REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-13

Subject: Medical Record and Reporting Standardization Update

Presented by: Charles F. Willson, MD, Chair

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At the 2012 Interim Meeting, the House of Delegates adopted as amended Council on Medical Service Report 2-I-12, "Medical Record and Reporting Standards," which was amended to direct the development of a "report back to the House on progress with regard to medical record and reporting standardization" (Policy D-260.995[4]). The Board of Trustees referred the requested study to the Council on Medical Service for a report back to the House at the 2013 Interim Meeting.

## BACKGROUND

Testimony at the 2012 Interim Meeting was in strong support of standardizing laboratory and radiology reports. Speakers stressed the urgency of addressing usability and standardization of laboratory report results, making the American Medical Association's (AMA) involvement with the Office of the National Coordinator for Health Information Technology (ONC) a high priority and supporting the continued efforts of relevant national medical specialty societies to clarify terminology and work in consultation with physicians likely to be end users. This follow-up report was requested due to this issues' impact on patient safety, quality of care and physician efficiency. For example, physicians who work in more than one hospital or interface with more than one laboratory must often review incongruent report formats that may compromise patient safety and quality of care.

Since the 2012 Interim Meeting, the AMA has continued to advocate on behalf of physicians regarding electronic health records (EHRs), including standardized laboratory reports. The AMA has been involved in advocating for physician safeguards in the Medicare/Medicaid meaningful use EHR program and continues to advocate that the meaningful use laboratory requirements be more flexible.

## AMA ADVOCACY

### *Meaningful Use Program*

Established under the American Recovery and Reinvestment Act (ARRA) of 2009, the meaningful use program went into effect as an EHR incentive program in 2011. The AMA has provided ongoing input since the inception of the program and has urged greater flexibility to make the program more reasonable and achievable for physicians. In May 2012, in response to the proposed rule for meaningful use Stage 2 requirements, the AMA and 100 state medical associations and national medical specialty societies commented on the proposed Department of Health and Human Services (HHS) requirements, including the use of standardized laboratory formats in EHRs.[1] The comments provided recommendations to eliminate physician barriers and encourage greater physician participation. The AMA supports widespread EHR adoption and use, but has repeatedly expressed concern that the meaningful use program has been moving toward

Stage 3 without a comprehensive evaluation of the earlier stages to resolve existing problems. The AMA advocates that a full evaluation of Stages 1 and 2, in addition to more flexible program requirements, will help physicians in different specialties and practice arrangements successfully adopt and use EHRs.

In January 2013, the AMA submitted formal comments to ONC on the Health Information Technology Policy Committee's proposal for Stage 3 of the meaningful use program requirements.[2] ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology (HIT) and the electronic exchange of information. The AMA's comment letter outlined the following five concerns and recommendations to improve the program:

- The program lacks an evaluation process: An external, independent evaluation is necessary to improve and inform the future of the program.

- A 100 percent pass rate is not the right approach: The pass rate should be reasonable and achievable. Failing to meet just one measure by one percent would make a physician ineligible for incentives and subject to financial penalties.

- One size does not fit all: Program requirements should be more flexible and better structured to accommodate various practice patterns and specialties.

- Usability of certified EHRs should be addressed: EHRs should facilitate care coordination, practice efficiencies and enhance processes that improve health outcomes.

- HIT infrastructure barriers should be resolved: Infrastructure improvement that allows an efficient and secure electronic information exchange must be a priority because the current HIT infrastructure does not enable physicians to readily share electronic patient data with other health care providers.

The AMA comment letter to ONC on Stage 3 of the meaningful use program helped persuade HHS in March 2013 to announce a delay in rulemaking for Stage 3.[3] Accordingly, HHS is assessing the program's success and reviewing input from stakeholders. In addition, the agency plans to use this delay in Stage 3 implementation to focus on achieving greater interoperability across EHR systems and to increase the exchange of health information.

