August 12, 2014

The Honorable Ron Wyden
Chairman, Senate Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Chuck Grassley
Member, Senate Committee on Finance
United States Senate
Washington, DC 20510

Submitted electronically to: data@finance.senate.gov

Re: Availability and Utility of Health Care Data

Dear Chairman Wyden and Senator Grassley:

The College of Healthcare Information Management Executives (CHIME) is writing in response to the stakeholder letter inquiring about data transparency and access in digital healthcare, published June 12, 2014.

CHIME has more than 1,400 members, including chief information officers (CIOs) and other top information technology executives at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business information technology (IT) systems that will facilitate healthcare transformation.

The Committee’s questions related to digital health are timely, given the state of health IT policy, with many key federal programs stimulating technology adoption and encouraging data sharing to improve care quality in the U.S. healthcare system. As the nation’s premier organization of senior health IT executives, CHIME offers a focused set of recommendations to advance the availability and utility of healthcare data by encouraging the:

- Development of data standards and robust testing requirements for certified EHR technology and other components of health IT referenced in federal policies;
- Adoption of a national patient matching strategy; and
- Harmonization of privacy laws to reduce burdens on providers attempting to exchange data.

HHS has made great strides in recent years to make health data more available and usable. Open Government Initiatives, such as Healthdata.gov, Health Datapalooza and numerous challenge grants managed by the Office of the National Coordinator for Health IT (ONC) have generated wide interest from entrepreneurs, health researchers and policymakers alike. However, the potential impact of these efforts pale in comparison to the potential impact of a concentrated focus on clinical data fluidity.
A high degree of data fluidity is imperative to reducing waste and improving quality in the U.S. healthcare system. CHIME’s recommendations cover priority policy areas meant to increase health data fluidity, which will then enable compilation of a longitudinal healthcare record for patients. The concept of a longitudinal healthcare record should reflect the patient’s experience across episodes of care, payers, geographic locations and stages of life. It should consist of provider-, payer- and patient-generated data, and be accessible to all members of a patient’s care team, including the patient, in a single location. A longitudinal healthcare record, supported by widely adopted standards, also should improve a patient’s ability to manage consent privileges and diminish privacy concerns related to the digitization of personal health information (PHI).

The landscape of standards related to health IT and health data exchange are developing, yet many standards are still immature. HHS has initiated a process, through ONC’s Standards and Interoperability Framework, to help identify and refine key health IT standards. However, these efforts have been muted by limited resources, insufficient testing and a lack of strategic prioritization across numerous HHS programs.

CHIME looks forward to the release of ONC’s Nationwide Interoperability Roadmap, a 10-year plan for improving the exchange of health data between IT systems. The roadmap is an opportunity for the administration to revisit the certification program and acknowledge the need to focus key existing standards rather than the creation of new ones. The roadmap should include a reimagined testing process, including beta testing, post-certified performance and live-setting standards adherence. CHIME calls on Congress to work with federal regulators to successfully establish a nationwide interoperability roadmap (complete with articulate, time-bound goals), fully fund the components of that roadmap and aggressively monitor progress towards the accomplishment of the enumerated goals.

Further, patient data-matching continues to be a dangerous and costly process for hospitals and health systems. As data exchange increases among providers, patient data-matching errors and mismatches will become exponentially more problematic and potentially dangerous. CHIME calls on Congress to remove the prohibition baring federal regulators from developing and requiring adherence to standards for a unique patient identifier as a means to dramatically enhance the sharing of healthcare data. While some basic patient demographic data standards were included in the proposed 2015 edition for certification, that rule has yet to be finalized, and it is expected to lack a comprehensive solution for patient matching issues.

The exchange of data among providers in various locations and settings will require the harmonization of state and federal privacy laws. As an example, consent policy varies by jurisdiction and personal health information (PHI) type, and similar to most privacy policy, there is no national consent policy. CHIME calls on Congress to lead an open 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 HIPAA.

We would be remiss if we didn’t mention the need for payment reform, perhaps the clearest area where new legislation is needed. Without a fundamental reworking of Medicare’s fee-for-service reimbursement model, Congress can anticipate increased healthcare costs, marginal quality improvements and a declined position among other countries of the world in healthcare delivery innovation. We supported the glide path described
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by S. 2110 and commend congressional leadership for working on a plan to fully repeal and replace Medicare’s Sustainable Growth Rate. The effort to design a sensible transition toward a population health and outcomes focused reimbursement protocol should not be understated. CHIME stands ready to help solutions-oriented lawmakers understand the technical challenges and opportunities of relying on performance data to determine reimbursement – this is a transition we fully support.

Lastly, CHIME commends the Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee for their Fiscal Year 2015 report language calling on ONC to evaluate technical barriers to information exchange that hinder data sharing. CHIME believes ONC’s best lever to improve interoperability is through its certification program. But the promise of this program has been hampered by stringent timelines and a lack of focus on how to best utilize certification to achieve a more aligned ecosystem of health IT. We support the Committee’s suggestion regarding ONC’s certification authority as a means to remove the technical obstacles to health information exchange. The need is clear for ONC to certify only those products that conform to standards and to decertify products that proactively block the sharing of information and make CEHRT less valuable.

