

June 16, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius:

The role of health IT in supporting healthcare transformation is a critical topic of discussion this spring. Eligible professionals (EPs) and Eligible hospitals (EHs), and supportive organizations are working tirelessly to prepare for Stage 1 Meaningful Use of the Medicare and Medicaid Electronic Health Records (EHRs) Incentive Programs, as outlined in the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA). The undersigned organizations request a meeting with you and the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator (ONC) senior leaders to discuss the issues identified in this letter.

In February, at HIMSS11 in Orlando, you encouraged the healthcare community to provide you answers for the following question: “Short of regulatory or legislative change, what are the top five solutions the U.S. Department of Health & Human Services (HHS) can implement to ensure greater success in meeting Meaningful Use Stage 1 for EPs and EHs?” Since that time, American Hospital Association (AHA), American Medical Association (AMA), Association of Medical Directors of Information Systems (AMDIS), College of Health Information Management Executives (CHIME), Electronic Health Record Association (EHRA), Federation of American Hospitals (FAH), and Healthcare Information and Management Systems Society (HIMSS), have collaborated to respond to your request and, based on subsequent consultation with our memberships, colleagues, and several members of the Authorized Testing and Certification Bodies (ATCB) Community, we have determined the five areas of greatest opportunity and challenge include:

- (1) Reduce Regulatory Complexity
- (2) Clarify Certification and Site Certification Processes
- (3) Address Providers’ Meaningful Use Resource Requirements
- (4) Clarify and Improve Registration, Attestation, and Compliance Processes
- (5) Evaluate Regulatory Timeline

At the outset, we wish to commend your Department, and in particular CMS and ONC, for your diligence in operationalizing these programs. Your team is carrying out a multitude of tasks necessary to implement this complex program, including the creation of educational tools, producing numerous Frequently Asked Questions (FAQs), dialoging with our members, and responding to inquiries on a range of topics.

The success of future stages will hinge on the outcomes and lessons learned from Meaningful Use Stage 1. Going forward, everyone realizes much remains to be done. To that point, we believe the collective efforts between the public and private sectors to address the five areas noted above will enhance EP and EH involvement in the Medicare and Medicaid EHR Incentive programs.

Reduce Regulatory Complexity

Healthcare providers are in the midst of an enormous information system change. As these stakeholders attempt to become Meaningful Users, they are concurrently preparing for the conversion to new administrative transaction code sets and operating rules (ICD-10, 5010) and new Patient Protection and Affordable Care Act initiatives.

Central Location for Meaningful Use Incentive Programs Guidance Needed

The Medicare and Medicaid EHR Incentive Programs include large numbers of very specific requirements promulgated through regulation and sub-regulatory guidance. Healthcare providers and the vendors that serve them are often challenged in fully understanding and staying abreast of regulatory requirements for Certification and Meaningful Use requirements. Although sub-regulatory guidance may be available through town hall meetings, webinars, and in various locations on the ONC and CMS websites, the information is sometimes conflicting within and between sites, can be hard to find, and may be difficult to understand.

Clarification on Use of Sub-Regulatory Guidance Needed

An additional challenge arises regarding reliance on sub-regulatory guidance. Although FAQs can be very helpful in providing clarification on issues not addressed in sufficient detail in regulation, in practice some FAQs have resulted in uncertainty.

For example, the quality measure specifications have been updated since the final rule was published. However, there is no mechanism in place to notify users of updates to the quality measures program specifications. Additionally, a summary of the changes to the quality measure specifications was not provided with the updated documents, requiring users to compare the original version with the update to identify the changes. Therefore, some providers have used the measure specifications as originally published, while others have updated their systems based on the post-regulatory guidance. From a compliance perspective, the lack of specific guidance has made it unclear which approach is correct.

Given the transformative nature of the incentive programs and associated funding and legal obligations, the healthcare community needs authoritative, timely, unambiguous, clear information, and resources that address the policy and operational implications for EPs and EHs.

