HIMSS Electronic Health Record Association

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October 24, 2016

Vindell Washington, MD, MHCM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Dr. Washington,

On behalf of the members of the Electronic Health Record Association (EHRA), we offer the following comments and suggestions on the Office of the National Coordinator for Health IT's (ONC's) 2017 Interoperability Standards Advisory (ISA). We appreciate the ongoing improvements applied to the Interoperability Standards Advisory. Having a single place for those interested in available interoperability standards and implementation guidance is valuable. This response was developed through a collaborative effort by member company representatives with deep experience in supporting the interoperability needs of hospitals and ambulatory care organizations across the country that are using EHRs to provide safer, more effective, and efficient care to their patients. We offer the following overall considerations, while providing more detailed feedback in the attached document.

- **Purpose and Focus**
  - *Clarify the purpose and focus of the ISA, including its relationship to the certification program.* Understanding the purpose of the ISA remains a challenge, as it does not set a clear expectation regarding how entries in the ISA may progress to inclusion in a future certification edition (e.g., maturity and adoption level thresholds). However, it does include a new paragraph in the *Purpose* section inviting agencies to consider using standards in this ISA (*"Stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components are encouraged to look first to the ISA in order to more fully inform their goals"*), rather than referencing the most current certification edition first. This may lead to interoperability requirements that are aspirational, but not yet practical to achieve; or worse, may conflict with capabilities already provided through the certification edition, albeit it an earlier version or alternate standard.

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- *Clarify the applicability of the ISA to health IT in general and capabilities such as electronic health record technology (EHRT), lab information systems (LIS), radiology information systems (RIS), etc., in particular.* With the inclusion of many new standards (e.g., around research), the existing impression with prior ISAs that the full set of standards is generally applicable to all EHRT seems further amplified. We suggest that the ISA introduction clearly indicate that the scope includes interoperability across all of health IT supporting clinical and healthcare processes (e.g., EHRT, LIS, RIS, health information management (HIM), registries, research, etc.), but cannot be considered to be applicable to all categories of such health IT. Individual programs focusing on specific areas of clinical health IT support would identify which interoperability requirements apply. For example, research-focused standards likely would not apply to EHRT in general, or LIS-EHRT interoperability, but rather to health IT involved in the collection of research data that is to be communicated with other research parties. Such clarification will further help communicate that not all health IT currently supports all standards listed, nor they are expected to implement all standards.

- *Clarify considerations for health IT developers regarding when to focus on standards requiring further development vs. those ready for initial implementation vs. those that are widely deployed.* Focusing particularly on health IT developers, the expectation should be further clarified that these developers are not expected to implement and pursue all standards referenced, particularly emerging standards. Most emerging standards, such as FHIR, are not ready for wide deployment and endorsement, primarily due to a lack of well-defined and widely agreed-upon implementation guides and profiles. FHIR in its current state is subject to varying interpretations, akin to the initial rollout of HL7 V2, V3, and CDA. Early efforts to deploy such standards beyond individual provider/healthcare organizations into, for example, the inter-provider and provider-patient space has resulted in many variations, making such interoperability still challenging. We recognize that we do want to promote activity in those areas to accelerate adoption, but health IT developers must recognize that early adoption of not "fully-baked" standards will likely result in updates or re-writes as more mature versions are adopted. Early adoption is not for everybody, thus cannot be set as an expectation or requirement.

- *Clarify the focus of the federal program requirement to identify ISA candidates.* It is unclear what a "federal program requirement" represents in the table. Programs established through regulations are clear, but it is unclear whether there are any other programs that are tied to regulations that should introduce requirements for the ISA. The EHRA is concerned that when federal procurement and contract requirements are included, such requirements get equal weight as a federal regulation, while private contracts do not have that weight. A federal contract is, in effect, no different than a private contract, where certain standards may or may not be a prerequisite for being able to qualify for that contract. We, therefore, suggest that federal contracts, similar to private contracts,

should not be considered a source for the ISA and request that this section be changed from *"Federally Required"* to *"Regulatory Requirement"* to clarify that is to be restricted to federal regulations.

- **Use Case Clarity**
    - *The question "the best standard for what?" remains a challenge*. Single use case titles do not create the necessary clarity to always understand whether the proposed standard is best suited for the purpose. We suggest that each "interoperability need" would be better described by including a paragraph clarifying the context. This is equally valuable in the vocabulary section as in the other sections. Such a paragraph may also help the authors consider the adoption level more appropriately. For example, in a number of instances LOINC is marked with a high adoption level (five bullets); but, while LOINC is generally widely adopted, for a particular vocabulary and a particular use case, it is not necessarily accurate and a far lower adoption level should be identified. We will further clarify this concern in the individual sections below.

- **Semantic Interoperability**
    - *Continue facilitation of terminology harmonization across standards and implementation guides.* Various standards references use terminology for similar purposes, but different values. Convergence to general vocabulary standards such as LOINC, SNOMED, RxNorm, etc., is making major strides to the necessary harmonization to achieve semantic interoperability. However, more efforts are required to ensure that provider organizations, public agencies, and registries are aligned. We suggest that this be recognized as an area of ongoing focus, requesting critical stakeholders to move this important work forward.

    - *Establish clear criteria regarding when to include a value set.* We suggest that terminology should only be included where a value set authority center object identifier (VSAC OID) is available.

    - *Focus additional facilitation to align common data definitions across standards development organizations.* The wide variety of standards starts to further emphasis the need for harmonization across standards to consistently express common data. For example, patient demographic data is included in most of the standards, yet have varying rules and guidance on lengths, data types, and vocabulary. We suggest that the Office of the National Coordinator for Health IT (ONC) work with the respective standards development organization (SDOs) to initiate the necessary efforts to harmonize such overlapping data sets to ensure that data can be consistently exchanged.

