed via the Assertions (Authorization Framework) to inform its local authorization policy decision.

The initiating HIH must include all REQUIRED attributes in each request message. It is at the discretion of the receiving esMD CONNECT Gateway to decide which attributes to consider in its local authorization decision against its policy decision controller.

The initiating HIH is responsible for the authentication and authorization of its users and system requests.

5.3.5.3 Assertions Transaction Standard

- NHIN Authorization Framework v 2.0
- OASIS SAML V2.0,
- Authentication Context for SAML V2.0,
- Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of SAML for Healthcare Version 1.0 OASIS Web Services Security: SAML Token Profile 1.1 specifications.

5.3.5.4 Specific NHIN Assertions

The following set of SAML Assertions are designated as required (R) for all communications between the HIH and the CMS esMD CONNECT Gateway.

649 **Table 3: Standard SAML Assertions in SOAP Envelope**
650

SAML Assertions in SOAP Envelope		
Element / Attribute	**esMD Required**	**Who Create? - Gateway or Manual**
SAML ASSERTION	**R**	
Version	R	CONNECT Gateway
ID	R	CONNECT Gateway
IssueInstant	R	CONNECT Gateway
Issuer	R	CONNECT Gateway
Subject	R	CONNECT Gateway
Authn Statement	**R**	
AuthnContext	R	HIH Application shall add under assertion
SubjectLocality	R	HIH Application shall add under assertion
AuthnInstant	R	HIH Application shall add under assertion
SessionIndex	O	HIH Application shall add under assertion
Attribute Statement	**R**	
subject-ID	R	CONNECT Gateway
organization	R	HIH Application shall add under assertion
homeCommunityID	R	HIH Application shall add under assertion
purposeofuse	R	HIH Application shall add under assertion
NPI	R	HIH Application shall add under assertion – 'userInfo.userName'
Intended Recipient	R	HIH Application shall add under assertion - 'uniquePatientId'
Authorization Decision Statement	**O**	
Action	R	HIH Application shall add under assertion
Decision	R	HIH Application shall add under assertion
Resource	R	HIH Application shall add under assertion
Evidence	R	HIH Application shall add under assertion

651 **5.3.5.5 esMD SAML Assertions details**
652
653 The following table provides the esMD SAML Assertion details.
654
655 **Table 4: esMD SAML Assertion Details**

S.No	SAML assertion Attribute	Definition and Example	R/ R2 / O	Source / CONNECT software allowed	References to esMD Domain specific values
1	homeCommunityId	*<urn1:homeCommunityId > <urn1:description>Description of the submitting HIH CONNECT or CONNECT Compatible Gateway</urn1:description> <urn1:homeCommunityId>urn:oid:1.3.6.1.4.1.101420.6.1</urn1:homeCommunityId> <urn1:name>Name of the submitting HIH CONNECT or CONNECT Compatible Gateway</urn1:name> </urn1:homeCommunityId>*	R	esMD Requirement / Yes	HIH OID
2	organizationId	*<urn1:organizationId > <urn1:description>Description of Broker Organization between Provider and the submitting HIH CONNECT or CONNECT Compatible Gateway</urn1:description>*		esMD Requirement / Yes	HIH OID or any broker organization (its OID) between Providers and HIH

		<urn1:homeCommunityId>urn:oid:1.3.6.1.4.1.101420.6.1</urn1:homeCommunityId> *<urn1:name>Name of Broker Organization between Provider and the submitting HIH CONNECT or CONNECT Compatible Gateway</urn1:name>* *</urn1:organizationId>*			
3	intendedRecipient	***Note: Temporarily, add the Intended Recipient value in the unique Patient ID as OID.*** *<urn1:uniquePatientId>urn:oid:2.16.840.1.113883.13.34.110.1.110.9</urn1:uniquePatientId>* *In the next spec factory changes, the intended recipient values will be change to HL7 XON.* The intendedRecipient field in the XDS Metadata shall use the HL7 XON data type for this profile. This data type contains 10 subfields separated by a ^ sign, of which three are required: 1) XON.1 is the name of the organization that is the intended recipient. In this profile, this shall be the name of the RAC that is intended to receive the submission. 2) XON.6 identifies the assigning authority for the identifiers appearing in XON.10. This field shall be completed using the following string: &*CMS OID FOR RACS*&ISO [ed. Note: Replace CMD OID FOR RACS with a CMS assigned OID]. 3) XON.10 is the CMS Identifier for the RAC. An example appears below (bold text should be replaced with the appropriate values): [Ed. Note: Replace CMD OID FOR RACS with a CMS assigned OID] **RAC ORGANIZATION NAME**^^^^^&*CMS OID FOR RACS*&ISO^^^^**CMS ASSIGNED IDENTIFIER***<urn1:intendedReceipient >* *<urn1:description>Description of receiving Review Contractor</urn1:description>* *<urn1:organizationId>DCS^^^^^&2.16.840.1.113883.13.34.110.1.100.1&ISO^^^^^2.16.840.1.113883.13.34.110.1</urn1:organizationId>* *<urn1:name>Name of Review Contractor, to whom Claim Medical Documentation shall be submitted.</urn1:name>* *</urn1:intendedReceipient>*	R	esMD Requirement / **NO***	See Table 4
4	npi	*In the future – NPI will be added to connect assertions. Until then esMD will use the 'username' attribute field for 'NPI' value.*	R	esMD Requirement / **NO***	

		<urn1:userInfo> ***<urn1:userName>610</urn1:userName>*** *<urn1:org>* *<urn1:description>Description of Provider NPI </urn1:description>* *<urn1:homeCommunityId>Any Broker organization in between Provider and HIH or HIH OID</urn1:homeCommunityId>* *<urn1:name>Name of Provider from whom Claim Medical Documentation are submitted</urn1:name>* *</urn1:org>* *</urn1:userInfo>*			
5	purposeOfDisclosure Coded	HIH shall enter appropriate values. This is used by the CONNECT Gateway for SOAP header SAML processing *<urn1:purposeOfDisclosureCoded>* *<urn1:code>PAYMENT</urn1:code>* *<urn1:codeSystem>2.16.840.1.113883.3.18.7.1</urn1:codeSystem>* *<urn1:codeSystemName>esMD CMS Purpose</urn1:codeSystemName>* *<urn1:codeSystemVersion>1.0</urn1:codeSystemVersion>* *<urn1:displayName>Medical Claim Documentation Review</urn1:displayName>* *<urn1:originalText>Medical Claim Documentation Review</urn1:originalText>* *</urn1:purposeOfDisclosureCoded>*	R	esMD Requirement / Yes	
6	samlAuthnStatement	HIH shall enter appropriate values. This is used by the CONNECT Gateway for SOAP header SAML processing *<urn1:samlAuthnStatement>* *<urn1:authInstant>2011-01-05T16:50:01.011Z</urn1:authInstant>* *<urn1:sessionIndex>987</urn1:sessionIndex>* *<urn1:authContextClassRef>urn:oasis:names:tc:SAML:2.0:ac:classes:X509</urn1:authContextClassRef>* *<urn1:subjectLocalityAddress>158.147.185.168</urn1:subjectLocalityAddress>* *<urn1:subjectLocalityDNSName>cms.hhs.gov</urn1:subjectLocalityDNSName>* *</urn1:samlAuthnStatement>*	R	esMD Requirement / Yes	
7	samlAuthzDecisionStatement	Except ID attribute in samlAuthzDecisionStatement, all the other appropriate values shall be entered by HIH. ID attribute will be used by esMD application and other values will be used by the CONNECT Gateway for SOAP header SAML processing.	R	esMD Requirement / Yes	

		ID attribute will be used to correlate the request to response and to verify the double submission of Claim Document submission. Each Claim Document Submission SOAP Message from CONNECT Gateway shall have a Unique ID populated by HIH CONNECT Adapter or CONNECT Compatible software. This unique ID shall be created by HIH using the JAVA UUID api and populate into "id" attribute of this SAML Authorization Decision Statement. <urn1:id>40df7c0a-ff3e-4b26-baeb-f2910f6d05a9</urn1:id> *Note: Unique ID is different from CONNECT Gateway Message ID.CONNECT Gateway automatically adds the message id to the SOAP Header. This message ID is unique for any outgoing messages.* *<urn1:samlAuthzDecisionStatement > <urn1:decision>Permit</urn1:decision> <urn1:resource>https://158.147.185.168:8181/esMD/DocumentSubmission</urn1:resource> <urn1:action>TestSaml</urn1:action> <urn1:evidence> <urn1:assertion> **<urn1:id>40df7c0a-ff3e-4b26-baeb-f2910f6d05a9</urn1:id>** <urn1:issueInstant>2011-01-05T16:50:01.011Z</urn1:issueInstant> <urn1:version>2.0</urn1:version> <urn1:issuerFormat>urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName</urn1:issuerFormat> <urn1:issuer>CN=HIH SAML User,OU=QSSI,O=QSSI,L=Baltimore,ST=MD,C=US</urn1:issuer> <urn1:conditions> <urn1:notBefore>2011-01-05T16:50:01.011Z</urn1:notBefore> <urn1:notOnOrAfter>2011-01-05T16:53:01.011Z</urn1:notOnOrAfter> </urn1:conditions> <urn1:accessConsentPolicy>Claim-Ref-1234 NA for esMD</urn1:accessConsentPolicy> <urn1:instanceAccessConsentPolicy>Claim-Instance-1 NA for esMD</urn1:instanceAccessConsentPolicy> </urn1:assertion> </urn1:evidence> </urn1:samlAuthzDecisionStatement>*			

The current NHIN CONNECT 3.1 Software implementation doesn't support the "Intended Recipient" and "NPI" fields as a part of assertions. So, the esMD Team is working on a patch to provide a collection placeholder in assertions to accommodate the key/value pairs. This collection could hold all the application or project specific values (e.g., Intended Recipient and NPI). This patch will be provided to all the participating esMD HIHs as a jar file and shall be easily integrated to CONNECT 3. Later this updated source code will be contributed to the CONNECT team.

The Interim solution is to **populate the 'Intended Recipient' and 'NPI' values into 'uniquePatientId' and 'userInfo.userName' field of the current CONNECT software AssertionType object.**

5.3.5.6 SAML Assertion Attributes

This will be added in the Authorization Decision Statement.

5.3.5.6.1.1 Version attribute

The version attribute defines SAML v2.0 as the version.

5.3.5.6.1.2 ID attribute

The ID Attribute is an xs:ID as defined by **http://www.w3.org/TR/xml-Id/.**

5.3.5.6.1.3 Issue Instant

The IssueInstant attribute is an xs:dateTime as defined by **http://www.w3.org/TR/xmlschema-2/**.

5.3.5.6.1.4 Issuer

The <Issuer> element identifies the individual gateway system responsible for issuing the Assertions carried in the message. Since esMD doesn't have the user IDs, the issuer will be the HIH System Name. This element includes a NameID Format attribute which declares the format used to express the value contained in this element. The Name ID format is ***urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName*** for the sending NHIO (Health Information Organization acting as a node on the NHIN).

5.3.5.6.1.5 Subject

The Subject element shall identify the Subject of the assertion. This element also includes a NameID. The Format attribute declares the format used to express the value contained in this element: the HIH System Name making the request at the initiating NHIO. The Name ID format is ***urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName*** for the sending NHIO.

5.3.5.6.1.6 SAML Statement Elements

The esMD SAML statement elements used are separated into Authentication and Attribute. Each statement will be further defined in the following paragraphs.

5.3.5.7 Attribute Statement

The Attribute Statement element describes a statement by the SAML authority asserting that the requesting HIH system is associated with the specified attributes. The Attribute Statement is required to contain attribute elements as defined by the OASIS XSPA profile of SAML and described in the sections that follow. The Attribute Statement is comprised of the following attributes: Subject ID, Subject Organization, Home Community ID, Purpose of Use, NPI, and Intended Recipient.

The value on the Subject ID and Subject Organization attributes shall be a plain text description of the user's name (not user ID) and organization, respectively. These are primarily intended to support auditing.

5.3.5.7.1.1 Subject ID Attribute

This Subject Identifier element has the HIH initiating gateway Name. The name of the system as required by HIPAA Privacy Disclosure Accounting is placed in the value of the element.

```
<urn1:QualifiedSubjectIdentifier xmlns:urn1="urn:gov:hhs:fha:nhinc:common:nhinccommon>
        <urn1:SubjectIdentifier>HIH esMD Initiating Gateway </urn1:SubjectIdentifier >
        <urn1:AssigningAuthorityIdentifier>HIH Name</urn1: AssigningAuthorityIdentifier >
</ urn1:QualifiedSubjectIdentifier>
```

5.3.5.7.1.2 Subject Organization Attribute

This Assigning Authority Identifier element has the subject organization Name under which the initiating gateway (subject name) is running. In plain text, the organization to which the user belongs, as required by HIPAA Privacy Disclosure Accounting, is placed in the value of the Attribute Value element.

```
<urn1:QualifiedSubjectIdentifier xmlns:urn1="urn:gov:hhs:fha:nhinc:common:nhinccommon>
        <urn1:SubjectIdentifier>HIH esMD Initiating Gateway </urn1: SubjectIdentifier >
        <urn1:AssigningAuthorityIdentifier>HIH Name</urn1: AssigningAuthorityIdentifier >
</ urn1:QualifiedSubjectIdentifier>
```

5.3.5.7.1.3 Home Community ID Attribute

This attribute element has the HIH gateway Name attribute. The value is the HL7 issued Home Community ID (an Object Identifier) assigned to the HIH that is initiating the request, using the URN format (i.e., "urn:oid:" appended with the OID). One home community gateway can have multiple organization IDs. Organization IDs act as a broker to home community organizations. If there are no brokers to the organizations, then both the home community ID and the organization ID attributes will be the same.

See the sample in the above Table4: esMD SAML Assertion Details

5.3.5.7.1.4 Purpose of Use Attribute

This attribute element has the purpose of use disclosure Name attribute. The value of the attribute element is a child element, “PurposeOfUse”, in the namespace “urn:hl7-org:v3”, whose content is defined by the “CE” (coded element) data type from the HL7 version 3 specification. The PurposeOfUse element contains the coded representation of the Purpose for Use that is, in effect, for the request. The PurposeofUse is defined in NHIN Authorization Framework document.

741
742 See the sample in the above Table4: esMD SAML Assertion Details

743 **5.3.5.7.1.5 National Provider Identifier (NPI) Attribute**

744
745 An NPI is a unique 10-digit identification number issued to health care providers in the United States by
746 CMS. This attribute provides the ability to specify an NPI value as part of the SAML Assertion that
747 accompanies a message that is transmitted across the NHIN.

748 **5.3.5.7.1.6 Intended Recipients Attribute**

749
750 Intended Recipients are review contractors, to whom the esMD needs to send the HIH submitted Claim
751 Medical documentation payloads. The valid values are addressed in section 5.3.8.

752 **5.3.5.8 Authentication Statement**

753
754 The SAML Authentication Assertions are associated with authentication of the Subject (HIH Gateway
755 Identification). The <AuthnStatement> element is required to contain an <AuthnContext> element and an
756 AuthnInstant attribute. The SAML AuthnStatement contains one AuthnContextClassRef element
757 identifying the method by which the subject was authenticated. Other elements of SAML AuthnStatement
758 include <SubjectLocality> element and a SessionIndex attribute. The saml:Authentication is comprised of
759 the 4 Attributes or Elements: AuthnContext, Subject Locality, AuthnInstant, and Session Index.

760 **5.3.5.8.1.1 Authentication Method (AuthnContext)**

761
762 An authentication method, the <AuthnContext> element indicates how that authentication was done. Note
763 that the authentication statement does not provide the means to perform that authentication, such as a
764 password, key, or certificate. This element will contain an authentication context class reference.
765
766 *Authentication Method - X.509 Public Key*
767 *URN - urn:oasis:names:tc:SAML:2.0:ac:classes:X509*

768 **5.3.5.8.1.2 Subject Locality**

769
770 Subject Locality references from where the user was authenticated. The Subject Locality element
771 specifies the DNS domain name and IP address for the system entity that was authenticated.

772 **5.3.5.8.1.3 Authentication Instant (AuthnInstant)**

773
774 The Authentication Instant, <AuthnInstant>, attribute specifies the time at which the authentication took
775 place which is an xs:dateTime as defined by **http://www.w3.org/TR/xmlschema-2/**.

776 **5.3.5.8.1.4 Session Index**

777
778 The Session Index, SessionIndex, attribute identifies the session between the Subject and the
779 Authentication Authority.
780
781 Example:
782
783 See the sample in the above Table4: esMD SAML Assertion Details,

5.3.5.9 Authorization Decision Statement

This is an optional element which could convey all the valid NPI submissions.

The *Authorization Decision Statement* element describes a statement by the SAML authority asserting that a request for access, by the statement's subject to the specified resource, has resulted in the specified authorization decision on the basis of some optionally specified evidence. This element provides the HIH an opportunity to assert that it holds an Access Consent Policy which the CMS esMD CONNECT Gateway may wish to evaluate in order to determine if access to the requested resource(s) should be allowed for the submitted provider.

The information conveyed within the Authorization Decision Statement may be used by the CMS esMD CONNECT Gateway to retrieve the asserted Access Consent Policy. The format of the Access Consent Policy is defined in the NHIN Access Consent Policy specification.

The Authorization Decision Statement will be used when the provider has granted permission to submit the documentation to the CMS esMD CONNECT Gateway, and the HIH needs to make that authorization known to the CMS esMD CONNECT Gateway.

The Authorization Decision Statement has the following content: Action, Decision, Resource, Evidence, and Assertions.

5.3.5.9.1.1 Action

This action must be specified using a value of Execute.

5.3.5.9.1.2 Decision

The Decision attribute of the Authorization Decision Statement must be Permit.

