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January 29, 2016

The Honorable Lamar Alexander
Chair, Senate Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

Marc Probst (Chair)
Intermountain Healthcare

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Partners Healthcare

Zane Burke (Foundation Rep.)
Cerner

Submitted electronically to: HealthIT@help.senate.gov

Re: Bipartisan Legislation to Improve Health Information Technology for Patients and Families

Dear Chairman Alexander and Ranking Member Murray,

Myra Davis
Texas Children's Hospital

On behalf of the College of Healthcare Information Management Executives (CHIME), which represents more than 1,700 chief information officers (CIOs) and other senior information technology executives at hospitals and clinics nationwide, we thank you for the opportunity to provide input on the discussion draft of the Senate Committee on Health, Education, Labor and Pensions (HELP) bipartisan legislation to improve health information technology.

Cletis Earle
St. Luke's Cornwall Hospital

David Finn (Foundation Rep.)
Symantec Corporation

Indranil Ganguly FCHIME, CHCIO, FHIMSS
JFK Health System

CHIME members are responsible for the selection and implementation of clinical and business information technology (IT) systems that aid in the transformation of healthcare. CHIME shares the vision of an e-enabled, modern healthcare delivery system as envisioned in the Committee's discussion draft released on January 20, 2016. We applaud the Committee's commitment to improving how health information technology can be leveraged by providers and patients alike to improve healthcare.

Liz Johnson MS, FCHIME, FHIMSS, CHCIO, RN-BC
Tenet Healthcare Corporation

Theresa Meadows
Cook Children's Healthcare System

Frank Nydam (Foundation Rep.)
VMWare

Further digitizing healthcare and improving data sharing are essential as we march toward the Triple Aim of advancing population health, improving the quality of care and reducing costs. Healthcare CIOs have experience implementing technology that must interoperate with dozens of independent systems, ranging from diagnostic imaging and biomedical devices to financial and remote access systems. Several converging factors present federal regulators and congressional leaders with a unique opportunity to pursue and implement policies to bolster the digital infrastructure that will play a pivotal role in transforming the delivery of healthcare across the nation.

Albert Oriol
Rady Children's Hospital-San Diego

Donna Roach, FHIMSS, CHCIO
Via Christi Ascension Information Systems

Jan-Eric Slot (International Rep.)
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CHIME is encouraged to see some pivotal health IT issues addressed in this draft legislation, specifically the committee's direction to:

- Require a Government Accountability Office study on patient matching
- Ensure that accurate patient information is provided for the correct patient at the appropriate time
- Establish a nationwide provider directory
- Reduce the administrative burden plaguing the provider community, specifically concerning the immaturity and cumbersome nature of reporting and leveraging clinical quality measures
- Prioritize the harmonization of standards as a means to facilitate interoperability
- Enable patients to have access to a longitudinal healthcare record

The recommendations outlined below are meant to inform your continued efforts to refine the bipartisan health information technology legislation. CHIME appreciates the opportunity to submit comments on this draft and we support the committee's efforts to help modernize the nation's healthcare digital infrastructure to enable an interoperable delivery system.

Sec. 2. Assisting Doctors and Hospitals in Improving the Quality of Care for Patients

Strategy for Administrative Burden Reduction

We applaud the committee's recognition that healthcare organizations face a multitude of administrative burdens while complying with federally orchestrated programs, especially in the context of health IT adoption and assessing healthcare quality. We appreciate the committee's request of the Centers for Medicare and Medicaid Services (CMS) to outline a strategy to reduce administrative burdens, particularly relating to the need for improved alignment and simplification of quality measurement across both federal programs and private payer initiatives.

Certification of Health Information Technology for Medical Specialties

Specific patient populations, including pediatrics, and specialty providers may have unique technology needs which are not accounted for under the current voluntary electronic health record (EHR) certification authored by the Office of the National Coordinator for Health IT (ONC.) For example, measures that have been developed for the adult population do not always work for the pediatric population. As such, the CERT process should incorporate the metrics developed under the Pediatric Quality Measures Program (PQMP) as a certification requirement.

We agree that offering certification for medical specialties, as well as other providers along the care continuum (long-term care, behavioral health) will be beneficial. The value of the additional certifications, whether they be for standalone systems or modules relevant to specialties, must be improved data capture and exchange to enable interoperability in order to better meet patient and clinician needs.

Sec. 3 Transparency Ratings on Usability and Security to Transform Information Technology.

We applaud the committee's interest in ensuring providers and organizations who are making substantial investments in health information technology systems for compliance with the Meaningful Use program and other federally-administered initiatives have as much information available to them as possible to influence their decision making. We appreciate the committee's focus on security, usability, and interoperability features of the technology.

