

**Certification for Meaningful Use  
Experiences and Observations from the Field  
June 2011**

# Agenda

- Purpose
- Introduction
- Suggestions
  - Clarify and simplify requirements for possession and designation of Certified EHR Technology
  - Create a common understanding of the Meaningful Use and certification requirements
  - Build realistic implementation timelines into future regulatory requirement
- Conclusions

# Purpose

- To identify the challenges that the current certification rules create for vendors and providers who must use certified EHRs to achieve meaningful use and attest to their use to receive incentives.
- To identify where clarification and improvements are needed immediately and over the longer term.

# Introduction

# Principles for Certification to Support Meaningful Use

- Certification should promote EHR adoption by giving providers assurance that products/systems will help them achieve meaningful use - without posing unnecessary burdens, unduly changing IT market dynamics, or limiting innovation in the delivery system.
- Choice of the specific, certified technology used should be driven by clinical goals and operations, not restrictive certification requirements.
- Certification and meaningful use requirements should be neutral to the use of complete vs. modular approaches to complying with certification requirements.
- Certification and meaningful use requirements should give providers flexibility to pursue any of the following approaches to implementing EHRs through site-certification, purchase of vendor products, or a combination of both:
  - a single complete EHR;
  - an all-modular installation;
  - complete EHR plus certified modules; and
  - pieces of a complete EHR plus certified modules.

# Market Realities

- Delivery system goal is support for safe, high-quality patient care.
- Many providers have a base of legacy technological systems, that are often a mix of complete and modular certified systems.
- Examples of commonly deployed modules:
  - System designed for the emergency department
  - Separate or separately hosted patient portal
  - Public health reporting
  - Quality reporting
  - Clinical decision support tools created by subject matter experts in a given clinical area
- Some federal policies promote achieving meaningful use through alternate mechanisms that can use certified modules, such as quality or public health reporting through an HIE.

# Patient Safety and Quality of Care are Overarching Concerns

- Providers, often supported by vendors, must meet the meaningful use requirements (including use of certified EHR technology) , as well as their organization's clinical objectives while continuing to provide safe, high quality care.
- Rushed development and implementations might compromise patient safety.
- Upgrades are not a small undertaking:
  - Advanced planning with clinical involvement is crucial
  - Extensive testing and training is needed whenever a system is changed
- Confusion, distracting details, unnecessary changes, and redundancies all have a potentially negative effect on patient safety.

# Current Challenges

- The current regulatory structure and guidance on possession and attestation to use of certified EHR technology is constraining and burdensome.
  - For providers, ensuring they have met the EHR certification requirements can be confusing, costly, and as currently constructed will lead to possessing redundant technologies.
  - For vendors, certification of multiple combinations brings considerable cost to certify initially and to maintain over time.
  - For ONC-ATCBs, lack of clear guidance leads to inconsistency among ATCBs.
- The way that certification criteria are linked to meaningful use objectives sometimes creates unnecessary situations where providers must site certify third party or self-developed systems.
  - For providers, the process is costly and often overwhelming.
  - For vendors, it creates bias to single vendor solutions.
- Multiple agencies play regulatory roles, leading to apparent contradictions and no “single source of truth.”
- Unrealistic future timelines are creating additional pressures and diverting attention from deploying systems to support clinical care.

# Suggested Solutions

- Clarify and simplify requirements for possession and attestation to use of certified EHR technology\*
  - Simplify rules for providers
  - Simplify certification processes for vendors and ONC-ATCBs
  - Streamline the attestation process
- Create common understanding of the requirements of Meaningful Use and Certification\*
  - Provide a “single source of truth” within HHS to ensure success
  - Align guidance across federal agencies
- Build realistic implementation timelines into regulatory requirements
  - Align requirements for certification with stage of meaningful use
  - Establish 18-month effective dates for all newly adopted certification criteria

*\* = Stage 1 problems are immediate and must be addressed to support current efforts.*