Proposed Solutions:

1. Launch a unified HHS website that serves as the “single source of truth” for CMS’s Meaningful Use and ONC’s Certification programs.
2. Launch “Meaningful Use and Health IT” checklist of tools detailing what each EP or EH needs to address, as well as linking to resources from the Health Information Technology Resource Center (HITRC), which should be publicly available to all.
3. Increase HHS efforts to provide a technical assistance resource for hospitals, similar to the Regional Extension Centers (RECs), focused on rural hospitals and those providing care to patients in underserved areas.

4. Extend REC services to specialist categories, and evaluate the effectiveness of the RECs' physician outreach and assistance efforts.
5. Establish a clear process to manage updates to specifications for quality measures, making sure that all published updates to quality measure specifications include release notes so users can easily identify what has been updated in the quality measure specifications. We ask that CMS provide clear guidance as to whether the implementation of the updated measure specifications is a requirement to meet incentives qualification, or is an optional update to qualify for incentive payments. We also urge HHS to include a process by which providers and vendors can access guidance on specific measures and their specifications as well as to provide feedback on problematic or unclear measures.

Clarify Certification and Site Certification Processes

There is a growing level of confusion and frustration regarding elements of the certification process. In particular, complex scenarios can arise regarding modular certification and the treatment of the ancillary and non-certifiable IT applications that are often used with a certified system to meet EP or EH goals for quality, safety, efficiency, or data sharing. Our organizations are receiving numerous questions from members and customers on these issues, such as:

- What must one do to use certified EHRs modules independent of a complete system or when one's existing core system was certified as complete?
- Must one possess all software components or products used by the vendor to attest to use of certified Complete EHR?
- If a laboratory system interfaces data to an EHR, under what circumstance would the lab system need to be certified?
- What are the certification requirements for interfaces and interface engines?
- To demonstrate Meaningful Use, why do I need to "possess" technology I will not use?

Many of these issues have been generally addressed in ONC and CMS FAQs, often with considerable clarity. Due to the variability of individual provider and vendor situations, some uncertainty remains. We emphasize that these concerns pose an immediate challenge to providers seeking to be Meaningful Users, and there is opportunity and necessity to address the challenges now.

Several of the organizations who signed onto this letter have outlined the current challenges and possible approaches to addressing these issues. This analysis is included in the attached presentation, which will be separately conveyed to ONC, CMS, and the Implementation Workgroup of the Health IT Standards Committee.

Proposed Solutions:

1. Review the attached presentation articulating the observations and suggestions designed to foster greater understanding and compliance with the Certification Process and implement the proposed solutions as soon as possible.

Address Providers' Resource Requirements to Meet Meaningful Use

The sheer volume and specificity of requirements for EPs and EHs, as well as the limited amount of information available to help them meet the requirements, is a cause for concern. To maximize the success of the EHR Incentive Programs, much can be learned from Stage 1.

Feedback Loop

We believe it will be critical for CMS or ONC to create a mechanism for evaluating how Stage 1 is working; identifying barriers to compliance; and making the findings public. This need includes understanding when providers are having particular trouble meeting certain objectives or measures, whether existing thresholds are too high, if certain providers are lagging in compliance, or unable or unwilling to participate, and if cost is preventing some from participating. Understanding early lessons learned will be critical in establishing future requirements which are achievable.

Appeals Process

The Stage 1 final rule outlined an appeals process for Medicaid providers. Although CMS indicated in the final rule their intention to establish an appeals process for Medicare providers, to date no details have been shared. We believe it is also critical that CMS establish a fair and straightforward process for providers who believe they have been inappropriately excluded from Meaningful Use eligibility or have received an incorrect incentive payment. We also believe that a more straightforward process is needed for EPs to determine whether they are "hospital-based". Today EPs must register first before learning if they are considered ineligible; they should have the opportunity to appeal these eligibility decisions and to alert CMS through a straightforward process when their status changes.