In the attachment below, CHIME details recommendations based on the areas listed above that will improve the quality of and increase the fluidity of health data.

We appreciate the opportunity to provide comments on this important subject. We hope this feedback is helpful. If there are questions about CHIME’s recommendations or more information is needed, please contact Jeffery Smith, Vice President of Public Policy, at jsmith@cio-chime.org or (703) 562-8876.

We look forward to a continuing dialogue with your offices on this and related matters.

Sincerely,

Russell P. Branzell, FCHIME, CHCIO
President and CEO
CHIME

Randy McCleese, M.B.A., M.S., FCHIME,
LCHIME, CHCIO
Chair
CHIME Board of Trustees
Vice President of IS and CIO

Attachment
Below, please see CHIME’s recommendations on developing data standards and test methods to improve health information exchange and patient engagement; adopting a national patient matching strategy; and harmonizing privacy laws to reduce burdens on providers exchanging data.

### Standards Development

#### Background

Providers and vendors remain able within the Meaningful Use Program to configure and store data in different ways because of the lack of standards. If there were a standard data exchange format, there would be less interference with physician workflow and increased likelihood that data could be used more effectively in a clinical setting.

It would be incorrect to state that exchange and interoperability of health data is completely absent, but failures related to the health IT market must be addressed. Specifically, EHR-to-EHR interoperability remains elusive for most providers. Many CHIME members who wish to connect a patient portal module to their enterprise EHR system, for example, must use expensive interfaces, despite the fact that both products are government certified. Summary of Care Records required for transitions of care will soon be routinely exchanged, but the information contained in Summary of Care Records will not likely integrate with existing patient information. A recent study outlines the various errors experienced when exchanging Summary of Care Records, which could have grave consequences for downstream patient safety. One key takeaway from this research is that live exchange of these documents is likely to omit relevant clinical information, increase the burden of manual review for provider organizations receiving Summary of Care Records and increase the likelihood of a patient safety incident based on incomplete or inaccurate data.

We understand the landscape for health information exchange is evolving, and we believe that new models of exchange will develop over time to serve local markets. CHIME encourages both ONC and CMS to continue a strategy that stresses local flexibility while looking for ways to lead stakeholders in the development of technical standards, services and policies that both solve core problems and reduce costs and complexity of exchange.

Specifically, we believe ONC should reconsider the role and composition of its certification program to address patient safety risks and interoperability. ONC’s certification program was built out of regulatory necessity to accommodate misguided timelines driven by Meaningful Use, not in acknowledgement of how technology is developed, tested, implemented and optimized. This has led to a market dynamic that incentivizes data silos, vendor lock-in and rewards developers who are “first to certify” rather than a market characterized by usable, safe and mature health IT products.

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[http://jamia.bmj.com/content/early/2014/06/26/amiajnl-2014-002883.full](http://jamia.bmj.com/content/early/2014/06/26/amiajnl-2014-002883.full)
Insofar as certification appears to be one of the government’s best tools to assure adherence to technical standards and specifications, we believe the form and function of certification needs to adapt. CHIME asks Congress to urge ONC to retool its certification program to have a specific focus on beta-testing, post-certified performance and live-setting standards adherence. Designing a certification program that more closely resembles the software development lifecycle would have a tremendously positive impact on both interoperability and patient safety. Further, we believe the results from these more robust tests should be made publicly available to ensure providers know which products are performing well and adhering to standards in the real world. By reorienting and leveraging its certification program, ONC could help the private/non-profit sector establish a learning health system, characterized by continuous improvement and consistent accountability.

**Recommendation**

CHIME believes congressional action is needed to ensure that ONC re-examines its certification program, incorporates more robust interoperability testing in future Certified EHR Technology (CEHRT) Edition updates, and assigns reasonable timelines for development and implementation. To eliminate data silos created by new technology, CHIME believes standards must be developed and implemented to seamlessly integrate data from telehealth services, patient portals and remote monitoring technologies, among other sources, into EHRs.

CHIME also supports the adoption of SGR language from that proposed in S. 2110 declaring the national goal of widespread exchange of health information through interoperable certified EHR technology by the end of 2017. Further, CHIME commends the Senate Labor-H Appropriations report language concerning the need for ONC to re-examine the certification program to encourage data sharing, and thus not reward information blocking.

**Patient Engagement and Data Integration**

**Background**

One of the data sources most undeveloped and underutilized in healthcare is data generated by the patient. Patients should be able to access their data; a patient’s ability to interact with and contribute data to their electronic health record will be invaluable in increasing patient accountability, and will involve patients in ways not yet imagined in the industry. Just as consumers can verify transactions with their financial accounts in the banking industry (thus potentially noting, irregularities and false charges, for example), so should healthcare consumers be similarly engaged with their medical records. Patients must be able to view, download, transmit their data and have control over their health information from one trusted source. Under the concept of a longitudinal record, all providers, and even patients, would enter or send data through a trusted information exchange.