- **ISA Response Process**
    - *Provide feedback on inclusion/exclusion rationale for comments submitted.* We strongly recommend that rationale for not including suggestions be provided to those who provided them, perhaps through a companion document. The EHRA provided a number of suggestions in response to the follow-up request when the 2016 ISA was published, but

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many of those suggestions were not included without a clear explanation as to why not. Consequently, we determined that it would be best to re-submit most of those suggestions. To further clarify this concern, we suggested that projected items for the 2017 ISA should only be included if enough support was expressed through the feedback process, not simply because there was no feedback and/or support from the SDOs. It is not clear whether all additions clearly received such support from health IT developers and user communities (e.g., providers, registries, agencies, etc.).

We look forward to ongoing collaboration with ONC and other stakeholders to move forward on this important initiative.

Sincerely,
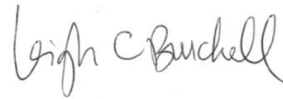
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

Attachment:

Protect Access to Medicare Act Provisions for AUC for Advanced Diagnostic Imaging [Referenced on page 11 of our comments]

Introduction

- **ISA Structure**
  - The EHRA suggests the addition of a section to include standards and implementation guides for future consideration that were brought up as suggested additions to this 2017 ISA. Including such suggestions in a separate section would allow all stakeholders to further review the applicability and appropriateness of such standards and implementation guides for a future ISA.   Examples include the set of implementation guides for vital and health statistics reporting that could be considered but would be too early to include without wider review and feedback. Additionally, other suggestions may not be as prominent as FHIR or other standards currently included but are areas that can raise awareness of something of interest (e.g., blockchain). At the same time, we recognize that the ISA should not reflect every possibility, thus a more clearly-defined scope and relationship with upcoming certification editions, as identified in our earlier comments, can help determine how to better strike this balance.

  - As the ISA is further deployed through a web site, we suggest considering various filtering capabilities to enable the reader to find what they are looking for more easily. This may include filtering by:
    - Use case - including information from all three sections;
    - Adoption level - for example, those with three or more bullets;
    - Standards maturity - e.g., emerging standards for those interested in standards development in early pilots.

- **Test Tool Availability**
  - The categories "Yes" and "Yes – open" give the impression that "Yes – open" is more restrictive than "Yes." We suggest renaming "Yes" to "Yes – Free." This further reinforces that tools that are not open source, yet free, are not as helpful as those that are also open source.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

The EHRA suggests that terminology value set references should only be included where a VSAC OID is available. We highlight where this does not appear to be available.

- **I-A: Allergies**
  - Interoperability Need: Representing Patient Allergic Reactions
    - We suggest inclusion of the VSAC urn:OID for the Adverse Clinical Reaction starter set. Additionally, the link to the LOINC value set should be included.
  - Interoperability Need: Representing Patient Allergens: Medications
    - No comments
  - Interoperability Need: Representing Patient Allergens: Food Substances
    - No comments
  - Interoperability Need: Representing Patient Allergens: Environmental Substances
    - No comments

- **I-B: Encounter Diagnosis**
  - Interoperability Need: Representing Patient Medical Encounter Diagnosis

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- We suggest making it clearer that ICD-9 is not intended to be used for new entries.
    - o Interoperability Need: Representing Patient Dental Encounter Diagnosis
        - No comments

- **I-C: Family Health History**
    - o Interoperability Need: Representing Patient Family Health History
        - We suggest inclusion of the VSAC urn:OID for the genomic data.
    - o Interoperability Need: Representing Patient Family Health History Observations
        - No comments

- **I-D: Functional Status/Disability**
    - o Interoperability Need: Representing Patient Functional Status and/or Disability
        - No comments

- **I-E: Health Care Provider**
    - o Interoperability Need: Representing Care Team Member (Healthcare Provider)
        - No comments
    - o Interoperability Need: Representing Provider Role in Care Setting
        - We suggest that further harmonization is required across the three value sets before including this requirement in an upcoming ISA rather than including only three. We note that this should allow for free text roles, as it is unlikely that any set will accommodate all relevant roles at a given point (particularly considering time to approve and include new values). If all three are needed, clarify when each one is needed.

- **I-F: Imaging (Diagnostics, Interventions and Procedures)**
    - o Interoperability Need: Representing Imaging Diagnostics, Interventions and Procedures
        - We request clarification as to what vocabulary from DICOM is being considered, as DICOM contains a variety of vocabularies used for various purposes.
        - Unless the intent is to use the older version of LOINC, this designation should be "Balloted Draft," not "Final," as the work to merge with Radlex is not completed.
        - LOINC for radiology procedures is only used by a few health systems (e.g., the VA), if it is the old version. It is the future version that is being merged with Radlex, and its adoption level should be "none" today as it is being used in only a limited number of pilot sites, so at best one bullet.
        - Note that the adoption of LOINC in this space is much lower. We suggest one bullet for LOINC procedures; while for interventions and diagnosis, it is not applicable.
        - We also suggest including the relevant value sets that are intended to be used in VSAC and include the appropriate OID in the ISA for reference.

- **I-G: Immunizations**
    - o Interoperability Need: Representing Immunizations – Historical
        - We suggest to include a VSAC urn:OID for the MVX value set.
    - o Interoperability Need: Representing Immunizations – Administered
        - No comments

- **I-H: Industry and Occupation**
    - o Interoperability Need: Representing Patient Industry and Occupation
        - No comments

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- **I-I: Lab Tests**
  - Interoperability Need: Representing Laboratory Tests
    - It is unclear to what "(questions)" this *Interoperability Need* header refers. Is this meant to refer to "ask-at-order-entry" questions, or only for the tests? If so, that must be made clear as part of a paragraph that provides context to the need. We suggest clarification that LOINC is suggested for both the tests and the ask-at-order-entry questions.