CHIME agrees with the committee's suggestion that the entity to determine technology ratings should be outside of ONC. Similarly, we agree with the recommendations set forth by the Certified Technology Comparison (CTC) Task Force convened by the Health IT Standards Committee that articulate how to

strengthen the information available on ONC's Certified Health IT Product List (CHPL) and what should be available via a non-government stakeholder¹.

Further drawing upon the recommendations made by the CTC Task Force, there is value in including only audience-specific information or offering filters for provider/practice characteristics to inform consumers. Additionally, the ability for peer-to-peer knowledge sharing will be invaluable to inform decision making.

Concerning the information made available by the rating body, CHIME reminds the committee about the unique nature of each installation in healthcare settings and the complexity of determining a rating based on one installation. Further, we would recommend that the size of the rating scale be increased, from one-to-three stars to one-to-five stars. We also suggest that the committee consider providing additional granularity at the functionality level with the appropriate justification to the potential purchasers to explain in detail the selected rating. CIOs determined that nuances in technological functionality may not be captured in the proposed three star scale.

Hardship Exemption

Concerning the availability of a hardship exemption for a user whose product received one star and is ultimately decertified, it is important to understand the complexity of installing and changing software. In a hospital setting, it may take years to transition safely from one system, or version of a system, to another. We encourage the committee to add a renewal option on a case-by-case basis for up to three years for those organizations and providers that find their software has been decertified.

The use of certified EHRs are becoming increasingly mandated for other Medicare and Medicaid reimbursement programs, including to bill for chronic care management codes and to participate in an alternative payment models (APM) as dictated by Medicare Access & CHIP Reauthorization Act of 2015 (MACRA). The committee must consider the downstream impact of a health IT product falling out of certification beyond just the Meaningful Use program.

Sec. 4. Information Blocking.

While we commend the committee for its interest in combatting information blocking practices within the healthcare industry, we also offer a note of caution relative to the legal complexity that can ensue depending how information blocking is defined. A broad definition may be taken too literally or leave too much area for legal exploitation. Every attempt must be made to provide clarity and mitigate the legal complexity for providers and hospitals, ensuring their exchange practices and understanding of the law will not be unfairly construed as information blocking.

As the nation shifts to a value-based reimbursement model, embracing APMs, the forces to share data across providers in unprecedented ways will be inevitable. The needs of a patient must be at the forefront of any determination to share information, and therefore, any attempt to refuse a request in the best interest of a patient must be rebuked.

Any direction from ONC, or the Department of Health and Human Services (HHS) more broadly, must be carefully executed and strike the right balance of detail and direction without being overly prescriptive about how patient care should be delivered. Currently providers find themselves questioning the bounds of state and federal privacy laws as it relates to the flow of patient data. Thus we encourage ONC and HHS to

¹ Ross, C., Somplasky, A.. (2016) Certified Technology Comparison (CTC) Task Force Final Recommendations [Power Point Slides]. Retrieved from <https://www.healthit.gov/facas/calendar/2016/01/20/joint-hit-committee-meeting>

provide clear guidance to allow providers to delineate circumstances of expected exchange and those exceeding the limits of such regulation. Technology, social, economic and community factors must all be accounted for and meticulously evaluated when determining what constitutes information blocking.

CHIME believes that when clear, enforceable standards are in play and patients can be safely and securely matched to their data in order to facilitate exchange, acts of blatant information blocking will become apparent.

Sec. 5. Interoperability.

The committee's recognition of the need for interoperability and willingness to provide solutions is of the utmost importance. As referenced by the multitude of witnesses that appeared before the committee during its series of hearings last year, there are a myriad of technical, policy and process challenges associated with realizing an interoperable health system resulting in the creation of longitudinal health records. The nation's shift toward alternative payment models will be in jeopardy until we achieve sincere interoperability.

We appreciate the committee's commitment to prioritizing, harmonizing and adopting standards to facilitate data exchange. Relative to this section, and throughout the legislation, CHIME encourages the committee to first evaluate what progress has been made to date prior to directing the generation of additional work. Conducting gap analyses on existing standards before authoring priorities for standards adoption and development would be invaluable in ensuring we can expedite the journey toward interoperability.

Interoperability

CHIME suggests that the committee consider defining healthcare interoperability in the following way:

In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged.² Data exchange schema and standards should permit data to be shared across clinicians, lab, hospital, pharmacy, and patient regardless of the application or application vendor.³ Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.⁴ There are three levels of health information technology interoperability:⁵ 1) Foundational; 2) Structural; and 3) Semantic.

