

NCVHS Hearing



MARCH 10, 2014

ROBERT DIETERLE

electronic submission of Medical
Documentation (esMD) Initiative
Coordinator

CONNIE LEONARD

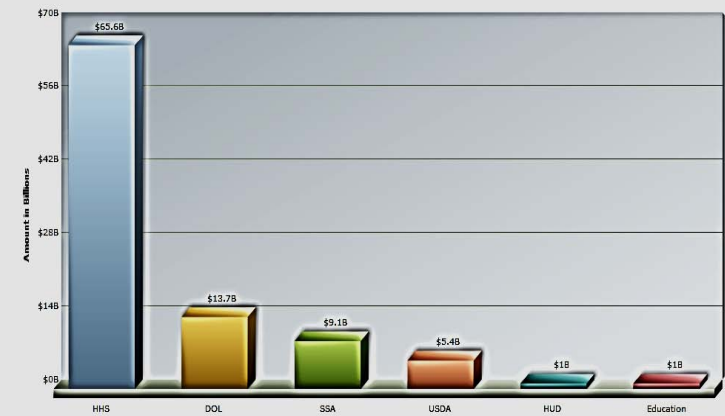
Acting Deputy Director,
Provider Compliance Group (PCG)
CMS' Office of Financial Management

Improper Payment

- Medicare receives 4.8 M claims per day.
- CMS' Office of Financial Management estimates that each year (based on 2013 audit information)

- the Medicare FFS program issues more than **\$36.0 B** in improper payments (error rate: 10.1%).
- **\$21.7 B** of improper payment is due inadequate documentation to support payment for services billed
- **\$10.1 B** of improper payment is due to services that were not medical necessary based on Medicare coverage policies

Improper Payments by Agency (FY 2011)



- 1.8 million Medical Documentation Requests are sent annually 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)

Goals and Policy Issues

PCG/esMD Goals

- **Prevent improper payment through**
 - prior-authorization (e.g. PMD)
 - pre-payment review
- **Minimize provider burden through**
 - electronic communication of medical information (esMD)
 - structured data to facilitate review process
 - digital signatures to establish data integrity and provenance

Medicare FFS policy

- **No limitations on providers right to submit documentation**
 - NCDs/LCDs policies allow providers to submit any documentation they deem required to support that the service was/is medically necessary and appropriate
 - Medicare cannot limit submission to specific information (e.g. H&P)

Limitation of Current Standards

Consolidated Clinical Document Architecture (C-CDA)

- C-CDA documents require a limited number of sections
- EHR vendors frequently support inclusion of only required sections even if information exists in the medical record for “optional” sections
- Testing and Certification only verify EHR support for required information

Consequences for Providers

- Large variability in C-CDA ability to support submission of existing medical documentation to support a specific service
- Inability to submit “complete” documentation may inappropriately
 - increase denial rates,
 - force providers to use unstructured documentation, and/or
 - require additional requests for documentation
- ❖ thereby increasing substantially error rate and administrative costs

Solution

esMD open forum solution to protect provider rights

- Complete Documentation Templates (CDT) to support providers right to submit documentation to justify proposed or completed services
- Constraints allow certification of EHR support for C-CDA optional sections when information exists
- CDT templates are available for both administrative and clinical purposes where exchange of more complete documentation is appropriate

without impacting existing use cases

- Leverages C-CDA R2 templates – does not replace them
- Does not require providers to perform additional documentation
- Does not impact the commercial payer or clinical user's ability to request existing C-CDA R2 templates

***The combination of the C-CDA and the new templates
provide a solution for all providers and payers***

Frequently Asked Questions

➤ **Will providers be required to use the CDT documents?**

Providers may use any standard support by the attachments rule to submit documentation -- the CDT documents provide for a more complete submission when providers deem it is appropriate

➤ **Are the CDA documents significantly larger than C-CDA documents?**

A CDT document is between 1% and 5% larger than a typical C-CDA document when optional information is included in both. However, CDT documents are typically <10% the size of an unstructured document.