# **Possession and Attestation to Use of Certified Technology**

# Current Rules on Possession and Attestation to Use of Certified Technology

- Providers must “possess” EHR technology (Complete, Modular, or both) certified against ALL certification criteria, including criteria that apply to meaningful use objectives they intend to defer until Stage 2 or for which they can claim an exclusion.
- Providers are being told they must “possess” all meaningful use functionalities of a vendor developed product as it was certified and posted on the Certified Health IT Product List (CHPL)- whether they intend to use all of the individual functions or not.
- If multiple components are used to certify an EHR or module to one criterion, any modifications or substitutions of any of these components (e.g. interface engines, repositories, document management systems) require that the EHR or module be recertified for that criterion.
- If multiple products are used to perform a single meaningful use objective, each must be certified.
- Providers attest to use of certified EHR technology by identifying the specific collection of certified products (complete, Modular, or both) that are used to meet meaningful use requirements on the CHPL, which could include duplicative certified technologies.

***Note: The concept of EHR possession is spelled out in ONC FAQs #17 and #21***

# Current Rules on Possession and Attestation to Use of Certified Technology are Burdensome

- Compliance with these requirements can involve some or all of the following:
  - Complex analysis of existing solutions to ensure certification requirements are met without unnecessary replacements and/or duplications;
  - Labor-intensive and redundant recertification of multiple product combinations by vendors to meet customer needs;
  - Complex legal arrangements between providers and vendors to “possess” software that is not licensed, not installed and not used to meet Stage 1;
  - Replacement of existing EHR technology to match the certified products; and
  - Complex and costly site certification of the whole or part of installed systems that were previously vendor certified.
- The current requirements are especially problematic for hospitals, which tend to have multiple vendor systems combined to satisfy functions of an EHR.

*Note: See the appendix for a detailed analysis of current challenges to using modular certification.*

# Suggestions for Immediate Action:

## Temporary Certification Process

### *For Providers, clarify the certification requirements to:*

- Recognize possession of a subset of a vendor's certified complete or modular EHR as long as providers:
  - Possess certified EHR technology for all applicable criteria
  - Identify all of the certified products they are using, and
  - Document the MU objectives for which they are using each product
- Enable consistent identification by a provider of the subset of MU objectives achieved through a given licensed product as listed on the CHPL. For example, a provider could:
  - Use Vendor 1's certified "complete EHR" for all objectives EXCEPT clinical quality measures and public health reporting
  - Use Vendor 2's certified module for clinical quality measures
  - Use an HIE that has a certified module for public reporting
- Allow providers to modify or substitute technology components, including those that may not be certifiable, incorporated in a single MU criterion as long as:
  - The original module or EHR was certified to that criterion
  - The provider can demonstrate ability to meet the MU objective or attest to the software's continuing ability to support the MU objective (for deferred items)
- Make publicly available all CMS EHR Certification IDs that have been created through combining specific certified products on the CHPL, in order to facilitate the registration and attestation process for group practices or multiple providers that share the same combination of certified technology

# Suggestions for Immediate Action: Temporary Certification Process

*For vendors and providers who choose site certification, streamline the requirements to:*

- Permit specified subsets of a complete EHR to derive certification from the complete EHR
  - Allow vendors to designate infrastructure products/components that are foundational to the EHR and those that can be added or removed to achieve functional combinations without requiring a retest or recertification of the same capabilities.
- Extend need to test compliance with Privacy and Security Certification criteria to modular certifications on a more rational basis, rather than assume that Privacy and Security criteria must be recertified multiple times within a single provider system.

# Suggestions for Longer Term Certification: Provider Needs

- Consider requiring providers to possess EHR technology certified only against those objectives they use to demonstrate meaningful use.

# Suggestions for Longer Term Certification:

## Permanent Certification Process

- Evaluate rationale and effectiveness of the current certification process based on experience
- Change the certification process so that vendors can, at their option, list the products included in a certified system by name, indicate the objectives supported by each named product, and designate exclusions that could apply.
  - For either complete or modular certification, indicate the product used by objective for greater clarity.
  - Indicate in both modular and complete certifications the products and related objectives that can be eliminated from the “combination” without negative impact on core infrastructure or security.
  - Identify and require use of products that are significant to infrastructure (security, privacy, and other core functions) as foundational components.
- This approach mirrors market, where vendors and providers identify products by name and provides flexibility.