AMA advocacy efforts also directly resulted in convincing Congress to pay more attention to the overall meaningful use program, which includes the certification of EHR products for use in the program. A group of Senators consisting of John Thune (R-SD), Lamar Alexander (R-TN), Pat Roberts (R-KS), Richard Burr (R-NC), Tom Coburn (R-OK) and Michael Enzi (R-WY) has been convened to review the meaningful use program and determine whether there is a need to make changes. The Senators issued a white paper in April 2013, entitled "Reboot: Re-examining the Strategies Needed to Successfully Adopt Health IT," which outlines the following key implementation deficiencies in the meaningful use program: lack of a clear path toward interoperability, increased costs to the health care system, lack of oversight to prevent waste and fraud, patient privacy being put at risk, and program sustainability. [4] The white paper solicited feedback from the administration and stakeholders. In response, the AMA submitted formal comments in strong support of the need for incentives to help drive future EHR adoption, while also outlining a series of recommendations expressing concerns with the way the meaningful use program has been structured and the direction it is moving.[5] In July 2013, AMA Chief Executive

Officer and Executive Vice President James L. Madara, MD, and the American Hospital Association's President/Chief Executive Officer Rich Umbdenstock issued a joint letter to HHS Secretary Kathleen Sebelius regarding the meaningful use program.[6] The letter provided the following recommendations advocating that the best way to move the program forward and ensure that no providers, particularly small and rural ones, are left behind is to realign the meaningful use program's current requirements to ensure a safe, orderly transition to Stage 2:

- Allow health professionals at Stage 1 to meet meaningful use requirements using either 2011 certified edition EHRs or 2014 certified edition EHRs.

- Establish a 90-day reporting period for the first year of each new stage of meaningful use for all health professionals, similar to what was allowed for Stage 1.

- Allow physicians and hospitals in meeting Stage 2 to avoid the "all or nothing" problem with requirements and recognize that the level of change desired in Stage 2 will take time to accomplish.

- Extend each stage of meaningful use to no fewer than three years for all health professionals.

*Usability of Electronic Health Records (EHRs)*

During his tenure as Chair of the AMA Board of Trustees, Steven J. Stack, MD, testified in May 2013 to the Centers for Medicare & Medicaid Services (CMS) on the EHR meaningful use program.[7] Dr. Stack stated that the AMA believes that EHRs, when done well, have the potential to improve patient care. However, EHRs present substantial challenges to physicians and other clinicians who are required to use them. Dr. Stack's testimony concluded with the following suggestions:

- ONC should immediately address EHR usability concerns raised by physicians and take prompt action to add usability criteria to the EHR certification process.

- CMS should provide clear and direct guidance to physicians concerning the permissible use of EHR clinical documentation for the purposes of coding and billing, including active dialogue with the physician community so as not to further hinder patient care or further erode physician productivity.

- Stage 2 of the meaningful use program should be reconsidered to allow more flexibility to providers to meet the requirements while the EHRs are better adapted to accommodate the diversity of clinical settings and appropriate variation in workflows.

In July 2013, the AMA provided testimony to ONC's Health Information Technology Policy Committee's workgroup on Adoption/Certification and Implementation regarding implementation and usability of certified EHRs.[8] The testimony outlined recommendations to ONC to improve the current certification process.

*Standardizing Laboratory Results*

In April 2013, the AMA submitted formal comments to CMS and ONC in response to a request for information on advancing interoperability and health information exchanges (HIEs).[9] Regarding

standards-based electronic exchange of laboratory results, the AMA outlined concerns pertaining to strict meaningful use requirements and costly laboratory interfaces.

In the comment letter, the AMA advocated that the meaningful use laboratory requirements must be more flexible. The incorporation of clinical laboratory results into EHRs as structured data is dependent on the EHR vendor and the laboratory, not just the physician's use of the EHR. HIT interoperability and standards efforts have continued to evolve, and industry adoption is steadily increasing. However, customized interfaces between an EHR and laboratory systems, which are predominantly hospital-based, do not exist on a widespread basis today. Even when they are technically feasible, customized interfaces are difficult and costly for physician practices to implement, test and maintain.