Synchronizing Incentive Programs

Medicare has implemented a growing number of incentive and reporting programs that rely on submission of quality or use metrics from providers. These programs, such as the Physician Quality Reporting System (PQRS) program, the physician e-prescribing incentive program, the hospital inpatient quality reporting program (IQR), the readmissions reduction program, and the electronic health record (EHR) incentive program were created under separate federal laws and each includes unique eligibility criteria, incentive and penalty, and participation requirements. Better alignment among the programs is needed in order to reduce the regulatory burden on providers. While criteria for each program are already established in regulation, we believe more conversations are needed to review how these many programs can be better aligned in the future. Alignment may include both intentional overlap in reporting requirements, or limiting reporting on a given measure to a single program to avoid duplication.

Representation on Advisory Workgroups

We believe the workgroups of the Health IT Policy Committee, in particular the Meaningful Use Workgroup, would be better served if there was greater representation by those who are developing and implementing systems and particularly those who understand the unique needs of small practices. According to an AMA survey, seventy-eight percent of office-based physicians in the U.S. are in a practice with nine physicians or less. The majority of those physicians are either in a solo practice or in a practice of between two and four physicians. Providers are a critical resource for providing input on how health IT can be used to improve practice workflow and enhance care processes and clinical decision-making. We are happy to recommend EPs who are willing to participate in and share their experiences and expertise at these workgroups.

Proposed Solutions:

1. Develop and conduct field surveys of EPs, EHs, and vendors to identify barriers and solutions that enhance participation in the Meaningful Use EHR Incentive Programs. The surveys would be most effective if conducted with both registered and non-registered EPs and EHs.
2. Engage the industry in a dialogue on recommendations to better synchronize the Meaningful Use, E-prescribing, PQRS, and IQR incentive programs.
3. Include greater representation of those who develop and implement EHRs on advisory workgroups, in particular the Meaningful Use Workgroup.
4. Engage the healthcare community to develop and collect feedback loop information.
5. Establish a Meaningful Use appeals process for Medicare providers.

Clarify and Improve Registration, Attestation, and Compliance Processes

We commend CMS for establishing the registration and attestation process under extremely challenging timeframes. We also recognize and applaud CMS for providing educational sessions and tools for providers in an effort to help them participate in the EHR incentive programs. However, the complexity of these processes requires even greater educational efforts and resolution of specific issues.

Registration

While some providers have found the registration process simple, others have encountered challenges that take weeks or even months to resolve. Providers are handed off to multiple offices, and spend undue effort trying to resolve data concerns.

Attestation

We appreciate the fact that CMS has recently clarified that providers need only attest to the fact that they have accurately transferred the quality measure results from their certified EHR technology. There was some concern and confusion over the component of the attestation process that requires providers to attest to the accuracy of the clinical quality measures, given issues with the development of the Clinical Quality Measures (CQM) and their roll-out into certified EHRs. In addition, given the large number of measures associated with the program and the inclusion of several measures that may require providers to calculate a denominator across both paper and electronic records, we are concerned that the 60 days provided after the end of the reporting year and before attestation must occur is inadequate and believe CMS should afford more time. Under the current hospital quality reporting program, for example, hospitals are provided more than 100 days to complete their reporting.

Compliance

The healthcare community would greatly benefit from clarification of the HHS audit and validation processes associated with the Meaningful Use attestation. Such clarification is needed regarding the possession of certified EHR technology, the meaning of each specific attestation statement, and specific documentation that will be required to support the attestation. To ensure such clarification addresses the questions of the healthcare community, we would be happy to assist in the development or review draft materials prior to publication.

Taking the following action steps will allow those on the front lines of healthcare to focus on how the functionality provided through use of an adopted EHR can improve workflow and quality. By acting upon the following recommendations, your Department will clearly demonstrate the intent of the EHR Incentive Program: improving care by helping EPs understand and use EHRs appropriately.

