Electronic Submission of Medical Documentation

electronic submission of Medical Documentation (esMD) Author of Record

Presentation to HITSC

July 17, 2013

MELANIE COMBS-DYER, RN
Deputy Director,
Provider Compliance Group
Office of Financial Management, CMS

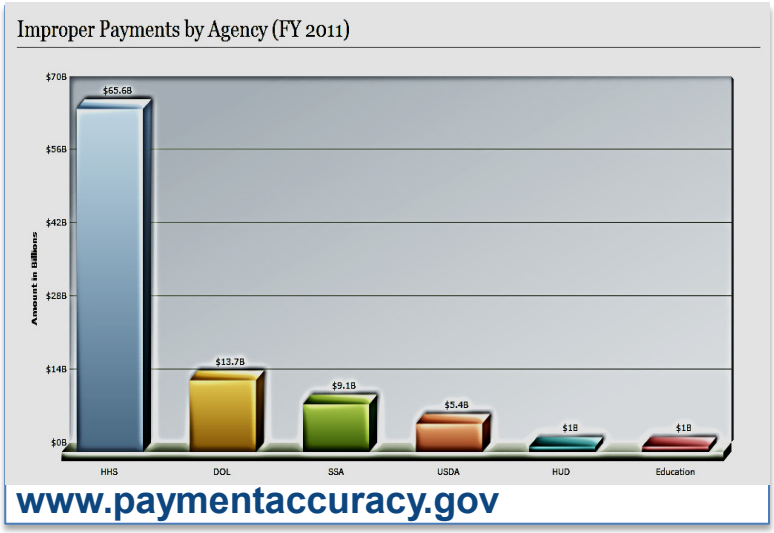
ROBERT DIETERLE
esMD Initiative Coordinator
Signature Consulting Group

Overview

1. esMD Background
2. S&I esMD Initiative
   a) Sending a secure eMDR to a provider
   b) Replace “wet signature”
   c) Move to structured documentation submissions
3. AoR workgroup recommendations
4. AoR Level 1 (Digital Signature on transactions and document bundle)
5. AoR Level 2 (Digital Signature on C-CDA)

Improper Payment

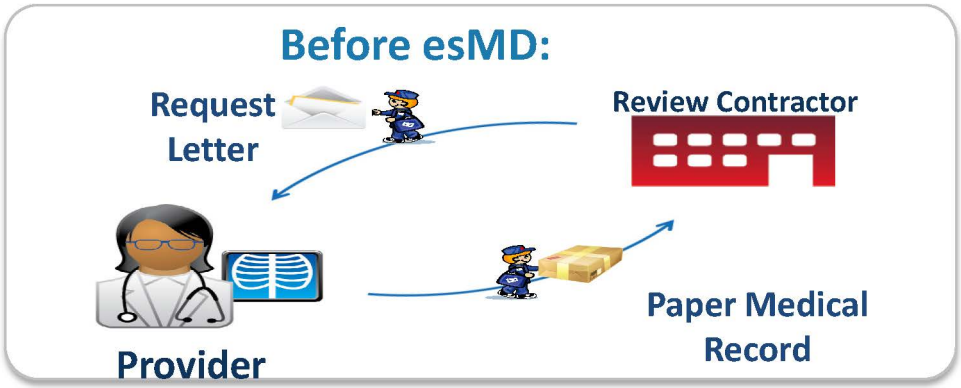
- Medicare receives **4.8 M** claims per day.
- CMS' Office of Financial Management estimates that each year
  - the Medicare FFS program issues more than **$28.8 B** in improper payments (error rate 2011: **8.6%**).
  - the Medicaid FFS program issues more than **$21.9 B** in improper payments (3-year rolling error rate: **8.1%**).
- Most improper payments can only be detected by a **human** comparing a **claim** to the **medical documentation.**



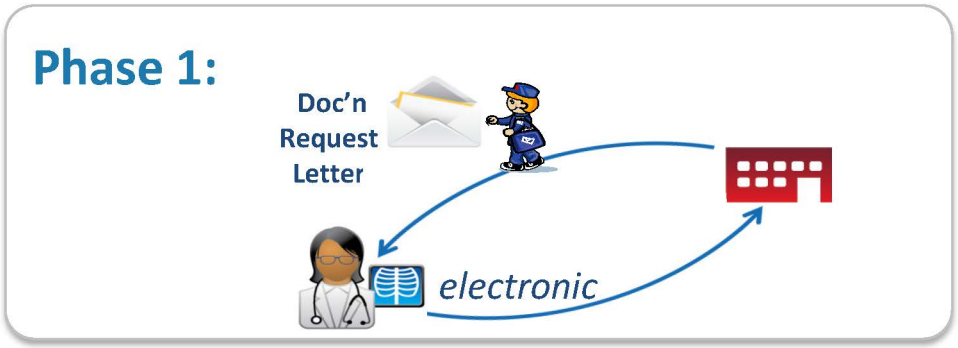
- **Medical Documentation Requests are sent by**:
  - Medicare Administrative Contractors (MACs) Medical Review (MR) Departments
  - Comprehensive Error Rate Testing Contractor (CERT)
  - Payment Error Rate Measurement Contractor (PERM)
  - Medicare Recovery Auditors (formerly called RACs)
- Claim review contractors issue over **1.5 million** requests for medical documentation each year.
- Claim review contractors currently receive most medical documentation in **paper** form or via fax.

eSMD Electronic Submission of Medical Documentation

esMD Background

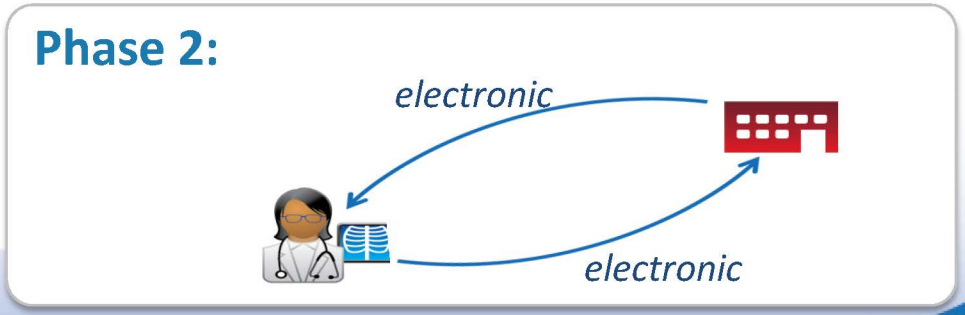


Healthcare payers frequently request that providers submit additional medical documentation to support a specific claim(s). Until recently, this has been an entirely paper process and has proven to be burdensome due to the time, resources, and cost to support a paper system.



Phase I of esMD was implemented in September of 2011. It enabled Providers to send Medical Documentation electronically

The ONC S&I Framework Electronic Submission of Medical Documentation (esMD) initiative is developing solutions to support an entirely electronic documentation request.