# Example of CHPL with Products Listed

- Clinical EHR - Version 1.1
- Certifying ATCB: CCHIT | CHPL Product Number: CC-1118-914405-6  
Classification: Complete EHR | Practice Setting: Inpatient
- \* Products included: Clinical Pharmacy Expert, Clinical CPOE, Clinical Care Alert, Clinical Expert Reporting, EHR Clinical Master Module, Clinical PHR Portal, Clinical Quality Reporting Module
- Additional Software Required: Open Source Tool, .NET Encryption Test Harness, xxxx

*\* This section doesn't currently exist in the CHPL, all other information is present today*

Criteria Type	Criteria Description	Product (* indicates base product, must be selected)
170.302	<a href="#">a) Drug-drug, drug-allergy interaction checks</a>	Clinical Pharmacy Expert
170.302	<a href="#">(b) Drug formulary checks</a>	Clinical Pharmacy Expert
170.302	<a href="#">(i) Generate patient lists</a>	Clinical Expert Reporting (BO)
170.302	<a href="#">(j) Medication reconciliation</a>	EHR Clinical Master Module
170.306	<a href="#">(a) Computerized provider order entry</a>	<b>Clinical CPOE *</b>
170.306	<a href="#">(b) Record demographics</a>	<b>Clinical Base EHR*</b>
170.306	<a href="#">(c) Clinical decision support</a>	Clinical Care Alert
170.302	<a href="#">(n) Automated measure calculation</a>	Clinical Quality Report Module
170.302	<a href="#">(o) Access control</a>	<b>Clinical Base EHR*</b>
170.302	<a href="#">(p) Emergency access</a>	<b>Clinical Base EHR*</b>
170.302	<a href="#">(q) Automatic log-off</a>	<b>Clinical Base EHR*</b>

# Common Understanding

# Lack of Alignment of Federal Agency Activity

- Multiple Federal agencies play a role in setting certification criteria, establishing testing mechanisms, and administering the incentive programs
- Guidance, while improving, is still voluminous, complex, and sometimes contradictory
- Clinical quality measures need additional attention from CMS, ONC, and relevant external organizations (e.g., NQF, the Joint Commission) to ensure accurate specifications and thorough field testing prior to implementation

# Create Common Understanding

- Coordinate guidance regarding certification and Meaningful Use across HHS agencies
  - Create a single public source for all policies, guidance, and FAQs.
  - Review all guidance for consistency.
- Work with external organizations (NQF, the Joint Commission, etc.) to create a systematic approach to development, deployment, use, and maintenance of e-measures to facilitate accurate reporting

# **Realistic Implementation Timelines**

# Timelines for Future Certification and Meaningful Use Requirements are Not Aligned

- ONC has tied valid certification to the adoption of new certification criteria, and not the individual provider's stage of meaningful use.
- If this approach is maintained, when ONC adopts new certification criteria, all meaningful users will need to upgrade to newly certified products, regardless of their meaningful use path.
- ONC has reserved the right to adopt new certification criteria outside of meaningful use rule-making.
- The Health IT Policy Committee has recommended 18 month lead time between when final rules are released and when providers must be in compliance with new certification requirements.
  - Current regulatory timelines would not allow 18-month lead time.

# Impact of Misaligned Timelines for Certification and Meaningful Use

- Providers will need to upgrade software to newly certified EHRs, regardless of their stage of meaningful use
  - Burdensome and unnecessary
  - Disruptive to care process
- Vendors will have very short window to support upgrades for all customers, which could lead to sub-optimal results and may be impossible.
- Lack of predictability limits all participants' capacity to plan and invest

# Suggestions:

## Create Realistic Timelines

- ONC and CMS should link valid certification to the individual provider's stage of Meaningful Use
  - Generates clarity
  - Synchronizes upgrade for functionality with upgrade for certification
- ONC should limit changes to certification criteria to minimum necessary at predictable intervals
- ONC should establish a minimum of 18-months between final publication and the effective date for all newly adopted certification criteria
  - Allows sufficient time for planning
  - Allows sufficient time for upgrade and roll-out across all providers