Proposed Solutions:

1. Simplify and resolve issues with the registration and attestation processes.
2. Allow adequate time for EPs and EOs to attest for a particular year. We encourage CMS to allow at least a three-month post-reporting period to attest for a particular year to allow EPs or EOs sufficient time to calculate the Meaningful Use measures and the CQM summary report. We make this recommendation due to the complexity of generating this type of summary report - particularly for EPs that recently purchased and implemented a certified EHR.
3. Beyond 2011, we strongly encourage CMS to accept the summary information for quality measures electronically should providers want to submit in that format, as EHRs are capable of reporting in this manner.
4. Publish HHS's process for conducting Meaningful Use and Certification compliance audits, including:
 - a. Clarify how reliance on FAQs will be viewed from a compliance perspective, particularly given the fact that the HHS Office of Inspector General has included audits in its work plan;
 - b. Identify the type of documentation needed to demonstrate compliance in the event of an audit; and
 - c. Specify whether requirements in the final rule or clarifications from the FAQs are going to be enforced.
5. Establish a CMS appeals process for providers to resolve disputes on program eligibility, qualification for incentive payments, and payment calculations.

Evaluate Regulatory Timeline

We support and appreciate the Department's efforts to work collaboratively with a broad community of stakeholders to discuss these concerns. Such collaboration includes establishing a prioritized health transformation timeline that sets goals and priorities for healthcare improvement enabled through health IT, while balancing other mandates competing for similar resources like those required under HIPAA (e.g. 5010 and ICD-10). We envision the timeline as the basis for implementing all transformation activities, including but not limited to incentives, processes, and technology improvements.

To allow adequate time for safe development, implementation, and adoption of software, the timeline for the next stage of Meaningful Use needs to be at least 18 months between final rules on Meaningful Use, Certification, and standards, and the start of the next stage of Meaningful Use, as recommended by the Health IT Policy Committee. Given the context of the health IT changes in ARRA, ACA, and ICD-10, sufficient time for Meaningful Use Stage 2 is especially critical for EPs and EOs.

Proposed Solutions:

1. Publish official and immediate CMS guidance on the timeline for the start of Meaningful Use Stage 2 to enable planning and investments to take place, followed as soon as possible by publication of associated proposed and final regulations and Certification test methods.

2. Establish a process to prioritize Meaningful Use, ACA, HIPAA, and ICD-10 initiatives based on healthcare community input and use this input to inform the Meaningful Use Stage 2 proposed and final rules.
3. Include at least 18 months between the final rules on Meaningful Use, Certification, and standards and the start of the next stage of Meaningful Use.

In conclusion, we thank you for reaching out to us to seek our engagement and suggestions. We share your goal of increasing the engagement of EPs, EHs, and vendors, and are excited to provide our thoughts to you. Our collaborative group stands ready to work with your Department and its leaders to ensure our shared goals are realized and to work with you on these five key points. Our point of contact is Tom Leary, HIMSS Senior Director for Federal Affairs, who can be reached at 703-562-8814 or tleary@himss.org.

Sincerely,

AHA – American Hospital Association
AMA – American Medical Association
AMDIS – Association of Medical Directors of Information Systems
CHIME – College of Health Information Management Executives
EHRA – Electronic Health Record Association
FAH – Federation of American Hospitals
HIMSS – Healthcare Information and Management Systems Society

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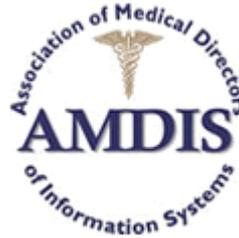
Donald M. Berwick, M.D., M.P.P, Administrator, Centers for Medicare and Medicaid Services
Farzad Mostashari, MD, ScM, National Coordinator for Health IT

Attachment:

PowerPoint Presentation: “Certification for Meaningful Use -- Experiences and Observations from the Field, June 2011”



American Hospital
Association



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

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 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) Drug-drug, drug-allergy interaction checks	Clinical Pharmacy Expert
170.302	(b) Drug formulary checks	Clinical Pharmacy Expert
170.302	(i) Generate patient lists	Clinical Expert Reporting (BO)
170.302	(j) Medication reconciliation	EHR Clinical Master Module
170.306	(a) Computerized provider order entry	Clinical CPOE *
170.306	(b) Record demographics	Clinical Base EHR*
170.306	(c) Clinical decision support	Clinical Care Alert
170.302	(n) Automated measure calculation	Clinical Quality Report Module
170.302	(o) Access control	Clinical Base EHR*
170.302	(p) Emergency access	Clinical Base EHR*
170.302	(q) Automatic log-off	Clinical Base EHR*

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

Timelines for Future Certification and Meaningful 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

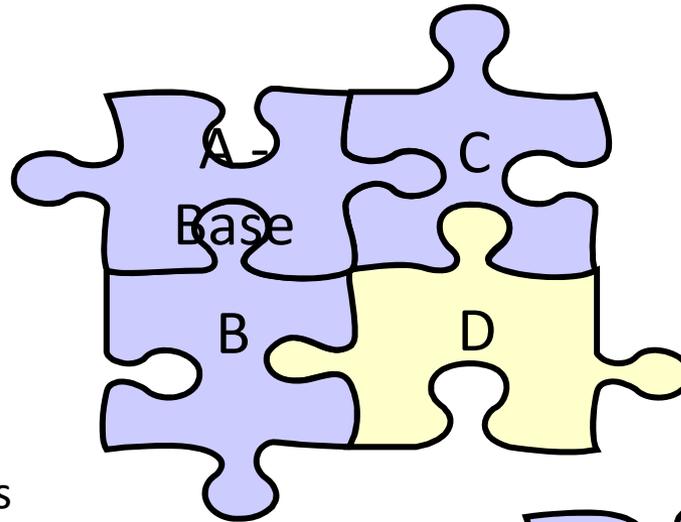
- Commitment to EHR adoption and use is high
- Considerable confusion remains over current and future regulatory requirements
- ONC and CMS have addressed many current issues through FAQs
- Opportunities exist to take immediate steps that will increase adoption by:
 - Clarifying and simplifying requirements 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

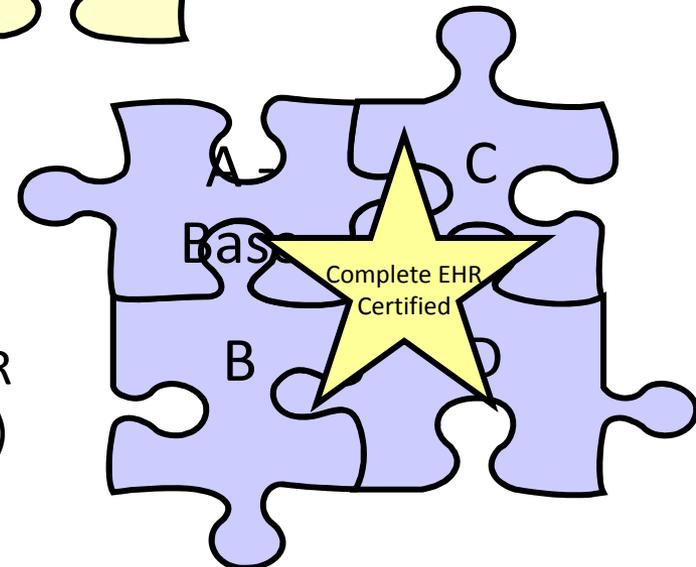
Certification rules may require providers to “possess” duplicate products