Electronic Submission of Medical Documentation

4

Goals of esMD

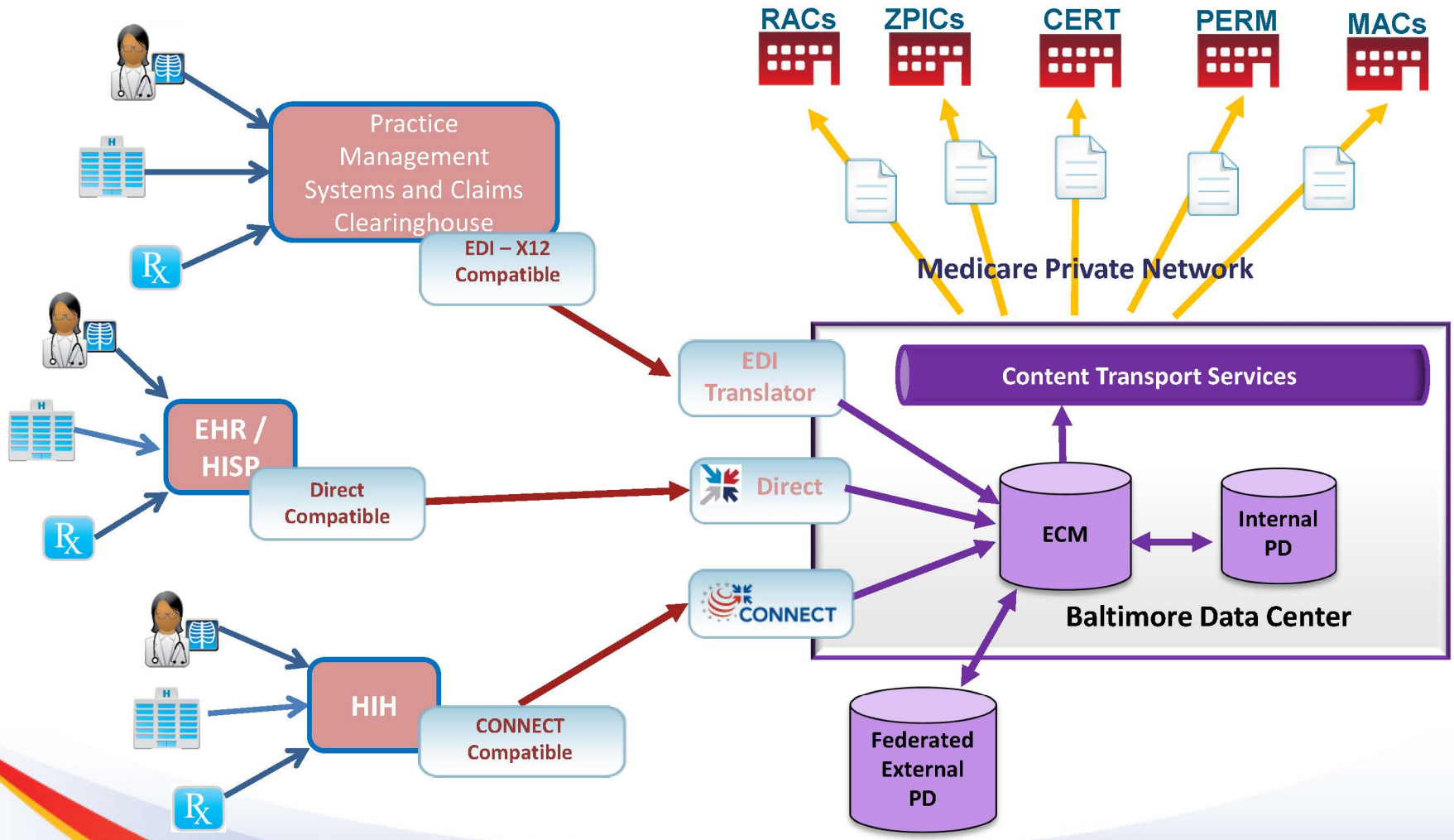
1) Reduce administrative burden
2) Reduce improper payment
3) Move from “post payment audit” to prior-authorization or pre-payment review

Requirements

1) Move from paper to electronic communication
2) **Replace “wet signatures” with digital signatures**
3) Migrate to structured data from unstructured data

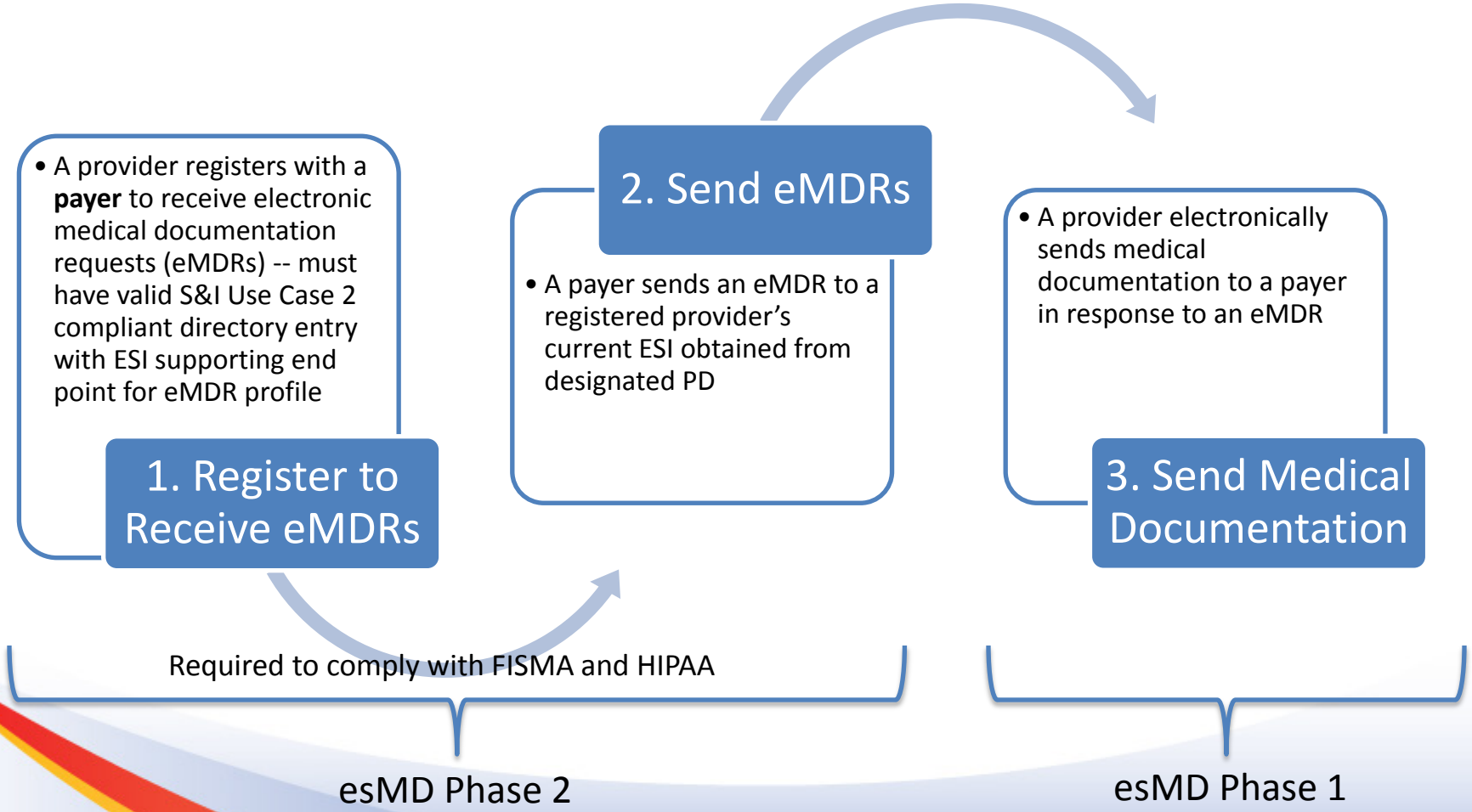
Electronic Submission of Medical Documentation