- **I-J: Medications**
  - Interoperability Need: Representing Patient Medications
    - No comments

- **I-K: Numerical References & Values**
  - Interoperability Need: Representing Units of Measure (For Use with Numerical References and Values)
    - No comments

- **I-L: Nursing**
  - Interoperability Need: Representing Nursing Assessments
    - We suggest inclusion of the relevant OIDs for the LOINC and SNOMED value sets, even where they represent harmonization work in progress.
  - Interoperability Need: Representing Nursing Interventions
    - We suggest inclusion of the relevant OIDs for the LOINC and SNOMED value sets, even where they represent harmonization work in progress.
  - Interoperability Need: Representing Outcomes for Nursing
    - We suggest inclusion of the relevant OIDs for the LOINC and SNOMED value sets, even where they represent harmonization work in progress.
  - Interoperability Need: Representing Patient Problems for Nursing
    - We suggest inclusion of the relevant OIDs for the LOINC and SNOMED value sets, even where they represent harmonization work in progress.
  - Interoperability Need: Representing Nursing Interventions and Observations (Observations are Assessment Items)
    - We suggest inclusion of the relevant OIDs for the LOINC and SNOMED value sets, even where they represent harmonization work in progress.

- **I-M: Patient Clinical "Problems" (i.e., Conditions)**
  - Interoperability Need: Representing Patient Clinical "Problems" (i.e., Conditions)
    - No comments

- **I-N: Preferred Language**
  - Interoperability Need: Representing Patient Preferred Language (Presently)
    - No comments

- **I-O: Procedures**
  - Interoperability Need: Representing Dental Procedures Performed
    - We suggest inclusion of the VSAC urn:OID for the CDT.
  - Interoperability Need: Representing Medical Procedures Performed

- ▪ We suggest inclusion of the VSAC urn:OID for the respective value sets.

- **I-P: Race and Ethnicity**
  - o Interoperability Need: Representing Patient Race and Ethnicity
    - ▪ No comments

- **I-Q: Research**
  - o Interoperability Need: Representing Analytic Data for Research Purposes
    - ▪ We suggest inclusion of the VSAC urn:OID for the respective value sets.

- **I-R: Sexual Orientation and Gender Identity**
  - o Interoperability Need: Representing Patient Gender Identity
    - ▪ No comments
  - o Interoperability Need: Representing Patient Sex (At Birth)
    - ▪ No comment
  - o Interoperability Need: Representing Patient-Identified Sexual Orientation
    - ▪ No comments

- **I-S: Social Determinants [See Questions 10 and 11, Section IV]**
  - o Interoperability Need: Representing Financial Resource Strain
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Financial Resource Strain and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Level of Education
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Level of Education and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Stress
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Stress and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Depression
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Depression and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Physical Activity
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Physical Activity and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Alcohol Use
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Alcohol Use and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Social Connection and Isolation
    - ▪ We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Social Connection and Isolation and the adoption level should be marked with one bullet.
  - o Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)

- We suggest that, while LOINC has been generally accepted and deployed for a number of terminologies, LOINC is not yet widely used for Exposure to Violence and the adoption level should be marked with one bullet.

- **I-T: Tobacco Use (Smoking Status) [See Question 12, Section IV]**
  - Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions
    - We are concerned with the focus on just tobacco smoking vs. tobacco use and suggest that this is not yet ready for inclusion in an upcoming ISA until these variances have been addressed.

- **I-U: Unique Device Identification**
  - Interoperability Need: Representing Unique Implantable Device Identifiers
    - No comment

- **I-V: Vital Signs**
  - Interoperability Need: Representing Patient Vital Signs
    - No comment

Section II: Content/Structure Standards and Implementation Specifications

- **II-A: Admission, Discharge, and Transfer**
  - Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers
    - While we appreciate that the standard has been narrowed to V2.5.1, we remain concerned with referencing HL7 standards rather than implementation specifications. We do suggest that there may be an opportunity with the increased interest in event notification to start to work with SDOs (HL7 and/or IHE, e.g., the PAM profile) to arrive at implementation specifications and be able to remove a reference to a standard and add more specific, less ambiguous guidance for this interoperability need. We note this applies to inter-provider interoperability only, as intra-provider interoperability has already been addressed. We suggest adding as a separate ADT interoperability need for Patient ID Management within a community using:
      - Standard: HL7 2.5.1 / V3;
      - Implementation Specification: IHE PIX and PDQ (both V2 and V3).
  - Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy
    - We suggest that an alternative standard may be X12 278, as that could be used in this notification space as well. However, neither X12 nor HL7 have much traction yet.

- **II-B: Care Plan**
  - Interoperability Need: Documenting Patient Care Plans
    - We suggest that this interoperability need would benefit from a paragraph to clarify the context. We understand that this need focuses on snapshot exchange of care plans and is not intended to support a "virtual," integrated care plan maintenance process. Efforts to establish the necessary standards to support the latter are very much in the early stages.

- o Interoperability Need: Documenting, Planning and Summarizing Care Plans for Patients with Cancer
  - ▪ We suggest that this interoperability need would benefit from a paragraph to clarify the context. We understand that this need focuses on snapshot exchange of care plans and is not intended to support a "virtual," integrated care plan maintenance process. Efforts to establish the necessary standards to support the latter are very much in the early stages.

- **II-C: Clinical Decision Support**
  - o Interoperability Need: Shareable Clinical Decision Support
    - ▪ We suggest that this is a good example of where many health IT developers would be concerned about beginning widespread implementation using these emerging standards. It should be clearer that these standards are in very early stages of definition.
  - o Interoperability Need: Provide Access to Appropriate Use Criteria
    - ▪ We suggest that this is a good example where many health IT developers would be concerned about beginning widespread implementation using these emerging standards. It should be clearer that these standards are in very early stages of definition. For example, the Government Accountability Office (GAO) profile still requires critical input from the Centers for Medicare and Medicaid Services (CMS) before it can be widely used.
  - o Interoperability Need: Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims.
    - ▪ We suggest that, as also indicated in our letter to CMS on appropriate use criteria (AUCs) (attached), the CDS-OAT profile is not applied with a requirement to use the full underlying RAD framework and corresponding order messages, but rather that CDS-OAT can be used in combination with any other valid HL7 V2 order message. Separately, we then can focus on what the relevant implementation specification should be for communicating any imaging order to an imaging center to mature the transition from paper to electronic order management.