# Conclusions

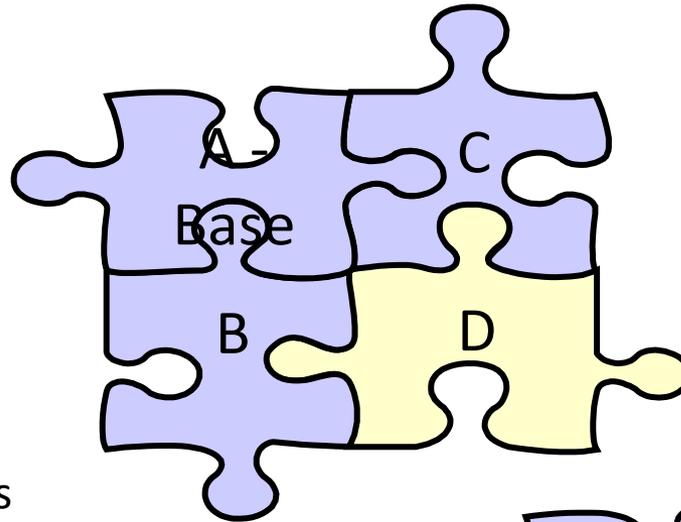
- Commitment to EHR adoption and use is high
- Considerable confusion remains over current and future regulatory requirements
- ONC and CMS have addressed many current issues through FAQs
- Opportunities exist to take immediate steps that will increase adoption by:
  - Clarifying and simplifying requirements for possession and designation of Certified EHR Technology
  - Creating a common understanding of the Meaningful Use and certification requirements
  - Building realistic implementation timelines into future regulatory requirement

# **Appendix:**

## **Detailed Analysis of Challenges to Use of Modular Certification**

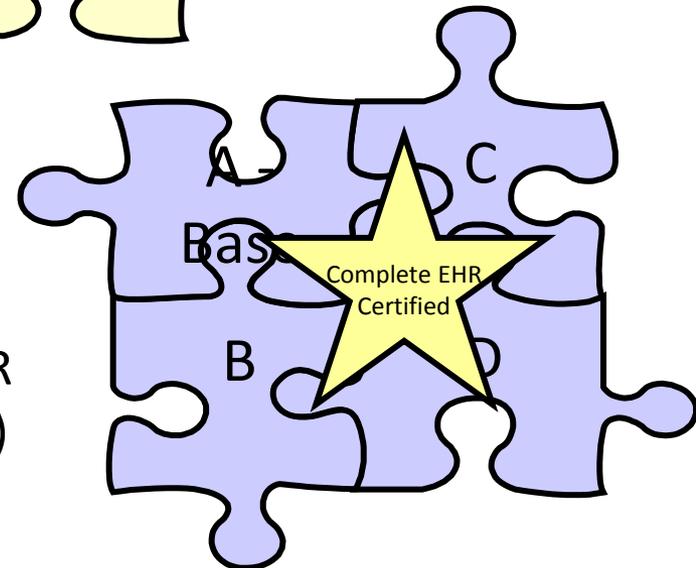
# Certification rules may require providers to “possess” duplicate products

- Providers have been told they must possess all certified function that the vendor took to certification under a single CHPL number.
- As a result, unless vendor 1 has created a Complete EHR or modular combination that meets a specific provider’s needs, a provider using another vendor’s products to meet an objective will need to “possess” duplicate technology from both vendors.