5.3.5.9.1.3 Resource

The Resource attribute of the Authorization Decision Statement must be the Uniform Resource Identifier (URI) of the endpoint to which the CMS esMD CONNECT Gateway request is addressed or an empty URI reference.

5.3.5.9.1.4 Evidence

The Authorization Decision Statement must contain an <Evidence> element, containing a single <Assertion> child element.

5.3.5.9.1.4.1 Assertions

This <Assertion> element must contain an ID attribute, an IssueInstant attribute, a Version attribute, an Issuer element, and an Attribute Statement element. Please, see section 5.3.7.3.1 for more details on building the Assertion.

There must be at least one of the following Attributes in the Attribute Statement.

- An <Attribute> element with the name AccessConsentPolicy and NameFormat **http://www.hhs.gov/healthit/nhin**. The value(s) for this attribute will be the OIDs of the access policies that the asserting entity has previously agreed to with other entities. The OIDs MUST be expressed using the urn format (e.g., - urn:oid:1.2.3.4).

- An <Attribute> element with the name InstanceAccessConsentPolicy and NameFormat **http://www.hhs.gov/healthit/nhin**. The value(s) of this attribute will be the OIDs of the patient specific access policy instances. The OIDs MUST be expressed using the urn format (e.g., - urn:oid:1.2.3.4.123456789). If a requestor specifies this Attribute, the requestor MUST support the ability for the specified policy document(s) to be retrieved via the transactions defined in HITSP TP30.

- The "ContentReference", "ContentType", and "Content" attributes from the Trial Implementation specifications have been removed and should no longer be used.

See the sample in the above Table4: esMD SAML Assertion Details.

5.3.6 Target Communities

The target communities must specify the targeted CMS esMD CONNECT Gateway OID details. It contains three values:

- **Description:** The esMD CONNECT Gateway with an XDR document submission endpoint to accept claim related document submissions to CMS;
- **HomeCommunityId**: The esMD CONNECT Gateway Home Community ID (OID);
- **Name:** The Name of the esMD CONNECT Gateway Home Community ID (OID).

```
<urn:nhinTargetCommunities>
        <urn1:homeCommunity>
                <urn1:description>
                        esMD CONNECT Gateway Home Community ID Description
                </urn1:description>
                <urn1:homeCommunityId>urn:oid:1.3.6.1.4.1.101420.6.1</urn1:homeCommunityId>
                <urn1:name>Name of the esMD CONNECT Gateway Home Community ID<urn1:name>
        </urn1:homeCommunity>
</urn:nhinTargetCommunities>
```

For CMS response Message to HIH, these nhinTargetCommunities shall have the HIH OID information.

5.3.7 Metadata Fields

The HIH adopts the IHE Cross Enterprise Document Reliable Interchange (XDR) profile in a SOAP envelope with an XDS Repository Submission Request-Provide and Register Document set, b (ITI-41) transaction metadata and C62 document payload with MTOM, base 64 encoded attachments.

```
<urn:ProvideAndRegisterDocumentSetRequest>
<urn2:SubmitObjectsRequest id="999" comment="comment">
        <urn4:RegistryObjectList>
                <urn4:ExtrinsicObject id="Document01" mimeType="text/xml"
                objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">
                <urn4:RegistryPackage id="SubmissionSet01">
```

```
                <urn4:Classification id="classification01" classifiedObject="SubmissionSet01"
                classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-b4633d873bdd"/>
                <urn4:Association id="association01" associationType="HasMember"
                sourceObject="SubmissionSet01" targetObject="Document01">
        </urn4:RegistryObjectList>
        <urn4:RegistryObjectList>
                <urn4:ExtrinsicObject id="Documentxx" mimeType="text/xml"
                objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">
                <urn4:RegistryPackage id="SubmissionSetxx">
                <urn4:Classification id="classificationxx" classifiedObject="SubmissionSetxx"
                classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-b4633d873bdd"/>
                <urn4:Association id="associationxx" associationType="HasMember"
                sourceObject="SubmissionSetxx" targetObject="Document01">
        </urn4:RegistryObjectList>
<urn2:SubmitObjectsRequest>
<urn5:Document id="Document02">
        <ClinicalDocument …(Encoded Message)
                …..
                <nonXMLBody>
        2PD943454OIJKD2lvbj0iMS4wIiBlbmNvZGluZz0iVVRGLTgiPz4NjxDbGluaWNhbERvY3VtZW5=
                </nonXMLBody>
        </ClinicalDocument>
</urn5:Document>
<urn5:Document id="Documentnn">
nnPD94bWwgdlvj0iMS4wIiBlbmNvZGluZz0DLKFALDFALDECjxDbGluaWNhbERvY3VtZW5=
</urn5:Document>
</urn:ProvideAndRegisterDocumentSetRequest>
```

"SubmitObjectsRequest" is a collection of repository metadata of multiple MTOM base64 encoded document attachments transferred between an HIH and the esMD Gateway.

An ExtrinsicObject (XDSDocumentEntry) represents a single attached document metadata in the XDR esMD Document Submission SOAP message, which refers to its attached document.

"RegistryPackage" is a collection of repository metadata of just one MTOM base64 encoded document.

Following are the esMD Functional (mandatory) and Transmission (mandatory) metadata elements needed for the esMD Gateway to process the submitted claim medical document. For further details on each of the tags, review XDS IHE_ITI_TF Volume 3, Revision 6.

5.3.8 esMD Functional Specific Submission Set Metadata Attributes

Table 5 details the esMD Functional Specific Submission Set Metadata Attributes to confirm with the IHE ITI Technical Framework Volume 3, Revision 6 and XDR Interoperability Testing.

The following table indicates if the esMD XDR Submission Set metadata attributes are required (R), required if known (R2), or optional (O). To confirm the IHE XDR interoperability test, add xml tag with the value as "NA", if R2 or Optional.

926 **Table 5: esMD Functional Specific Submission Set Metadata Attributes**

S.No	esMD XDR Submission Set Metadata Attribute	Definition and Example	R/ R2 / O*	Source	References to Possible esMD Domain specific values	Data Type (Length)
1	**esMDClaimId**	Claim Identifier is the identifier with which the provider submits the Claim to CMS. This could be found in the Additional Documentation Request (ADR) letter from Review Contractor. *<urn4:Slot name="esMDClaimId">* *<urn4:ValueList>* *<urn4:Value>12345678901234567890AB* *</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	esMD Requirement	ADR Letter	Alphanumeric string (32)
2	**esMDCaseId**	Case Identifier is the identifier, generated by the Review Contractor to open a claim specific case. This could be found in Additional Documentation Request (ADR) letter from the Review Contractor if the request is from MACs. *<urn4:Slot name="esMDCaseId">* *<urn4:ValueList>* *<urn4:Value>12345678901234567890AB* *</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R2	esMD Requirement	ADR Letter (if MAC is the Review Contractor)	Alphanumeric string (32)
3	IntendedRecipient	Intended Recipient represents the organization(s) or person(s) for whom the Document Submission set is intended for In esMD, the Intended Recipient will be an organization (Review Contractor) to whom the sender (HIH) will submit the message with esMD Claim supporting Documents. This Intended Recipient will be identified by a HL7 issued organizational identifier (OID) Example: Review Contractor OID *<urn4:Slot name="intendedRecipient">* *<urn4:ValueList>* *<urn4:Value>*2.16.840.1.113883.13.34.110**.2.100.1***</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	See Table 4 in this Implementation Guide	String (64)
4	Author	Represents the provider (NPI), who submits the Claim Supporting Documents in response to the Additional Documentation Request letter (ADR) from the CMS Review Contractor This attribute could either contain the following	R	IHE ITI TF Rel 6 Vol3	NPI. Table 4.1-5 Document Metadata	Numeric (10)

		sub-attributes based on who (either Provider or institution NPI) submits the documentation: This is esMD Required Field. authorInstitution authorPerson *<urn4:Classification id="cl08" classificationScheme="urn:uuid: a7058bb9-b4e4-4307-ba5b-e3f0ab85e12d" classifiedObject=" SubmissionSet01" nodeRepresentation="author">* *<urn4:Slot name="authorInstitution">* *<urn4:ValueList>* *<urn4:Value>604123</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Slot name="authorPerson">* *<urn4:ValueList>* *<urn4:Value>603111</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *</urn4:Classification>*			Attribute Definition in IHE ITI TF Volume 3 Revision 6.0	
5	authorInstitution (sub-attribute of author)	If there is only one document in the SubmissionSet, authorInstitution attribute of the SubmissionSet shall have the same NPI as the one used in the authorInstitution attribute at the document level. If there is more than one document in the SubmissionSet, authorInstitution attribute of the SubmissionSet shall have the NPI of the organization/institution which put together all the documents included in the SubmissionSet. Please note: At the SubmissionSet level, either the authorInstitution or authorPerson attribute shall be used but never both. *<urn4:Slot name="authorInstitution">* *<urn4:ValueList>* *<urn4:Value>604123</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R2	IHE ITI TF Rel 6 Vol3	NPI Institution Name	Numeric (10)
5.1	authorPerson (sub-attribute of author)	If there is only one document in the SubmissionSet, authorPerson attribute of the SubmissionSet shall have the same NPI as the one used in the authorPerson attribute at the document level. If there is more than one document in the SubmissionSet, authorPerson attribute of the SubmissionSet shall have the NPI of the provider who put together all the documents in the SubmissionSet. Please note: At the SubmissionSet level, either	R2	IHE ITI TF Rel 6 Vol3	NPI Person or Machine Name.	Numeric (10)

		the authorInstitution or authorPerson attribute shall be used but never both. *<urn4:Slot name="authorPerson"> <urn4:ValueList> <urn4:Value>603111</urn4:Value> </urn4:ValueList> </urn4:Slot>*				
6	Comments	Comments associated with the Submission Set. Free form text *<urn4:Description> <urn4:LocalizedString value="esMD Claim Document Submission in response to Review Contractor ADR Letter"/> </urn4:Description>*	O	IHE ITI TF Rel 6 Vol3		String (256)
7	contentTypeCode	The submission set is a response to Additional Documentation Request (ADR) from the Review Contractor. The ContentTypeCode is the code that specifies this – a Response to ADR *<urn4:Classification id="cl09" classificationScheme="urn:uuid:aa543740-bdda-424e-8c96-df4873be8500" classifiedObject="SubmissionSet01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1"> <urn4:Slot name="contentTypeCode"> <urn4:ValueList> <urn4:Value>1</urn4:Value> </urn4:ValueList> </urn4:Slot> <urn4:Name> <urn4:LocalizedString value="Response to Additional Documentation Request (ADR)"/> </urn4:Name> </urn4:Classification>*	R	IHE ITI TF Rel 6 Vol3	See Table : 6 in this Implementation Guide	String (16)
8	entryUUID	A unique ID or a globally unique identifier within the document submission request for the SubmissionSet. For example, "***SubmissionSet01"*** can be *entryUUID.* It can also be in the UUID format. In the below example "***SubmissionSet01"*** *is used as entryUUID. This can also be UUID format.* Example: *<urn4:RegistryPackage id="**SubmissionSet01**"> …. </urn4:RegistryPackage>*	R	IHE ITI TF Rel 6 Vol3	Unique Name for each attached document with a submitted document. Either UUID or some unique identifier.	String (64)
9	patientId	Since this is a required XDR field and we need to use it, we are going to populate this field with Claim ID. Since this field follows Root + Extension format, we are going to include CMS OID as the root and Claim ID as the extension,	R	IHE ITI TF Rel 6 Vol3	CMS OID.Claim ID	String (256)

		like so: CMS OID.ClaimID It is important to remember that Claim ID will also be populated in the attribute mentioned in row 1 of this table in addition to being populated here. Note: Soon, IHE might change PatientId to R2 'Required if known'. *<urn4:ExternalIdentifier id="ei03" registryObject="Document01" identificationScheme="urn:uuid:6b5aea1a-874d-4603-a4bc-96a0a7b38446" value="2.16.840.1.113883.13.34.110.1.1000.1^^^^&12345">* *<urn4:Name>* *<urn4:LocalizedString value="XDSDocumentEntry.patientId"/>* *</urn4:Name>* *</urn4:ExternalIdentifier>*				
10	sourceId	Globally unique identifier, in OID format, identifying the Health Information Handler (HIH) Gateway through which document/s were sent to the CMS esMD Gateway. *<urn4:ExternalIdentifier id="ei04" registryObject="SubmissionSet01" identificationScheme="urn:uuid:554ac39e-e3fe-47fe-b233-965d2a147832" value="12.16.840.1.113883.13.34.110.2">* *<urn4:Name>* *<urn4:LocalizedString value="XDSSubmissionSet.sourceId"/>* *</urn4:Name>* *</urn4:ExternalIdentifier>*	R	IHE ITI TF Rel 6 Vol3	HIH OID	String (64)
11	submissionTime	Point in Time when the SubmissionSet was created at the HIH CONNECT Adapter. *<urn4:Slot name="submissionTime">* *<urn4:ValueList>* *<urn4:Value>20041225235050</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	Timestamp	Date (YYYYMMDDHHMMSS)
12	title	Represents the title of the Submission Set. esMD Title for the Document SubmissionSet shall be – 'Claim Supporting Medical Documentation'. <urn4:Name> <urn4:LocalizedString value="Claim Supporting Medical Documentation"/> </urn4:Name>	O	IHE ITI TF Rel 6 Vol3	Text	String (256)
13	uniqueId	A globally unique identifier, in OID format, assigned by the HIH to the submission set in the transmission. The length of this Unique Identifier	R	IHE ITI TF Rel 6 Vol3	Unique Identifier shall not	TBD

		shall not exceed 128 bytes. <urn4:ExternalIdentifier id="ei05" registryObject="SubmissionSet01" identificationScheme="urn:uuid:96fdda7c-d067-4183-912e-bf5ee74998a8" value="554ac39e-ef6343434-b233-965d34345555"> <urn4:Name> <urn4:LocalizedString value="XDSSubmissionSet.uniqueId"/> </urn4:Name> </urn4:ExternalIdentifier>			exceed 128 bytes	

Table 6 details the esMD specific Document Metadata Attributes. To confirm with the IHE ITI Technical Framework Volume 3, Revision 6 and XDR Interoperability Testing.

The following table indicates if the esMD XDR Document metadata attributes are required (R), required if known (R2), or optional (O). To confirm IHE XDR interoperability test, add xml tag with the value as “NA”, if R2 or Optional.

Table 6: esMD Document Metadata Attributes

S.No	esMD XDR Documents Metadata Attribute	Definition and Example	R/ R2/ O *	Source	References to Possible esMD Domain specific values	Data Type (Length)
1	author	Represents the provider NPI or institution NPI who authored the individual Document included in the Submission Set This attribute contains either the following sub-attributes and never both: authorInstitution authorPerson *<urn4:Classification id="cl01" classificationScheme="urn:uuid:93606bcf-9494-43ec-9b4e-a7748d1a838d" classifiedObject="Document01" nodeRepresentation="author">* *<urn4:Slot name="authorInstitution">* *<urn4:ValueList>* *<urn4:Value>603111</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Slot name="authorPerson">* *<urn4:ValueList>* *<urn4:Value>603</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *</urn4:Classification>*	R2	IHE ITI TF Rel 6 Vol3	Table 4.1-5 Document Metadata Attribute Definition in IHE ITI TF Volume 3 Revision 6.0	Numeric (10)
1.1	authorInstitution (sub-attribute of author)	Represents the NPI of the institution or the organization under which the human	R2	IHE ITI TF Rel	Institution NPI of the	Numeric (10)

		or machine authored the individual document included in the SubmissionSet. Please note: At the Document Metadata level, either the authorInstitution or authorPerson attribute shall be used but never both. *<urn4:Slot name="authorInstitution">* *<urn4:ValueList>* *<urn4:Value>604</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*		6 Vol3	Provider	
1.2	authorPerson (sub-attribute of author)	Represents the NPI of the provider who authored the individual document included in the SubmissionSet Please note: At the Document Metadata level, either the authorInstitution or authorPerson attribute shall be used but never both. *<urn4:Slot name="authorPerson">* *<urn4:ValueList>* *<urn4:Value>603</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R2	IHE ITI TF Rel 6 Vol3	Document author NPI	Numeric (10)
2	classCode	The code specifying the particular kind of document. <urn4:Classification id="cl02" classificationScheme="urn:uuid:41a5887f-8865-4c09-adf7-e362475b143a" classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1"> <urn4:Slot name="classCode"> <urn4:ValueList> <urn4:Value>1</urn4:Value> </urn4:ValueList> </urn4:Slot> <urn4:Name> <urn4:LocalizedString value="See Table 5 in this Implementation Guide "/> </urn4:Name> </urn4:Classification>	R	IHE ITI TF Rel 6 Vol3	See Table 5 in this Implementation Guide	String (64)
3	classCode DisplayName	The name to be displayed for communicating to a human the meaning of the classCode. Shall have a single value for each value of classCode used *<urn4:Name>* *<urn4:LocalizedString value= "See Table 5 in this Implementation Guide "/>* *</urn4:Name>*	R	IHE ITI TF Rel 6 Vol3	See Table 5 in this Implementation Guide	String (256)
4	comments	Comments associated with the Document in a free form text format	O	IHE ITI TF Rel		String (256)