- **II- D: Clinical Quality Measurement**
  - o Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives
    - ▪ No comment

- **II-E: Clinical Quality Reporting**
  - o Interoperability Need: Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives
    - ▪ To be consistent with other areas, we suggest making reference to FHIR-based activities to express quality measures and reports using FHIR resources, whether to be used as part of application programming interfaces (APIs), documents, or otherwise.
    - ▪ However, generally the ISA should more clearly indicate that such activities are in very early stages and are mostly of interest to those who would like to contribute to the development of these standards, not to those who are making implementation decisions.
  - o Interoperability Need: Reporting Patient-level Quality Data to Federal Quality Reporting Initiatives

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- To be consistent with other areas, we suggest making reference to FHIR-based activities to express quality measures and reports using FHIR resources, whether to be used as part of APIs, documents, or otherwise.
- However, generally the ISA should more clearly indicate that such activities are in very early stages and are mostly of interest to those who would like to contribute to the development of these standards, not to those who are making implementation decisions.

- **II-F: Data Provenance**
  - Interoperability Need: Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners.
    - We suggest that the data provenance specifications should be marked as "emerging" to clarify that adoption is still in very early stages.
    - We suggest inclusion of a reference to the IHE XDS metadata standard to indicate that this addresses data provenance for document exchange.
    - This indicates a larger challenge: data provenance should not be defined in its own section; but, rather, it should be part of all other exchange standards to highlight, as necessary, that it includes the necessary data provenance metadata or point to the standard to be used to further document data provenance. There are no transactions, services, or documents that just convey data provenance as it always should be part of the exchange of the main data set in focus.

- **II-G: Drug Formulary & Benefits**
  - Interoperability Need: The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems
    - No comment

- **II-H: Electronic Prescribing**
  - Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy
    - No comment
  - Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the Pharmacy
    - No comment
  - Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription
    - No comment
  - Interoperability Need: Cancellation of a Prescription
    - No comment
  - Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status
    - No comment
  - Interoperability Need: A Prescriber's Ability to Obtain a Patient's Medication History
    - No comment
  - Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor.
    - No comment
  - Interoperability Need: Prior Authorization Cancel Request
    - No comment

- **II-I: Family health history (clinical genomics)**

- o   Interoperability Need: Representing Family Health History for Clinical Genomics
  - ▪   No comment
- o   Interoperability Need: Representing Patient Family Health History Observations
  - ▪   This section appears to be a repeat from the *Vocabulary* section, as this does not represent a structural standard. We suggest this be removed.

- **II-J: Images**
  - o   Interoperability Need: Medical Image Formats for Data Exchange and Distribution
    - ▪   No comment
  - o   Interoperability Need: Format of Medical Imaging Reports for Exchange and Distribution
    - ▪   No comment
  - o   Interoperability Need: Format of Radiology Reports for Exchange and Distribution
    - ▪   We believe the industry is not ready to support inclusion of this specification into the main ISA. Further piloting is required to provide a sufficient starting point for the industry to adopt. We suggest that this needs to be marked as an emerging implementation specification.

- **II-K: Laboratory**
  - o   Interoperability Need: Receive Electronic Laboratory Test Results
    - ▪   No comment
  - o   Interoperability Need: Ordering Labs for a Patient
    - ▪   No comment
  - o   Interoperability Need: Support the Transmission of a Laboratory's Directory of Services to Health IT.
    - ▪   While the adoption level was appropriately downgraded, we suggest that this should be further downgraded to one bullet as there is little EHRT that supports this capability.

- **II-L: Medical Device Communication to Other Information Systems/Technologies**
  - o   Interoperability Need: Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies
    - ▪   We suggest to include the following implementation specifications specifically:
      - •   IHE-PCD (Patient Care Device Profiles) - Communication Management (ACM)
      - •   IHE-PCD (Patient Care Device Profiles) - Device Enterprise Communication (DEC)
      - •   IHE-PCD (Patient Care Device Profiles) - Implantable Device – Cardiac Observation (IDCO)
      - •   IHE-PCD (Patient Care Device Profiles) - Point-of-Care Infusion Verification (PIV)
      - •   IHE-PCD (Patient Care Device Profiles) - Rosetta Terminology Mapping (RTM)
    - ▪   These specifications are all final, in production, with an adoption level of two bullets, and freely available.

- **II-M: Patient Education Materials**
  - o   Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge From Online Resources
    - ▪   No comment

- **II-N: Patient Preference/Consent**
  - ○ Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share Their Health Information with Other Care Providers
    - ▪ No comment

- **II-O: Public Health Reporting**
  - ○ Interoperability Need: Reporting Antimicrobial Use and Resistance Information to Public Health Agencies
    - ▪ We suggest adding a Limitations, Dependencies, and Preconditions for Consideration bullet that the IHE SDC profile depends on the IHE RFD profile, which is final text.
  - ○ Interoperability Need: Reporting Cancer Cases to Public Health Agencies
    - ▪ No comment
  - ○ Interoperability Need: Case Reporting to Public Health Agencies
    - ▪ No comment
  - ○ Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies
    - ▪ No comment
  - ○ Interoperability Need: Sending Health Care Survey Information to Public Health Agencies
    - ▪ No comment
  - ○ Interoperability Need: Reporting Administered Immunizations to Immunization Registry
    - ▪ No comment
  - ○ Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)
    - ▪ No comment

- **II-P: Representing Clinical Health Information as a "Resource" [See Question 13, Section IV]**
  - ○ Interoperability Need: Representing Clinical Health Information as a "Resource"
    - ▪ We are concerned with this use case as it does not represent a user need, but rather a technology/architectural approach. A use case should focus on the users' interoperability needs that in turn may indicate whether it is most appropriate to use a document, message, or service approach, or whether a query for data should be able to return data element-level responses. The ISA should not at any point indicate how software solutions are internally architected, rather only how data should be exchanged.
    - ▪ However, if the interoperability need is stated to have access to individual data elements such as those defined in the Common Clinical Data Set (CCDS) to enable query/view of such data by third-party applications, or to enable focused data collection (two separate interoperability needs), then this section may be appropriate, but should be included in Section III. We note that Section III already includes a data element-level query interoperability need but not yet an update/write need.