1 - Foundational: Allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.

2 - Structural: An intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.

² HIMSS Dictionary of Healthcare Information Technology *Terms, Acronyms and Organizations*, 2nd Edition, 2010, Appendix B, p190, original source: Wikipedia.

³ American Academy of Family Physicians (AAFP), Center for Health IT, 2013

⁴ HIMSS Dictionary of Healthcare Information Technology *Terms, Acronyms and Organizations*, 3rd Edition, 2013, p. 75

⁵ National Committee on Vital and Health Statistics (NCVHS) *Report on Uniform Data Standards for Patient Medical Record Information*, July 6, 2000, pp. 21-22.

3 - Semantic: Provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged.⁶ Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data. This level of interoperability supports the electronic exchange of patient summary information among caregivers and other authorized parties via potentially disparate electronic health record (EHR) systems and other systems to improve quality, safety, efficiency, and efficacy of healthcare delivery.⁷

To truly reach a state of interoperability, we must ensure that the data received from an outside entity or system can be comprehensively understood and acted upon as if it were generated internally.

Further, as patient health data becomes digital and more fluid, we must ensure the implementation of stringent privacy and security standards. CHIME calls upon the committee address the growing nature of cyber threats to patient data and ensure that security is included in any policy recommendations. As we increase interoperability, additional threats to data integrity will arise. Without proper safeguards, the safe and secure transmission of sensitive data will continue to be a challenge.

Establishing a Trust Exchange Framework

CHIME appreciates the committee's recognition that full network-to-network exchange is not possible today. However, we also caution that the deadlines set forth in this section are aggressive. Additionally, existing frameworks being implemented by private organizations and federal agencies for the purpose of information sharing today can be leveraged to realize the goals of this section. While these networks are not perfect, nor universally endorsed, CHIME would suggest we build upon current progress rather than starting anew toward the creation of a completely new "Trusted Exchange Framework."

The framework should be flexible enough to accommodate what works but not so loose that data sharing is difficult. A substantial portion of the framework must focus on the legal issues regarding data sharing across state lines. However, there is no discussion of how this framework will be funded or other foundational interoperability challenges like how patients will be linked to their data.

Provider Digital Content Information Index

CHIME applauds the committee's direction for the establishment of a nationwide provider directory. The lack of robust directories are a barrier to accurate and appropriate exchange. The inability to identify a provider's electronic exchange capability and other necessary details causes organizations to waste their limited resources and risk data breaches. We believe this is an important and significant step toward improved interoperability and robust information exchange. We advocate that a directory to be published sooner than two years.

HIT Advisory Committee

CHIME appreciates the role the health IT federal advisory committees have played since passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, however, the current make-up of the Health IT Policy Committee (HITPC) and Health IT Standards Committee (HITSC) do not adequately represent the views of providers, arguably the most heavily impacted segment of stakeholders in this policy conversation. Therefore, we appreciate the committee's willingness to rethink how stakeholders shall advise HHS and ONC on health IT policy matters.

⁶ Institute of Electrical and Electronics Engineers, *IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries*, New York, NY: 1990.

⁷ *HIMSS Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations*, 2nd Edition, 2010, Appendix B, p190, original source: HIMSS Electronic Health Record Association.

The current makeup of 25 members is too many for the advisory committee. CHIME suggests no more than 15 members with real-world experience developing, implementing and using health information technology. CHIME also encourages the committee to ensure that the new advisory body does not duplicate past work done by the HITPC and HITSC.

We also encourage the committee to begin with a gap analysis of standards particularly before dictating specific areas of development. While additional standards may be necessary as technology and the industry develop, there are standards that can be identified and universally adopted in key priority areas immediately.

Further, CHIME appreciates the committee's interest in driving toward standards harmonization in order to achieve uniform and consistent implementation of standards and implementation specifications to facilitate interoperability.

Testing

The draft bill instructs NIST to pilot test interoperability. We acknowledge that experience to-date with testing suggests that current processes lack efficacy and value. More stringent testing will be important in the certification context, including the use of scenario-based testing and post-implementation testing. For example, it is not sufficient to know whether an HIT product has certain basic capabilities; it is also important to know how that product reacts to common scenarios (such as the failure to populate all required fields).