- 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

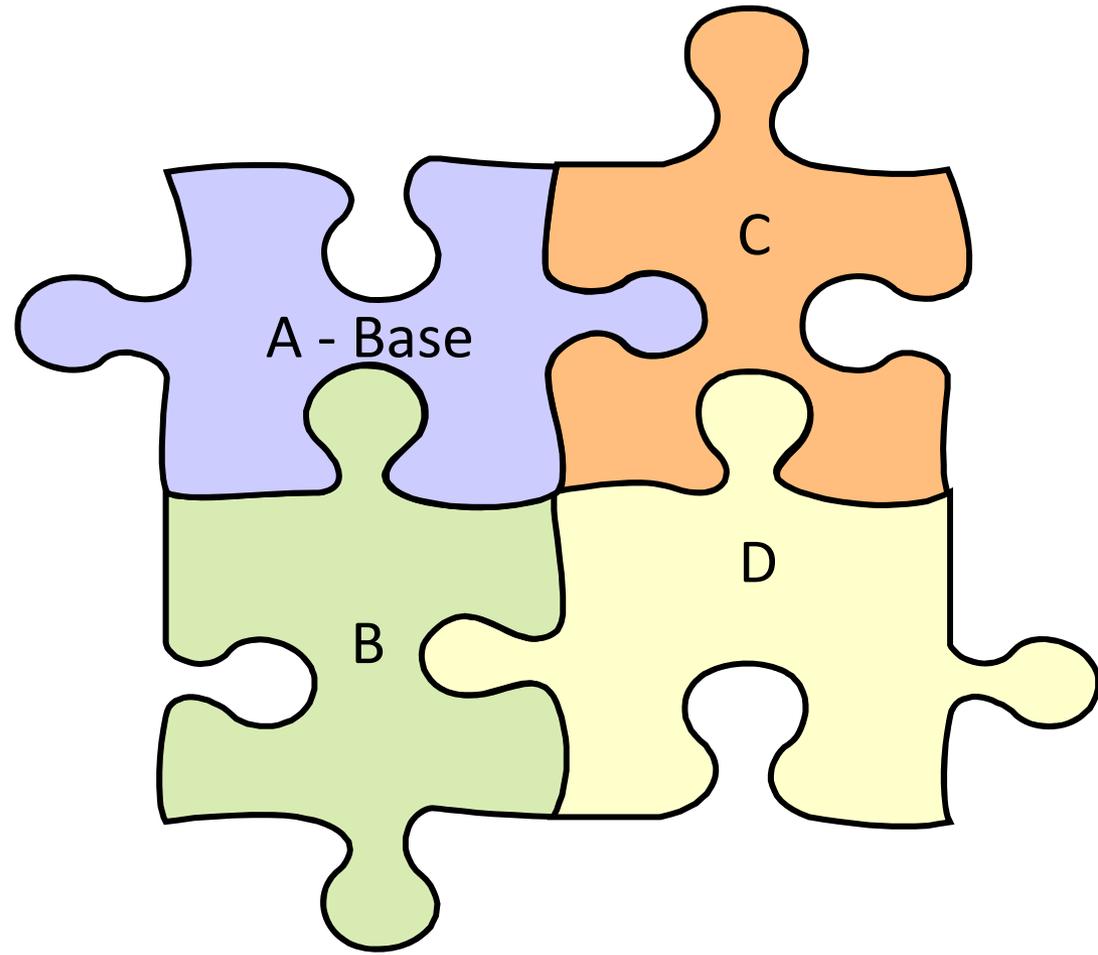
Vendor 1 Certified Complete EHR (A + B + C + D)



Provider must possess duplicate Vendor 1 “D”.