- **II-Q: Research**
  - ○ Interoperability Need: Submission of Analytic Data to FDA for Research Purposes
    - ▪ No comment
  - ○ Interoperability Need: Pre-population of Research Forms from Electronic Health Records
    - ▪ No comment

- o Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements
  - ▪ No comment
- o Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements
  - ▪ No comment
- o Interoperability Need: Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators
  - ▪ No comment
- o Interoperability Need: Complete Disease Registry Forms and Submit to Reporting Authority (ACC)
  - ▪ No comment
- o Interoperability Need: Registering a Clinical Trial
  - ▪ No comment

- **II-R: Segmentation of sensitive information**
  - o Interoperability Need: Document-Level Segmentation of Sensitive Information
    - ▪ We believe that there still remains too much variance within this subset to be recognized for use now. That is, the vocabulary is not universally understood and, although some concepts are well-defined, others are completely unusable. There is a mix of codes that are just flags with other codes that are demands (obligations). This approach makes it unclear as to what should be done with the codes either on the publication side or the use side. Ultimately, even this subset of DS4P requires further implementation guidance or profiling. We recommend that the Advisory includes no more than the DS4P subset refined by the IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P), noting that piloting is insufficient.
    - ▪ As the EHRA commented on the first version of the Interoperability Standards Advisory in May 2015, we are concerned with the maturity of this standard. While DS4P is clearly used as part of C-CDA, it is only used at the document level. For section/data element level segmentation, this should be referred to as an emerging implementation specification. The terminology *"Document-level segmentation of sensitive information"* is confusing and ambiguous in this regard. We suggest that the limitations to document-level vs. section-level be clearly indicated in the Limitations section to avoid the perception that this may include section-level segmentation. Introducing a new section as drafted below may help clarify this further. We suggest that the adoption level be changed to no more than two bullets to appropriately reflect adoption.
    - ▪ We suggest also that this capability is typically applied in the context of conveying other information (e.g., sharing of a C-CDA). Therefore, this capability may be better addressed in other use cases where this standard would be applicable.

- **II-S: Summary care record**
  - o Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider
    - ▪ No comment

Section III: Standards and Implementation Specifications for Services

- **III-A: "Push" Exchange**
  - Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems
    - The reference to FHIR remains very confusing in this context, even with the explanation in the Limitations section. Is FHIR intended to be referenced for its transport or its representation of a payload? Some interpret FHIR as RESTful (although it is not limited to that), and others recognize FHIR for all its resource definitions/syntax. Perhaps the entry should just be RESTful FHIR Document Resource-based API Specifications.
    - We suggest clarifying how to use the numbers in the first column on each row.
    - It is unclear why the MHD row includes both 3 and 4. Rather, we suggest it should be 4 as it only works with RESTful FHIR Document Resource-based APIs
    - We suggest adding SOAP as Final, Production, four bullets, Yes, Free, Yes.
    - For IHE-XDR standard, we suggest adding a link for the test tool: http://ihexds.nist.gov/.
  - Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems
    - For IHE-XDR standard, we suggest to add a second link for a test tool: http://ihexds.nist.gov/.
  - Interoperability Need: Push Communication of Vital Signs from Medical Devices
    - No comment

- **III-B: Clinical Decision Support Services**
  - Interoperability Need: Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision support
    - We note that the OAT profile is a message-based profile based on HL7 V2, not a service-based specification. Consequently, it does not belong in Section III, rather it should be in Section II.
  - Interoperability Need: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care
    - No comment

- **III-C: Image Exchange**
  - Interoperability Need: Exchanging Imaging Documents Within a Specific Health Information Exchange Domain
    - We suggest that MHD-I should be listed together with FHIR (as above), IHE-PDQm, and IHE-PIXm. Both PDQm and PIXm should be balloted draft, pilot, and one bullet for adoption level.
    - We suggest including PDQm, PIXm, and RESTful FHIR Document Reference-based API Specifications.
    - For XDS-1.b implementation specification we suggest to add a link to the test tool: https://gazelle.ihe.net/content/xdstarclient.
    - For IHE-PIX implementation specification, we suggest to change Test Tool Availability to Yes and to add a link to the test tool: https://gazelle.ihe.net/content/patient-manager-pixpixv3-identity-cross-reference-manager
    - For IHE-PDQ implementation specification, we suggest to change Test Tool Availability to Yes and to add a link to the test tool:

https://gazelle.ihe.net/content/patient-manager-pdqpdqv3-patient-demographic-consumer.

- o Interoperability Need: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain
  - ▪ For the XCA implementation specification, we suggest adding a link to the test tool: https://gazelle.ihe.net/content/xdstarclient.
  - ▪ For XCPD implementation specification, we suggest to change Test Tool Availability to Yes and to add a link to the test tool: https://gazelle.ihe.net/content/xcpd-responding-gateway.

- **III-D: Healthcare Directory, Provider Director**y
  - o Interoperability Need: Listing of Providers for Access by Potential Exchange Partners
    - ▪ For the HPD implementation specification we suggest to add a second link for the test tool: https://gazelle.ihe.net/content/xdstarclient.

- **III-E: Public Health Exchange**
  - o Interoperability Need: Query/Response for Immunization Reporting and Exchange
    - ▪ We suggest the interoperability need should be clarified that it is the "Transport for Query/Response for Immunization Reporting," which can be used in combination with the Immunization implementation guide used for the content. Without that clarification, there is confusion about whether this replaces the Immunization implementation guide.

- **III-F: Publish and Subscribe**
  - o Interoperability Need: Publish and Subscribe Message Exchange
    - ▪ We suggest that the ISA should include more than go-forward standards; we should also indicate when existing standards are at end-of-life. We suggest that the NwHIN specification falls in that category and should not be promoted moving forward.
    - ▪ For the DSUB implementation specification we suggest to change the Test Tool Availability to Yes and to add the link to the test tool: https://gazelle.ihe.net/content/xdstarclient.