Electronic Submission of Medical Documentation (esMD) Supporting Multiple Transport Standards and Provider Directory

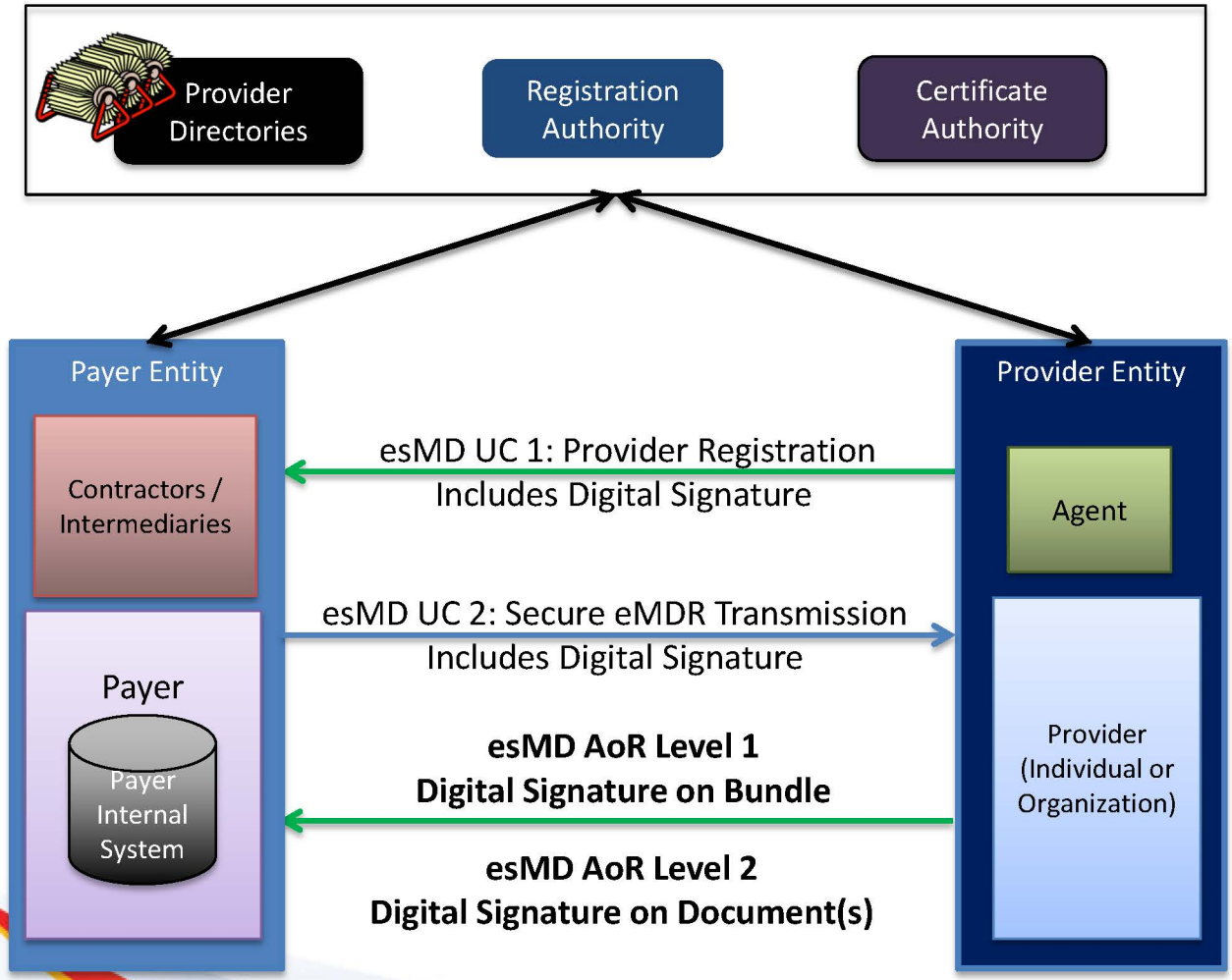


esMD eMDR Process Flow

The overall esMD eMDR process can be divided into three steps:



S&I Framework esMD eMDR Overview

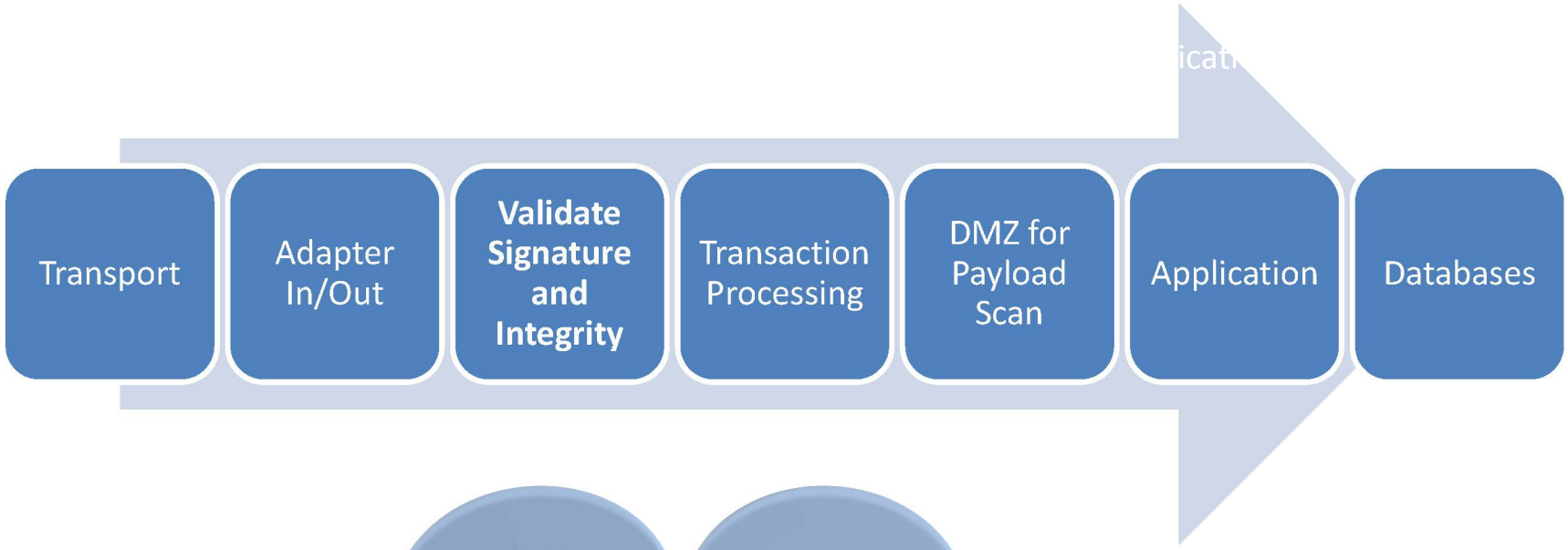


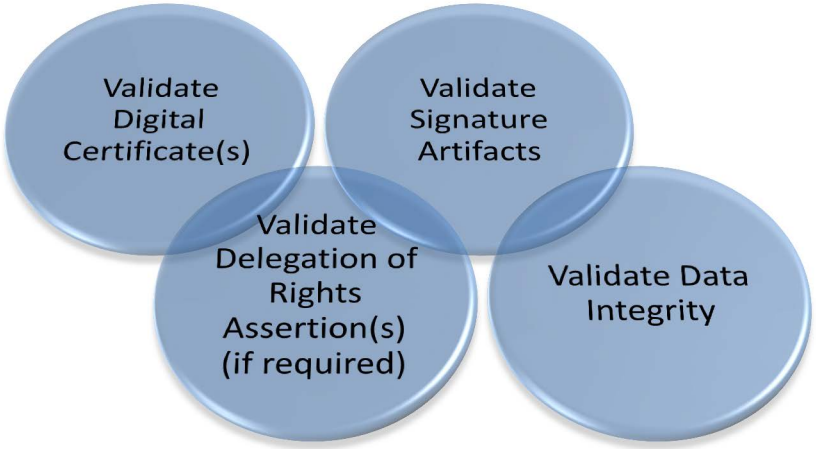
User Story

- **All Actors obtain and maintain a non-repudiation digital identity**
- **Provider registers for esMD (see UC1)**
- **Payer requests documentation (see UC2)**
- **Provider submits digitally signed document (bundle) to address request by payer**
- **Payer validates the digital credentials, signature artifacts and, where appropriate, delegation of rights**
- **If Documents are digitally signed, then payer validates document digital signature artifacts**

Electronic Submission of Medical Documentation

General esMD Flow





Definitions

Identity (Proposed)

A set of attributes that uniquely describe a person or legal entity within a given context.

Identity Proofing (Proposed)

The process by which a CSP and a Registration Authority (RA) collect and verify information about a person or legal entity for the purpose of issuing credentials to that person or legal entity.

Digital Signature (NIST)

The result of a cryptographic transformation of data that, when properly implemented, provides a mechanism for verifying origin authentication, data integrity and signatory non-repudiation.

Data Integrity (NIST)

Data integrity is a property whereby data has not been altered in an unauthorized manner since it was created, transmitted or stored. Alteration includes the insertion, deletion and substitution of data.

Non-repudiation (NIST)

Non-repudiation is a service that is used to provide assurance of the integrity and origin of data in such a way that the integrity and origin **can be verified by a third party**. This service prevents an entity from successfully denying involvement in a previous action.

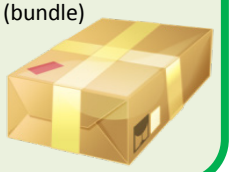
Delegation of Rights

The ability to delegate rights or authority to another to act in a specific capacity on behalf of the grantor of the right. Must include the digital identity of the grantor, the digital identity of the grantee, the rights granted, duration of grant in a format that is usable in transaction and AoR signature events and is verifiable by a third party for non-repudiation purposes.

AoR -- Phased Scope of Work

Level 1 – Current Focus

Digital signature on *aggregated* documents (bundle)



- Focus is on **signing a bundle of documents** prior to transmission to satisfy an eMDR
- Define requirements for esMD UC 1 and UC 2 Signature Artifacts
- May assist with EHR Certification criteria in the future

Level 2 - TBD

Digital signature on an *individual* document

- Focus is on **signing an individual document** prior to sending or <u>at the point of creation by providers</u>
- Will inform EHR Certification criteria for signatures on patient documentation

Level 3 - TBD

Digital signature to allow traceability of *individual contributions to a document*

- Focus is on **signing documents and individual contributions** at the point of creation by providers
- Will inform EHR Certification criteria for one or multiple signatures on patient documentation

esMD AoR Sub-Workgroups

1. Identity Proofing

- Define required process for identity proofing of healthcare individuals and organizations for esMD
- Proof of identity requirements
- Allowed proofing processes

2. Digital Credentials

- Define required process for issuing and managing digital credentials for esMD
- Credential Life Cycle (issuance, maintenance and revocation)
- Credential uses (Identity, Signing, Proxy, Encryption, Data Integrity)
- Specific use credentials (e.g. Direct)

3. Signing and Delegation

- Define process, artifacts and standards for transaction and document bundle digital signatures and delegation of rights for esMD
- Signature and Delegation artifacts
- Workflow issues
- Delegation process

Deliverables from all SWGs include:

- Statement of problem and assumptions
- Review of Standards
- Recommended standards
- Operational/Implementation Considerations
- Analysis of Gaps in standards and policy

Identity Proofing

Standards

Document Link	Title & Version / Notes	Date
FBCA X.509 Certificate Policy	*X.509 Certificate Policy for the Federal Bridge Certification Authority*, Version 2.25	Dec 9 2011
FICAM Roadmap and Implementation Guidance	*Federal Identity, Credential, and Access Management Roadmap and Implementation Guidance*, Version 2.0	Dec 2 2011
NIST SP 800-63-1	*Electronic Authentication Guideline*	Dec 2011

Federal Bridge Certification Authority – Medium Assurance

Level	Identification Requirements
Medium	Identity shall be established by in-person proofing before the Registration Authority, Trusted Agent or an entity certified by a State or Federal Entity as being authorized to confirm identities; information provided shall be verified to ensure legitimacy. A trust relationship between the Trusted Agent and the applicant which is based on an in-person antecedent may suffice as meeting the in-person identity proofing requirement. Credentials required are one Federal Government-issued Picture I.D., one REAL ID Act compliant picture ID1, or two Non-Federal Government I.D.s, one of which shall be a photo I.D. (e.g., Non-REAL ID Act compliant Drivers License). Any credentials presented must be unexpired. ...

Identity Proofing Recommendations and Gaps

Recommendations

- Identity Proofing compliant with FBCA Medium Assurance
- In-person or acceptable antecedent event
- Must include verification of NPI or alternative provider ID if used for Author of Record (not required for recipient of delegation of rights)
- One Identity Proofing for all credentials as same level of assurance or lower from all CSPs
- Federation of RAs to achieve required scale through use of current in-person healthcare verification process
  - Credentialing
  - Licensure
  - HR functions

Gaps

- Policy for Individual Identity Proofing acceptable to all cross-certified CSPs that participate
- Policy for Organizational Identity Proofing (e.g. for group certificate)
- Policy for RA Accreditation (including duration and termination)
- Policy for Certification of RA Accreditors
- Agreement by FBCA cross-certified CA's to recognize the policies and process
- Policy for acceptance of prior in-person verification (antecedent)

Standards for Signing Credentials

Standards for Signing Credentials

Document Link	Title & Version / Notes	Date
FBCA X.509 Certificate Policy	*X.509 Certificate Policy for the Federal Bridge Certification Authority*, Version 2.25	Dec 9 2011
FICAM Roadmap and Implementation Guidance	*Federal Identity, Credential, and Access Management Roadmap and Implementation Guidance*, Version 2.0	Dec 2 2011

Digital Credential Recommendations and Gaps

Recommendations

- X.509v3 signing certificates with the non-repudiation bit set must be used to sign all AoR Transactions, Bundles and Documents
- All CSP/CAs must be cross-certified with FBCA
- There may only be one level of sub-CAs (e.g. sub-CA may only issue end user certificates)
- Providers must authenticate to the signing module with at least one additional authentication factor prior to the actual signing event