		<urn4:Description> *<urn4:LocalizedString value="esMD Claim Document Submission in response to Review Contractor ADR Letter"/>* *</urn4:Description>*		6 Vol3		
5	confidentialityCode	The code specifying the level of confidentiality of the Document. *<urn4:Classification id="cl03" classificationScheme="urn:uuid:f4f85eac-e6cb-4883-b524-f2705394840f" classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.5.25">* *<urn4:Slot name="confidentialityCode">* *<urn4:ValueList>* *<urn4:Value>V</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Name>* *<urn4:LocalizedString value="Very"/>* *</urn4:Name>* *</urn4:Classification>*	R	IHE ITI TF Rel 6 Vol3	See Table : 7 in this Implementation Guide	String (64)
6	creationTime	Represents the time the HIH created the document. *<urn4:Slot name="creationTime">* *<urn4:ValueList>* *<urn4:Value>20110101165910</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	Timestamp (DTM). HIH XDR created/submitted timestamp.	Date (YYYYMMDDHHMMSS)
7	entryUUID	A unique ID or a globally unique identifier for each document in the Submission Set In the below example "***Document01"*** *is used as entryUUID. This can also be UUID format.* Example: *<urn4:ExtrinsicObject id="**Document01**" mimeType="application/pdf" objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">* *….* *</urn4:ExtrinsicObject>*	R	IHE ITI TF Rel 6 Vol3	Unique Name for each attached document with a submitted document. Either UUID or some unique identifier.	String (64)
18	formatCode	Globally unique code for specifying the format of the document. For example, the format code for esMD is HITSP C62 urn:hitsp:c62:cda:pdf *<urn4:Classification id="cl05" classificationScheme="urn:uuid:a09d5840-386c-46f2-b5ad-9c3699a4309d" classifiedObject="Document01"*	R	IHE ITI TF Rel 6 Vol3	See Table : 10 in this Implementation Guide	String (64)

		nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1"> *<urn4:Slot name="formatCode">* *<urn4:ValueList>* *<urn4:Value>1</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Name>* *<urn4:LocalizedString value="see description from table 10"/>* *</urn4:Name>* *</urn4:Classification>*				
9	Hash	Hash key of the XDR payload – C62 Document attachment based on the SHA1 Hash Algorithm *<urn4:Slot name="hash">* *<urn4:ValueList>* *<urn4:Value>ad18814418693512b767676 006a21d8ec7291e84</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	SHA1 hash	String (256)
10	healthcareFacility TypeCode	This code represents the type of organizational or Provider setting of the claim or clinical encounters or during which the documented act occurred. *<urn4:Classification id="cl05" classificationScheme="urn:uuid:f33fb8ac-18af-42cc-ae0e-ed0b0bdb91e1" classifiedObject="Document01" nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1">* ***<urn4:Slot name="*** **healthcareFacilityTypeCode *****">*** ***<urn4:ValueList>*** ***<urn4:Value>1</urn4:Value>*** ***</urn4:ValueList>*** ***</urn4:Slot>*** *<urn4:Name>* *<urn4:LocalizedString value="see description from table"/>* *</urn4:Name> </urn4:Classification>*	R	IHE ITI TF Rel 6 Vol3	See Table : 8 in this Implementation Guide	String (64)
11	healthcareFacility TypeCodeDisplay Name	The name to be displayed for communicating to a human the meaning of the healthcareFacilityTypeCode. Shall have a single value corresponding to the healthcareFacilityTypeCode. *<urn4:Classification id="cl05" classificationScheme="urn:uuid:f33fb8ac-18af-42cc-ae0e-ed0b0bdb91e1" classifiedObject="Document01" nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1">* *<urn4:Slot name="* healthcareFacilityTypeCode *">*	R	IHE ITI TF Rel 6 Vol3	See Table : 8 in this Implementation Guide	String (128)

		<urn4:ValueList> *<urn4:Value>1</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* ***<urn4:Name>*** ***<urn4:LocalizedString value="see description from table"/>*** ***</urn4:Name>*** *</urn4:Classification>*				
12	languageCode	Specifies the human language of character data in the document. The values of the attribute are language identifiers as described by the IETF (Internet Engineering Task Force) RFC 3066. *<urn4:Slot name="languageCode">* *<urn4:ValueList>* *<urn4:Value>en-us</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	esMD value may be “en-us”	String (16)
13	mimeType	MIME type of the document. *<urn4:ExtrinsicObject id="Document01"* ***mimeType="application/pdf"*** *objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">* *….* *</urn4:ExtrinsicObject>*	R	IHE ITI TF Rel 6 Vol3	esMD value shall be “Application/pdf” for PDF and “image/tiff” for TIFF.	String (64)
14	patientId	This is a required XDR field. Since esMD is Claim centric (and not Patient centric), esMD shall populate this field with Claim ID using the format Root + Extension. esMD shall include CMS OID as the root and Claim ID as the extension, last follows: CMS OID.esMDClaimID Please note: this value shall be the same as the one used at the Submission Set level. Not applicable to esMD but required by XDR Interoperability. *<urn4:ExternalIdentifier id="ei01" registryObject="Document01" identificationScheme="urn:uuid:58a6f841-87b3-4a3e-92fd-a8ffeff98427" value="* CMS OID.esMDClaimID*">* *<urn4:Name>* *<urn4:LocalizedString value="XDSDocumentEntry.patientId"/>* *</urn4:Name>* *</urn4:ExternalIdentifier>*	R	IHE ITI TF Rel 6 Vol3	esMD value may be “NA”	String (256)
15	practiceSettingCode	The code specifying the clinical specialty where the act that resulted in the document was performed.	R	IHE ITI TF Rel 6 Vol3	esMD value may be “1”.	String (64)

		This value will not be used by esMD (i.e., will be ignored). However, since this field is required by XDR, an input is required. Not applicable to esMD but required by XDR Interoperability. *<urn4:Classification id="cl07" classificationScheme="urn:uuid:cccf5598-8b07-4b77-a05e-ae952c785ead" classifiedObject="Document01" nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1">* *<urn4:Slot name="practiceSettingCode">* *<urn4:ValueList>* *<urn4:Value>1</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Name>* *<urn4:LocalizedString value="Practice Settings Code description"/>* *</urn4:Name> </urn4:Classification>*				
16	practiceSettingCode DisplayName	The name to be displayed for communicating to a human the meaning of the practiceSettingCode. Shall have a single value corresponding to the practiceSettingCode. This value will not be used by esMD (i.e., will be ignored). However, since this field is required by XDR, an input is required. Any possible value assigned by the sender will be accepted. *<urn4:Name>* *<urn4:LocalizedString value="NA"/>* *</urn4:Name>*	R	IHE ITI TF Rel 6 Vol3	esMD value may be “NA”.	String (64)
17	serviceStartTime	Represents the start time of the provider service being documented. This value will not be used by esMD (i.e., will be ignored). However, since this field is required by XDR, an input is required. Any possible value assigned by the sender will be accepted. Not applicable to esMD but required by XDR Interoperability. *<urn4:Slot name="serviceStartTime">* *<urn4:ValueList>* *<urn4:Value>20110101165910</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	DateTimeStamp (HL7 V2 DTM). To pass the Interoperability Test - entry HIH submitted timestamp.	Date (YYYYMMDDHHMMSS)
18	serviceStopTime	Represents the stop time of the provider	R	IHE ITI	DateTimeSta	Date

		service being documented. This value will not be used by esMD (i.e., will be ignored). However, since this field is required by XDR, an input is required. Any possible value assigned by the sender will be accepted. *<urn4:Slot name="serviceStopTime">* *<urn4:ValueList>* *<urn4:Value>20110101165910</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*		TF Rel 6 Vol3	mp (HL7 V2 DTM). To pass the Interoperability Test - entry HIH submitted timestamp.	(YYYYMMDDHHMMSS)
19	size	Size in bytes of the C62 attachment byte stream that was provided through the request. *<urn4:Slot name="size">* *<urn4:ValueList>* *<urn4:Value>1024000</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>*	R	IHE ITI TF Rel 6 Vol3	In Bytes	Numeric (10,2)
20	title	Represents the title of the document. Max length, 128 bytes, UTF-8. <urn4:ExtrinsicObject id="Document01" mimeType="application/pdf" objectType="urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1"> ***<urn4:Name>*** ***<urn4:LocalizedString value="Get value from Table 9"/>*** ***</urn4:Name>*** …….. </urn4:ExtrinsicObject>	O	IHE ITI TF Rel 6 Vol3	Possible Titles – See Table : 9 in this Implementation Guide No validation for this Title	String (256)
21	typeCode	The code specifying the precise kind of document (e.g., Claim Document Summary, ADR, ADMC, Progress Notes, Orders, Appeal Request). *<urn4:Classification id="cl07" classificationScheme=" urn:uuid:f0306f51-975f-434e-a61c-c59651d33983 " classifiedObject="Document01" nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1">* *<urn4:Slot name=" codingScheme ">* *<urn4:ValueList>* *<urn4:Value>1</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* *<urn4:Name>* *<urn4:LocalizedString value="see description from table 6"/>* *</urn4:Name> </urn4:Classification>*	R	IHE ITI TF Rel 6 Vol3	See Table : 6 in this Implementation Guide	String (64)

22	typeCodeDisplay Name	The name to be displayed for communicating to a human the meaning of the typeCode. Shall have a single value for each value of typeCode. *<urn4:Classification id="cl07" classificationScheme=" urn:uuid:f0306f51-975f-434e-a61c-c59651d33983 " classifiedObject="Document01" nodeRepresentation=" 2.16.840.1.113883.13.34.110.1.1000.1">* *<urn4:Slot name=" codingScheme ">* *<urn4:ValueList>* *<urn4:Value>1</urn4:Value>* *</urn4:ValueList>* *</urn4:Slot>* ***<urn4:Name>*** ***<urn4:LocalizedString value="see description from table 6"/>*** ***</urn4:Name>*** *</urn4:Classification>*	R	IHE ITI TF Rel 6 Vol3	See Table : 6 in this Implementation Guide	String (64)
23	legalAuthenticator	The authenticator of the document at the provider. <urn4:slot name="legalAuthenticator"> <urn4:ValueList> <urn4:Value>NA</urn4:Value> </urn4:ValueList> </urn4:slot>	O	IHE ITI TF Rel 6 Vol3	NA	String (32)
24	uniqueId	A globally unique identifier assigned by the HIH to each document in the SubmissionSet. The length of the Unique Identifier shall not exceed 128 bytes. The structure and format of this ID shall be consistent with the specification corresponding to the format attribute. This ID will be generated based on the UUID. Generated based on the UUID. The same ID will be returned with the response message. *<urn4:ExternalIdentifier id="ei02" registryObject="Document01" identificationScheme="urn:uuid:96fdda7c-d067-4183-912e-bf5ee74998a8" value="1.3.6.1.4.1.21367.2005.3.9999.33" >* *<urn4:Name>* *<urn4:LocalizedString value="XDSDocumentEntry.uniqueId"/>* *</urn4:Name>* *</urn4:ExternalIdentifier>*	R	IHE ITI TF Rel 6 Vol3	UUID. See ITI TF 4.1.7.2 Volume 3 Revision 6	String (64)

Table 7 provides the CMS assigned OIDs for each intended recipient. Intended recipients are the review contractors who accept the medical documentation submitted by providers in response to ADR letter requests.

941 **Table 7: Intended Recipient (Review Contractor) OIDs**

S.No	Review Contractor	Description / Review Contractor Organization Name	Intended Recipient Valid Values (There are no spaces in these values.)	CMS assigned OIDs
1	RAC A	DCS	RACA	2.16.840.1.113883.13.34.110.**1.100.1**
2	RAC B	CGI	RACB	2.16.840.1.113883.13.34.110.**1.100.2**
3	RAC D	HDI	RACD	2.16.840.1.113883.13.34.110.**1.100.4**
4	MAC J 1	Palmetto	MACJ1	2.16.840.1.113883.13.34.110.**1.110.1**
5	MAC J 3	Noridian	MACJ3	2.16.840.1.113883.13.34.110.**1.110.3**
6	MAC J 4	Trailblazer	MACJ4	2.16.840.1.113883.13.34.110.**1.110.4**
7	MAC J 5	WPS	MACJ5	2.16.840.1.113883.13.34.110.**1.110.5**
8	MAC J 9	FCSO	MACJ9	2.16.840.1.113883.13.34.110.**1.110.9**
9	MAC J10	Cahaba	MACJ10	2.16.840.1.113883.13.34.110.**1.110.10**
10	MAC J11	Palmetto	MAC J11	2.16.840.1.113883.13.34.110.**1.110.11**
11	MAC J12	Highmark	MACJ12	2.16.840.1.113883.13.34.110.**1.110.12**
12	MAC J13	NGS	MACJ13	2.16.840.1.113883.13.34.110.**1.110.13**
13	MAC J14	NHIC	MACJ14	2.16.840.1.113883.13.34.110.**1.110.14**
14	CERT	Livanta	CERT	2.16.840.1.113883.13.34.110.**1.200.1**
15	PERM	A+ Government Solutions	PERM	2.16.840.1.113883.13.34.110.**1.200.2**
16	ZPIC Z1	Safeguard Solutions	ZPICZ1	2.16.840.1.113883.13.34.110.**1.300.1**
17	ZPIC Z7	Safeguard Solutions	ZPICZ7	2.16.840.1.113883.13.34.110.**1.300.7**
18	DME MAC A	NHIC	DMEMACA	2.16.840.1.113883.13.34.110.**1.150.1**
19	DME MAC B	NGS	DMEMACB	2.16.840.1.113883.13.34.110.**1.150.2**
20	DME MAC C	NAS	DMEMACC	2.16.840.1.113883.13.34.110.**1.150.3**
21	DME MAC D	CGS	DMEMACD	2.16.840.1.113883.13.34.110.**1.150.4**

942
943 Table 8 provides the ClassCodes and corressponding ClassCode Display Names.
944
945 Metadata Vocabulary - Class Schema: urn:uuid:41a5887f-8865-4c09-adf7-e362475b143a
946 Reference URL:
947
948 **Table 8: ClassCodes and corressponding ClassCode Display Names**

Class Code	Class Code Display Name	Coding Schema / Code System
1	Unstructured Document Submission	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
2	Structured Document Submission	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
3	Structured Documentation Request	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
4	Unstructured Unsolicited Documentation	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
5	Structured Unsolicited Documentation	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema

949
950

Table 9 provides the Type Codes and coressponding Type Code Display Names.

Metadata Vocabulary - Class Schema: urn:uuid:f0306f51-975f-434e-a61c-c59651d33983
Reference URL:

Table 9: Type Codes and coressponding Type Code Display Names

Type Code	Type Code Display Name	Coding Schema / Code System
1	**Response to Additional Documentation Request (ADR)**	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
2	Response to Enrollment Documentation Request	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
3	Response to Cost Report Audit Documentation Request	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
4	Structured Order	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
5	Structured Progress Notes	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
6	Structured Additional Documentation Request (ADR)	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
7	Unsolicited Claim Attachment Paperwork	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
8	ADMC Request	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Class Codes - CMS Schema
9	Appeal Request	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Class Codes - CMS Schema

Table 10 provides the Confidentiality Codes.

Metadata Vocabulary - Class Schema: urn:uuid:f4f85eac-e6cb-4883-b524-f2705394840f
Reference URL: http://xml.coverpages.org/CDA-Release2-Unofficial.html

Table 10: Confidentiality Codes

Confidentiality Code	Description	Coding Schema / Code System
N	Normal	2.16.840.1.113883.5.25
R	Restricted	2.16.840.1.113883.5.25
V	Very Restricted (default for esMD)	2.16.840.1.113883.5.25

The esMD will only accept the Very Restricted Confidentiality Code.

Table 11 provides the HealthCare Facility Type Codes.

Metadata Vocabulary - Class Schema: urn:uuid:f33fb8ac-18af-42cc-ae0e-ed0b0bdb91e1
Reference URL:

Table 11: HealthCare Facility Type Code

HealthCare Facility Type Code	HealthCare Facility Type Code Display Name	Coding Schema / Code System
1	Health Information Handler (HIH)	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Class Codes
2	Health Care Provider	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Class Codes
3	CMS Review Contractor	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Class Codes

Table 12 provides the Submission Set or Document Title.

Table 12: Submission Set/Document Title

Submission Set or Document Title
Solicited Supporting Documentation
Additional Documentation Request
Unsolicited Documentation

Table 13 provides the Document Format Code and Payload Type**.**

Metadata Vocabulary - Class Schema: urn:uuid:a09d5840-386c-46f2-b5ad-9c3699a4309d
Reference URL:

Table 13: Document Format Code and Payload Type

	Format Code	Format Description	Coding Schema / Code System
1	HITSP C62 urn:hitsp:c62:cda:pdf	Scanned PDF Document in Clinical Document Architecture (CDA) C62 Construct	2.16.840.1.113883.13.34.110.1.1000.1 **–** CMS Schema
2	HITSP C62 urn:hitsp:c62:cda:tiff	Scanned TIFF Document in CDA C62 Construct	2.16.840.1.113883.13.34.110.1.1000.1 **–** CMS Schema
3	HITSP C83	HITSP C83	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
4	HITSP C32	HITSP C32	2.16.840.1.113883.13.34.110.1.1000.1 - CMS Schema
5	urn:ihe:iti:xds-sd:pdf:2008	Scanned PDF Document in XDS	1.3.6.1.4.1.19376.1.2.3
6	urn:ihe:iti:xds-sd:text:2008	Scanned Documents with text (XDS-SD)	1.3.6.1.4.1.19376.1.2.3

Table 14 details the overall mapping of the Document submission with the Class and Type Codes.

This table shows the possible combinations/mappings between Title, Format Code, Class Code and Type Code.