- **III-G: Query**
  - o Interoperability Need: Query for Documents Within a Specific Health Information Exchange Domain
    - ▪ MHD is based on the FHIR document resource. We suggest also adding the PIXm and PDQm standards targeted to apply this interoperability need in the mobile space. We suggest adding them as follows:
      - • 2,2 - Emerging Implementation Specification; IHE-PIXm (Patient Identifier Cross-Reference for Mobile); Balloted Draft; Pilot; 1 bullet; No; Free; No
      - • 2,3 - Emerging Implementation Specification: IHE-PDQm (Patient Identifier Cross-Reference for Mobile); Balloted Draft; Pilot; 1 bullet; No; Free; No
    - ▪ Additionally, we suggest to modify the Limitations section to read:
      - • IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need along with XDS.
      - • IHE-PIXm and IHE-PDQm are used for the purposes of patient matching and to support this interoperability need along with MHD.

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- The MHD, PIXm and PDQm profile supplements are is based on the most recent version of FHIR, the FHIR DSTU 2.0. Test tools are planned by IHE in 2017.
- See IHE projects in the Interoperability Proving Ground.
  - For the XDS implementation specification. we suggest adding links to two test tools: http://ihexds.nist.gov/ and https://gazelle.ihe.net/content/xdstarclient.
  - For the PDQ implementation specification, we suggest adding a link to one test tool: https://gazelle.ihe.net/content/patient-manager-pdqpdqv3-patient-demographic-consumer.
  - For the PIX implementation specification, we suggest adding a link to one test tool: https://gazelle.ihe.net/content/patient-manager-pixpixv3-identity-cross-reference-manager.
- o Interoperability Need: Query for Documents Outside a Specific Health Information Exchange Domain
  - For the IHE-XCA implementation specification, we suggest changing the Test Tool Availability to Yes, and to add a link to the test tool: https://gazelle.ihe.net/content/xdstarclient.
  - For the IHE-XCPD implementation specification, we suggest changing the Test Tool Availability to Yes, and to add a link to the test tool: https://gazelle.ihe.net/content/xcpd-responding-gateway.
- o Interoperability Need: Data Element Based Query for Clinical Health Information
  - No comment

- **III-H: Resource Location**
  - o Interoperability Need: Resource Location Within the US
    - No comment

Section IV: Questions and Requests for Stakeholder Feedback

General

1. For each standard and implementation specification there are six assessment characteristics, for which detailed information has been received and integrated. However, some gaps remain. Please help complete information that is missing or noted "feedback requested." Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct.
   - Answer: See our feedback above.

2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.
   - Answer: See our feedback above

3. For the Implementation Maturity characteristic for the standards and implementation specifications, ONC plans to publish a link, where available, to published maturity assessments based on known published criteria. Please help identify any publications that are publically available and provide the hypertext links to those resources.
   - Answer: We suggest using a set of pragmatic criteria. We are not aware of an analysis for establishing a broad set of such criteria along with the evaluation to confirm the robustness of these criteria. We could suggest one for these criteria, the results of the structure testing event, testing

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actual implementations for interoperability such as the IHE Connectathons.

These results linked to a "named" developer have been used for many years by public authorities, industry and health information exchange projects world-wide as a gauge for maturity of the specifications to determine whether the specification is ready for wider adoption. It is important to set clear requirements for the rigor of the Developer Testing Event.

We suggest using the IHE Connectathon rigor that has demonstrated its effectiveness: formally registered developer participants, publicly available test plans, oversight and passing/failing judgments from qualified and neutral monitors under formal management, resulting in updated and published specifications, as well as implementers feedback and maturity. This drives wider adoption.

Additionally, as part of HL7's FHIR development the introduction of the FHIR Maturity Model (FMM) also introduced rigor to measure the maturity of the specifications. As the FHIR development process further matures, the FMM rating is being refined with the expectation that it is a reliable gauge when a resource, profile, or other FHIR artifact is ready for adoption as a standard for wider implementation.

To further inform whether the Implementation Maturity is moving from pilot to production, using information from efforts such as the emerging IHE's Conformity Assessment or HIMSS Concert can determine whether the specification is not only ready for wider implementation by applications, but also whether applications have been enabled and conform to the specification and are ready for wider implementation by the user community.

4. For the Adoption Level characteristic for the standards and implementation specifications, ONC plans to publish reference annotations or links to publicly available documentation known about adoption levels for listed standards. Please help identify any publications that are publicly available and provide the hypertext links to those resources.
   - Answer: This is an area where the EHRA would like to see more information on the sources that lead to the adoption levels identified. We have an Interoperability Measurement Task Force exploring this area to determine what metrics could be made available.

5. For the Test Tool Availability characteristic for the standards and implementation specifications, ONC plans to publish references, where available, to the publicly available test tool. Please help identify any publicly available test tools.
   - Answer: We have provided suggested updates in the detailed responses above.

Section I: Vocabulary/Code Set

6. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets.
   - Answer: See feedback above.

7. For subsection I-D: Functional Status/Disability, the Health Information Technology Standards Committee recommends using SNOMED®/LOINC® observation paring for this interoperability need. Do you support this approach?
   - Answer: We support this approach.

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8. For subsection I-H: Industry and Occupation, there continues to be varied opinion on the standards or implementation specifications to be sited in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.
   - Answer: See feedback above.

9. For subsection I-R: Sexual Orientation and Gender Identity, Interoperability Need: Representing patient sex (at birth), what are the appropriate genetic identifiers or gender determinants (e.g., gonadal sex, karyotype sex) for potential inclusion in the ISA.
   - Answer: See feedback above.

10. For subsection I-S: Social Determinants please help identify the adoption level of LOINC® for each of the Interoperability Needs.
    - Answer: See feedback above.

11. Are there additional psychosocial Interoperability Needs with corresponding standards that should be included in the ISA?
    - Answer: See feedback above.