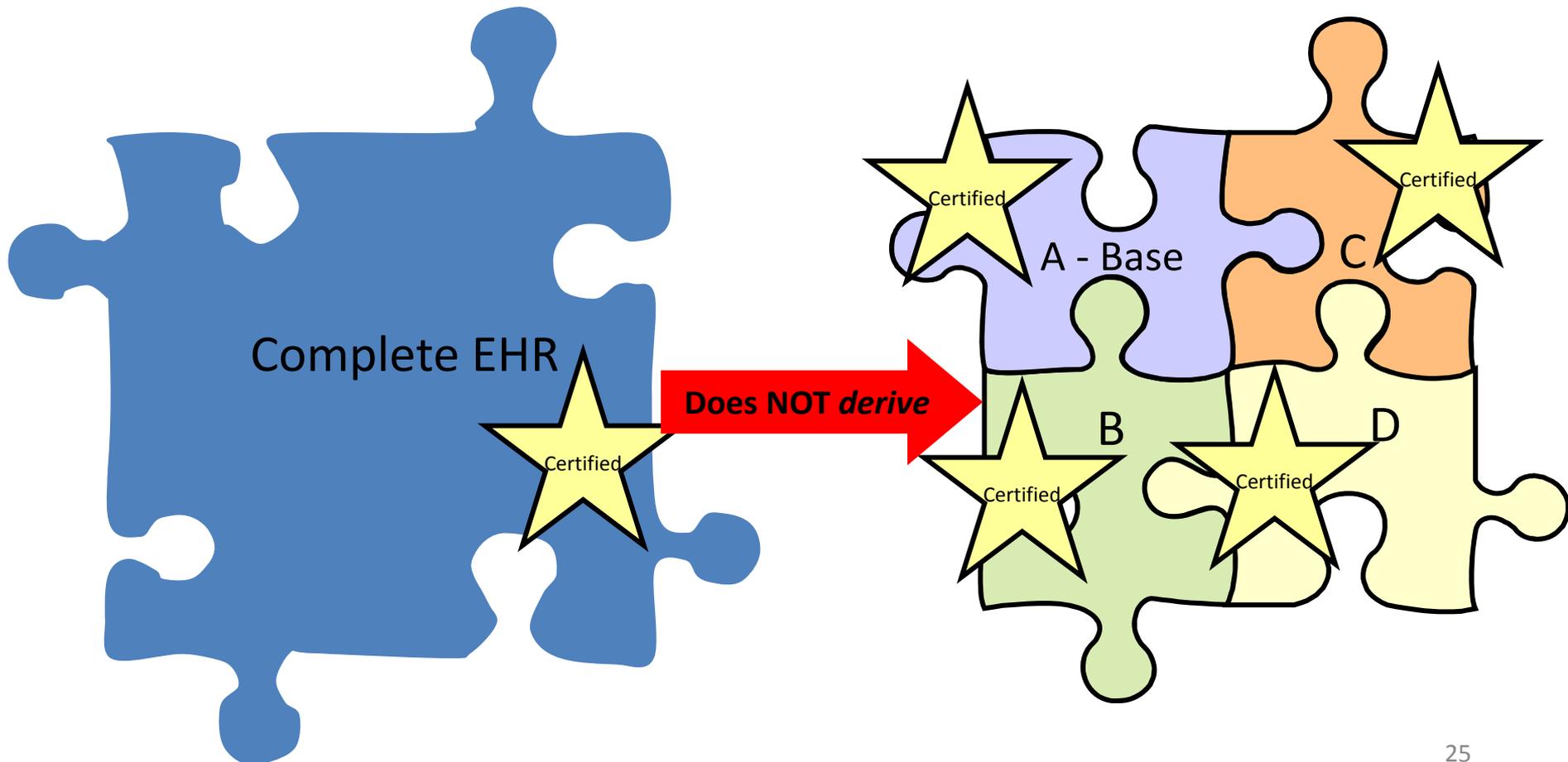
To enable providers to “avoid duplicates” requires some vendors to support and certify product combinations