Gaps

- Long term validation
- Long term access to certificate revocation
- Policy for organizational certificates

Digital Signatures and Delegation of Rights (DoR)

Standards for Digital Signatures and Delegation of Rights Assertions

Standard and Link	Issued by	Version / Date
FBCA X.509 Certificate Policy	*X.509 Certificate Policy for the Federal Bridge Certification Authority*, Version 2.25	Dec 9 2011
FIPS PUB 186-3	*Digital Signature Standard*	Jun 2009
XML DigSig / XADES-XL	*XML Signature Syntax and Processing (Second Edition), W3C Recommendation*	Jun 10 2008
OASIS SAML Assertions ***All SAML v2.0 files***	*Assertions and Protocols for the OASIS Security Assertion Markup Language (SAML), Version 2.0*	Mar 15 2005

Digital Signature and DoR Recommendations

Digital Signature

- XML DigSig
- XADES – XL
- signature artifact
  - Digest of Message
  - Time stamp (UTC)
  - Role
  - Purpose

Delegations of Rights Assertion

signed SAML 2.0 Assertion containing the following elements:

- Unique ID for assertion
- Time stamp (UTC)
- Issuer and serial number right recipient
- Valid date range
- Right(s) delegated

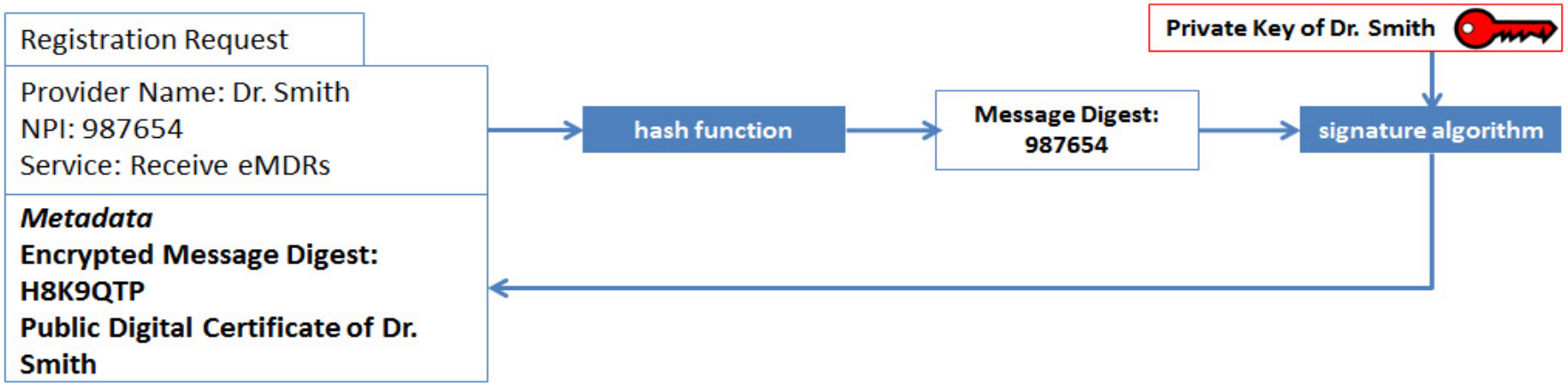
Gaps

- Long term validation
- Validation/Revocation of Assertion

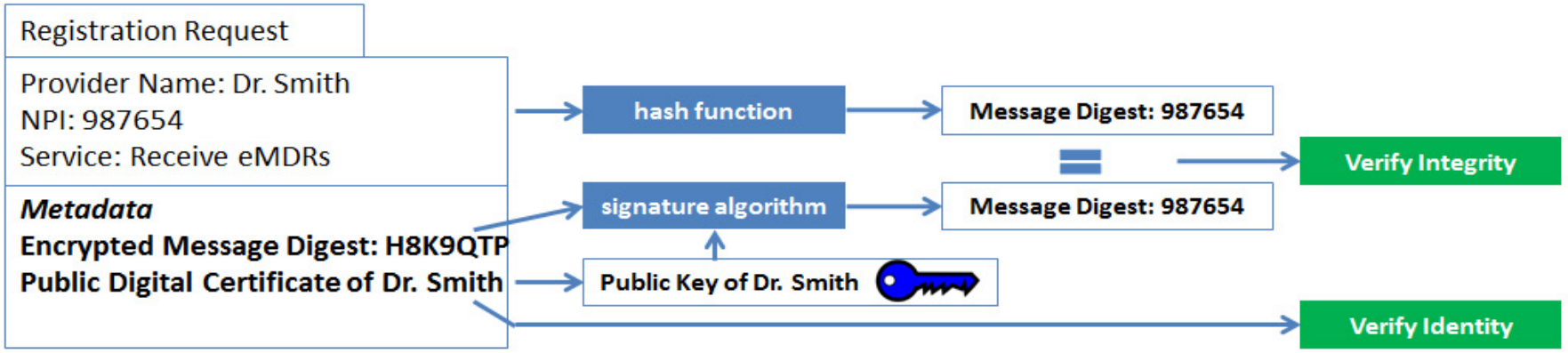
eSMD Electronic Submission of Medical Documentation