12. For subsection I-T: Tobacco Use (Smoking Status), because of the current limitations, what surveys, instruments or tools are being used to collect tobacco use information that is more complete that the current coding methodologies?
    - Answer: See feedback above.

Section II: Content / Structure

13. For the existing interoperability need, "representing clinical health information as a resource," public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.
    - Answer: See feedback above.

14. Opinions vary in the way (messaging vs. transport) the ISA should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.
    - Answer: We suggest representing FHIR as content for the appropriate use case. When the use case needs to clarify the transport, there should be a separate/additional perspective which does not have to use "FHIR," rather "RESTful" or "SOAP" or whatever is appropriate.

Appendix I: Sources of Security Standards
15. Are there other authoritative sources for Security Standards that should be included in Appendix I?
    - Answer: No comment.

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HiMSS Electronic Health Record Association

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Office Practicum
Practice Fusion
QuadraMed Corporation
Sevocity, Division of
    Conceptual MindWorks Inc.
SRS Software, LLC
STI Computer Services
Vālant Medical Solutions, Inc.
Varian Medical Systems
Wellsoft Corporation

March 24, 2016

JoAnna Baldwin
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Baldwin,

On behalf of the Electronic Health Record (EHR) Association member companies, we want to thank you for giving us the opportunity in the listening session held on February 5, 2016 to provide our feedback to the Protect Access to Medicare Act (PAMA 218) provision for appropriate use criteria (AUC) for advanced diagnostic imaging. As discussed, we would like to offer additional comments and recommendations in this letter and the attached appendix on the implementation of AUC in health information technology (IT).

PAMA requires that physicians ordering advanced diagnostic imaging consult with qualified clinical decision support (CDS) systems and provide the furnishing professional with information confirming that consult by January 1, 2017. The EHR Association appreciates the recognition by the Centers for Medicare and Medicaid Services (CMS) that this date is unrealistic, given the very short time between the detailed requirements being available in the final 2017 Physician Fee Schedule (PFS) rule (anticipated sometime before November 1, 2016) and the proposed implementation date. As CMS considers setting a revised date in the forthcoming regulation, the Association reiterates our comments to the 2016 PFS proposed rule [http://www.ehra.org/docs/EHRA%20Comments%20PFS%20NPRM.pdf]. We strongly urge CMS to consider the time needed to successfully implement the program, inclusive of finalizing the necessary interoperability standards and guidance discussed in the appendix, as well as efforts to enter into business agreements with AUC content providers. In addition, adequate time must be allowed for software developers to code, test, and deliver this new software after approved AUC mechanisms become
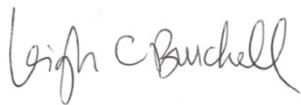
available, as well as for providers to implement the new software and educate their providers on the appropriate workflow requirements. While we usually suggest that 18 months is the amount of time needed between the release of final regulations (including all necessary detailed guidance) and the use of updated software versions to comply with new rules, in this case, because of negotiations that are required with content providers, we suggest that at least 24 months would be required.

Additionally, as discussed in the attached appendix, we strongly suggest that CMS and the Office of the National Coordinator for Health IT (ONC) consider whether there might be a simpler approach to the complex data flow than what is currently proposed. We would welcome participation in any discussion with the appropriate stakeholders in order to find a more optimal workflow.

Finally, the attached appendix includes our detailed comments and recommendations around the current and most optimal state of the standards that are needed to support the successful implementation for our customers.

We appreciate the opportunity to provide feedback to CMS and ONC, and look forward to our ongoing collaboration towards our shared goals of more effective, efficient healthcare for all Americans.
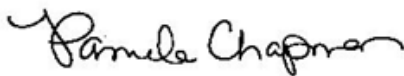
Sincerely,

Leigh Burchell
Chair, EHR Association
Allscripts

Sarah Corley, MD
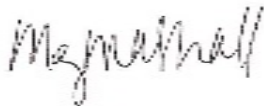Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion

Meg Marshall, JD
Cerner Corporation

Rick Reeves, RPh
Evident

Ginny Meadows, RN
McKesson Corporation

Sasha TerMaat
Epic

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cc: Sarah Fulton, CMS

Joseph Hutter, CMS

Kevin Larsen, ONC

Appendix 1

Suggestions for Appropriate Use Criteria (AUC) to the Centers for Medicare and Medicaid Services (CMS) for Upcoming Physician Fee Schedule (PFS) Notice of Proposed Rulemaking (NPRM)

As multiple professional societies and other organizations can offer appropriate use criteria (AUC) and supporting mechanisms, it is important to ensure that industry-accepted standards are available and supported to enable minimum, core interoperability. We note, however, that this policy approach should not preclude individual trading partners from utilizing other and/or more comprehensive interoperability capabilities, as long as the minimum, core standards remain available as a choice out-of-the-box.

While we suggest standards below for integrating decision support as part of placing orders, we do not think that standards for decision support triggered by orders should preclude or restrict other approaches. For example, in a case where an electronic health record (EHR) that integrates clinical decision support (CDS) rules has already assessed and perhaps even suggested the need for an order for advanced imaging, this would satisfy the requirement.

We note that the current proposed flow of data involves five or six integration points. These integration points include:

- Local AUC mechanism to knowledge provider;
- Order placer to AUC mechanism;
- Order placer to radiology information system (RIS);
- RIS to accounting;
- Revenue management to CMS;
- CMS to AUC mechanism to validate/audit claims.

The complex data flow as suggested would create potential challenges with scaling, considering the number of these connections. Additionally, the benefits primarily lie with the fulfilling provider at the imaging center, thus making it challenging to prompt the engagement of the ordering provider and justify their investments into the necessary technology. We suggest that there is a simpler approach that would instead require the imaging center to serve as the primary source of AUC data and, through arrangements between the imaging center and ordering provider, encourage availability of relevant clinical data that support the image request.   With such an approach, further interaction with the ordering provider may only need to occur in case of failure to obtain an appropriate AUC, thus improving efficiency. Perhaps further discussions among parties such as CMS, the Office of the National Coordinator for Health IT (ONC), the American College of Radiology (ACR), the American College of Physicians (ACP), and the American Medical Association (AMA), as well as standards developers such as HL7, X12, and IHE, will help find a more optimal flow.