➤ **Will providers need to do additional work documenting a patient visit?**

- The provider is not required to collect any additional information when using the CDT documents -- CDT just ensures that desired information can be reliably submitted
- EHR vendors can provide the capability to use the default indicators when no information is present or the provider believes that specific patient information is not applicable as part of their exchange standard.
- Signing a CDA document using a digital signature does not take significantly more time than applying an electronic signature. We estimate it will take 2 to 10 minutes to sign 20 documents at one time.

Recommendations

esMD recommends the following:

- Delay rule making until 2015 to understand the impact of C-CDA R2 and the CDT Implementation guides on any proposed Attachments regulations
- Clinical/administrative content standards recommended for inclusion in an Attachment regulation must include full support for provider's right to submit documentation under Medicare FFS policies
- Include digital signatures requirements to ensure data integrity and non-repudiation of providers signatures on submitted attachments
- Provide flexibility in message format, message wrapping and transport standards to ensure compatibility with Meaningful Use and EHR certification requirements to support CONNECT and Direct for the clinical exchange of "attachments"

Supporting Information

The following slides include:

- Response to the specific questions posed by NCVHS for this session
- Response to gaps identified by esMD at the last NCVHS testimony
- Diagrams of current, C-CDA document and CDT document submissions
- Diagrams of Digital Signature workflow

What is the status of development of attachment standards?

➤ Standards for Content

- ONC S&I and HL7 continue to evolve the CDA standard implementation guides based on industry experience and feedback (C-CDA R2, CDT)
- Experience in implementing CDA standards has uncovered limitations are currently being addressed (C-CDA R2, CDT)
- CDAs are not currently used by any payers for attachments in any significant volume

➤ Standards for Messaging, Wrapping and Transport

- ASC X12 is not currently used for attachments by any major players in any significant volume – it should be considered only a potential standard for attachments messaging and transport
- Strong / emerging clinical and administrative use of XDR
- Continued exchange of clinical information via CONNECT and Direct

Have there been any significant changes since the Committee issued its recommendations – in terms of clinical data standard, enveloping/wrapper, transport/connectivity, etc.?

➤ Clinical Data Standards:

- C-CDA R1.1 will be replaced by C-CDA R2
- CDT (additional document, section and entry templates0

➤ Digital Signatures:

- HL7 standard for digital signatures embedded in the CDA

➤ Message/Transport (in addition to ASC X12N) :

- esMD substantial increase in documentation submissions via CONNECT using XDR
- Emerging use of Direct to exchange clinical attachments

Has there been any message content changes or additions (new data sections, new codification of templates) need to be incorporated into the standard?

- Additional content added to the C-CDA R2
 - 3 new document templates (Care Plan, Referral Note, Transfer Summary)
 - 41 updated sections
 - 6 new sections
 - 51 updated entry level templates
 - 28 new entry level templates
- Additional content added by the CDT
 - 5 new document templates
 - 4 new section templates
 - 4 additionally constrained sections
 - 8 new/constrained entry level templates

What are your perspectives with respect to alternative attachment standards being considered for balloting and approval?

- Complete Documentation Templates are:
 - not alternative attachments standards
 - built on and require support for the underlying C-CDA R2 templates
 - provide additional constrained templates for use by providers when a more comprehensive exchange of documentation is appropriate
 - compatible with existing C-CDA document level templates
 - do not create additional requirement on the part of the recipient – recipient must be able to consume any legal C-CDA document (open templates)

How are clinical data and administrative data exchanges taking place to help drive the quality and cost improvement and facilitate population health goals?

