



Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave., S.W.
Washington, DC 20201

RE: RIN 0991–AB58

Dear Dr. Blumenthal:

Intel appreciates this opportunity to comment on the Interim Final Rule on the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (Interim Final Rule). We know the HIT Standards Committee and the Office of the National Coordinator (ONC) have committed an extensive amount of time to developing these standards. To improve the quality and efficiency of the health care system, more than simple adoption of EHRs is needed. These standards, implementation specifications, and certification criteria will ensure the interoperability of the technologies by setting standards that will enable the exchange, receipt, and validation of the information. Intel commends the ONC for its development of this Interim Final Rule and would like to use this opportunity to make recommendations, which we feel will enhance the Interim Final Rule.

Intel is certainly known as a world leader in silicon innovation, but our company is not traditionally seen as a “health care” company.¹ Nonetheless, our technologies help to power the Internet, the broadband connected world, and many health care institutions around the world, who we increasingly work with to connect patients, families, providers, and health care

¹ Additional information about Intel is available at www.intel.com/pressroom and <http://blogs.intel.com/policy>.

researchers with one another. In fact, for more than a decade now, Intel has focused its research and development efforts specifically on health care to better understand how to connect all of the major players through a wide array of health information technologies. Intel social scientists, medical informaticists, clinicians, and engineers have studied more than 1,000 patient homes and 250 hospitals and clinics in more than 20 countries to inform the development of products and solutions that can help bring forth a connected world for health care, particularly for the care of seniors and chronic disease patients in the community through home-based health technologies. Five years ago, we formed a dedicated business group, the Intel Digital Health Group, which reports to the Chief Executive Officer and a dedicated brand, Intel Health, to focus our company's efforts on health care innovation.

Thus, Intel is *becoming* a health care innovation company that is broader than silicon. For example, Intel has designed the mobile clinical assistant (MCA) reference architecture. When used with appropriate software, the MCA enables clinicians to access patient care records at the point of care and document a patient's condition in real time. Intel has also developed and released the Intel Health Guide, which allows for remote patient monitoring (RPM) and care of chronic disease patients in their own homes with the Intel® Health Care Management Suite, an online interface that allows clinicians to monitor those patients and remotely manage care. Furthermore, Intel has developed SOA Expressway for Healthcare, which enables the exchange of health care information inside hospitals and within health information networks. We have created a group of validated independent software vendors (ISVs) that provide best-of-breed capabilities to deploy a complete health network powered by the Intel SOA Expressway. These capabilities include controlled medical vocabulary translation, clinical patient portal applications, enterprise master patient index, clinical data repository, and operating system support.

Intel also has a strong commitment to supporting industry-led, voluntary standards since market-driven solutions have often proved the best way to maximize the dynamic efficiencies of innovation and the beneficial effects on the economy. However, in order to protect the public welfare, the U.S. government may need to coordinate and specify certain technology requirements from time to time. As technology will evolve and present more efficient and effective solutions, requirements should also allow for flexibility that can reflect these market innovations. We support the many references within the ONC's Interim Final Rule, which acknowledge the role of the markets in determining which standards are most useful as technology changes and lessons are learned from patient experiences.

Interoperability

With our experience in developing advanced health technologies, we believe it is extremely important for the ONC, as well as the Centers for Medicare and Medicaid Services (CMS) which is developing the meaningful use definition for EHRs, to build on the existing advances in the HIT space, such as the ONC has done with the HL7 versions and National Council for Prescription Drug Programs (NCPDP) standards for medications, rather than to create an entirely new foundation. Many technologies are already employed by providers and are currently being used to improve patient monitoring, treatment, and outcomes. To the extent that these devices are already achieving the goals of Stage 1 meaningful use, and in many cases the goals of Stages 2 and 3, Intel is recommending that CMS' definition of meaningful use include language that will serve as a glidepath toward more extensive use of RPM devices and telehealth. Without incorporation of these technologies into the meaningful use rule and utilization by providers, EHRs will not demonstrate their full potential to capture patient data at the point of origin.