Provider has Vendor 1 Product for A + B + C and Vendor 2 for D

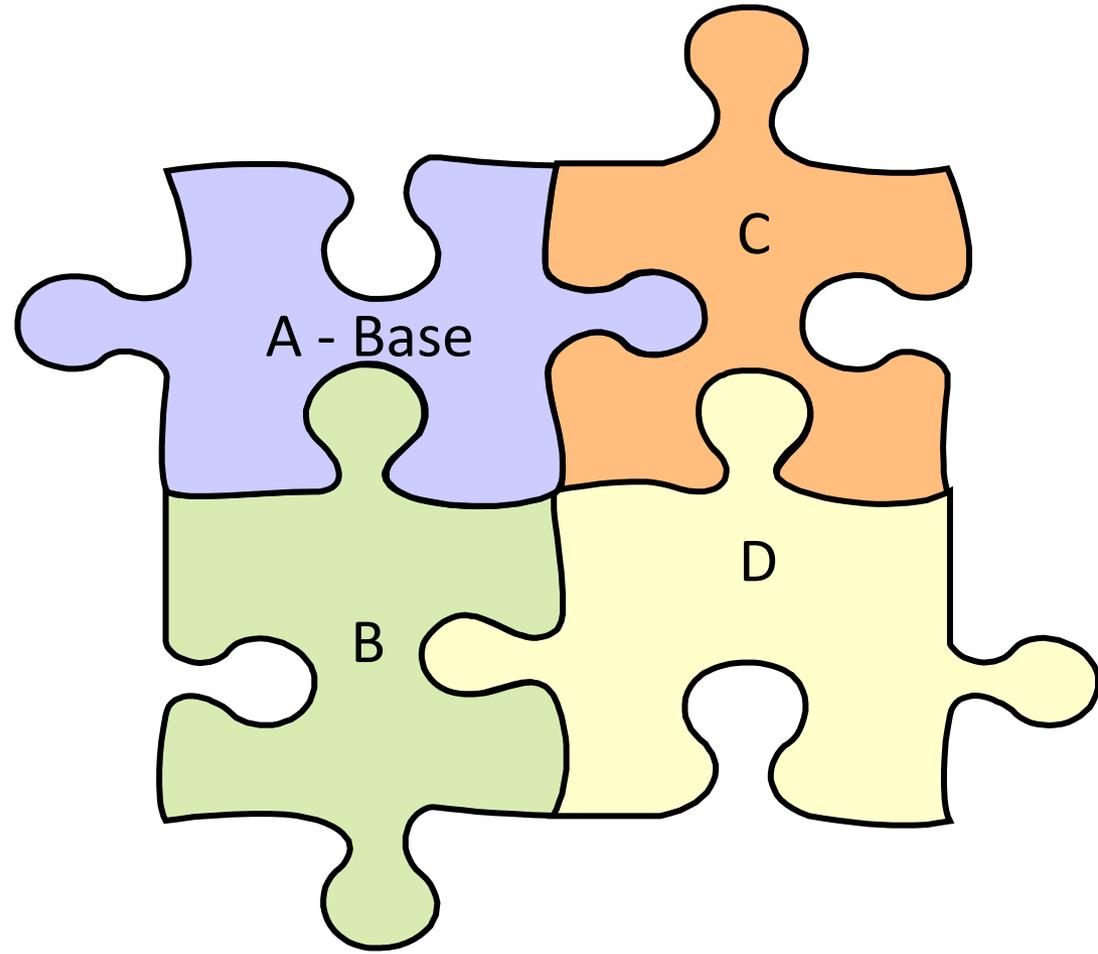
Vendor 1 Certified Complete EHR (A + B + C + D)



Provider must possess duplicate Vendor 1 “D”.