- Expand use of medical review to reduce inappropriate payment and post payment denial

prior-authorization (e.g. PMD)

pre-payment review

- Minimize provider burden and improve audit response by supporting

electronic communication of medical information (esMD)

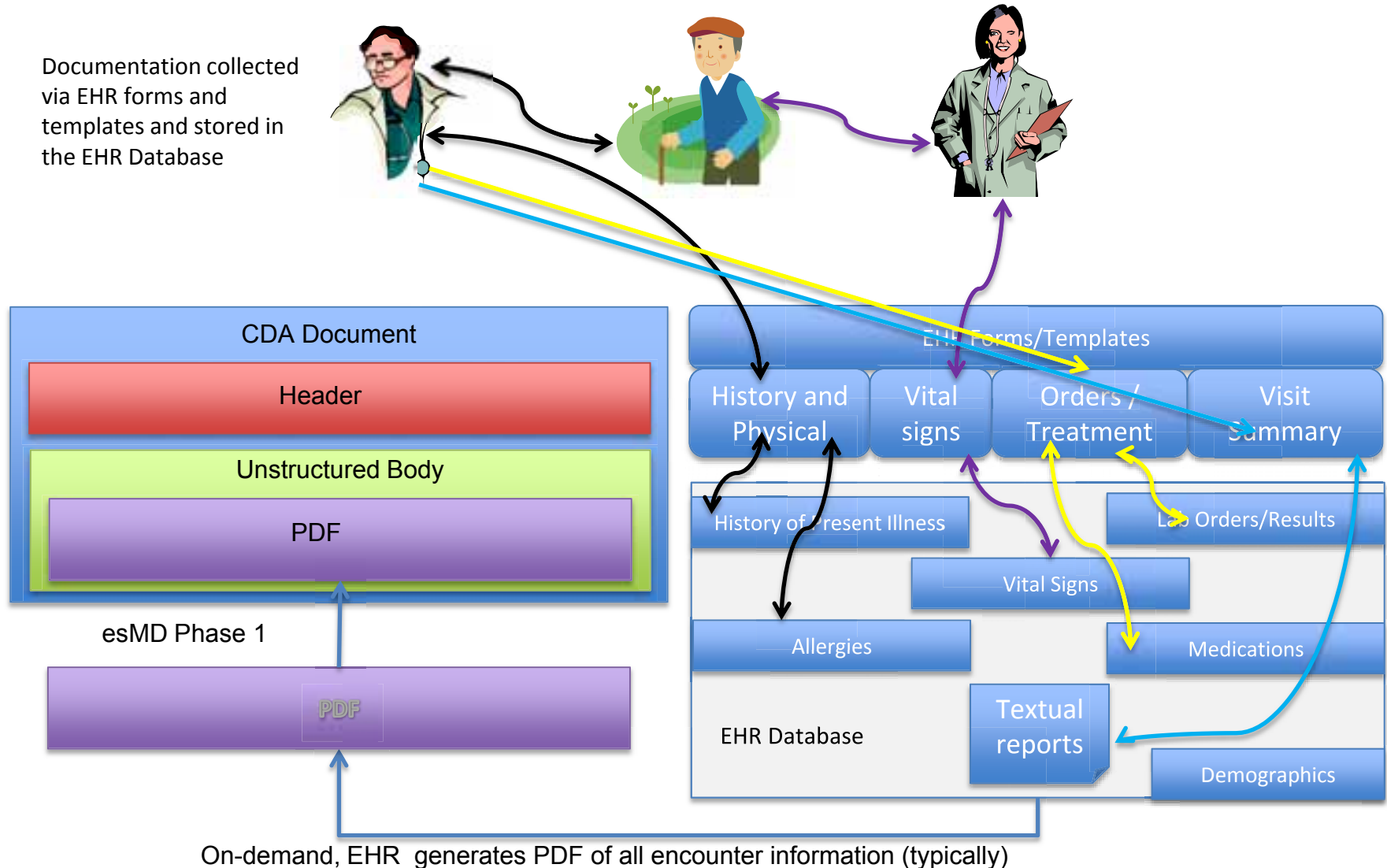
structured data to facilitate review process

digital signatures from wet signatures

Addressing Gaps in Standards?