Intel notes that the HIT Policy Committee included incorporation of data from home monitoring devices as an objective for Stage 2 and medical device interoperability as an objective for Stage 3. We understand that the ONC will update the standards, implementation specifications, and certification criteria as needed to meet Stages 2 and 3 of meaningful use in future rulemakings, but we note the importance of ensuring that the initial set includes standards, implementation specifications, and certification criteria, where applicable, that will lay the foundation for widespread incorporation of these technologies in the future. We believe it is important and cost-efficient to build off the standards already being used in current products. Intel is pleased to see the adoption of many of the HL7v3 standards and would urge the ONC to consider the profiling work done by organizations such as Continua and the Healthcare Technology Standards Panel (HITSP). To ignore these standards is to discount years of progress in the HIT space that have already been made and, as a result, would drive up the cost of deployment.

The ONC has an opportunity to tighten implementation guidance around transmission standards through the development of Simple Object Access Protocol (SOAP) and Representational State Transfer (REST) profiles for each transaction type. Without such implementation guidance,

states and regional health information exchanges (HIEs) will develop independent approaches that will delay the national goal of interoperability.

Encryption

In the Interim Final Rule, the ONC states:

It is important to note, under 45 CFR 164.312(a)(2)(iv) and (e)(2)(ii), a HIPAA covered entity must assess whether encryption as a method for safeguarding electronic protected health information is a reasonable and appropriate safeguard in its environment.²

Intel supports CMS' decision to require Certified EHR Technology to be capable of encryption. Given the current state and availability of encryption technologies and practices, we believe encryption should never be optional, even while the specific implementation might vary within a constrained set of options. It is better to specify requirements, such as requiring personal health information (PHI) and personal identifiable information (PII) to be protected at rest and in transit (all industry-accepted methods that employ different forms of encryption). A database application might employ database encryption or disk-level encryption, along with encryption of sensitive login credentials and connection strings. Encryption in transit might employ Transport Layer Security/Secure Sockets Layer (TLS/SSL), Virtual Private Network (VPN) over SSL, or Hypertext Transfer Protocol (HTTP) over SSL (HTTPS), along with bidirectional authentication (using digital certificates or other two-factor authentication). In order to achieve EHR certification, the EHR system or module should be required to support transport and storage encryption or document how the equivalent protection is provided as a part of a comprehensive solution. Although entities can determine under HIPAA whether encryption is a reasonable and appropriate safeguard, we believe requiring Certified EHR Technology to have this capability will encourage the use of encryption throughout the implementation process and further increase confidence in the privacy of EHRs.

² Office of the National Coordinator for Health Information Technology, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2034 (January 13, 2010).

In addition, in Table 2B³, which lists the adopted privacy and security standards, Intel recommends that the encryption standards adopted in Row 1 should be stated as "minimum of" standards as the encryption strength is always increasing with the smaller key sizes and the older encryption algorithms are rapidly becoming obsolete.

Additionally, hardware encryption and security features built into Certified EHR Technology are available today and should be considered within adopted certification criteria accepted by the ONC. As discussed on pages 2034-2035 of the Interim Final Rule, Intel would like to recommend technologies for encryption and security that are emerging for the health care industry.

Intel has also been able to advance the security of the computer hardware by adding technology that will help secure the computer during the bootup process. This aspect of security will help ensure the computer that holds health related data is indeed secure – through hardware hooks which is ultimately the best security possible. Intel calls this Intel® Trusted Execution Technology. This capability is available in the Intel vPro product lines already available today. Computers deployed by healthcare professionals and hospitals that are powered by the Intel® Core™ vPro™ processor address security concerns by taking advantage of these unique but standard hardware-assisted security and manageability features.

An area that is a more subtle concern with security but can play a large role in acceptance and success of deployment is remote manageability. Platforms with Intel vPro technology integrate hardware-based security and maintenance and management capabilities that work with independent ISV consoles. Because these capabilities are built into the hardware, Intel vPro technology provides the healthcare marketplace with Operating System (OS)- absent manageability even when the PC is off, the OS is unresponsive, or software agents are disabled.