The disparate nature of patient data is only heightened by the need for each provider attesting to Meaningful Use to have patient portals, patients may need to visit numerous portals to piece together the results from one episode of care. Our members note that it is common to implement a certified complete
EHR alongside a certified patient portal module that do not interoperate. The certification program should enable providers to choose a mix of certified products to meet market demands and stay competitive; yet the certification program incentivizes a single-vendor approach that replaces old data silos with new ones.

This is cumbersome for patients because they will have to sign into a portal for each of their providers to find their patient information. They face similar issues as do providers—they do not have the tools to aggregate and analyze their own data because it doesn’t appear in one central place.

A community faced with a plethora of patient portals and private Health Information Exchanges (HIE) is not good for the patients, providers or population health analysis. CHIME emphasizes the importance of engaging patients in their own records, whether through Personal Health Records (PHR), portals or exchanges.

**Recommendations**

CHIME recommends Congress require federal agencies to develop a strategic roadmap and extensible architecture that will enable HIEs to collect, display and normalize clinical data. This will enable the creation of a longitudinal care record so physicians and patients will not suffer from fragmented data.

In addition, the ideal longitudinal health record could share patient data for syndromic surveillance, public health reporting and for research purposes after the data is properly de-identified. As large bodies of data are shared, researchers may be able to find treatment patterns and could identify opportunities not previously explored. Health IT tools can provide a faster and more accurate way of moving critical information from providers to health departments, where outbreaks are identified, tracked and managed. The Meaningful Use program includes requirements around public health reporting components like lab results, immunizations and number of cases of certain diseases.

**National Patient Matching Strategy**

**Background**

To establish an individual patient’s longitudinal care record, a strategy to uniquely identify each patient is necessary. Data fragmentation exists within the records of a single patient because of the absence of a national patient data matching strategy. Despite years of development, no clear strategy has emerged to accurately and consistently match patients with their longitudinal data across different settings of care. A congressional prohibition baring federal regulators from developing and requiring adherence to standards for a unique patient identifier has confounded the patient safety issue immeasurably. In the more than 15 years since the prohibition was placed in report language, the healthcare industry has faltered in developing a private-sector solution, and federal regulators have been slow to acknowledge the prevalence of dangers posed by inaccurate matching.
The results of a 2012 CHIME survey suggest that swift action is needed to ensure the right data is matched with the right patient. Survey findings suggest that a majority of hospitals are employing unique patient identifiers (64.8%) concurrent with other matching strategies. Of the nearly 65 percent of CIOs reporting use of unique identifiers, more than half (58%) are using at least one other strategy – probabilistic, deterministic, biometric, etc. Yet, even with the use of such varied strategies, false negative and false positive error rates are still unacceptably high. While a majority of CIOs believe their false negative and false positive error rates are at or below industry standards, a considerable percentage believe their health records have error rates that far exceed 8 percent. And perhaps more alarmingly, nearly one-fifth of survey respondents said they can attribute at least one adverse event to a patient mismatch within the last year. This is not only a patient safety issue, but a financial issue as well. Some hospitals have reported spending nearly $1 million a year to match duplicate records and separate records that were erroneously merged.

Unintended injury or illness attributable to patient data-matching error is a considerable, and growing, problem in this era of health information exchange. And with a substantial portion of CIOs involved with HIEs that use differing approaches to data matching, we can expect the inconsistency and variability inherent in healthcare IT systems to persist – and become more endemic – without national leadership and consistent standards.

**Recommendation**

CHIME calls on Congress to remove the prohibition barring the development of and requiring adherence to standards for a unique patient identifier as a means to dramatically enhance the sharing of healthcare data. At a minimum, Congress should support administration efforts to help identify possible solutions that can address this staggering patient safety issue.

**Alignment of Privacy Laws**

**Background**

The exchange of data requires harmonization among state and federal privacy laws. Consent policy varies by jurisdiction and personal health information (PHI) type, and similar to most privacy policy, there is no national consent policy. As health information exchange becomes more prominent, the issue of consent becomes a more daunting challenge. How providers capture patient consent preferences, whether health information exchanges have to abide by policies such as opt-in/opt-out, and federal policies (e.g. mental health) are all confounding issues to the topic of consent. Currently, CHIME is unaware of any technical solution or policy approach shared among a majority of providers to capture consent preferences. We know that ONC is leading an initiative called the Data Segmentation for Privacy (DS4P) through its Standards & Interoperability Framework, and we know that SAMHSA is working on a solution that could help deal with sensitive PHI. However, these solutions are years away from scaling, from a technical perspective. From a policy perspective, the privacy outcomes sought will never be realized because of the fractured, state-based scheme guiding current policy.

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Recommendation

CHIME calls on Congress to lead an open 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 HIPAA.

A longitudinal care record that gives patients access to their records might also solve the consent management issue faced by most healthcare providers. If consent management functionalities are built in at the record level, patients can designate which providers or care teams can access their information for care.