Table 14: Overall Mapping of Document Submission with Class and Type Codes

Title	Format Code (Payload Construct)	Class		Type	
		Class Code	Class Code Display Name	Type Code	Type Code Display Name
Solicited Supporting Documentation	**HITSP C62**	**1**	**Unstructured Document Submission**	**1**	**Response to Additional Documentation Request (ADR)**
				2	Response to Enrollment Documentation Request
				3	Response to Cost Report Audit Documentation Request
	TBD	2	Structured Document Submission	4	Structured Order
	TBD			5	Structured Progress Notes
Additional Documentation Request	TBD	3	Structured Documentation Request	6	Structured Additional Documentation Request (ADR)
Unsolicited	HITSP C62	4	Unstructured	7	Unsolicited Claim Attachment

Documentation			Unsolicited Documentation		Paperwork
	TBD	5	Structured Unsolicited Documentation	8	ADMC Request
				9	Appeal Request

5.3.9 HITSP C62 (Construct on top of CDA) Document Constraints

This section outlines the content of the unstructured HITSP C62 Construct (on top of the HL7 CDA) constraints for the document. The requirements specified below are to ensure the presence of a minimum amount of wrapper data in order to enhance description and facilitate submitting the claim documentation.

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
classCode="DOCCLIN" moodCode="EVN" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
   <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
        <id root="eab8765b-1424-47cc-9495-ddc934cf5f5d"/>
        <templateId root="2.16.840.1.113883.10.20.3" assigningAuthorityName="CDT General Header
        Constraints"/>
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1" assigningAuthorityName="IHE Medical Document"/>
        <templateId root="1.3.6.1.4.1.19376.1.2.20" assigningAuthorityName="IHE Scanned Document"/>
        <templateId root="2.16.840.1.113883.3.88.11.62.1" assigningAuthorityName="HITSP Unstructured
        Document"/>
        <languageCommunication>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
          <languageCode code='en-US'/>
        </languageCommunication>
        <title>ADR Response Supported Claim Documentation</title>
        <confidentialityCode code="V" codeSystem="2.16.840.1.113883.5.25" codeSystemName="Confidentiality"
        displayName="Very Restricted"/>
        <effectiveTime value="20100319083838-0500"/>
            <recordTarget>
            <patientRole>
               <id extension="12345" root="2.16.840.1.113883.3.933"/>
               ...
            </patientRole>
            </recordTarget>
            <author>
               <templateId root=”1.3.6.1.4.1.19376.1.2.20.1”/>
               ....
            </author>
            <author>
               <templateId root=”1.3.6.1.4.1.19376.1.2.20.2”/>
               ...
            <dataEnterer>
               <templateId root=”1.3.6.1.4.1.19376.1.2.20.3”/>
                 ...
            </dataEnterer>
            <custodian>
               ...
            </custodian>
            <legalAuthenticator>
               ....
            </legalAuthenticator>
            <documentationOf>
               <serviceEvent >
                  <effectiveTime>
```

```
                    <low value="19800127"/>
                      <high value="19990522"/>
                  </effectiveTime>
               </serviceEvent>
            </documentationOf>
            <component>
               <nonXMLBody>
                  <text mediaType="application/pdf" representation="B64">
                     JVBERi0xLjMKJcfsj6IKNSAwIG9iago8PC9MZW5ndGggNiAwIFIvRmlsdGVyIC9GbGF0
                     </text>
               </nonXMLBody>
            </component>
</ClinicalDocument>
```

Table 15 details the CDA Document Constraints Specifications.

Table 15: CDA Document Constraints Specifications

S. NO	HISTP C62 Construct →HL7 CDA Header element	Description and Source / Value	R/R 2/O	References to Possible esMD Domain specific values
1	ClinicalDocument/typeId	Fixed, per CDA version in use. <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>	R	
2	ClinicalDocument/templateId	This element shall be present. The root attribute shall contain the oid, '2.16.840.1.113883.3.88.11.62.1', to indicate what type of document is an XDR document. <templateId root="2.16.840.1.113883.10.20.3" assigningAuthorityName="CDT General Header Constraints"/> <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1" assigningAuthorityName="IHE Medical Document"/> <templateId root="1.3.6.1.4.1.19376.1.2.20" assigningAuthorityName="IHE Scanned Document"/> <templateId root="2.16.840.1.113883.3.88.11.62.1" assigningAuthorityName="HITSP Unstructured Document"/>	R	
3	ClinicalDocument/id	This element shall be present. The root attribute shall contain the OID, which Represents the unique instance identifier of a clinical document. Computable. <id root="eab8765b-1424-47cc-9495-ddc934cf5f5d"/>	R	
4	ClinicalDocument/code	Values for this code are dictated by the CDA R2 documentation, but are permissible to extend to fit the particular use case. Attributes code@code and code@codeSystem shall be present. Entered by operator, or possibly can be taken from the scanned content.	R	

		<code code="34133-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="esMD Document Submission"/>		
5	ClinicalDocument/title	This shall be present if known. Entered by operator, or possibly can be taken from the scanned content. <title>ADR Response – Supported Claim Documentation</title>	R2	
6	ClinicalDocument/confidentiality Code	Shall be assigned by the operator in accordance with the scanning facility policy. The notion or level of confidentiality in the header may not be the same as that in the Affinity Domain, but in certain cases could be used to derive a confidentiality value among those specified by the Affinity Domain. Attributes confidentialityCode@code and confidentialityCode@codeSystem shall be present. Assigned by the operator Computed. This is the scan time. <confidentialityCode code="V" codeSystem="2.16.840.1.113883.5.25" codeSystemName="Confidentiality" displayName="Very Restricted"/>	R	See Table : 5
7	ClinicalDocument/effectiveTime	This shall denote the time at which the original content was scanned. Signifies the document creation time, when the document first came into being. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT. Computed. This is the scan time. <effectiveTime value="20050329224411+0500"/>	R	
8	ClinicalDocument/languageCode	This element in accordance with the HL7 CDA R2 documentation, specifies the human language of character data. Entered by operator <languageCommunication> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/> <languageCode code='en-US'/> </languageCommunication>	R	
9	ClinicalDocument/recordTarget	The ClinicalDocument/recordTarget contains identifying information about the patient concerned in the original content. Taken from scanned content, supplemented by operator. <recordTarget> <patientRole> <id extension="12345" root="2.16.840.1.113883.3.933"/> <addr> <streetAddressLine>NA</streetAddressLine>	R	Data is optional for esMD. If submitting, need to provide de-identified data or NA.

		<city>NA</city> <state>NA</state> <postalCode>NA</postalCode> <country>NA</country> </addr> <patient> <name> <prefix>NA</prefix> <given>NA</given> <family>NA</family> </name> <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/> <birthTime value="19600127"/> </patient> </patientRole> </recordTarget>		
10	ClinicalDocument/author/assignedAuthor/assignedPerson	This element represents the author of the original content. It additionally can 1040 encode the original author's institution in the sub-element represented Organization. Information regarding the original author and his/her institution shall be included, if it is known. Taken from scanned content, supplemented by operator. This is the original author. <author> <templateId root="1.3.6.1.4.1.19376.1.2.20.1"/> <time value="19990522"/> <assignedAuthor> <id extension="11111111" root="1.3.5.35.1.4436.7"/> <assignedPerson> <name> <prefix>NA</prefix> <given>NA</given> <family>NA</family> <suffix>NA</suffix> </name> </assignedPerson> <representedOrganization> <id extension="aaaaabbbbb" root="1.3.5.35.1.4436.7"/> <name>NA</name> </representedOrganization> </assignedAuthor> </author>	R2	Data is optional for esMD
11	ClinicalDocument/author/assignedAuthor/authoringDevice	This element shall be present and represent the scanning device and software used to produce the scanned content. Can be computed or fixed based on the scanning device and software. This is the information about the scanning device. <author> <templateId root="1.3.6.1.4.1.19376.1.2.20.2"/> <time value="20050329224411+0500"/>	R	Data is optional for esMD

		<assignedAuthor> <id root="1.3.6.4.1.4.1.2835.2.1234"/> <assignedAuthoringDevice> <code code="CAPTURE" displayName="Image Capture" codeSystem=" 1.2.840.10008.2.16.4" /> <manufacturerModelName>NA</manufacturerModelName> <softwareName>NA</softwareName> </assignedAuthoringDevice> <representedOrganization> <id root="1.3.6.4.1.4.1.2835.2"/> <name>SOME Scanning Facility</name> <addr> <streetAddressLine>NA</streetAddressLine> <city>NA</city> <state>NA</state> <postalCode>NA</postalCode> <country>NA</country> </addr> </representedOrganization> </assignedAuthor> </author>		
12	ClinicalDocument/dataEnterer	This element represents the information about the scanner operator. <dataEnterer> <templateId root="1.3.6.4.1.4.1.19376.1.2.20.3"/> <time value="20050329224411+0500"/> <assignedEntity> <id extension="22222222" root="1.3.6.4.1.4.1.2835.2"/> <assignedPerson> <name> <prefix>NA.</prefix> <given>NA</given> <family>NA</family> </name> </assignedPerson> </assignedEntity> </dataEnterer>	R	Data is optional for esMD
13	ClinicalDocument/custodian	Represents the HIH organization from which the document originates and that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. In most cases this will be the scanning facility. <custodian typeCode="CST"> <assignedCustodian classCode="ASSIGNED"> <representedCustodianOrganization classCode="ORG" determinerCode="INSTANCE"> <id root="1.300011"/> <name>QSSI INC.</name> <telecom use="WP" value="(555)555-5500"/> <addr>	R	Data related to HIH and sin sync with the Submission set meta data.

		<streetAddressLine> 100 Governor Warfield Parkway</streetAddressLine> <city>Columbia</city> <state>MD</state> <postalCode>21044</postalCode> <country/> </addr> </representedCustodianOrganization> </assignedCustodian> </custodian>		
15	ClinicalDocument/documentationOf/serviceEvent/effectiveTime	This element is used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator. Denotes the time/date range of the original content. <documentationOf> <serviceEvent > <effectiveTime> <low value="19800127"/> <high value="19990522"/> </effectiveTime> </serviceEvent> </documentationOf>	R	
16	ClinicalDocument/component/nonXMLBody	The scanned/base64 encoded content.	R	

5.3.10 Third Parties

The sending provider may be 1) the provider whose claim is in question, 2) the provider who orders the item on service listed on the claim in question, or 3) a provider who rendered a service related to the claim in question. HIHs may include the digital signature and date stamp associated with the medical record entry being transmitted. Though not required, HIHs may also list the Certification Commission for Health Information Technology (CCHIT) certification number associated with the medical record entry.

6 Validation

a) TLS Authentication
b) OID Validation (Authorization) - Home Community OID Verification against the CMS Certified HIHs based on CMS On-boarded Process
c) Check for Duplicate Unique ID
d) Claim reviewer Participation Validation
e) Affinity Values validation
f) Document Availability in submission.
g) Base64 SHA1 Decoding Validation for Payload attachments

7 Error Messages

The following table provides details for each error message.

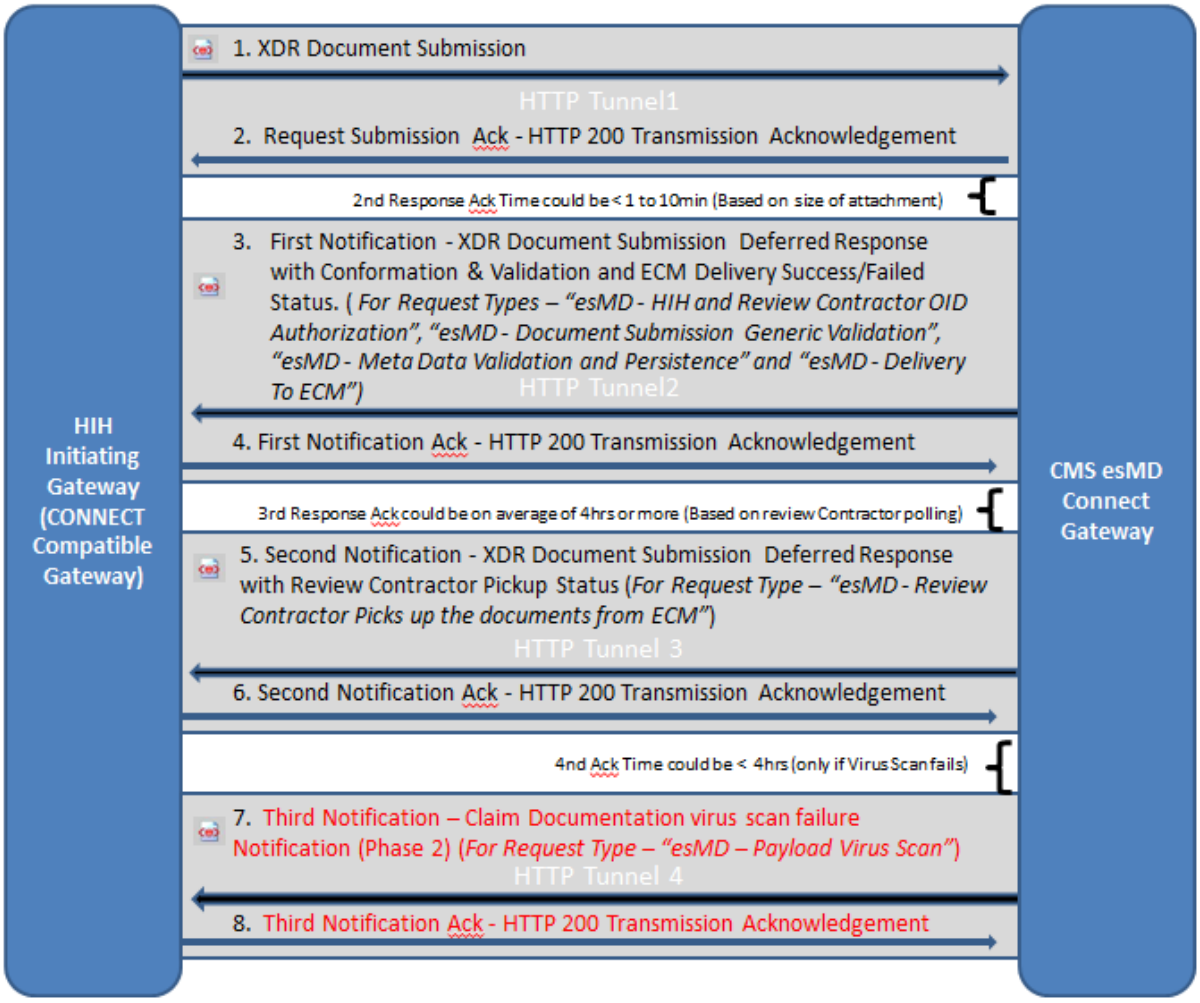
Table 16: Error Messages

S.No	Fatal Error Code	Discussion
1	XDSHOIDIdDoesNotMatch	The XDR specifies where the submitted HIH Home Community IDs must match between documents (i.e., submission sets and CMS On-boarded HIH OID).
2	XDSDuplicateUniqueIdInRegistry	The UniqueID received was not unique within the Registry. The UniqueID could have been attached to earlier XDSSubmissionSet .
3	XDSMissingDocumentMetadata	The MIME package contains the MIME part with Content-ID header not found.
4	XDSRegistryMetadataError	An Error detected in the metadata. The Actor name indicates where error was detected. The CodeContext indicates the nature of problem. This error code is considered for any of the following: Class Code, Type Code, Format Code, HealthCare Facility Type Code, Confidentiality Code and Intended Recipient validation failures.
5	XDSMissingDocument	The Metadata exists with no corresponding attached document.
6	XDSNonIdenticalHash	The Hash code of the attached document does not match.
7	CMSDocumentVirusScanError	Any Antivirus scan failures that occur in the process of delivery and at review contractor end.
8	XDSRegistryError	Internal esMD Registry/Repository Error
9	XDSRegistryBusy	Too Much Activity

Warning messages are to be considered as information, not fatal errors.

8 Status and Notification Messages

Figure 4: Document Submission Deferred Responses with Multiple HTTP Connections



8.1 Transport Acknowledgment – HTTP 200 (real Time Acknowledgment)

The HTTP 200 Confirmation message is sent after successful two-way TLS authentication, SAML Assertion validation, and message download.

8.2 Syntax and Semantics Validation Status Acknowledgment

Based on following validations, an asynchronous XDR Response message with success or detailed failed acknowledgment messages will be sent out to the HIH.

- Validate the syntaxes.
- Validate Semantics with the esMD affinity domain values.
- Validate duplicate Unique ID for the message.

- Validate participation of intended recipient claim reviewers.
- Validate OID authorization based on the CMS On-boarding.

This acknowledgment will be sent anywhere from less than one minute up to ten minutes after validation and is based on the size of attachment.

8.3 Claim Reviewer Delivery Notification (Response time could be ~ 4 hrs. or more)

A Notification message will be sent to the HIH after the review contractor picks up the submitted documents from the Enterprise Content Management (ECM) system. This notification acknowledgment will take an average 4 hours or more after the transaction is sent and is dependent upon the review contractor polling process of the esMD repository.

This notification message could have an error message in the event there is a Virus scan failure at the review contractor end or ECM repository.

8.4 Claim Reviewer virus scan failure Notification

The Response time could be within 4 hours after the third message.

This notification message could have an error message in the event there is a Virus scan failure at review contractor end or ECM repository.

8.5 Service Level Agreement for Acknowledgments –

8.5.1 First Acknowledgment - HTTP Status Code

HIHs shall take actions based on the HTTP Status code. The HTTP Status code of 200 indicates a successful submission while the HTTP status codes from 300 through 499 indicate the possibility of a fatal error. The esMD team expects HIHs to take appropriate action to fix fatal errors. The esMD specific HTTP Status codes series will begin from 500.

HTTP status codes are the codes that the client (HIH) Web server uses to communicate with the esMD Web browser or user agent.

The HTTP status codes will allow HIHs to control their Web server with a higher degree of accuracy and effectiveness.

Table 17 indicates the category assigned to each HTTP Status Code numerical series.

Table 17: HTTP Status Codes

HTTP Status Code Series	Code Category
HTTP Status Codes 100-101	Informational Status Codes
HTTP Status Codes 200-206	Successful Status Codes
HTTP Status Codes 300-307	Redirection Status Codes
HTTP Status Codes 400-416	Client Error Status Codes
HTTP Status Codes 500-505	Server Error Status Codes

For more details please visit: http://webdesign.about.com/od/http/a/http_status_codes.htm.

8.5.2 Syntax and Semantics Validation Status Acknowledgment (Second Acknowledgment)

In the event, the sender does not receive the second acknowledgement response within 20 minutes of the document submission they may take the following steps.

- The sender can resubmit the claim documentation a second time. After this second submission, the sender should allow 20 minutes to receive an acknowledgement response.

- The sender may attempt submissions for a total of three attempts. If the acknowledgement is not received after the third attempt, the sender should contact the esMD Team (esMDTeam@qssinc.com) for further resolution.

8.5.3 Claim Reviewer Delivery Notification (Third Notification)

The sender may take some time, not exceeding 8 hours, to receive the third acknowledgement. If no response is received after 8 hours, the sender should contact the esMD Team (esMDTeam@qssinc.com).

8.5.4 Claim Reviewer virus scan failure Notification (Fourth and final Notification)

This notification is slated for future Phases (i.e., In Release 1.1, the fourth notification will not be implemented.

This notification message could have an error message in the event there is a Virus scan failure at the review contractor end or the ECM repository. After the third notification, the sender may get the fourth acknowledgment within 4 hours. The submission may be considered successful only if there is no fourth notification response within 4 hours after third notification.

9 Response Message

The XDR Deferred Document Submission Response SOAP message will have the Assertions, Target Communities (as HIH OID, Description, and Name) and Response.

To correlate the request to the response, the unique ID (AssertionType.getSamlAuthzDecisionStatement().getEvidence().getAssertion().getId()) and message ID will be copied back into the response message.

9.1 First Acknowledgment:

```
<?xml version="1.0" encoding="UTF-8"?>
<S:Envelope xmlns:S="http://www.w3.org/2003/05/soap-envelope">
   <S:Header>
      <To xmlns="http://www.w3.org/2005/08/addressing">http://www.w3.org/2005/08/addressing/anonymous</To>
      <Action
xmlns="http://www.w3.org/2005/08/addressing">urn:gov:hhs:fha:nhinc:nhincentityxdr:async:request:ProvideAndRegisterDocu
mentSet-bAsyncRequest_ResponseMessage</Action>
      <MessageID xmlns="http://www.w3.org/2005/08/addressing">uuid:68ee5397-c4df-46d6-a1e1-
3239c1c6f18c</MessageID>
      <RelatesTo xmlns="http://www.w3.org/2005/08/addressing">202</RelatesTo>
   </S:Header>
   <S:Body>
```

```
        <ns15:XDRAcknowledgement xmlns:ns2="urn:oasis:names:tc:ebxml-regrep:xsd:query:3.0"
xmlns:ns3="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0" xmlns:ns4="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
xmlns:ns5="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0" xmlns:ns6="http://www.hhs.gov/healthit/nhin/cdc"
xmlns:ns7="http://docs.oasis-open.org/wsrf/bf-2" xmlns:ns8="http://www.w3.org/2005/08/addressing"
xmlns:ns9="http://docs.oasis-open.org/wsn/b-2" xmlns:ns10="urn:gov:hhs:fha:nhinc:common:nhinccommon"
xmlns:ns11="http://schemas.xmlsoap.org/ws/2004/08/addressing" xmlns:ns12="urn:oasis:names:tc:emergency:EDXL:DE:1.0"
xmlns:ns13="urn:ihe:iti:xds-b:2007" xmlns:ns14="http://nhinc.services.com/schema/auditmessage"
xmlns:ns15="http://www.hhs.gov/healthit/nhin"
xmlns:ns16="urn:gov:hhs:fha:nhinc:common:subscriptionb2overridefordocuments"  xmlns:ns17="http://docs.oasis-
open.org/wsn/t-1" xmlns:ns18="urn:gov:hhs:fha:nhinc:common:nhinccommonentity"
xmlns:ns19="urn:gov:hhs:fha:nhinc:common:subscriptionb2overrideforcdc"
xmlns:ns20="urn:gov:hhs:fha:nhinc:common:subscription">
            <ns15:message status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:RequestAccepted"/>
        </ns15:XDRAcknowledgement>
    </S:Body>
</S:Envelope>
```

9.2 Success Message without Warnings:

```
<?xml version='1.0' encoding='UTF-8'?>
<S:Envelope xmlns:S="http://www.w3.org/2003/05/soap-envelope">
    <S:Header>
        <To
xmlns="http://www.w3.org/2005/08/addressing">http://localhost:8080/CONNECTAdapter/AdapterComponentXDRResponse_Service</To>
        <Action
xmlns="http://www.w3.org/2005/08/addressing">urn:gov:hhs:fha:nhinc:adaptercomponentxdrresponse:XDRResponseInputMessage</Action>
        <ReplyTo xmlns="http://www.w3.org/2005/08/addressing">
            <Address>http://www.w3.org/2005/08/addressing/anonymous</Address>
        </ReplyTo>
        <MessageID xmlns="http://www.w3.org/2005/08/addressing">5a3d7012-029e-4559-9a55-49e3d80d0190</MessageID>
    </S:Header>
    <S:Body>
        <ns21:AdapterRegistryResponse xmlns:ns2="http://schemas.xmlsoap.org/ws/2004/08/addressing"
            xmlns:ns3="http://www.w3.org/2005/08/addressing"
            xmlns:ns4="http://docs.oasis-open.org/wsn/b-2"
            xmlns:ns5="http://docs.oasis-open.org/wsrf/bf-2"
            xmlns:ns6="http://docs.oasis-open.org/wsn/t-1"
            xmlns:ns7="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
            xmlns:ns8="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
            xmlns:ns9="urn:oasis:names:tc:ebxml-regrep:xsd:query:3.0"
            xmlns:ns10="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0"
            xmlns:ns11="http://www.hhs.gov/healthit/nhin"
            xmlns:ns12="urn:ihe:iti:xds-b:2007"
            xmlns:ns13="http://nhinc.services.com/schema/auditmessage"
            xmlns:ns14="http://www.hhs.gov/healthit/nhin/cdc"
            xmlns:ns15="urn:gov:hhs:fha:nhinc:common:subscriptionb2overrideforcdc"
            xmlns:ns16="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
            xmlns:ns17="urn:oasis:names:tc:xacml:2.0:context:schema:os"
            xmlns:ns18="urn:oasis:names:tc:emergency:EDXL:DE:1.0"
            xmlns:ns19="urn:gov:hhs:fha:nhinc:common:subscriptionb2overridefordocuments"
            xmlns:ns20="urn:gov:hhs:fha:nhinc:common:nhinccommon"
            xmlns:ns21="urn:gov:hhs:fha:nhinc:common:nhinccommonadapter">
        <ns21:assertion>
            <ns20:haveSecondWitnessSignature>false</ns20:haveSecondWitnessSignature>
            <ns20:haveSignature>false</ns20:haveSignature>
            <ns20:haveWitnessSignature>false</ns20:haveWitnessSignature>
            <ns20:homeCommunity>
```

```
            <ns20:homeCommunityId>123.456.657.123</ns20:homeCommunityId>
         </ns20:homeCommunity>
         <ns20:userInfo>
            <ns20:personName>
               <ns20:familyName>na</ns20:familyName>
               <ns20:givenName>CMS</ns20:givenName>
               <ns20:secondNameOrInitials>Given Name - na C CMS Faimily Name -</ns20:secondNameOrInitials>
               <ns20:fullName>CMS Given Name - na C CMS Faimily Name - na</ns20:fullName>
            </ns20:personName>
            <ns20:userName>abcd</ns20:userName>
            <ns20:org>
               <ns20:homeCommunityId>123.456.657.123</ns20:homeCommunityId>
               <ns20:name>QSSI esMD Local Dev Gateway</ns20:name></ns20:org>
            <ns20:roleCoded><ns20:code>2.16.840.1.113883.6.96</ns20:code>
               <ns20:codeSystem>2.16.840.1.113883.6.96</ns20:codeSystem>
               <ns20:codeSystemName>SNOMED_CT</ns20:codeSystemName>
               <ns20:displayName>Claim Processing</ns20:displayName>
            </ns20:roleCoded>
         </ns20:userInfo>
            <ns20:authorized>false</ns20:authorized>
            <ns20:purposeOfDisclosureCoded>
               <ns20:code>2.16.840.1.113883.3.18.7.1</ns20:code>
               <ns20:codeSystem>2.16.840.1.113883.3.18.7.1</ns20:codeSystem>
               <ns20:codeSystemName>nhin-purpose</ns20:codeSystemName>
               <ns20:displayName>Use or disclosure of Psychotherapy Notes</ns20:displayName>
            </ns20:purposeOfDisclosureCoded>
            <ns20:samlAuthnStatement>
               <ns20:authInstant>2009-04-16T13:15:39.000Z</ns20:authInstant>
               <ns20:sessionIndex>987</ns20:sessionIndex>
               <ns20:authContextClassRef>urn:oasis:names:tc:SAML:2.0:ac:classes:X509</ns20:authContextClassRef>
               <ns20:subjectLocalityAddress>158.147.185.168</ns20:subjectLocalityAddress>
               <ns20:subjectLocalityDNSName>esmdg.cms.cmstest</ns20:subjectLocalityDNSName>
            </ns20:samlAuthnStatement>
            <ns20:samlAuthzDecisionStatement>
                <ns20:decision>Permit</ns20:decision>

<ns20:resource>https://localhost:8191/CONNECTAdapter/AdapterService/AdapterDocSubmissionDeferredResponseSecured</ns20:resource>
               <ns20:action>Execute</ns20:action>
               <ns20:evidence>
                  <ns20:assertion>
                     <ns20:id>40df7c0a-ff3e-4b26-baeb-f2910f6d0mc202</ns20:id>
                     <ns20:issueInstant>2009-04-16T13:10:39.093Z</ns20:issueInstant>
                     <ns20:version>2.0</ns20:version>
                     <ns20:issuer>CN=SAML User,OU=Harris,O=HITS,L=Melbourne,ST=FL,C=US</ns20:issuer>
                     <ns20:issuerFormat>urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName</ns20:issuerFormat>
                     <ns20:conditions><ns20:notBefore>2009-04-16T13:10:39.093Z</ns20:notBefore>
                        <ns20:notOnOrAfter>2009-12-31T12:00:00.000Z</ns20:notOnOrAfter>
                     </ns20:conditions>
                     <ns20:accessConsentPolicy>urn:oid:2.16.840.1.113883.13.34.110.3</ns20:accessConsentPolicy>
                     <ns20:instanceAccessConsentPolicy>urn:oid:2.16.840.1.113883.13.34.110.3</ns20:instanceAccessConsentPolicy>
                  </ns20:assertion>
               </ns20:evidence>
            </ns20:samlAuthzDecisionStatement>
            <ns20:samlSignature>
               <ns20:keyInfo>
                  <ns20:rsaKeyValueModulus></ns20:rsaKeyValueModulus>
                  <ns20:rsaKeyValueExponent></ns20:rsaKeyValueExponent>
               </ns20:keyInfo>
```

```
                <ns20:signatureValue></ns20:signatureValue>
            </ns20:samlSignature>
            <ns20:messageId>5a3d7012-029e-4559-9a55-49e3d80d0190</ns20:messageId>
        </ns21:assertion>
        <ns21:RegistryResponse requestId="esMD - Delivery To ECM" status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success">
            <ns7:ResponseSlotList>
                <ns8:Slot name="TransactionId">
                    <ns8:ValueList>
                        <ns8:Value>532</ns8:Value>
                    </ns8:ValueList></ns8:Slot>
                <ns8:Slot name="ClaimId">
                    <ns8:ValueList>
                        <ns8:Value>69777777</ns8:Value>
                    </ns8:ValueList></ns8:Slot>
                <ns8:Slot name="CaseId">
                    <ns8:ValueList>
                        <ns8:Value>6000045</ns8:Value>
                    </ns8:ValueList>
                </ns8:Slot>
            </ns7:ResponseSlotList>
        </ns21:RegistryResponse>
    </ns21:AdapterRegistryResponse>
  </S:Body>
</S:Envelope>
```

9.3 Error Message:

```
xmlns:ns5="urn:gov:hhs:fha:nhinc:common:nhinccommonentity"
<ns5:RegistryResponse
        xmlns="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
        status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Failure">
        <ns5:RegistryErrorList highestSeverity="urn:oasis:names:tc:ebxml-
        regrep:ErrorSeverityType:Error">
                <ns5:RegistryError errorCode="XDSHOIDIdDoesNotMatch"
                codeContext="Home Community OID Document (Document1) does not match
                Submission Set" location=""
                severity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error"/>
                <ns5:RegistryError errorCode="XDSRegistryMetadataError"
                        codeContext="Error in Metadata – with specific field details”
                        location=""
                        severity="urn:oasis:names:tc:ebxml-regrep:ErrorSeverityType:Error"/>
        </ns5:RegistryErrorList>
        <!—Warning -->
        <!—Success Messages -->
</ns5:RegistryResponse>

<?xml version='1.0' encoding='UTF-8'?>
<S:Envelope xmlns:S="http://www.w3.org/2003/05/soap-envelope">
  <S:Header>
    <To
xmlns="http://www.w3.org/2005/08/addressing">http://localhost:8080/CONNECTAdapter/AdapterComponentXDRResponse_S
ervice</To>
    <Action
xmlns="http://www.w3.org/2005/08/addressing">urn:gov:hhs:fha:nhinc:adaptercomponentxdrresponse:XDRResponseInputMess
```

```
age</Action>
    <ReplyTo xmlns="http://www.w3.org/2005/08/addressing">
      <Address>http://www.w3.org/2005/08/addressing/anonymous</Address>
    </ReplyTo>
    <MessageID xmlns="http://www.w3.org/2005/08/addressing">5a3d7012-029e-4559-9a55-49e3d80d0190</MessageID>
  </S:Header>
  <S:Body>
    <ns21:AdapterRegistryResponse xmlns:ns2="http://schemas.xmlsoap.org/ws/2004/08/addressing"
      xmlns:ns3="http://www.w3.org/2005/08/addressing"
      xmlns:ns4="http://docs.oasis-open.org/wsn/b-2"
      xmlns:ns5="http://docs.oasis-open.org/wsrf/bf-2"
      xmlns:ns6="http://docs.oasis-open.org/wsn/t-1"
      xmlns:ns7="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0"
      xmlns:ns8="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
      xmlns:ns9="urn:oasis:names:tc:ebxml-regrep:xsd:query:3.0"
      xmlns:ns10="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0"
      xmlns:ns11="http://www.hhs.gov/healthit/nhin"
      xmlns:ns12="urn:ihe:iti:xds-b:2007"
      xmlns:ns13="http://nhinc.services.com/schema/auditmessage"
      xmlns:ns14="http://www.hhs.gov/healthit/nhin/cdc"
      xmlns:ns15="urn:gov:hhs:fha:nhinc:common:subscriptionb2overrideforcdc"
      xmlns:ns16="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
      xmlns:ns17="urn:oasis:names:tc:xacml:2.0:context:schema:os"
      xmlns:ns18="urn:oasis:names:tc:emergency:EDXL:DE:1.0"
      xmlns:ns19="urn:gov:hhs:fha:nhinc:common:subscriptionb2overridefordocuments"
      xmlns:ns20="urn:gov:hhs:fha:nhinc:common:nhinccommon"
      xmlns:ns21="urn:gov:hhs:fha:nhinc:common:nhinccommonadapter">
    <ns21:assertion>
      <ns20:haveSecondWitnessSignature>false</ns20:haveSecondWitnessSignature>
      <ns20:haveSignature>false</ns20:haveSignature>
      <ns20:haveWitnessSignature>false</ns20:haveWitnessSignature>
      <ns20:homeCommunity>
        <ns20:homeCommunityId>123.456.657.123</ns20:homeCommunityId>
      </ns20:homeCommunity>
      <ns20:userInfo>
        <ns20:personName>
          <ns20:familyName>na</ns20:familyName>
          <ns20:givenName>CMS</ns20:givenName>
          <ns20:secondNameOrInitials>Given Name - na C CMS Faimily Name -</ns20:secondNameOrInitials>
          <ns20:fullName>CMS Given Name - na C CMS Faimily Name - na</ns20:fullName>
        </ns20:personName>
        <ns20:userName>abcd</ns20:userName>
        <ns20:org>
          <ns20:homeCommunityId>123.456.657.123</ns20:homeCommunityId>
          <ns20:name>QSSI esMD Local Dev Gateway</ns20:name></ns20:org>
        <ns20:roleCoded><ns20:code>2.16.840.1.113883.6.96</ns20:code>
          <ns20:codeSystem>2.16.840.1.113883.6.96</ns20:codeSystem>
          <ns20:codeSystemName>SNOMED_CT</ns20:codeSystemName>
          <ns20:displayName>Claim Processing</ns20:displayName>
        </ns20:roleCoded>
      </ns20:userInfo>
        <ns20:authorized>false</ns20:authorized>
        <ns20:purposeOfDisclosureCoded>
          <ns20:code>2.16.840.1.113883.3.18.7.1</ns20:code>
          <ns20:codeSystem>2.16.840.1.113883.3.18.7.1</ns20:codeSystem>
          <ns20:codeSystemName>nhin-purpose</ns20:codeSystemName>
          <ns20:displayName>Use or disclosure of Psychotherapy Notes</ns20:displayName>
        </ns20:purposeOfDisclosureCoded>
```