	Structured Documents	Unstructured Documents
Content Specification	<i>Yes, there are general and use case specific gaps – eDoC sub-workgroup will address (addressed with CDT IG)</i>	<i>No gap in the standards, only in the content</i>
Standard Elements and Vocabularies	<i>Yes, there are general and use case specific gaps – eDoC sub-workgroup will address (addressed with Structured Data Capture)</i>	<i>N/A</i>
Digital Signatures	<i>Yes, there is a general attachment gap and AoR is working on it. (addressed with HL7 Digital Signatures IG)</i>	<i>Yes, there is a general attachment gap and AoR is working on it.</i>

Typical Response to Medicare FFS request for Documentation

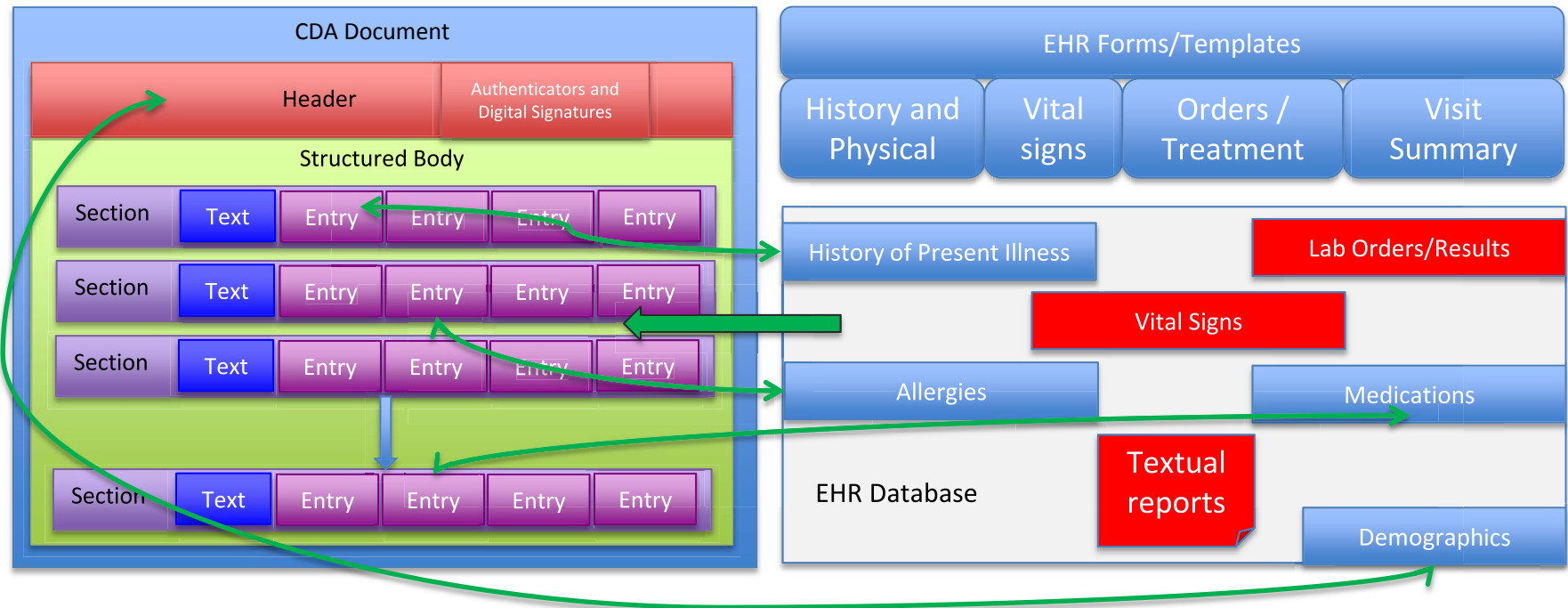
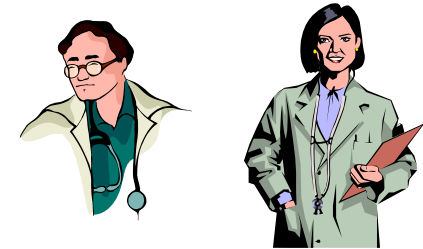