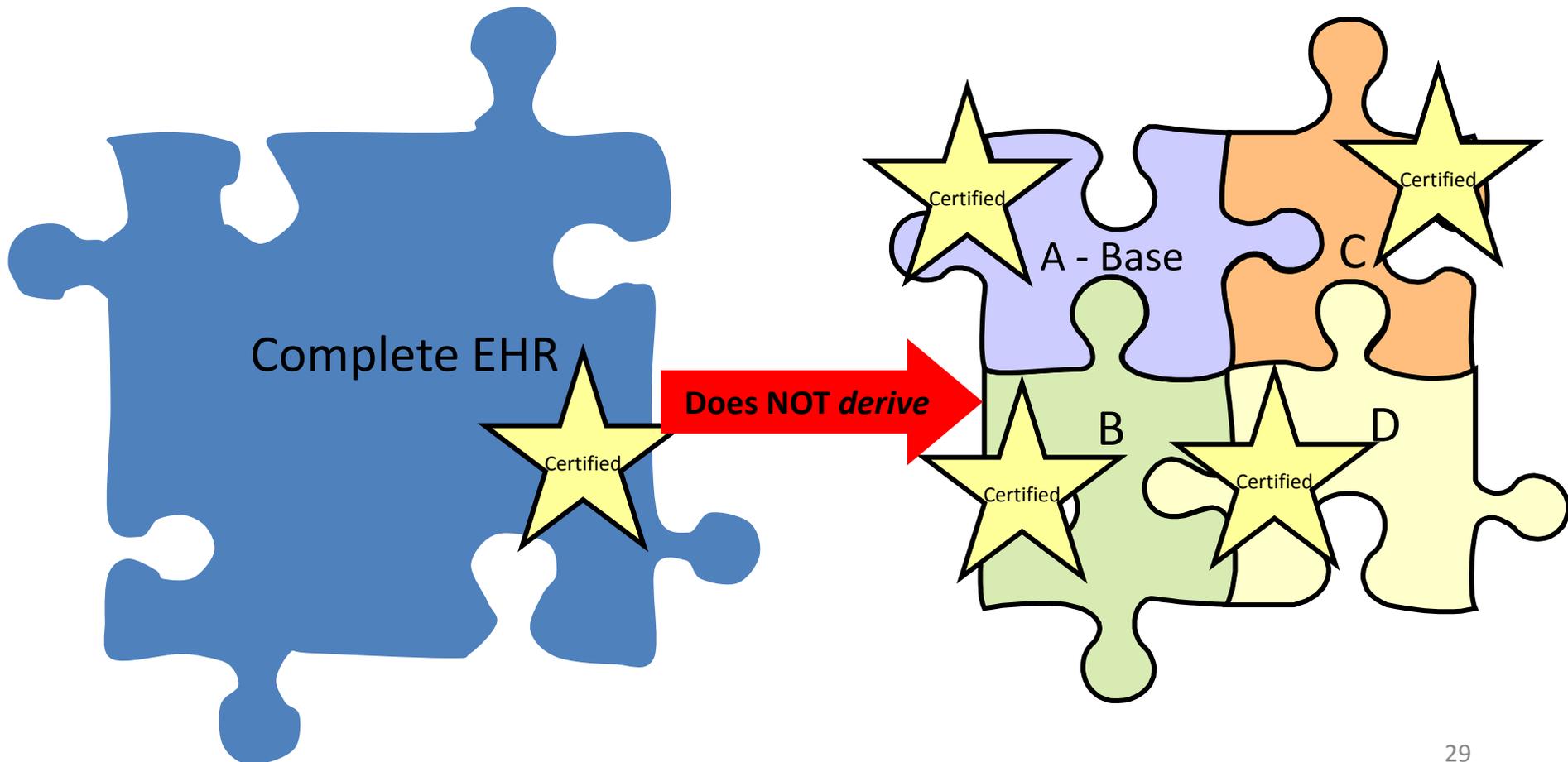
# To enable providers to “avoid duplicates” requires some vendors to support and certify product combinations

- An EHR vendor markets A, B, C, and D together and separately as certified.
- The vendor chooses to certify their complete EHR (A + B + C + D).
- Providers can purchase the base (A) and alternative third party products that are functional equivalents of B, C, and D.
- To enable the providers to mix and match, the vendor also wants to certify each product component separately.



# Principle: Derivation

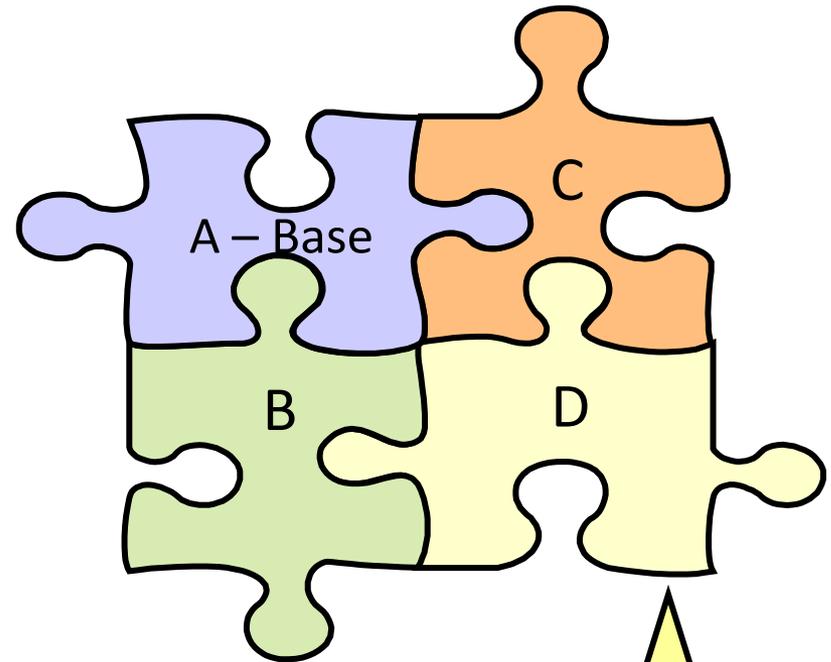
Because Certified Components A, B, C, D do not derive their certification from certified Complete EHR, the vendor must certify A, B, C, D separately.