```
1435            <ns20:samlAuthnStatement>
1436               <ns20:authInstant>2009-04-16T13:15:39.000Z</ns20:authInstant>
1437               <ns20:sessionIndex>987</ns20:sessionIndex>
1438               <ns20:authContextClassRef>urn:oasis:names:tc:SAML:2.0:ac:classes:X509</ns20:authContextClassRef>
1439               <ns20:subjectLocalityAddress>158.147.185.168</ns20:subjectLocalityAddress>
1440               <ns20:subjectLocalityDNSName>esmdg.cms.cmstest</ns20:subjectLocalityDNSName>
1441            </ns20:samlAuthnStatement>
1442            <ns20:samlAuthzDecisionStatement>
1443                  <ns20:decision>Permit</ns20:decision>
1444
1445   <ns20:resource>https://localhost:8191/CONNECTAdapter/AdapterService/AdapterDocSubmissionDeferredResponseSecured</n
1446   s20:resource>
1447                  <ns20:action>Execute</ns20:action>
1448                  <ns20:evidence>
1449                     <ns20:assertion>
1450                        <ns20:id>40df7c0a-ff3e-4b26-baeb-f2910f6d0mc202</ns20:id>
1451                        <ns20:issueInstant>2009-04-16T13:10:39.093Z</ns20:issueInstant>
1452                        <ns20:version>2.0</ns20:version>
1453                        <ns20:issuer>CN=SAML User,OU=Harris,O=HITS,L=Melbourne,ST=FL,C=US</ns20:issuer>
1454                        <ns20:issuerFormat>urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName</ns20:issuerFormat>
1455                        <ns20:conditions><ns20:notBefore>2009-04-16T13:10:39.093Z</ns20:notBefore>
1456                           <ns20:notOnOrAfter>2009-12-31T12:00:00.000Z</ns20:notOnOrAfter>
1457                        </ns20:conditions>
1458                        <ns20:accessConsentPolicy>urn:oid:2.16.840.1.113883.13.34.110.3</ns20:accessConsentPolicy>
1459
1460   <ns20:instanceAccessConsentPolicy>urn:oid:2.16.840.1.113883.13.34.110.3</ns20:instanceAccessConsentPolicy>
1461                     </ns20:assertion>
1462                  </ns20:evidence>
1463            </ns20:samlAuthzDecisionStatement>
1464            <ns20:samlSignature>
1465               <ns20:keyInfo>
1466                  <ns20:rsaKeyValueModulus></ns20:rsaKeyValueModulus>
1467                  <ns20:rsaKeyValueExponent></ns20:rsaKeyValueExponent>
1468               </ns20:keyInfo>
1469               <ns20:signatureValue></ns20:signatureValue>
1470            </ns20:samlSignature>
1471            <ns20:messageId>5a3d7012-029e-4559-9a55-49e3d80d0190</ns20:messageId>
1472         </ns21:assertion>
1473          <ns21:RegistryResponse requestId="esMD - Delivery To ECM" status="urn:oasis:names:tc:ebxml-
1474   regrep:ResponseStatusType:Success">
1475               <ns7:ResponseSlotList>
1476                  <ns8:Slot name="TransactionId">
1477                     <ns8:ValueList>
1478                        <ns8:Value>532</ns8:Value>
1479                     </ns8:ValueList></ns8:Slot>
1480                  <ns8:Slot name="ClaimId">
1481                     <ns8:ValueList>
1482                        <ns8:Value>69777777</ns8:Value>
1483                     </ns8:ValueList></ns8:Slot>
1484                  <ns8:Slot name="CaseId">
1485                     <ns8:ValueList>
1486                        <ns8:Value>6000045</ns8:Value>
1487                     </ns8:ValueList>
1488                  </ns8:Slot>
1489               </ns7:ResponseSlotList>
1490            </ns21:RegistryResponse>
1491         </ns21:AdapterRegistryResponse>
```

```
    </S:Body>
</S:Envelope>
```

9.4 Information Contained in Response Message

HIHs should look for the following information in the response message: Message ID, Unique ID, Request ID, Status, and Response Slots.

9.4.1 Message ID (Correlated with request MessageID.)

To correlate the Request MessageID with the response message, the message ID will be copied back to the response message.

Example:

```
<S:Header>
  …….
  <MessageID xmlns="http://www.w3.org/2005/08/addressing">5a3d7012-029e-4559-9a55-49e3d80d0190</MessageID>
</S:Header>
```

9.4.2 Unique ID (Correlated with request Unique ID)

To correlate the request Unique ID with the response, the Request Unique ID will be copied back to response message under Assertion.ID.

Example:

```
<ns20:assertion>
    <ns20:id>40df7c0a-ff3e-4b26-baeb-f2910f6d0mc202</ns20:id>
    …….
```

9.4.3 RequestID

The RequestID explains the type of response Type. The following table lists the possible request types:

Table 18: Possible Request Types

S.No	Request Type String	Request Type in Response Messages
1	esMD - HIH and Review Contractor OID Authorization	First Notification Ack
2	esMD - Document Submission Generic Validation	First Notification Ack
3	esMD - Meta Data Validation and Persistence	First Notification Ack
4	esMD - Delivery To ECM	First Notification Ack
5	esMD - Review Contractor Picks up the documents from ECM	Second Notification Ack
6	esMD – Payload Virus Scan	Third Notification Ack

Example: <ns21:RegistryResponse requestId="esMD - Delivery To ECM" status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success">

9.4.4 Status

Describes the status of the message:

a. urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success
b. urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Warning
c. urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Error

Example: <ns21:RegistryResponse requestId="esMD - Delivery To ECM" status="urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Success">

9.4.5 Response Slots

The esMD specific response slots will have esMD transaction information. The information in the slots is related to the following:

a) TransactionId
b) CaseId
c) ClaimId

Example:

```
<ns7:ResponseSlotList>
  <ns8:Slot name="TransactionId">
    <ns8:ValueList>
      <ns8:Value>532</ns8:Value>
    </ns8:ValueList></ns8:Slot>
  <ns8:Slot name="ClaimId">
    <ns8:ValueList>
      <ns8:Value>69777777</ns8:Value>
    </ns8:ValueList></ns8:Slot>
  <ns8:Slot name="CaseId">
    <ns8:ValueList>
      <ns8:Value>6000045</ns8:Value>
    </ns8:ValueList>
  </ns8:Slot>
</ns7:ResponseSlotList>
```

10 Release Notification Details

This table describes the various components and the number of participating organizations for esMD Phase 1 (Releases 1.1-1.3) and Phase 2 (Releases 2.1-2.2).

Table 19: Release Notification Details

	Sept. 2011	Nov. 2011	Jan. 2012	April 2012	July 2012	Oct. 2012
CONNECT Release #	3.1	3.1	3.x	3.x or later versions	3.x or later versions	3.x or later versions
Application Server	GlassFish	GlassFish	GlassFish Begin ST&E for WAS	WAS 7.0	WAS 7.0	WAS 7.0
Connect Modules	XDR Document Submission	XDR Document Submission	XDR Document Submission	XDR Document Submission X12 Document Submission	XDR Document Submission X12 Document Submission	XDR Document Submission X12 Document Submission
File Size (Allegedly)	Up to 19mb	Up to 19mb	Up to 19mb	Up to 19mb	Up to 19mb	Up to 19mb
Inbound Payload: provider to review contractor	HITSP C62 w/PDF	HITSP C62 w/PDF	HITSP C62 w/PDF	HITSP C62 w/PDF X12 275 w/PDF	HITSP C62 w/PDF X12 275 w/PDF X12 838 (esMD enrollment forms)	HITSP C62 w/PDF X12 275 w/PDF X12 838 (esMD enrollment forms) X12 276
Outbound Payload: review contractor to provider	None	None	None	None	None	ADR Denial Letters Feedback Reports
Reporting	None	Internal Web Viewer (CMS only)	External via MicroStrategy	Mobile based MicroStrategy	Mobile based MicroStrategy	Mobile based MicroStrategy
Acknowledgment and Notification	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup	HTTP 200 Ack. esMD Conformance Claim Reviewer Pickup
Review Contractors	3 RACs, 9 MACs, CERT, PERM	+ DME MACs + 2 ZPICS, + 1 RAC	+ more MACs	+ more MACs	+ more MACs	+ more MACs
HIH	6 HIHs	+ 10 HIHs	+ 20 HIHs	+ 20 HIHs	+ more HIHs	+ more HIHs
NHIN On- boarding Process	CMS Not on NwHIN HIHs Not on NwHIN	CMS Not on NwHIN HIHs Not on NwHIN	CMS Not on NwHIN HIHs Not on NwHIN	CMS Not on NwHIN HIHs Not on NwHIN	CMS Not on NwHIN HIHs Not on NwHIN	CMS Not on NwHIN HIHs Not on NwHIN

11 GLOSSARY

Acknowledgement (ACK)

Message (such as one used in 'handshaking' process between two systems) that indicates the status of communications received. It is commonly written as *ACK*.

CONNECT

CONNECT implements a flexible, open-source gateway solution that enables healthcare entities - Federal agencies or private-sector health organizations or networks - to connect their existing health information systems to the NHIN. CONNECT is fully functional out-of-the-box, while at the same time configurable and flexible to allow organizations to customize it to meet their needs and those of their existing health information systems.

Data Use Agreement

A satisfactory assurance between the covered entity and a researcher using a limited data set that the data will only be used for specific uses and disclosures. The data use agreement is required to include the following information: to establish that the data will be used for research, public health or health care operations (further uses or disclosure are not permitted); to establish who is permitted to use or receive the limited data set; and to provide that the limited data set recipient will: (1) not use or further disclose the information other than as permitted by the data use agreement or as required by law; (2) use appropriate safeguards to prevent use or disclosure of the information other than as provided in the agreement; (3) report to the covered entity any identified use or disclosure not provided for in the agreement; (4) ensure that any agents, including a subcontractor, to whom the limited data sets are provided agree to the same restrictions and conditions that apply to the recipient; and (5) not identify the information or contact the individuals.

De-identified Data

De-identified data is data from which patient identifiers consisting of Personally Identifiable Information (PII) is removed. The business rules for de-identified data will follow the HIPAA Privacy Rule including the de-identification of the specified identifiers.

Electronic Submission of Medical Documentation

A new mechanism for submitting medical documentation via an internet gateway utilizing the Nationwide Health Information Network (NHIN) connecting providers to the Centers for Medicare & Medicaid Services (CMS). In its second phase, esMD will allow Medicare Review Contractors to electronically send claim related Additional Document Request (ADR) letters to providers when their claims are selected for review.

Health Information Handler (HIH)

A Health Information Handler (HIH) is defined as an organization that oversees and governs the exchange of health-related claim reviewer information from Provider to CMS esMD Gateway according to nationally recognized standards.[1]

1 The National Alliance for Health Information Technology Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information Technology Terms April 28, 2008

Health Information Technology Standards Panel (HITSP)

HITSP is a volunteer-driven, consensus-driven organization that is sponsored through a contract from the Department of Health and Human Services (HHS). HITSP harmonizes and recommends the technical standards that are crucial to assure the interoperability of electronic health records.

HTTPs

A set of rules for speedy retrieval and transmission of electronic documents written in HTML over a secure connection. HTTPS addresses differentiate from HTTP ones because they encrypt and decrypt user pages to prevent unauthorized access to sensitive data. Online credit card processing and banking websites use HTTPS addresses to ensure privacy and provide secure processing for users.

Interoperability

Interoperability is the ability of health information systems to work together, within and across organizational boundaries, in order to advance the effective delivery of healthcare for individuals and communities.

Interface

A well-defined boundary where direct contact between two different environments, systems, etc., occurs, and where information is exchanged.

Nationwide Health Information Network (NHIN)

The Nationwide Health Information Network (NHIN) is a set of standards, protocols, legal agreements, and specifications that a consortium of health information organizations have agreed are necessary for secure and private exchange of health information over the internet. The NHIN is overseen by the Office of the National Coordinator for Health IT (ONC).

NHIN Exchange

The NHIN Exchange is designed to connect a diverse set of federal agencies and private organizations to securely exchange electronic health information. CMS believes the NHIN Exchange holds promise and intends to use it during the esMD pilot. More information on NHIN Exchange can be found by clicking the "NHIN Exchange" link:
http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_exchange/1407.

Performance

Accomplishment of a transaction measured against preset standards of accuracy, completeness, cost, and speed.

Privacy

An individual’s interest in protecting his or her individually identifiable health information and the corresponding obligation of those persons and entities, that participate in a network for the purposes of electronic exchange of such information, to respect those interests through fair information practices.

Response Time

It is the interval between a user-command and the receipt of an action, result, or feedback from the system. It is expressed as the sum of (a) transmission time of the command to the system, (b) processing time at the CPU, (c) access time to obtain required data from a storage device, and (d) transmission time of the result back to the user. When applied to a system component, it is the time taken to react to a system request or a given input.

SAML

Security Assertion Markup Language used for message authentication.

Security

The physical, technological, and administrative safeguards used to protect individually identifiable health information.

SOAP

Simple Object Access Protocol is a message exchange format for web services.

TLS

Transport Layer Security (TLS) and its predecessor, Secure Sockets Layer (SSL), are cryptographic protocols that "provide communications security over the Internet". TLS and SSL encrypt the segments of network connections above the Transport Layer, using symmetric cryptography for privacy and a keyed message authentication code for message reliability. TLS is an IETF standards track protocol, last updated in RFC 5246, and is based on the earlier SSL specifications developed by Netscape Corporation.

The TLS protocol allows client/server applications to communicate across a network in a way designed to prevent eavesdropping and tampering. A TLS client and server negotiate a stateful connection by using a handshaking procedure. During this handshake, the client and server agree on various parameters used to establish the connection's security.

- The handshake begins when a client connects to a TLS-enabled server requesting a secure connection, and presents a list of supported CipherSuites (ciphers and hash functions).
- From this list, the server picks the strongest cipher and hash function that it also supports and notifies the client of the decision.
- The server sends back its identification in the form of a digital certificate. The certificate usually contains the server name, the trusted certificate authority (CA), and the server's public encryption key.
- The client may contact the server that issued the certificate (the trusted CA as above) and confirm that the certificate is valid before proceeding.
- In order to generate the session keys used for the secure connection, the client encrypts a random number (RN) with the server's public key (PbK), and sends the result to the server. Only the server should be able to decrypt it (with its private key (PvK)): this is the one fact that makes the keys hidden from third parties, since only the server and the client have access to this data. The client knows PbK and RN, and the server knows PvK and (after decryption of the client's message) RN. A third party is only able to know RN if PvK has been compromised.
- From the random number, both parties generate key material for encryption and decryption.

- This concludes the handshake and begins the secured connection, which is encrypted and decrypted with the key material until the connection closes.

If any one of the above steps fails, the TLS handshake fails, and the connection is not created.

Transaction

Event or process (such as an input message) initiated or invoked by a user or system, regarded as a single unit of work and requiring a record to be generated for processing in a database.

12 ACRONYMS

ADR	Additional Documentation Request
AES	Advanced Encryption Standard
CA	Certificate Authority
CDA	Clinical Document Architecture
CCHIT	Certification Commission for Health Information Technology
CMS	Centers for Medicare & Medicaid Services
CERT	Comprehensive Error Rate Testing
DURSA	Data Use and Reciprocal Support Agreement
EHR	Electronic Health Record
esMD	Electronic Submission of Medical Documentation
FFS	Fee-For-Service
FIPS	Federal Information Processing Standards
HIE	Health Information Exchange
HIPAA	Health Information Portability and Accountability Act
HIT	Health Information Technology
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7
HIH	Health Information Handler
HTTP	Hypertext Transfer Protocol
HTTPS	Hypertext Transfer Protocol Secured
IHE	Integrating the Healthcare Enterprise
IP	Internet Protocol
MAC	Medicare Audit Contractors
NHIN	Nationwide Health Information Network
NIST	National Institute of Standards and Technology
NPI	National Provider Identifier
OASIS	Organization for the Advancement of Structured Information Standards
OID	Organizational Identification
ONC	Office of National Coordinator for HIT
PDF	Portable Document Format
PERM	Program Error Rate Measurement
RAC	Recovery Audit Contractors

ROI	Release of Information
RHIO	Regional Health Information Organizations
SAML	Security Assertion Markup Language
SHA	Secure Hash Algorithm
SOAP	Simple Object Access Protocol
TIFF	Tagged Image File Format
TLS	Transport Layer Security
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
XDR	External Data Representation
XML	Extensible Markup Language

13 Appendix A

Sample SOAP Message