C-CDA Documents

Use of C-CDA Documents

Create Structured CDA

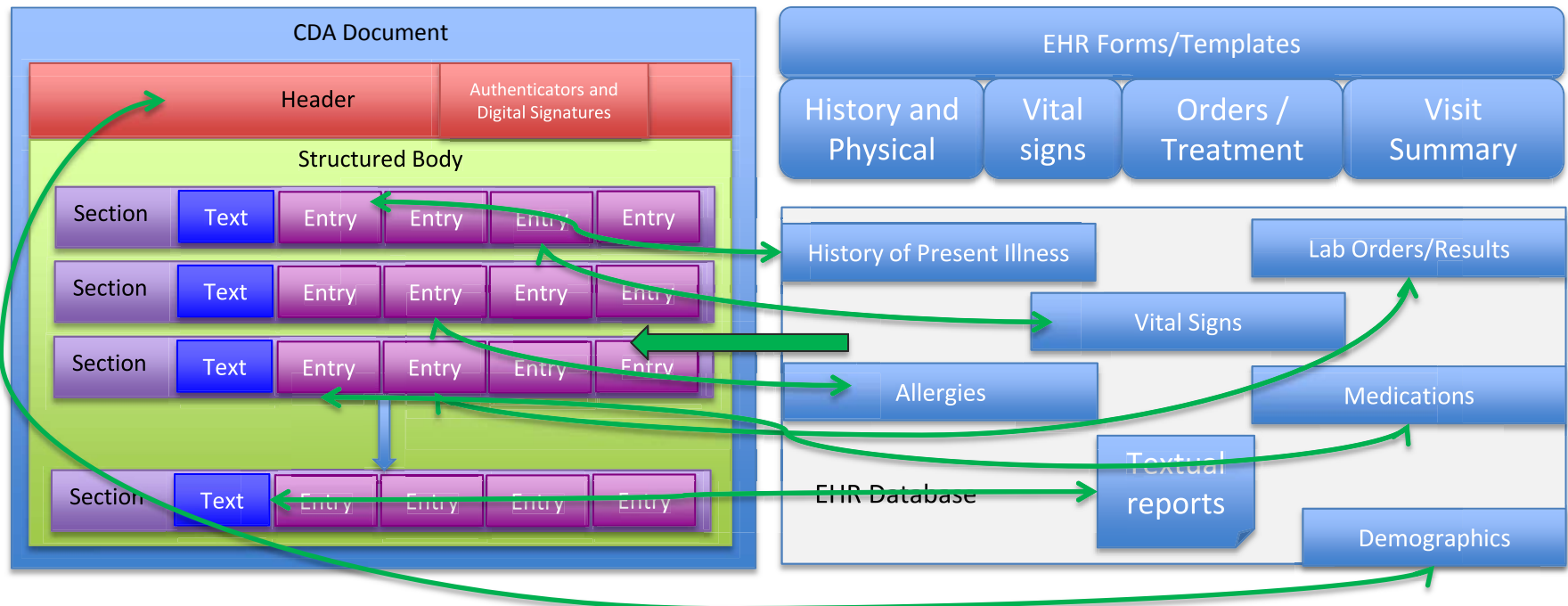
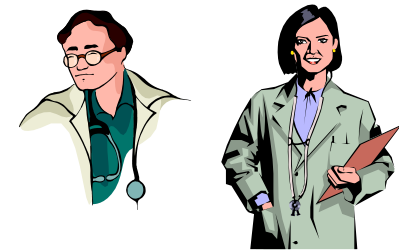
- 1) Works for required sections
- 2) Optional sections may not be supported by all EHR vendor
- 3) How does the provider meet documentation requirements?
- 4) Recipient of the document does not know if data does not exist or data is being withheld



Prior to or at time of signing – create CDT Document

Create Structured CDA using CDT Document (when appropriate)

- 1) All Document sections are populated or use appropriate nullFlavor
- 2) Ensures that all captured documentation is in the CDA prior to signing



Digitally Sign CDA (based on policy)

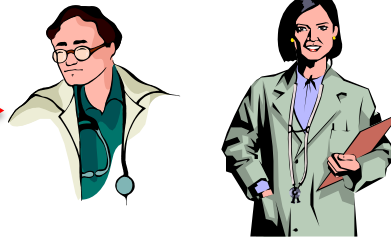
Universal Time
Long term validation

Authenticate

Signing
"Module"