Signature Artifact Example

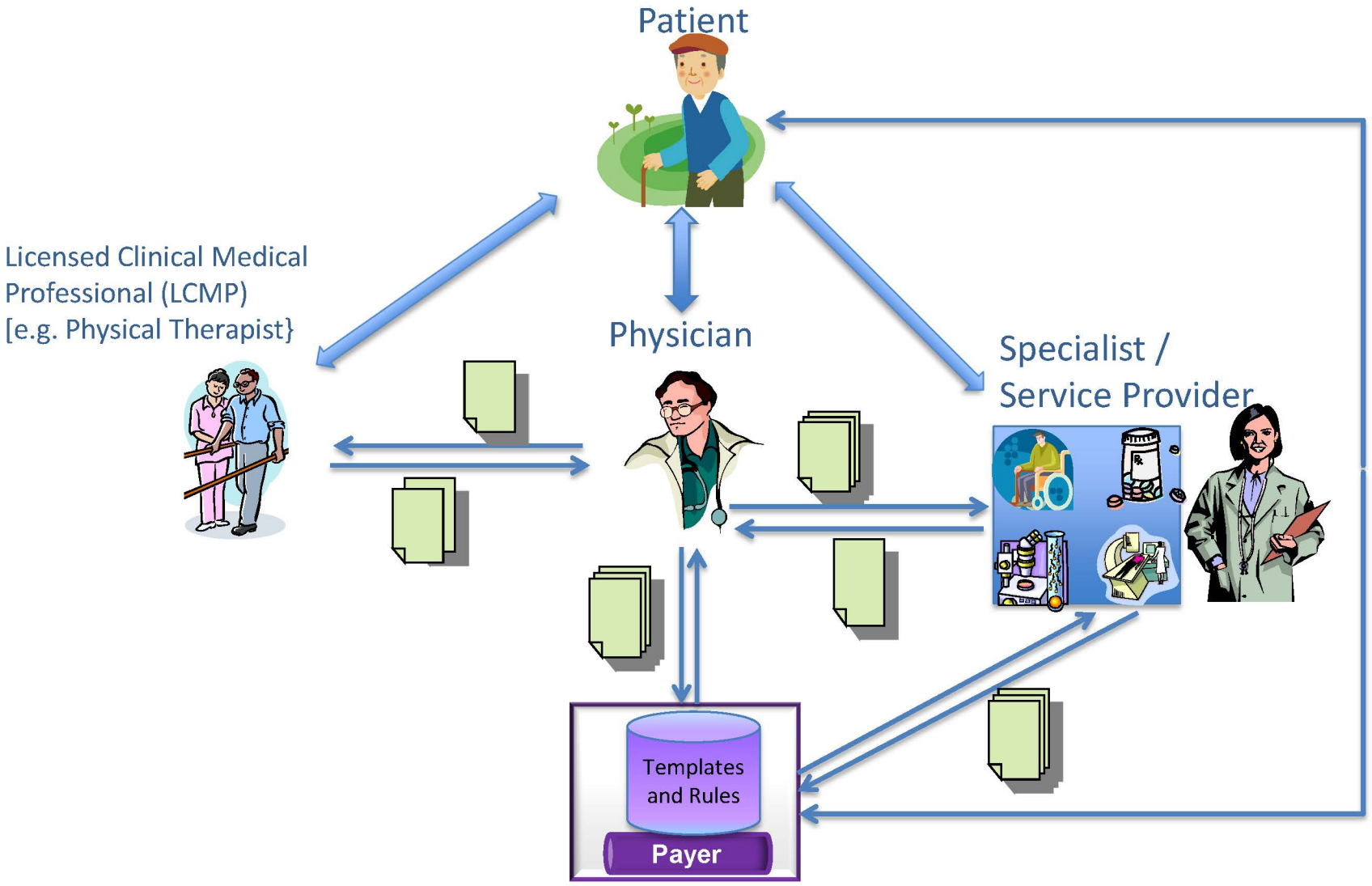
1. **Dr. Smith attaches signature artifact to Request to Register to Receive eMDRs**



2. **Payer verifies the Request came from Dr. Smith and has not been tampered with**



electronic Determination of Coverage (eDoC) Generic Workflow



Author of Record Level 1

Digital signature on bundle of documents

1) Standards
   a) PKI: X.509v3 Signing Certificates (FBCA Medium)
   b) IHE DSG (XAdES)
   c) SAML Assertion for delegation of rights

2) Environment (example)
   1) Created as part of sending documents from provider to payer
   2) Validated upon receipt
   3) One signer (submitter) only for the full bundle of documents
   4) Delegation of rights as required to support authorization chain

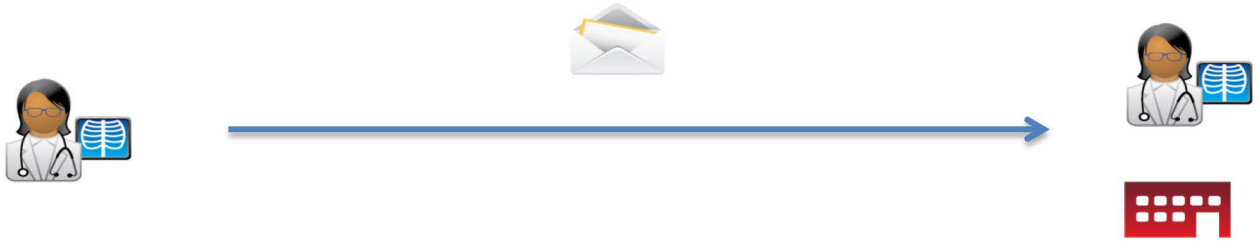
Author of Record Level 2 Requirements

1. Digital signature on documents for provenance (clinical and administrative)
   - Meets requirement for encapsulated non-repudiation
2. Signature should be applied at time of document creation, modification, review (Administrative – must be applied prior to claim submission)
3. Multiple signatures on same “document”
4. Certificate must be validated at time it is used (OCSP or CRL)
5. Support for validated delegation of rights assertion
6. Signature and delegation of rights must travel with document
7. Signature bound to signed document for life-time of document
8. Supports transition from unsigned to signed documents over time

Example: Multiple signatures in a pdf document (decoupled from transport)

Provider with Signed Documents

Document with embedded signature and delegation



Accepted and stored by all recipients regardless of AoR support

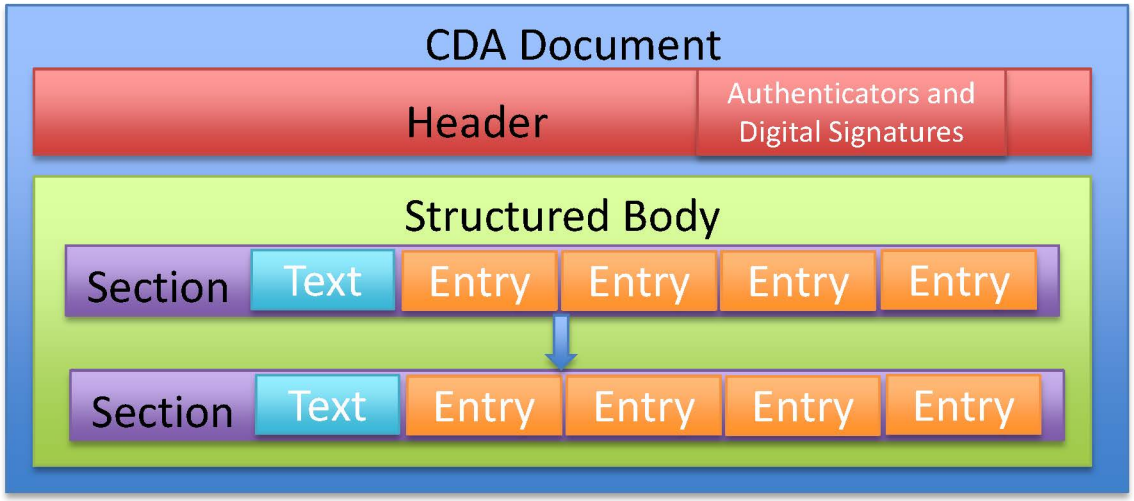
Document Delegation Signature

Signature and delegation only accepted by systems with AoR support
May drop only signature and delegation or error on entire transaction

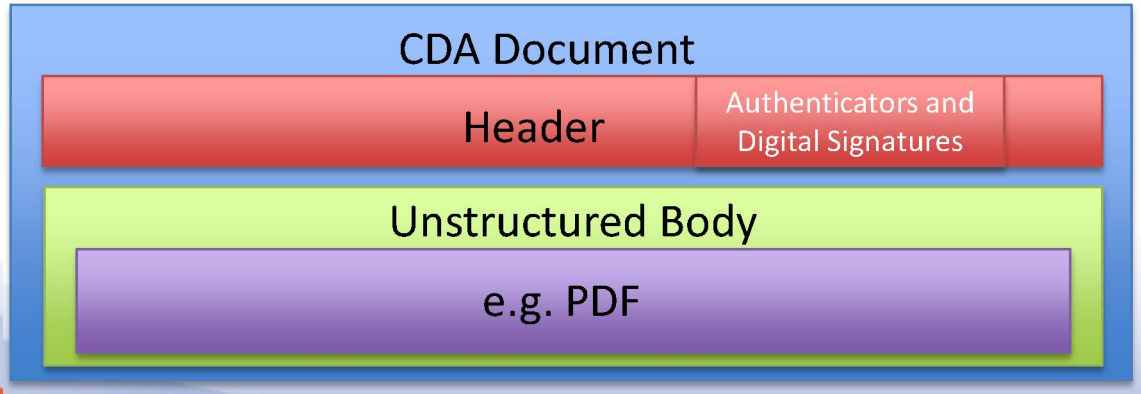
Signature on CDA

Solution: Add "signatureText" attribute to Participation occurrences for legalAuthenticator and authenticator in the CDA Header to hold Digital Signature and Delegations of Rights Assertion artifacts -- exclude these Participation occurrences from the calculated digest