- 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

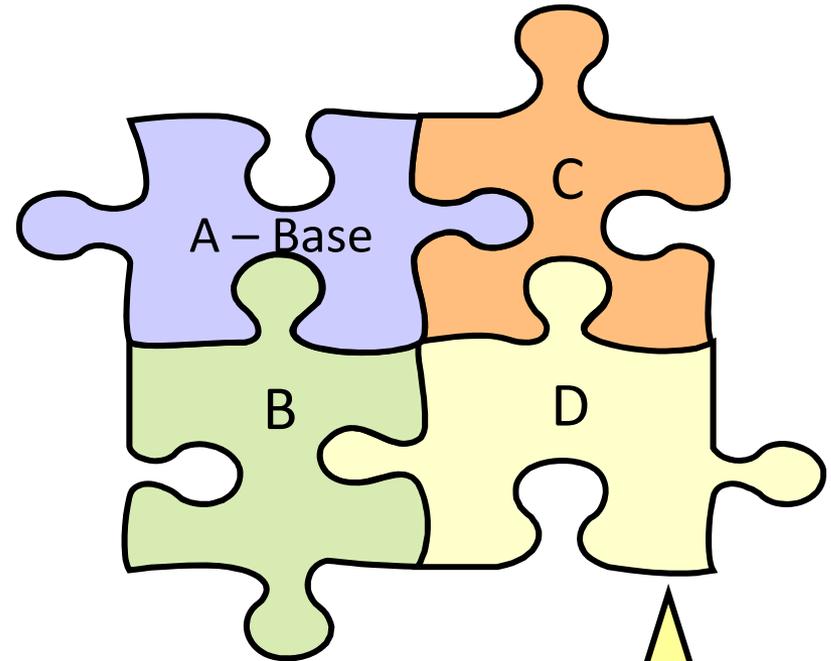
Because Certified Components A, B, C, D do not derive their certification from certified Complete EHR, the vendor must certify A, B, C, D separately.



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

EHR Module A is the base product.

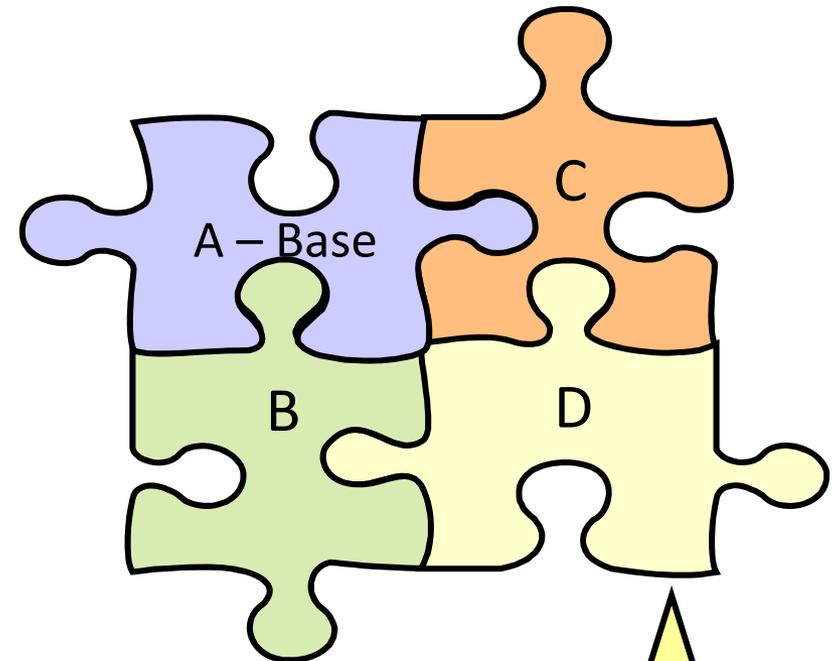
- Vendors market a base product and provide add-on modules that depend upon the base software.
- Because B and C depend upon A to meet security (user authentication, etc.) and other data flow requirements (CPOE, pharmacy) to meet a certification criteria, then it is necessary to create combined modules 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.