In many cases expensive customized EHR interfaces are still needed to support EHR integration with HIEs. Moreover, small or rural practices may never achieve a sufficiently high priority from the laboratory perspective to warrant the laboratory's implementation of an electronic interface. The AMA has received feedback from some physicians that even if they have made a formal request for an interface, they can expect to wait for long periods of time for their request to be prioritized. There have also been reports from physicians regarding the difficulties in matching patients within the laboratory compendium, resulting in problems with erroneous transactions and reports to incorrect patients.

Without the interface, physicians are excessively burdened with keying information into their EHRs in order to meet the meaningful use requirements or are faced with the possibility of having to purchase a costly interface. The AMA advocates that physicians and their staffs should not be expected to key in laboratory results simply because there is no ability for the laboratory to send these results directly to the EHR. The AMA advocates that it is incumbent upon ONC to ensure the interoperability of EHR systems. Specifically, ONC should advocate for a single standard that EHR vendors can adopt so that laboratory result interfaces can be easily created by EHR vendors and offered at little to no additional cost to physicians who use their products. The AMA's April 2013 comment letter suggested that CMS and ONC consider funding for these interfaces in order to further promote HIE in laboratories.

FEDERATION ACTIVITY

In preparation of this update on medical record and reporting standardization, the Council sought input from relevant members of the federation active on this issue. The College of American Pathologists and the American College of Radiology each provided invaluable insights regarding the depth and complexity of activity.

*The College of American Pathologists (CAP)*

CAP is an active participant on several of ONC's laboratory workgroups to advance laboratory interoperability and works on informatics initiatives that improve patient care, increase quality services, and reduce costs. In addition to actively participating in ONC's initiative on Structured Data, CAP has developed standardized cancer protocols and encoded, structured data templates incorporating the protocols to ensure comprehensive care and patient safety. The standardized cancer protocols streamline the flow of information to clinicians, public health entities, research registries and aid in decision support. Information on the protocols and electronic cancer checklists (eCC) are available on the CAP website at www.cap.org. Through its CAP Consulting division, CAP provides a range of advisory services and education to health care organizations to implement and improve the use of resources for standardization and interoperability. These advisory and

educational services include the management and use of clinical and diagnostic terminologies, such as Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT), International Classification of Diseases and Related Health Problems - 10th Edition (ICD-10), and Logical Observation Identifiers, Names and Codes (LOINC), among others (J. Cantor-Weinberg, Director, Economic and Regulatory Affairs, College of American Pathologists, email and oral communications, August 2013).

*The American College of Radiology (ACR)*

ACR develops and maintains various practice guidelines and technical standards related to radiology, interventional radiology, nuclear medicine, radiation oncology and medical physics. Among these are the ACR Practice Guideline for Communication of Diagnostic Imaging Findings, which addresses narrative formats and reporting by interpreting physicians; and the American College of Radiology, American Association of Physicists in Medicine and the Society for Imaging Informatics in Medicine (ACR-AAPM-SIIM) Technical Standard for Electronic Practice of Medical Imaging, which includes information on standards related to image and associated data exchange.

ACR's IT and Informatics Committee recently initiated a project known as ACR Commons to standardize terminology for radiologic procedures based on defining components of metadata that construct specific procedures. ACR believes that this activity will be critical for concepts like structured interpretative reporting, and will differ from other structured reporting and vocabulary standard initiatives because it will allow for flexibility, localization, and simplification. For example, ACR Commons will enable explicit procedure labeling as would be needed by radiologists and others, while also enabling less comprehensive descriptions of radiologic procedures and findings for ordering physicians and others without losing electronic or clinical meaning. ACR Commons will eventually be used in ACR's clinical decision support (CDS) product, reporting systems and registries related to ACR's imaging facility accreditation programs, and various HIT solutions.