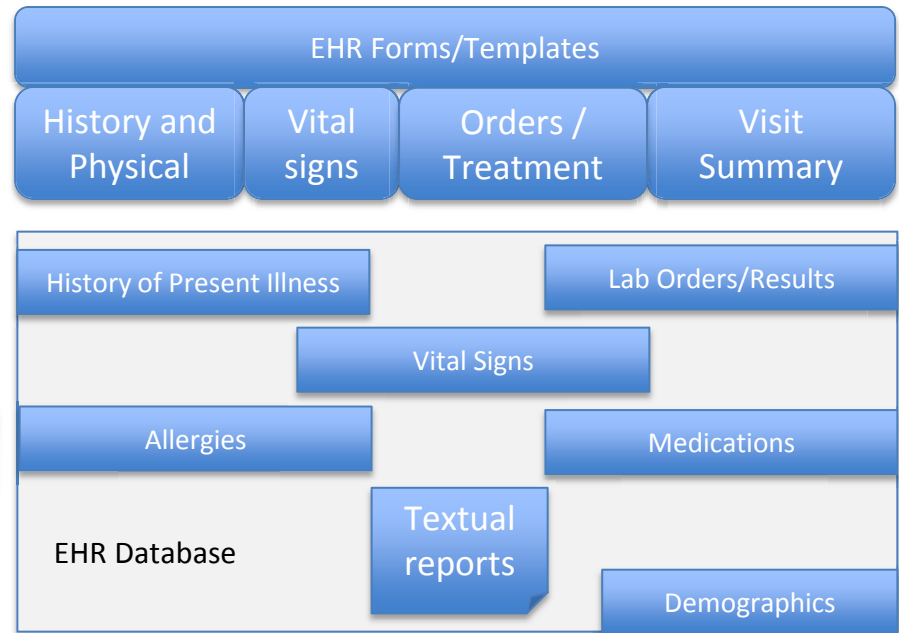
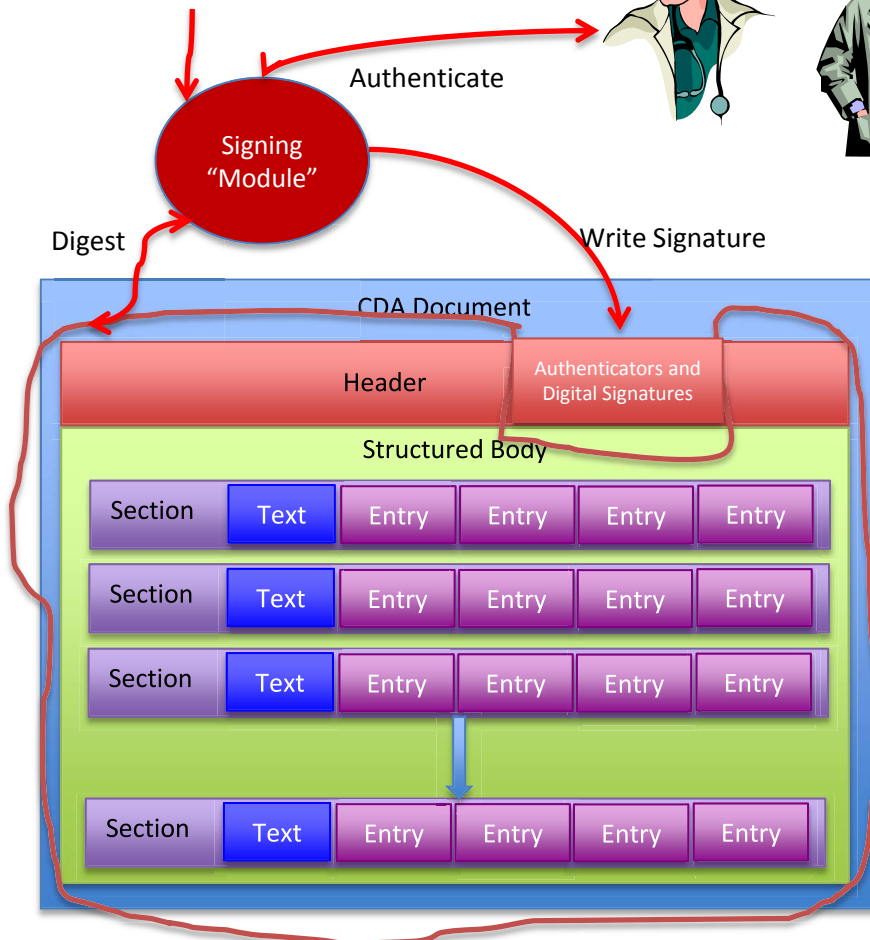
Digest