We note that in cases where data fields have been added or changed in claim forms, there have been substantial disruptions in health care operations, as well as substantial costs to the industry. Based on

CMS 2011 data for top procedures, this new workflow will affect some 23 million orders[1] and, if current trends were continued, would affect approximately 29 million orders in 2017. Based on prior experiences with changes like use of X12 5010 and inclusion of the national provider identifier (NPI) in claims, we would expect similar experiences with delays in processing claims, and increased rejection rates on the order of 10-40%,[2] given the fact that this proposed flow has numerous moving parts and thus the opportunity for more inefficiencies or errors.

Assuming the currently proposed flow and associated interoperability, while standards and implementation guidance are emerging, further efforts are required to solidify these guides. Specifically:

- ***Local AUC mechanism to knowledge provider***
  To support communication of appropriate use criteria definitions/knowledge, HL7's Clinical Decision Support Knowledge Artifact Implementation Guide should be considered. However, we also note that given the anticipated volume of content and change, the presence of such standards is not critical, nor should support of such standards by developers be required. Either way, to further spur innovation, we do suggest that appropriate use criteria knowledge/definitions/algorithms be available in an open, no-cost, computable format.
- ***Order Placer to AUC mechanism***
  To support access to a remote AUC mechanism at time of order placement, HL7's Guidelines on Appropriate Ordering should be considered. This FHIR-based implementation guide has gone to both an IHE and HL7 ballot. The materials have been through initial testing at IHE Connectathon and were demonstrated at RSNA in November of 2015 and at HIMSS in February 2016. However, further refinement will still be necessary once there is clarity on exactly what information is to be communicated from the AUC mechanism to the ordering provider, on to the filling provider, and finally included on a claim. The HL7 ballot is still undergoing reconciliation, which is conservatively expected to be completed in late summer, with subsequent publication in the second half of the year.
- ***Order Placer to RIS, RIS to Accounting***
  To support the communication of the AUC data with the order and charge to the fulfilling provider and revenue management system respectively, where multiple systems are involved, IHE's CDS-OAT profile is emerging as the relevant implementation guide. We note that in this space a variety of HL7 V2-based implementations are in production, not necessarily using the IHE Radiology Technical Framework. For communication of AUC data, we believe it only necessary to indicate that orders for advanced imaging use any version of HL7 Version 2, and comply with requirements for the OBR and OBX segments specified in the Placer Order Management transaction (RAD-2). Such a statement would not require complete conformance with RAD-2, nor with the CDS-OAT profile, enabling systems which do not use that specification for imaging ordering to continue to use whatever HL7 Version they presently use, but would require that the CDS information be communicated consistently in all systems. Please note that the CDS-OAT profile is also considered to be in trial implementation, and is expected to change based upon feedback from the IHE Connectathon, as well as the HIMSS and RSNA

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[1] See Part B Physician/Supplier National Data - CY - 2011 Top 200 Level 1 Current Terminology (HCPCS/CPT) Codes. http://bit.ly/Top200-Level1-2011
[2] 5010 Payment Claims Rejected? Clearinghouse Official Reveals Possible Reasons Why. 15-Feb-2012. AAFP News; Conn J. Up to 37% of Medicaid claims rejected after NPI. 30-May-2008. Modern Healthcare

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demonstrations that took place in Q4 2015 and Q1 2016. We expect revisions of this profile with more readily citable requirements to be available in the second half of 2016.

- ● **_Revenue Management to CMS_**
  To support the inclusion of the AUC data on the claim, updates to the X12 guidance must be provided. We understand that this work has not yet started, while X12 is preparing the 7030 version to be finalized this summer for consideration for inclusion in the next HIPAA version. We suggest that the next HIPAA version includes the necessary guidance on how to communicate the necessary AUC data.

- ● **_CMS to AUC mechanism to validate/audit claims._**
  Once the claim has arrived at CMS, we anticipate that some form of validation and/or audit is required. Depending on the format of the AUC data (e.g., some form of token vs. individual data), CMS may need to access the original AUC data generated by the AUC mechanism. We suggest that such a process does not involve the need for ongoing validation access to the ordering provider's health IT, but rather involves a separate registry populated by the AUC mechanism provider, direct access to the AUC mechanism provider, or achievement through an immutable token that contains all the information necessary to perform a comparison with the claim.

We strongly suggest that the AUC information be streamlined so that both the ordering and imaging provider workflow is simpler, more readily accomplished, and less prone to failure due to the many sequential steps described under the current requirements. We believe that section (q)(4)(B) of the legislation pertaining to information about the evaluation could be satisfied by providing a token that could be verified and queried via the certified AUC mechanism provider.

To further support these enhancements to finalize guidance, it is critical that CMS clarify exactly what AUC data is to be communicated from the AUC mechanism to the ordering provider, on to the filling provider, and finally included on a claim. We strongly suggest that the AUC information requirements be streamlined so that both the ordering and imaging provider workflow is simpler, more readily accomplished, and less prone to failure due to the many sequential steps described under the current requirements. As previously stated, we believe that this work should be done in consultation with relevant SDOs (e.g., HL7 and IHE) in order to ensure optimal workflow. To that end, we also suggest that AUC should be based on industry standard vocabularies such as SNOMED and ICD-10, rather than any development of separate, appropriate use criteria vocabulary that may not fit in the ordering providers' workflows or add additional translation steps. The more components that are added to a provider's workflow, the less likely it will be successfully adopted.

Adequate time must be available to complete these standards and implementation guides, including initial testing and pilots, as well as time for relevant HIT to incorporate such support and roll it out to their clients, who in turn must implement these. **_Again, we reiterate given the additional work that will need to be done should this work proceed, at least 24 months would be required from the time that final regulations and supporting materials are available before providers are required to comply._**