ACR is involved in a variety of relevant multi-organizational standards development initiatives, including "Digital Imaging and COmmunication in Medicine" (DICOM) and Integrating the Healthcare Enterprise (IHE), the latter of which is an initiative by health care professionals and industry groups to improve the way computer systems in health care share information (M. Peters, Director, Regulatory and Legislative Affairs, American College of Radiology, email communication, August 2013).

AMA REPORTS AND POLICY

AMA policy advocates for collaboration with federal entities, specialty societies and laboratories to support the meaningful use of HIT. The AMA will continue to prioritize its involvement with ONC's Health Information Technology Policy and Standards Committees urging the need for a process through which laboratory results can be communicated electronically (Policy D-260.995[1a]). Policy D-260.996 asks the AMA to work with the appropriate specialty societies and laboratories in the US for continued improvements in the reporting of clinical laboratory results.

Policy D-260.995[1b] supports AMA involvement in the appropriate initiatives to develop electronic standards and implementation guides for the electronic transmission of clinical laboratory results. Policy D-478.982 advocates working with federal entities to set realistic targets for meaningful use of electronic health records including laboratory results, and also supports

improving the electronic health records incentive program requirements to maximize physician participation.

In addition, Policy D-450.980[3] states that the AMA will continue to work with EHR system developers to ensure that the perspectives of practicing physicians are adequately incorporated, that standardization and integration of clinical performance measures are developed by physicians for physicians and to ensure a seamless integration of the EHR into the day-to-day practice of medicine. Policy D-478.995[2A] advocates for standardization of key elements of EMR and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology. The policy also advocates for more research on EHR, CPOE, clinical decision support systems, and vendor accountability for the efficacy, effectiveness, and safety of these systems (Policy D-478.995[2D]).

Policy D-260.995[3], updated by Council Report 2-I-12, asks the AMA to prioritize its involvement with ONC and its Health Information Technology Policy and Standards Committees. Policy D-260.995[2,3], also established by the Council with Report 2-I-12, encourages the College of American Pathologists, Health Level 7, the National Institute for Standards and Technology, and the Agency for Healthcare Research and Quality to urgently address usability and standardization of laboratory report results for physicians and non-physician practitioners to ensure patient safety. In addition, the policy supports the continued efforts of relevant national medical specialty societies, such as the American College of Radiology, the American Osteopathic College of Radiology and other like organizations whose members generate reports electronically to clarify terminology and work in consultation with physicians likely to be end users toward producing a standardized format with appropriate standard setting bodies for the presentation of radiology results, including clearly identifiable diagnoses and test results.[10]

Policy D-478.976[1a], established by Board of Trustees Report 23-A-13, advocates for CMS and ONC to support collaboration between and among EHR developers to help drive innovation in the marketplace. The policy also supports continued advocacy for research and physician education on EHR adoption, and to design best practices specifically concerning key features that can improve the quality, safety and efficiency of health care (D-478.976[1b]). The Board report concludes that it is important for the AMA to promote more transparency in the vendor marketplace, and to continue current advocacy efforts in support of usability, workflow, patient safety and interoperability.[11]

## CONCLUSION

The Council notes that the AMA has prioritized involvement with ONC as directed by Policy D-260.995[4]. Additional organizations such as the College of American Pathologists, the American College of Radiology, Health Level 7 (HL7), the National Institute for Standards and Technology, the Agency for Healthcare Research and Quality, and the American Osteopathic College of Radiology are all intensely engaged in ongoing efforts to address usability and standardization of laboratory and radiology reports. These organizations understand that medical record reporting, standardization and interoperability have an impact on patient safety, quality of care and physician efficiency. The AMA will continue to interact with these organizations and advocate for patient safety and usability issues associated with the use of EHRs.

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