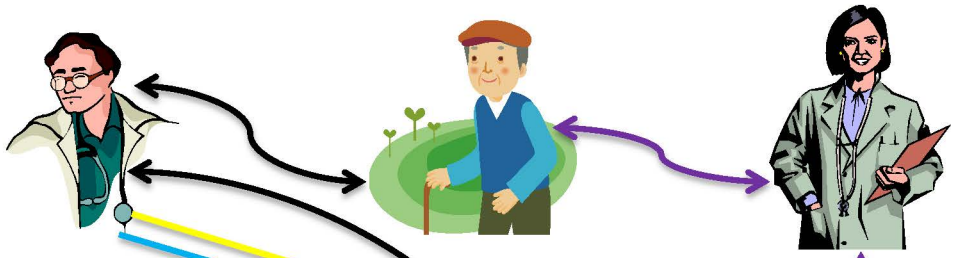
Structured Body

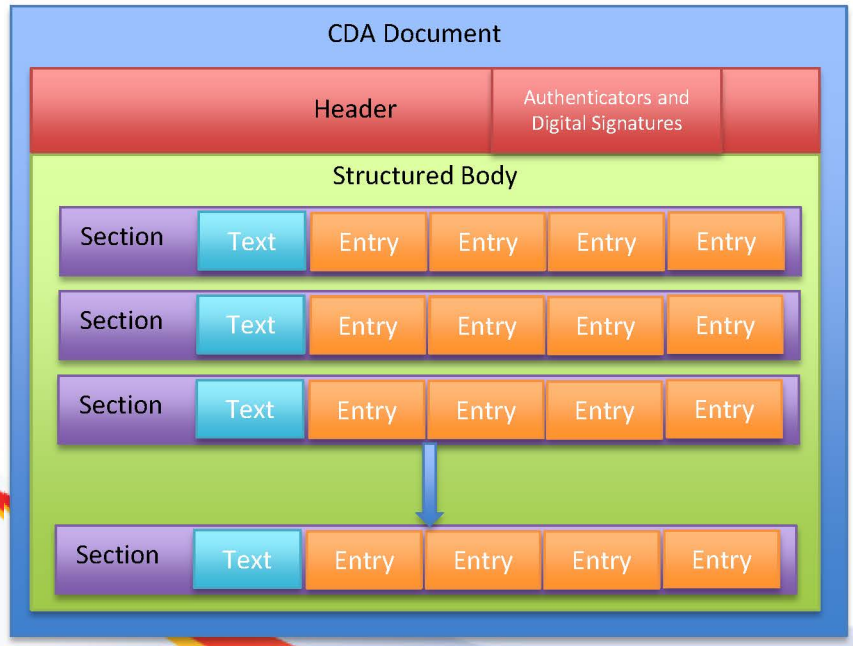


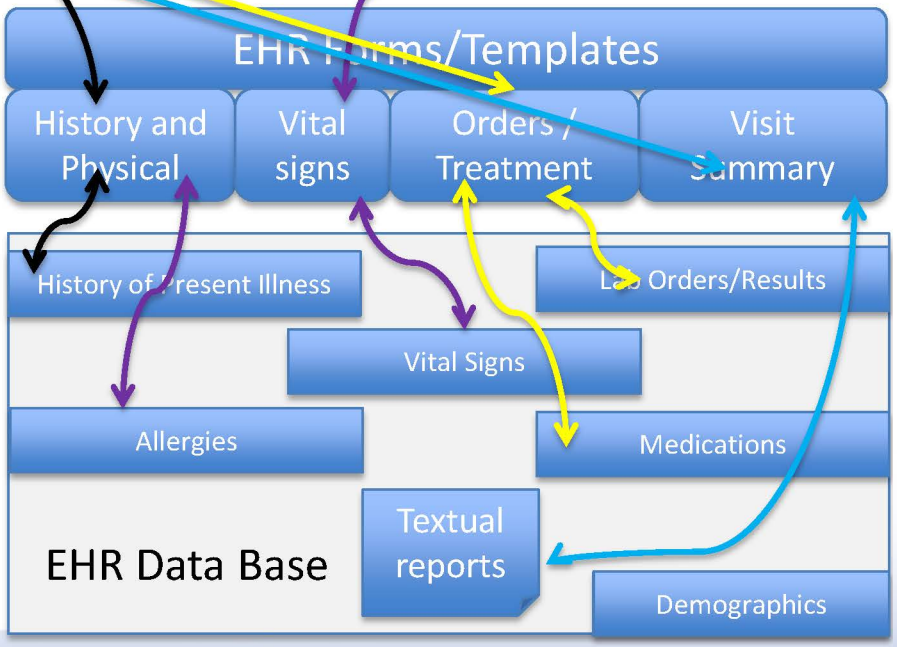
Unstructured Body



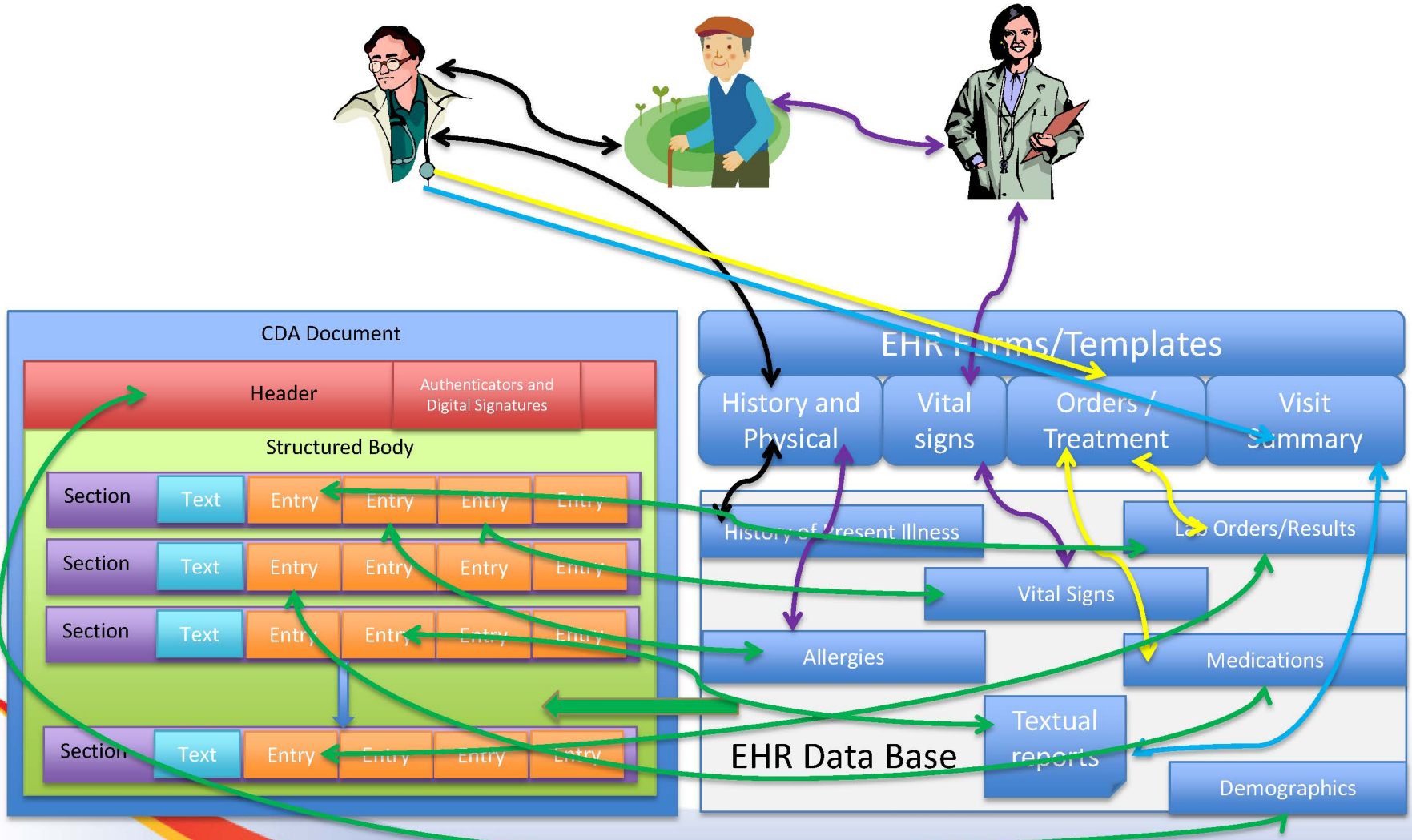
Document Encounter





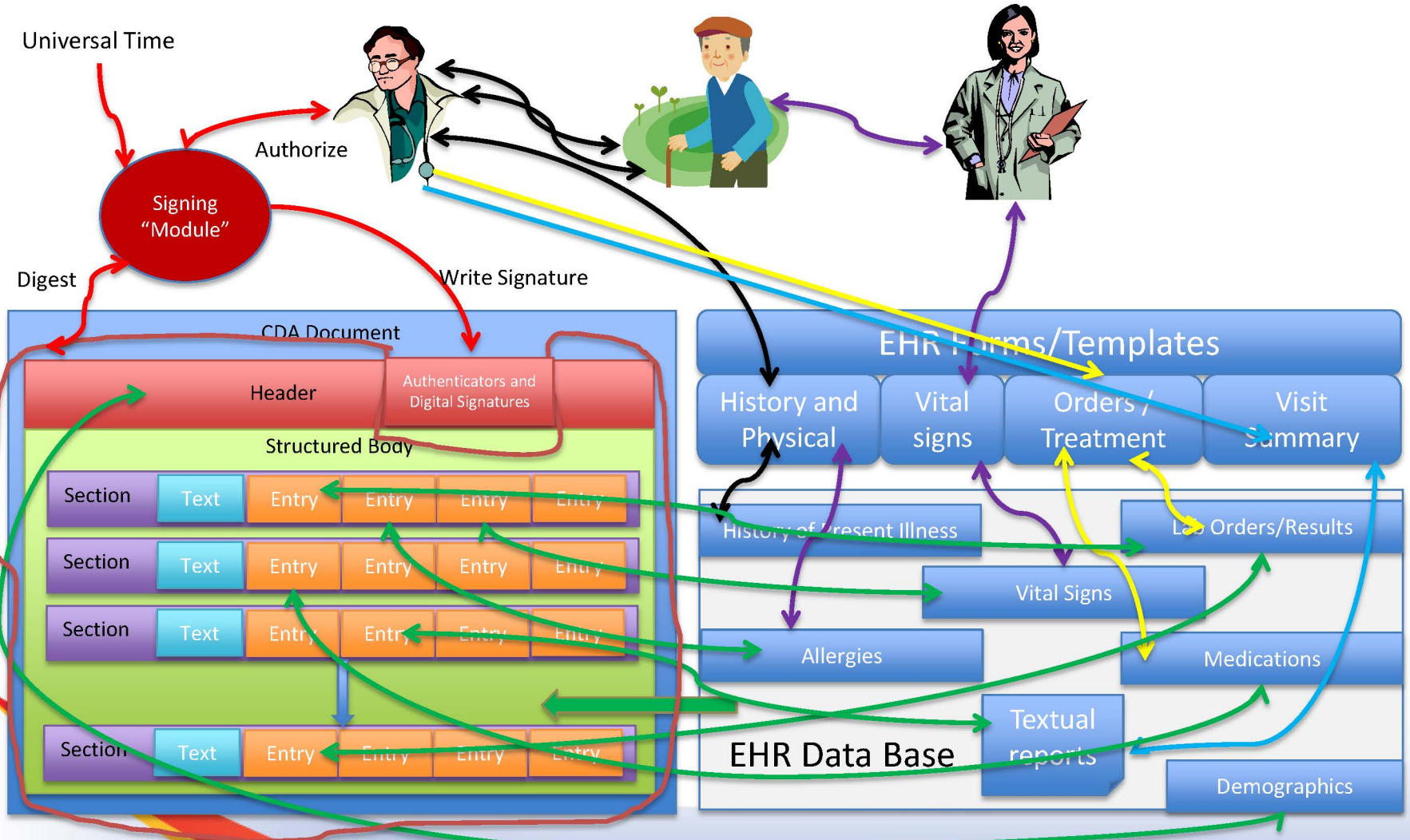


Create CDA


CDA Document
Header
Authenticators and Digital Signatures
Structured Body
Section
Text
Entry
Section
Text
Entry
Section
Text
Section
Text
Entry
EHR Forms/Templates
History and Physical
Vital signs
Orders / Treatment
Visit Summary
Lab Orders/Results
Vital Signs
Allergies
Medications
Textual reports
EHR Data Base
Demographics

Sign CDA

May repeat for co-signers and other authenticators



HL7 September Ballot Cycle

- Project Scope Statement for Digital Signature on C-CDA accepted
  - Primary Sponsor Work Group – Structured Documents
  - Co-sponsor Work Groups – Security, Attachments
  - Interested Parties – RMES
- For September 2013
  - May 19 – Project Scope (Done)
  - July 7 – Notification of Intent to Ballot (Done)
  - July 21 – Preview content due
  - July 28 – Reconciliation, Complete and Supporting Content
  - August 16 – Final Content Deadline
  - August 17 – Provisional Ballot Opening

Summary

esMD AoR identifies Best Practice for:

1) Establishing the identity of providers
   a) Identity Proofing of all participants (individual and organizations)
   b) Digital Credential Lifecycle management, including access to private keys,
   c) Digital Signatures Standards, and
   d) Delegation of Rights Standards
2) Addressing Author of Record requirements
3) Defining requirements for structured documentation that includes digital signatures for proof of provenance