# For the vendor to certify B, C, D separately, **At least Six “Certified Combinations”** May be Needed

EHR Module A is the base product.

- Vendors market a base product and provide add-on modules that depend upon the base software.
- Because B and C depend upon A to meet security (user authentication, etc.) and other data flow requirements (CPOE, pharmacy) to meet a certification criteria, then it is necessary to create combined modules that include A to meet certification criteria.
- If D is not dependent on the base and security requirements can be met independently, then it is not necessary to include it in the above combinations.

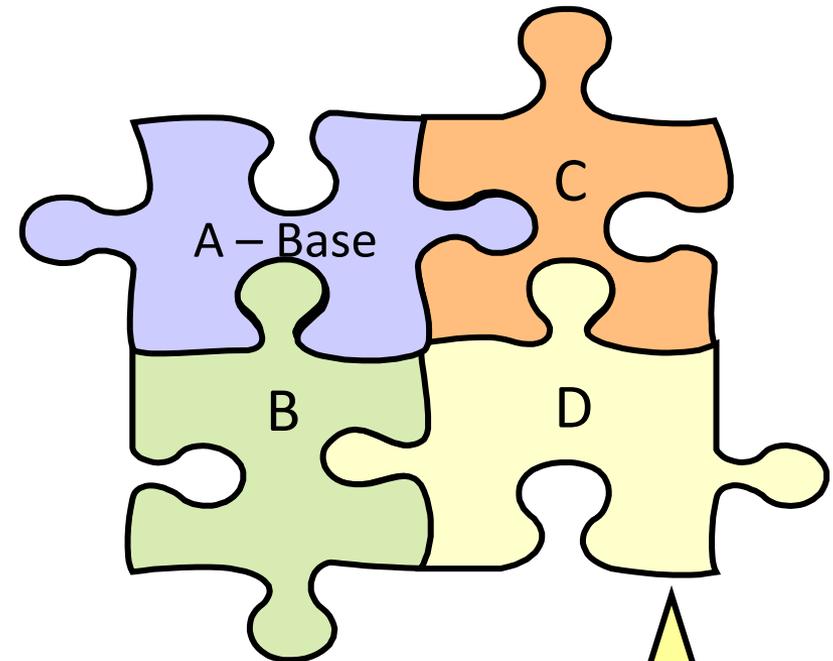


1. A (Base EHR)
2. A + B
3. A + B + C
4. A + C
5. A + B + C + D (complete)
6. D



# Impacts of Combinations: Complex, Rework, Costly, Hard to Maintain

- For vendors and ATCBs, creating multiple combinations is costly in terms of expense and rework necessary to obtain multiple modular certifications. There is also significant overhead and cost incurred to maintain and market multiple product versions.
- For providers, this approach requires considerable analysis by providers and time-consuming negotiation between parties.



1. A (Base EHR)
2. A + B
3. A + B + C
4. A + C
5. A + B + C + D (complete)
6. D



# Certification requirements may require many providers to “site certify”

- Achieving certification of a MU objective may require two or more product components.
- In this case, it is not possible to certify either of the components standalone because of the dependency.
- Therefore, providers using an alternate component product (e.g., data warehouse, interface engine, and / or document management system) offered by a third party must site certify the combination of these two separate product components.
- In this scenario, where a provider has an alternative product component, meeting security and privacy provisions makes this very challenging for some providers.