Write Signature



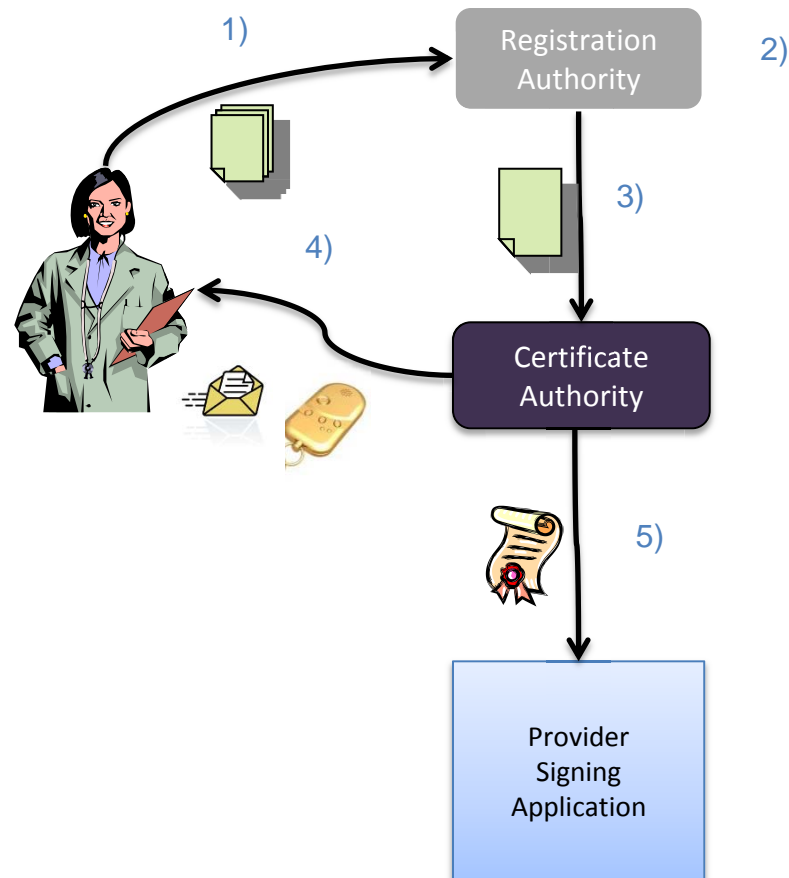
Notes:

- 1) Attestation as to authorship of document
- 2) Fixes the content, role and signature purpose at time of signing



Provider Setup for Digital Signatures

- 1) Individual provider supplies IDs and other information as part of credentialing or to a standalone Registration Authority (RA)
- 2) RA verifies credentials
- 3) Certificate Authority (CA) receives providers information from the RA
- 4) CA issues access information (e.g. hard token) to the individual provider
- 5) CA issues encrypted key to the signing application key store



Signing Process -- Potential

- 1) C-CDA created for activity to be signed (system or on- demand)
- 2) Signer views list of documents (C-CDAs) to be signed
- 3) Signer reviews documents and indicates ready for signature, role and signature purpose (will most likely be defaulted based on signer's experience and preferences)
- 4) Signer authenticates to Signing Application
- 5) Signer signs list of all reviewed and accepted documents