```
<?xml version="1.0" encoding="UTF-8"?>
<soapenv:Envelope xmlns:soapenv="http://www.w3.org/2003/05/soap-envelope"
xmlns:urn="urn:gov:hhs:fha:nhinc:common:nhinccommonentity" xmlns:urn1="urn:gov:hhs:fha:nhinc:common:nhinccommon"
xmlns:add="http://schemas.xmlsoap.org/ws/2004/08/addressing" xmlns:urn2="urn:oasis:names:tc:ebxml-regrep:xsd:lcm:3.0"
xmlns:urn3="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0" xmlns:urn4="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
xmlns:urn5="urn:ihe:iti:xds-b:2007">
   <soapenv:Header/>
   <soapenv:Body projectName="EndToEndSelfTest" testCase="XDR Async">
      <urn:RespondingGateway_ProvideAndRegisterDocumentSetRequest>
         <urn:assertion>
            <urn1:homeCommunity>
               <urn1:description>${#Project#LocalHCDescription}</urn1:description>
               <urn1:homeCommunityId>${#Project#LocalHCID}</urn1:homeCommunityId>
               <urn1:name>${#Project#LocalHCDescription}</urn1:name>
            </urn1:homeCommunity>
            <urn1:uniquePatientId>urn:oid:2.16.840.1.113883.13.34.110.1.110.9</urn1:uniquePatientId>
            <urn1:userInfo>
               <urn1:userName>610</urn1:userName>
               <urn1:org>
                  <urn1:description>${#Project#LocalHCDescription}</urn1:description>
                  <urn1:homeCommunityId>${#Project#LocalHCID}</urn1:homeCommunityId>
                  <urn1:name>${#Project#LocalHCDescription}</urn1:name>
               </urn1:org>
            </urn1:userInfo>
            <urn1:organizationId>
               <urn1:description>Description of Broker Organization between Provider and the submitting HIH CONNECT or CONNECT
Compatable Gateway</urn1:description>
               <urn1:homeCommunityId>urn:oid:1.3.6.1.4.1.101420.6.1</urn1:homeCommunityId>
               <urn1:name>Name of Broker Organization between Provider and the submitting HIH CONNECT or CONNECT Compatable
Gateway</urn1:name>
            </urn1:organizationId>
            <urn1:purposeOfDisclosureCoded>
               <urn1:code>PAYMENT</urn1:code>
               <urn1:codeSystem>2.16.840.1.113883.3.18.7.1</urn1:codeSystem>
               <urn1:codeSystemName>esMD CMS Purpose</urn1:codeSystemName>
               <urn1:codeSystemVersion>1.0</urn1:codeSystemVersion>
               <urn1:displayName>Medical Claim Documentation Review</urn1:displayName>
               <urn1:originalText>Medical Claim Documentation Review</urn1:originalText>
            </urn1:purposeOfDisclosureCoded>
            <urn1:samlAuthnStatement>
               <urn1:authInstant>2011-01-05T16:50:01.011Z</urn1:authInstant>
               <urn1:sessionIndex>987</urn1:sessionIndex>
               <urn1:authContextClassRef>urn:oasis:names:tc:SAML:2.0:ac:classes:X509</urn1:authContextClassRef>
               <urn1:subjectLocalityAddress>158.147.185.168</urn1:subjectLocalityAddress>
               <urn1:subjectLocalityDNSName>cms.hhs.gov</urn1:subjectLocalityDNSName>
            </urn1:samlAuthnStatement>
            <urn1:samlAuthzDecisionStatement>
               <urn1:decision>Permit</urn1:decision>
               <urn1:resource>https://158.147.185.168:8181/esMD/DocumentSubmission</urn1:resource>
               <urn1:action>TestSaml</urn1:action>
               <urn1:evidence>
                  <urn1:assertion>
                     <urn1:id>40df7c0a-ff3e-4b26-baeb-f2910f6d05a9esmd918</urn1:id>
                     <urn1:issueInstant>2011-01-05T16:50:01.011Z</urn1:issueInstant>
                     <urn1:version>2.0</urn1:version>
                     <urn1:issuerFormat>urn:oasis:names:tc:SAML:1.1:nameid-format:X509SubjectName</urn1:issuerFormat>
                     <urn1:issuer>CN=HIH SAML User,OU=QSSI,O=QSSI,L=Baltimore,ST=MD,C=US</urn1:issuer>
                     <urn1:conditions>
                        <urn1:notBefore>2011-01-05T16:50:01.011Z</urn1:notBefore>
                        <urn1:notOnOrAfter>2011-01-05T16:53:01.011Z</urn1:notOnOrAfter>
```

```
                    </urn1:conditions>
                    <urn1:accessConsentPolicy>Claim-Ref-1234 NA for esMD</urn1:accessConsentPolicy>
                    <urn1:instanceAccessConsentPolicy>Claim-Instance-1  NA for esMD</urn1:instanceAccessConsentPolicy>
                  </urn1:assertion>
                </urn1:evidence>
              </urn1:samlAuthzDecisionStatement>
            </urn:assertion>
            <urn:nhinTargetCommunities>
              <urn1:nhinTargetCommunity>
                <urn1:homeCommunity>
                  <urn1:description>${#Project#RemoteHCDescription}</urn1:description>
                  <urn1:homeCommunityId>${#Project#RemoteHCID}</urn1:homeCommunityId>
                  <urn1:name>${#Project#RemoteHCDescription}</urn1:name>
                </urn1:homeCommunity>
              </urn1:nhinTargetCommunity>
            </urn:nhinTargetCommunities>
            <urn:ProvideAndRegisterDocumentSetRequest>
              <urn2:SubmitObjectsRequest id="999" comment="esMD Claim Document Submission in response to Review Contractor ADR
Letter">
                <urn4:RegistryObjectList>
                  <urn4:ExtrinsicObject id="Document01" mimeType="application/pdf" objectType="urn:uuid:7edca82f-054d-47f2-a032-
9b2a5b5186c1">
                    <urn4:Classification id="cl01" classificationScheme="urn:uuid:93606bcf-9494-43ec-9b4e-a7748d1a838d"
classifiedObject="Document01" nodeRepresentation="author">
                      <urn4:Slot name="authorInstitution">
                        <urn4:ValueList>
                          <urn4:Value>603111</urn4:Value>
                        </urn4:ValueList>
                      </urn4:Slot>
                      <urn4:Slot name="authorPerson">
                        <urn4:ValueList>
                          <urn4:Value>603</urn4:Value>
                        </urn4:ValueList>
                      </urn4:Slot>
                    </urn4:Classification>
                    <urn4:Classification id="cl02" classificationScheme="urn:uuid:41a5887f-8865-4c09-adf7-e362475b143a"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                      <urn4:Slot name="classCode">
                        <urn4:ValueList>
                          <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                      </urn4:Slot>
                      <urn4:Name>
                        <urn4:LocalizedString value="Unstructured Document Submission"/>
                      </urn4:Name>
                    </urn4:Classification>

                    <urn4:Description>
                      <urn4:LocalizedString value="esMD Claim Document Submission in response to Review Contractor ADR Letter"/>
                    </urn4:Description>

                    <urn4:Classification id="cl03" classificationScheme="urn:uuid:f4f85eac-e6cb-4883-b524-f2705394840f"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.5.25">
                      <urn4:Slot name="confidentialityCode">
                        <urn4:ValueList>
                          <urn4:Value>V</urn4:Value>
                        </urn4:ValueList>
                      </urn4:Slot>
                      <urn4:Name>
                        <urn4:LocalizedString value="Very"/>
                      </urn4:Name>
                    </urn4:Classification>
                    <urn4:Slot name="creationTime">
                      <urn4:ValueList>
                        <urn4:Value>20110101165910</urn4:Value>
```

```
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Classification id="cl04" classificationScheme="urn:uuid:a09d5840-386c-46f2-b5ad-9c3699a4309d"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                    <urn4:Slot name="formatCode">
                        <urn4:ValueList>
                            <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
                    <urn4:Name>
                        <urn4:LocalizedString value="Scanned PDF Document in CDA C62 Construct"/>
                    </urn4:Name>
                </urn4:Classification>
                <urn4:Classification id="cl06" classificationScheme="urn:uuid:cccf5598-8b07-4b77-a05e-ae952c785ead"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                    <urn4:Slot name="practiceSettingCode">
                        <urn4:ValueList>
                            <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
                    <urn4:Name>
                        <urn4:LocalizedString value="NA"/>
                    </urn4:Name>
                </urn4:Classification>
                <urn4:Slot name="hash">
                    <urn4:ValueList>
                        <urn4:Value>ad18814418693512b767676006a21d8ec7291e84</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Classification id="cl05" classificationScheme="urn:uuid:f33fb8ac-18af-42cc-ae0e-ed0b0bdb91e1"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                    <urn4:Slot name="healthcareFacilityTypeCode">
                        <urn4:ValueList>
                            <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
                    <urn4:Name>
                        <urn4:LocalizedString value="Health Information Handler (HIH)"/>
                    </urn4:Name>
                </urn4:Classification>
                <urn4:Slot name="languageCode">
                    <urn4:ValueList>
                        <urn4:Value>en-us</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:slot name="legalAuthenticator">
                    <urn4:ValueList>
                        <urn4:Value>NA</urn4:Value>
                    </urn4:ValueList>
                </urn4:slot>
                <urn4:ExternalIdentifier id="ei01" registryObject="Document01" identificationScheme="urn:uuid:58a6f841-87b3-4a3e-92fd-
a8ffeff98427" value="2.16.840.1.113883.13.34.110.1.1000.1^^^&amp;12345">
                    <urn4:Name>
                        <urn4:LocalizedString value="XDSDocumentEntry.patientId"/>
                    </urn4:Name>
                </urn4:ExternalIdentifier>
                <urn4:Classification id="cl07" classificationScheme="urn:uuid:f0306f51-975f-434e-a61c-c59651d33983"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                    <urn4:Slot name="codingScheme">
                        <urn4:ValueList>
                            <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
                    <urn4:Name>
                        <urn4:LocalizedString value="Outpatient Evaluation And Management"/>
```

```
                    </urn4:Name>
                </urn4:Classification>
                <urn4:Slot name="serviceStartTime">
                    <urn4:ValueList>
                        <urn4:Value>20110101165910</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Slot name="serviceStopTime">
                    <urn4:ValueList>
                        <urn4:Value>20110101165910</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Slot name="size">
                    <urn4:ValueList>
                        <urn4:Value>1024000</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Name>
                    <urn4:LocalizedString value="Claim Supporting Medical Documentation"/>
                </urn4:Name>
                <urn4:Classification id="cl08" classificationScheme="urn:uuid:41a5887f-8865-4c09-adf7-e362475b143a"
classifiedObject="Document01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                    <urn4:Slot name="classCode">
                        <urn4:ValueList>
                            <urn4:Value>1</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
                    <urn4:Name>
                        <urn4:LocalizedString value="Unstructured Document Submission"/>
                    </urn4:Name>
                </urn4:Classification>
                <urn4:ExternalIdentifier id="ei02" registryObject="Document01" identificationScheme="urn:uuid:96fdda7c-d067-4183-912e-
bf5ee74998a8" value="1.3.6.1.4.1.21367.2005.3.9999.33">
                    <urn4:Name>
                        <urn4:LocalizedString value="XDSSubmissionSet.uniqueId"/>
                    </urn4:Name>
                </urn4:ExternalIdentifier>
            </urn4:ExtrinsicObject>

            <urn4:RegistryPackage id="SubmissionSet01">
                <urn4:Slot name="esMDClaimId">
                    <urn4:ValueList>
                        <urn4:Value>12345</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Slot name="esMDCaseId">
                    <urn4:ValueList>
                        <urn4:Value>67890</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Slot name="intendedRecipient">
                    <urn4:ValueList>
                        <urn4:Value>2.16.840.1.113883.13.34.110.2.100.1</urn4:Value>
                    </urn4:ValueList>
                </urn4:Slot>
                <urn4:Description>
                    <urn4:LocalizedString value="esMD Claim Document Submission in response to Review Contractor ADR Letter"/>
                </urn4:Description>
                <urn4:Classification id="cl11" classificationScheme="urn:uuid: a7058bb9-b4e4-4307-ba5b-e3f0ab85e12d" classifiedObject="
SubmissionSet01" nodeRepresentation="author">
                    <urn4:Slot name="authorInstitution">
                        <urn4:ValueList>
                            <urn4:Value>897654</urn4:Value>
                        </urn4:ValueList>
                    </urn4:Slot>
```

```
                        <urn4:Slot name="authorPerson">
                           <urn4:ValueList>
                              <urn4:Value>808</urn4:Value>
                           </urn4:ValueList>
                        </urn4:Slot>
                     </urn4:Classification>
                     <urn4:Classification id="cl09" classificationScheme="urn:uuid:aa543740-bdda-424e-8c96-df4873be8500"
classifiedObject="SubmissionSet01" nodeRepresentation="2.16.840.1.113883.13.34.110.1.1000.1">
                        <urn4:Slot name="contentTypeCode">
                           <urn4:ValueList>
                              <urn4:Value>1</urn4:Value>
                           </urn4:ValueList>
                        </urn4:Slot>
                        <urn4:Name>
                           <urn4:LocalizedString value="Response to Additional Documentation Request (ADR)"/>
                        </urn4:Name>
                     </urn4:Classification>
                     <urn4:ExternalIdentifier id="ei03" registryObject="SubmissionSet01" identificationScheme="urn:uuid:6b5aea1a-874d-4603-
a4bc-96a0a7b38446" value="2.16.840.1.113883.13.34.110.1.1000.1^^^&amp;12345">
                        <urn4:Name>
                           <urn4:LocalizedString value="XDSDocumentEntry.patientId"/>
                        </urn4:Name>
                     </urn4:ExternalIdentifier>
                     <urn4:ExternalIdentifier id="ei04" registryObject="SubmissionSet01" identificationScheme="urn:uuid:554ac39e-e3fe-47fe-
b233-965d2a147832" value="12.16.840.1.113883.13.34.110.2">
                        <urn4:Name>
                           <urn4:LocalizedString value="XDSSubmissionSet.sourceId"/>
                        </urn4:Name>
                     </urn4:ExternalIdentifier>
                     <urn4:Slot name="submissionTime">
                        <urn4:ValueList>
                           <urn4:Value>20110101165910</urn4:Value>
                        </urn4:ValueList>
                     </urn4:Slot>
                     <urn4:ExternalIdentifier id="ei05" registryObject="SubmissionSet01" identificationScheme="urn:uuid:96fdda7c-d067-4183-
912e-bf5ee74998a8" value="554ac39e-ef6343434-b233-965d34345555">
                        <urn4:Name>
                           <urn4:LocalizedString value="XDSSubmissionSet.uniqueId"/>
                        </urn4:Name>
                     </urn4:ExternalIdentifier>
                     <urn4:Name>
                        <urn4:LocalizedString value="Claim Supporting Medical Documentation"/>
                     </urn4:Name>
                  </urn4:RegistryPackage>
                  <urn4:Classification id="cl10" classifiedObject="SubmissionSet01" classificationNode="urn:uuid:a54d6aa5-d40d-43f9-88c5-
b4633d873bdd"/>
                  <urn4:Association id="as01" associationType="HasMember" sourceObject="SubmissionSet01" targetObject="Document01">
                     <urn4:Slot name="SubmissionSetStatus">
                        <urn4:ValueList>
                           <urn4:Value>Original</urn4:Value>
                        </urn4:ValueList>
                     </urn4:Slot>
                  </urn4:Association>
               </urn4:RegistryObjectList>
            </urn2:SubmitObjectsRequest>
            <!--1 or more repetitions:-->
         <urn5:Document id="Document01">C62 PayLoad_Here – Base 64 encoded PDF inside C62]</urn5:Document>
         </urn:ProvideAndRegisterDocumentSetRequest>
      </urn:RespondingGateway_ProvideAndRegisterDocumentSetRequest>
   </soapenv:Body>
</soapenv:Envelope>
```

14 C62 Payload Sample

<!—NOTE: The following CDA document shall be sent in binary form with base 64 encoding .Here it was shown for information purpose only -- >

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
classCode="DOCCLIN" moodCode="EVN" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
   <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
   <id root="eab8765b-1424-47cc-9495-ddc934cf5f5d"/>

<templateId root="2.16.840.1.113883.10.20.3" assigningAuthorityName="CDT General Header Constraints"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1" assigningAuthorityName="IHE Medical Document"/>
<templateId root="1.3.6.1.4.1.19376.1.2.20" assigningAuthorityName="IHE Scanned Document"/>
<templateId root="2.16.840.1.113883.3.88.11.62.1" assigningAuthorityName="HITSP Unstructured Document"/>
<languageCommunication>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
 <languageCode code='en-US'/>
</languageCommunication>
<title>ADR Response Supported Claim Documentation</title>
<confidentialityCode code="V" codeSystem="2.16.840.1.113883.5.25" codeSystemName="Confidentiality"
displayName="Very Restricted"/>
<effectiveTime value="20100319083838-0500"/>
        <recordTarget>
          <patientRole>
            <id extension="12345" root="2.16.840.1.113883.3.933"/>
            <addr>
              <streetAddressLine>NA</streetAddressLine>
              <city>NA</city>
              <state>NA</state>
              <postalCode>NA</postalCode>
              <country>NA</country>
            </addr>
            <patient>
              <name>
                <prefix>NA</prefix>
                <given>NA</given>
                <family>NA</family>
              </name>
              <administrativeGenderCode code="F"
                codeSystem="2.16.840.1.113883.5.1"/>
              <birthTime value="19600127"/>
            </patient>
          </patientRole>
        </recordTarget>
        <author>
          <templateId root=”1.3.6.1.4.1.19376.1.2.20.1”/>
            <time value=“19990522”/>
            <assignedAuthor>
              <id extension=“11111111” root=“1.3.5.35.1.4436.7”/>
                <assignedPerson>
                <name>
                  <prefix>NA</prefix>
                  <given>NA</given>
                  <family>NA</family>
                  <suffix>NA</suffix>
                </name>
                </assignedPerson>
                <representedOrganization>
                  <id extension=“aaaaabbbbb” root=“1.3.5.35.1.4436.7”/>
                    <name>NA</name>
                </representedOrganization>
            </assignedAuthor>
        </author>
        <author>
```

```
<templateId root="1.3.6.1.4.1.19376.1.2.20.2"/>
<time value="20050329224411+0500"/>
<assignedAuthor>
<id root="1.3.6.4.1.4.1.2835.2.1234"/>
<assignedAuthoringDevice>
<code code="CAPTURE" displayName="Image Capture" codeSystem=" 1.2.840.10008.2.16.4" />
<manufacturerModelName>NA</manufacturerModelName>
<softwareName>NA</softwareName>
</assignedAuthoringDevice>
<representedOrganization>
<id root="1.3.6.4.1.4.1.2835.2"/>
<name>SOME Scanning Facility</name>
<addr>
<streetAddressLine>NA</streetAddressLine>
<city>NA</city>
<state>NA</state>
<postalCode>NA</postalCode>
<country>NA</country>
</addr>
</representedOrganization>
</assignedAuthor>
</author>
<dataEnterer>
<templateId root="1.3.6.1.4.1.19376.1.2.20.3"/>
<time value="20050329224411+0500"/>
<assignedEntity>
<id extension="22222222" root="1.3.6.4.1.4.1.2835.2"/>
<assignedPerson>
<name>
<prefix>NA.</prefix>
<given>NA</given>
<family>NA</family>
</name>
</assignedPerson>
</assignedEntity>
</dataEnterer>
<custodian typeCode="CST">33333
<time value="19990522"/>
<signatureCode code="S"/>
<assignedEntity>
<id extension="11111111" root="1.3.5.35.1.4436.7"/>
<assignedPerson>
<name>
<prefix>NA</prefix>
<given>NA</given>
<family>NA</family>
<suffix>NA</suffix>
</name>
</assignedPerson>
</assignedEntity>
</legalAuthenticator>
<documentationOf>
<serviceEvent >
<effectiveTime>
<low value="19800127"/>
<high value="19990522"/>
</effectiveTime>
</serviceEvent>
</documentationOf>
<component>
<nonXMLBody>
<text mediaType="application/pdf" representation="B64">

1PD94bWwgdmVyc2lvLKDJFLKDFAASDOI34396Zz0iVVRGLTgiPz4NCjxDbGluaWNhbERvY3VtZW5
</text>
```

```
                </nonXMLBody>
            </component>
        </ClinicalDocument>
```

15 Codes.xml

This will be provided in the future.