Setting Priorities for Standards Adoption

CHIME continues to advocate for standards identification and harmonization in the following areas:

1. Patient identifiers
2. Standards for resource locators (e.g. provider directories)
3. Standard terminologies
4. Detailed clinical models
5. Standard clinical data query language based on the models and terminology
6. Standards for security (standard roles and standards for naming types of protected data)
7. Standard Application Program Interfaces (APIs)
8. Standard transport protocols
9. Standards for expressing clinical decision support algorithms

We appreciate the committee's direction to ensure stakeholder input can be offered and integrated throughout the standards adoption, harmonization and development processes.

Common Data Elements

CHIME is pleased the legislation includes language to establish common data sets. We would encourage the committee to build on existing valuable data elements that could be adopted within the two year deadline set in the legislation while a larger set to meet the priority categories is developed and agreed upon.

Further, we are extremely encouraged to see that providing accurate patient information to the correct patient is a priority in Sections 3 and 5. We would also suggest that the committee include the following under "Priorities" for common data sets:

(G) Technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

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Sec. 6. Leveraging Health Information Technology to Improve Patient Care Requirements Relating to Registries

Currently, the lack of standardization across registries has impeded the development and adoption of technology to be able to transmit, receive and accept data from the myriad of existing clinical registries. Certifying how registries will transmit, receive and accept as well as how certified health IT products can interact with registries will be valuable to the provider community.

Treatment of Health Information Technology developers with Respect to Patient Safety Organizations

We agree with the committee's allowance of health information technology vendors to be treated as provider organizations in reporting software-related patient safety events to patient safety organizations (PSOs.)

Sec. 7. Empowering Patients and Improving Patient Access to Their Electronic Health Information

CHIME appreciates the committee's recognition that ~~we~~ patients [should have] access to their electronic health information in a single, longitudinal format that is easy to understand, secure and may update such information automatically+and our members wholeheartedly agree that is ideal state is the goal. However, this ideal is not yet able to be a reality because of technical, political and regulatory barriers.

While we acknowledge that both standards and technology are maturing as it relates to the aggregation of healthcare data and patient-facing information, we must cite the need for additional time before the technology necessary to meet the committee's wishes for patient access to their clinical health information can be realized. The committee will drive these efforts through the inclusion of this request in certification, but until the industry coalesces around a defined set of standards, a common data set is adopted and patient matching is reliable at a national level, this ideal will not come to fruition.

The exchange of data among providers in various locations and settings will require the harmonization of state and federal privacy laws. Consent policy varies by jurisdiction, provider, and personal health information (PHI) type. Like most privacy policy, there is no national consent policy. As health information exchange becomes more prominent, as is the goal, the issue of consent becomes even more essential to success. CHIME calls on the committee to encourage a national dialogue to help states align privacy and consent policies that enable cross border exchange of health information in a secure manner. This should include re-examining certain provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Education of Providers

We agree with the committee that provider education is necessary on the role of health information exchanges as well as patient access to health information.

Sec. 8. Encouraging Trust Relationships for Certified Electronic Health Records

We applaud the committee's recognition that certified technology must be capable of trusted exchange with other EHRs.

The guidance requested from ONC and OCR on common legal and governance barriers preventing trusted exchange would be a welcome resource to our membership.

We support the committee's request for Meaningful Use statistics and standards development. Transparency about how the provider community is faring in the Meaningful Use program will be beneficial to ensure the program and other associated programs can be adjusted to best reflect the needs and experience of the provider community.

Sec. 9. GAO Study on Patient Matching

We strongly support the requirement that GAO study patient matching, to evaluate stakeholder activity to advance matching and how ONC to improve the likelihood that patients are linked to their data consistently, securely and accurately. We are particularly supportive of the provision requiring GAO to study the impact of defining additional data elements for the purposes of matching and the use of particular standards to be required to assist with linking patients to their healthcare data.

We absolutely agree that privacy and security should be at the top of the list of areas for the GAO to focus as they evaluate current patient matching methods. Ideally by linking patients to their records, we can better follow consent wishes and avoid requesting sensitive information multiple times from the same patient.

Given the value of the requested GAO report can bring to the industry, paying dividends for patient safety and care efficiency, we strongly encourage the committee to request the report submission within two years of enactment of this law.

We cannot stress enough the importance of a coordinated national approach to linking patients to their healthcare data. Ensuring that patients are positively identified and matched to their records is a linchpin to increasing interoperability and improving the quality and safety and patient care, especially in a highly digitized environment.

CHIME commends the committee for the bipartisanship demonstrated throughout your work on this important topic. We hope our comments are useful and hope to continue the dialogue with the committee regarding legislative solutions for making an interoperable healthcare delivery system a reality. Should you have questions about our recommendations or require additional information, please contact Leslie Krigstein, Vice President of Congressional Affairs at lkriegstein@chimecentral.org.



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