Use of CCD/CDA and CCR

Intel commends the ONC for incorporating flexibility into the Interim Final Rule. We understand that there is a fine line between being too prescriptive and not providing enough

³ *Id.* at 2035.

specificity to ensure interoperability. In the Interim Final Rule, the ONC states that providers can use Certified EHR Technology that uses the continuity of care document (CCD) standard for the exchange of patient summary data and receives this data in the continuity of care record (CCR) standard.⁴ The Certified EHR Technology must be capable of interpreting the CCR message into a human-readable format. We believe the ONC should specify that Certified EHR Technology must send and receive data using the CDA standard and simplifying templates should be included as a Stage 1 requirement. Requiring EHR vendors to support two standards will drive up the cost of HIT as EHRs will need ecosystems to support and validate these two formats, which will decrease the initial reliability of EHRs and result in higher integration costs (both monetary and decreased confidence).. We acknowledge the wide use of CCR in legacy systems and understand it may be easier to adopt in the short term. However, this standard will not provide the comprehensive, interoperable EHR networks necessary to provide patients with improved access to high quality, preventive health care. CDA is a powerful and expressive standard that can both encourage incremental adoption (delivering a relatively simple CDA supporting a minimum number of required fields and human readable format) while also offering a system to build an extremely expressive record. The more advanced organizations can deliver a complex CDA encompassing either a summary or longitudinal health record, which is both human and machine readable. As the health care system moves towards a single standard platform, the current development of software that will create simplified CDA formats for smaller physician offices should be encouraged by the ONC.

Many industry associations have already developed standards that are widely used, and we recommend that the ONC rely on these associations to determine which standards are appropriate. In instances where certain standards are already employed, the ONC should ensure that robust and specific standards are required by the Interim Final Rule. For example, the Continua Health Alliance (Continua xHR) has developed interoperability guidelines for the exchange of RPM patient data with an EHR based on CDA.

We also understand that the ONC may consider adopting an objective requiring one patient summary record in Stage 2. Intel would urge the ONC to include this objective in Stage 1 as it would advance the goal of interoperability.

⁴ *Id.* at 2030.

Certification of EHR Modules

Intel commends the ONC for allowing EHR modules to be certified as long as they meet one of the meaningful use certification criteria. Certification of EHR modules will provide flexibility to eligible professionals and hospitals that already employ devices and technologies that will enable them to meet certain meaningful use objectives and measures. Continued use of this HIT, upon certification, will allow these providers to build on progress already made towards the meaningful use of EHRs.

Intel wants to ensure that RPM devices can be certified as EHR modules. We believe these devices could be considered to fall under the definitional category of “an interface or other software program that provides the capability to exchange electronic health information.”⁵ Whether used in a physician’s office or in a patient’s home, RPM devices can be used to populate an individual’s EHR. Often these devices supply physicians with trend data that can be used to monitor a patient thereby providing cost-efficient, quality care that reduces readmission rates. These devices should be viewed as an extension of the physician’s office and, because they support the goals of meaningful use, should be certified as EHR modules, where they meet the applicable standards, implementation specifications, and certification criteria.

Conclusion

Intel is appreciative of this opportunity to comment on the Interim Final Rule. We believe the private industry has already made significant innovations in HIT, and we believe this government initiative to ensure adoption and meaningful use of EHRs will enhance the work that has already been advanced. In order to take advantage of these previous innovations, Intel believes it is critically important for the Interim Final Rule to build on this foundation rather than attempt to create a new set of standards, implementation specifications, and certification criteria.

We also understand that the standards, implementation specifications, and certification criteria have been developed expressly for the purpose of ensuring that eligible professionals and

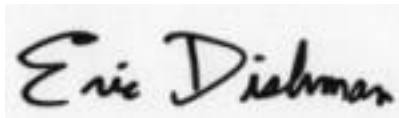
⁵ *Id.* at 2022.

hospitals are using certified EHR technology that will enable them to qualify as meaningful users under the Medicare and Medicaid incentive programs. To the extent that these are intricately intertwined, we will also be submitting comments to CMS on its Notice of Proposed Rulemaking for the Medicare and Medicaid Electronic Health Record Incentive Program (Proposed Rule).

Intel has spent years implementing complex systems, databases, and networks in its core business spread globally. Thus, our experience building some of the most complex integrated circuits in the world allows us to bring a unique perspective to this discussion. Intel has also been a key driver in many of the standards in common use today and understands and appreciates the pitfalls that can arise if some aspects of a proposed approach or standard are not articulated. We share the ONC's vision for providing recommendations that will be practical, implementable, and cost-effective. It is with these considerations that Intel submits its comments.

If we can be of further assistance to the ONC in the future, we would be pleased to share our experience and insights with the agency.

Sincerely,

A handwritten signature in black ink that reads "Eric Dishman". The signature is written in a cursive, slightly slanted style.

Eric Dishman
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