16 Appendix B

The following table provides test cases for HIHs.

Table 20: Test Cases

Test Case #	Test Case Description	Scenario	Expected Result
1	The esMD gateway shall ensure that the HIH is CMS on-boarded, by validating its Home Community Id (OID) in the XDR deferred document submission request against the esMD database.	1a. esMD reads the HIH Home Community ID (OID) from the Assertions attributes. 1.b. HIH OID is valid	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application
		1c. HIH OID is invalid/HIH not on-boarded	The esMD gateway shall respond to the submitting HIH with the 'XDSHOIDIdDoesNotMatch' error in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response.
2	The esMD gateway shall validate the participation of the intended recipient (Review Contractor) by validating its Home Community Id (OID) in the XDR deferred document submission request against the esMD database.	2a. esMD reads the Review Contractor's Home Community ID (OID) from the Assertions attributes 2.b. Intended Recipient OID is valid	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application.
		2c. Intended Recipient OID is invalid	The esMD gateway shall respond to the submitting HIH with the 'XDSHOIDIdDoesNotMatch' error in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response.
3	To avoid duplicate submission, esMD gateway shall validate the uniqueness of the XDR deferred document submission request by validating the Unique ID against the esMD database.	3a. Unique ID in the HTTP Header SAML Assertions is not present in the esMD database.	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application
		3b. Unique ID in the HTTP Header SAML Assertions is already present in the esMD database	The esMD gateway shall respond to the submitting HIH with the 'XDSDuplicateUniqueIdInRegistry' error in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response.
4	The esMD gateway shall validate the conformance of XDR message Submission Set and Document Set metadata attributes (as mentioned in	4a. XDR Submission Set and XDR Document Set attributes are present	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application

	the esMD Implementation Guide) in the XDR deferred document submission request sent by the HIH.	in the XDR deferred document submission request as per implementation guide specifications	
		4b. XDR Submission Set and/or XDR Document Set metadata attributes are missing in the XDR deferred document submission request	The esMD gateway shall respond to the submitting HIH with the 'XDSRegistryMetadataError' in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response.
5	The esMD gateway shall validate the esMD affinity values (Class Code, Type Code, Format Code, Healthcare Facility Type Code, Confidentiality Code -- as defined in the esMD Implementation Guide) in the submitted XDR Message of the XDR deferred document submission request against the esMD database.	5a. The esMD affinity values in the XDR Message are consistent with those specified in the esMD Implementation Guide	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application
		5b. The esMD affinity values are incorrect/missing	The esMD gateway shall respond to the submitting HIH with the 'XDSRegistryMetadataError' in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response.
6	The esMD gateway shall validate the presence of the C62 payload (PDF/TIFF document/s) in the XDR deferred document submission request.	6a. The payload is present	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application
		6b. The payload is absent	The esMD gateway shall respond to the submitting HIH with the 'XDSMissingDocument' error message in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response
7	The esMD gateway shall ensure the integrity of the payload by matching the hash code in the XDR deferred document submission request metadata with the generated hash code.	7a. The hash code in the metadata matches with the generated hash code	The XDR deferred document submission request shall proceed with further validation steps in the esMD Application
		7b. There is a mismatch in the two hash codes	The esMD gateway shall respond to the submitting HIH with the 'XDSNonIdenticalHash' error message in XDR deferred document submission response message. The esMD Transaction ID, Unique ID and Message IDs will be sent back to the HIH along with the failed status message in the response

8	Upon successful transmission of the XDR deferred document submission request by the HIH gateway, esMD gateway shall send an acknowledgement (1st message) to the HIH gateway.	8a. The XDR deferred document submission request is received at the esMD gateway	The esMD gateway shall respond to the submitting HIH gateway with a HTTP 200 transmission acknowledgement.
9	Upon conformation and validation checks, and submission of the payload to the CMS ECM Repository, esMD gateway shall send the status and notification message (2nd message) to the HIH gateway.	9a. The conformance and validation check is successful, and the payload is submitted to CMS ECM Repository	The esMD gateway shall respond to the submitting HIH gateway with a successful conformance and validation status, and a successful XDR deferred document submission response message.
		9b. The conformance and validation check is failed and the payload is not submitted to CMS ECM Repository	The esMD gateway shall respond to the submitting HIH gateway with a failed conformance and validation status, and a failed XDR deferred document submission response message.
10	The esMD gateway shall send a notification message (3rd message) to the HIH after the review contractor (Intended Recipient) picks up the submitted payload from the CMS ECM Repository.	10 a. The review contractor (Intended Recipient) picks up the payload from the ECM Repository	The esMD gateway shall respond to the submitting HIH gateway with a review contractor (Intended Recipient) pickup response message.

16. Appendix C: Types of Tests for HIHs

This section provides descriptions and details for the three phases of testing that need to be performed by the HIHs during the testing of their gateways with the CMS esMD gateway. Successful completion of these tests is essential for the HIHs before they are declared production-ready.

The three phases of testing are as follows:

- Connectivity Test (Performed using SOAP UI tool and HIH Gateway)
- Functionality Test (Performed using HIH application and HIH Gateway & not through SOAP UI tool)
- End to End Test (performed using HIH application, and HIH Gateway involving Review Contractor & not through SOAP UI tool)

The paragraphs below explain the above tests in greater detail.

16.1 Connectivity Test Using SOAP UI Tool

Tests are performed in this area to confirm connectivity between the HIH gateway and the CMS esMD gateway. Confirmation of connectivity between the two gateways is essential before the CMS esMD gateway can receive and process the XDR deferred document submission request sent from the HIH gateway. For details on how to configure SOAP UI, please, refer to Appendix D.

16.1.1 Testing Inbound Connection (HIH Gateway to CMS esMD Gateway)

This purpose of this test is to ensure that inbound connectivity between HIH Gateway and CMS esMD Gateway using the HIH IP Address validation at the CMS AT&T Router, CMS Firewalls, and TLS Mutual Certificate Authentication.

16.1.1.1 Inbound Telnet Test

The purpose of this sub-test is to verify whether the inbound network connection between the HIH Gateway and the CMS esMD Gateway were established by doing the simple telnet test from the HIH Gateway. Under this test, the HIH IP address Inbound Configurations at the CMS AT&T Router/CMS Firewall will be verified.

Pre-requisite**:**

- Participating HIHs shall submit their public facing IP address to CMS/QSSI esMD Team 7 weeks before the scheduled testing date. The HIH shall verify with their firewall team whether their environment might need and HIH outbound (HIH to CMS esMD Gateway) IP address NATing to CMS esMD Gateway. CMS esMD inbound IP address for 'esmdg.cms.cmsval' will be shared by esMD HIH coordinators.
- The CMS/QSSI esMD Gateway Contractor, CMS CITIC contractor and AT&T teams will process and configure the HIH IP address routing rules in the CMS AT&T router and CMS firewalls to allow the traffic from the HIH gateway.

The following is a sequence of events at this level:

1. The QSSI esMD team arranges a conference call with the HIH and the CMS CITIC contractor.

2. During the conference call, HIHs set up a telnet session between their gateway and the AT&T/CMS Firewall.
3. The CMS CITIC contractor watches over the incoming traffic from the HIH gateway at the AT&T/CMS firewall level and confirms the inbound telnet connectivity.
4. HIH Gateway and Firewall teams will confirm the inbound telnet connectivity test at HIH end.

A successful telnet session indicates established inbound telnet connectivity between the HIH network and the CMS network.

16.1.1.2 HIH Mutual TLS Certificate Authentication

Based upon a successful Telnet session (step 2.2.1.1), this step is performed during the same conference call, or a different conference call, depending upon the availability of resources from the QSSI esMD team, the CMS CITIC contractor, and the HIH.

Pre-requisite:

- Participating HIHs shall submit their Gateway Certificate Authority Public Certificate to the CMS/QSSI esMD Team 7 weeks before the scheduled testing date.
- The CMS/QSSI esMD Gateway Contractor, CMS CITIC contractor, and AT&T teams configure the HIH IP address routing rules in the CMS AT&T router and CMS firewalls to allow traffic from the HIH gateway.
- HIH Gateway domain configuration shall have esMD specific TLS CIPHER Suites with FIPS Mode. The CMS CIPHER Suites will be added in the future.

The following are the sequence of events at this level:

1. The HIH submits the XDR deferred document submission request to the CMS esMD Gateway using the SOAP UI tool.
2. The HIH TLS mutual Certificate authentication will occur between the HIH Gateway and the CMS esMD environment in two levels:
    - Mutual authentication between the CMS SSLM appliance and the HIH Gateway;
    - TLS Cipher Suite validation between the CMS SSLM appliance and the HIH Gateway;
    - HIH Certificate validation at the CMS esMD Gateway.

- The successful mutual authentication between the HIH Gateway and the CMS esMD Gateway will get an HTTP 200 Acknowledgment from the esMD Gateway to the HIH Gateway. The HIH shall submit the test results to the QSSI esMD team for confirmation.
- The QSSI esMD team and the CMS CITIC contractor will confirm the successful incoming mutual authentication.

16.1.1.3 Confirmation of Metadata Validation and Request Processing

This purpose of this step is to confirm successful metadata validation and request processing by the CMS esMD gateway. The QSSI esMD team along with CMS CITIC Contractor analyze the gateway and adaptor logs (Along with database) to confirm metadata validation and request processing. If any anomalies are found, they are reported to the HIH.

16.1.1.4 Confirmation of Metadata Persistence in the esMD Database

In this step, QSSI esMD DBA team analyzes the database for successful persistence of the audit events and data sent by the HIHs. All transaction related audit events and metadata persistence will be verified. Any errors or exceptions found are reported to the HIHs.

Also, esMD system will send the errors and exceptions as a part of esMD response message. These errors and exceptions can be found in the HIH esMD Gateway logs.

16.1.2 Testing Outbound Connection (CMS esMD Gateway to HIH Gateway)

The purpose of this test is to verify if the outbound connections are establishing between the CMS esMD gateway and the HIH gateway.

16.1.2.1 Outbound Telnet Test

The purpose of this sub-test is to verify whether the outbound network connection between the HIH Gateway and CMS esMD Gateway were established by doing the simple telnet test from the CMS esMD Gateway. Under this test, the HIH IP address outbound configurations at the CMS AT&T Router/CMS Firewall will be verified.

Pre-requisite**:**

- Participating HIHs shall configure their firewall to allow the CMS esMD Gateway IP address prior to the scheduled testing date. The CMS esMD gateway outbound IP address will be shared by esMD HIH coordinators.
- The HIH shall verify with their firewall team if their gateway has the NATing for the inbound request coming from the CMS esMD Gateway.

The following is a sequence of events at this level:

- The QSSI esMD team arranges a conference call with the HIH and the CMS CITIC contractor.
- During the conference call, the esMD team performs the telnet connection between the esMD gateway and the HIH Gateway.
- The HIH firewall team monitors the incoming traffic from the esMD Gateway at their firewall and confirms the outbound telnet connectivity.

A successful telnet session indicates established outbound telnet connectivity between the esMD Gateway and the HIH network.

This step is carried out in parallel to the Step 2.2.1.1. A telnet session is set up to check the connectivity between the CMS esMD Gateway and the HIH Gateway. A successful telnet session confirms connectivity between the two gateways.

16.1.2.2 Confirmation of Receiving the First Notification

Based on the results of the validations mentioned below, an asynchronous XDR Response message is sent to the HIH gateway by the CMS esMD gateway:

- Validation of the syntax
- Validation of the semantics with the esMD affinity domain values
- Validation for duplicate Unique ID

- Validation of the participation of intended recipient (i.e., the review contractor)
- Validation of the HIH OID

The response message could take anywhere from less than 1 minute up to 10 minutes based on the size of attachment (i.e., the payload). Confirmation of receipt of this response message by the HIH indicates a success scenario.

Completion of all the above steps successfully confirms connectivity between the HIH gateway and the CMS esMD gateway. A congratulatory email is sent by QSSI to the HIH indicating this success.

16.2 Functionality Testing (Testing with HIH Gateway Application)

Tests in this phase are performed to confirm that the HIH application will send proper metadata and payload (PDFs) to the CMS esMD Gateway using their esMD application and esMD HIH Gateway. The esMD Gateway validates and processes the metadata and will deliver payload to the ECM repository.

16.2.1 Inbound Tests (HIH to CMS esMD Gateway)

The purpose of this test is to establish that the HIH gateway is able to connect through their application and to verify that the HIH gateway is able to establish the connection without using the SOAP UI.

16.2.1.1 Validate Metadata and Request Processing

The XDR deferred document submission request is submitted by the HIH using its gateway application (and not SOAP UI). The QSSI esMD team analyzes the gateway and adaptor logs to confirm metadata validation and request processing. If any anomalies are found, they are reported to the HIH.

16.2.1.2 Metadata Persistence in the esMD Database

In this step, the QSSI esMD DBA team analyzes the database for successful persistence of the data sent by the HIHs. All transaction related audit events, submission related audit events, and metadata value persistence are checked for persistence. Any errors found are reported to the HIH.

16.2.1.3 Delivery to ECM

In this step, the QSSI esMD team confirms the payload delivery to the CMS ECM repository.

16.2.2 Outbound Tests (HIH to CMS esMD Gateway)

Delivery of second notification (about payload delivery to the ECM) to the HIH gateway from the CMS esMD gateway confirms a successful scenario.

At the end of the Functionality Testing, a congratulatory email is sent by the QSSI esMD team to the participating HIH.

16.3 End to End Testing (Testing with HIH Gateway Application & Not SOAP UI)

Tests in this phase are performed to ensure the HIH's submitted metadata is validated and delivered to the ECM and, ultimately, delivered on to the review contractor. In addition, this testing will ensure that once the review contractor picks up the submitted documents, the notification will be sent back to the HIH regarding the pickup status.

16.3.1 Testing With an Assigned Review Contractor

In this step, an HIH is matched with a specific review contractor. The HIH is provided the OID of this review contractor in advance.

In this step, the HIH sends the XDR deferred document submission request using their gateway application to the CMS esMD gateway.

16.3.2 Receipt of Third Notification (Review Contractor Pickup)

After sending the XDR deferred document submission request to the esMD gateway (step 2.3.1 above), it is verified if the HIH received the third notification from the CMS esMD gateway. Receipt of the third notification (review contractor pick-up) confirms and concludes a successful end-to-end testing.

17. Appendix D: SOAP UI Configuration

The purpose of this section is to provide the HIH with instructions for how to setup the SOAP UI in their environment. The HIH must configure the SOAP UI in order to use the SOAP UI test cases provided by QSSI. The SOAP UI is necessary to allow the HIH to perform the connectivity testing. The HIH will submit the test through the SOAP UI using the esMD gateway establishing a connection to the CMS esMD gateway.

Download and Initial Configuration

A. Download and install SoapUI 3.5.1 from http://sourceforge.net/projects/soapui/files/soapui/3.5.1

B. After SoapUI has been installed, perform the following steps to complete the configuration:

1. Launch SOAP UI.
2. Select the File -> Preferences option.
3. Make sure the HTTP version is set to 1.1.
4. Enter "300000" into the Socket Timeout field.
5. Press the "OK" button.
6. Select the File -> Save Preferences menu option.

C. Download the sample SOAP message from QSSI esMD Sharepoint site. Please, note that only authorized HIHs can access SharePoint. If you are an authorized HIH and don't have access to SharePoint, please, contact esMDTeam@qssinc.com.

Test Execution

The following steps outline the actions required to execute the Soap UI test.

1. Start Glassfish on the Gateway machine and verify all desired applications are deployed.

2. Start the SoapUI application from the Soap UI Installation Directory.

3. Open the EndToEndSelfTest soapUI project by selecting File->Import Project and navigate to the SoapUI Validation Suite Installation directory and select EndToEndSelfTest-soapui-project.xml.

4. Navigate to EndToEndSelfTest SoapUI project and change following custom properties before running the test :

   LocalAA = HIH's OID
   LocalHCID = HIH's OID

   RemoteAA = CMS Val Gateway's OID
   RemoteHCID = CMS Val Gateway's OID

5. Navigate to the EndToEndSelfTest TestSuite -> XDR Async -> Test Steps (1) -> EntityXDRRequest and double click it to open Soap message in XML Editor and change the **Unique ID** before running the test :

(i.e.,
<urn1:assertion>
<urn1:id>*[UniqueId]*</urn1:id>
……
……
</urn1:assertion>)

6. In the right panel (footer area) of the Soap UI tool, click on 'WS-A' button and change MessageID property before running the test :

Remember to change the UniqueID and Message ID before executing any test from the SOAPUI tool.