



July 1, 2015

The Honorable Lamar Alexander
Chairman
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

Re: Health Information Technology Policy Recommendations

Dear Chairman Alexander and Ranking Member Murray:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to offer solutions to realize the promise of electronic health records (EHRs) to improve patient care. We appreciate the Committee's continued leadership and interest in strengthening the nation's health information technology infrastructure.

CHIME has more than 1,600 members, comprised of 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 IT systems that are driving healthcare transformation. Our organization is a strong proponent of health IT and its role as a differentiator in improving care quality, affordability and outcomes.

As the professional association representing the nation's healthcare IT executives, CHIME members have a unique view of the barriers to interoperability and the necessary components needed to achieve fluid exchange of information. 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 address key challenges in the coming months. The frustrations voiced by providers and policymakers regarding the systems deployed in over 80 percent of hospitals and 60 percent of physician offices are real and, we believe, the solutions to address them are within reach. Five years after passage of HITECH, there exists an opportunity to make policy decisions apart from the arbitrary deadlines of the EHR Incentives Program and pivot towards the long-term goal of building and supporting a national digital health ecosystem.

CHIME appreciates the time the Committee has dedicated to the evaluation of existing policies and stakeholder engagement in pursuit of solutions that will have a tangible impact on how providers use health information technology to deliver better care to patients. CHIME outlines current challenges and resolute solutions for consideration to address the Committee's five use cases:

1. Help doctors and hospitals improve quality of care and patient safety;
2. Facilitate information exchange between different electronic record vendors and different health professionals, referred to as "interoperability;"
3. Empower patients to engage in their own healthcare through convenient, user-friendly access to their personal health information;
4. Leverage health information technology capabilities to improve patient safety; and
5. Protect patient privacy and security of health information.

Improving Quality of Care and Patient Safety

Challenge: The accurate and efficient matching of patients with their healthcare data is a significant threat to patient safety.

Solution: Remove the Congressional prohibition levied on HHS annually since 1999, prohibiting the use of federal funds for the development of a unique patient identifier.

We must first acknowledge that the lack of a consistent patient identity matching strategy is the most significant challenge inhibiting the safe and secure electronic exchange of health information. As our healthcare system begins to realize the innately transformational capabilities of health IT, moving toward nationwide health information exchange, this essential core functionality – consistency in patient identity matching – must be addressed. Patients and care providers are missing opportunities to improve people's health and welfare when information about care or health status is not easily available. As data exchange increases among providers, patient data matching errors and mismatches will become exponentially more problematic and dangerous.

Foundational to the vision espoused by the Committee to improve information exchange and improve patient care, is the ability of providers to accurately and consistently match patients with their data. CHIME calls on Congress to remove the prohibition barring federal regulators from identifying standards to improve positive patient identification. With the removal of the outdated prohibition, we believe then that the nation can sincerely engage in a dialogue on finding solutions to solve this fundamental patient safety problem

We caution those that may underscore concerns about patient privacy and safety, and would emphasize that a consistent strategy does not mean a single technology or solution, but an approach that will facilitate the realization of the full benefits and cost savings of nationwide health information exchange, while protecting patient safety and privacy. Robust information exchange and nationwide interoperability can flourish only once we can confidently identify a patient across providers, locations and vendors.

CHIME points to the concept of a longitudinal care record as an illustration of what is possible when the promise of health information technology becomes a reality. Unfortunately, the development of longitudinal healthcare records - reflecting the patient's experience across episodes of care, payers, geographic locations and stages of life – remains only an ideal at this time. We believe longitudinal care records 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. An information-rich record, supported by widely adopted standards, will improve a patient's ability to manage consent privileges and diminish privacy concerns related to the digitization of personal health information (PHI).

Challenge: Several trends are converging to reduce fee-for-service reimbursement, but misalignments among quality reporting programs and technical barriers threaten the ability for policymakers to determine quality through electronic metrics.

Solution: Increase efficiency in quality reporting to alleviate strains of provider time and resources. The harmonization of quality reporting mandates should extend to (1) the specific CQM, (2) how the CQM is reported, and (3) to whom it is reported.

As the future of value-based reimbursement is contingent on the ability to measure performance, Congress should prioritize a unified strategy for capturing and communicating quality in healthcare. Currently, hospitals and physicians are required to report clinical quality measures (CQMs) to several public and private entities. Many CHIME members submit over twenty reports across federal, state and private sector programs for various CQMs each month. Hours of work and expertise are required to comply with these reporting demands and such burdens are exacerbated by a lack of technical harmonization. In other words, even when the same CQMs are used among different reporting programs, they tend to require different technical specifications, diminishing gains made through alignment.

CHIME encourages the Committee support policies that will harmonize quality measure reporting across federal programs in order to eliminate the duplicative and burdensome reporting of meaningless measures. It has been our members' experience that although EHRs were able to automatically produce CQM reports, the data was inaccurate and largely incomparable across different providers. In fact, CHIME does not believe that generation of accurate and complete CQMs is possible with current EHR technology.

We remain concerned that CMS underestimates the complexity of generating valid, reliable and accurate electronic clinical quality measures (eCQMs) without human intervention given the proposal in the Fiscal Year 2016 Inpatient Prospective Payment System rule issued in April 2015, which mandates the electronic submissions of quality measures. CHIME believes it prudent to require electronic submission of eCQM data after such time when federal regulators rigorously test and validate the accuracy/completeness of CQMs required by Medicare and Medicaid. Our members continue to rely heavily on manual abstraction, a costly and cumbersome process, for gathering and reporting the measures to supplement electronically generated quality data, and this is likely to be the norm for some time to come.

CHIME recommends that the Committee direct CMS work in tandem with the Office of the National Coordinator for Health IT (ONC) and qualified measure developers/stewards to extensively test and validate eCQMs so that measuring quality is the byproduct of delivering care, not an end unto itself.

Health Data Exchange and Interoperability

Challenge: Without data standards, the digital health ecosystem will not realize its full potential to lower healthcare costs and improve care quality.

Solution: The federal government should drive the identification and use of standards in priority areas to ensure providers are capturing and exchanging data in the same fashion.

CHIME encourages the Committee to direct the federal government to drive standards identification and adoption in the following nine categories:

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

While a focus on standards may seem overly simplistic, we firmly believe that a more defined technical infrastructure is needed to catalyze innovations in digital health. Unless federal leadership emerges, the status quo will stifle future progress. The process for adopting and updating standards should be revised in the following ways:

1. HHS, with ONC, should develop an open, transparent process to identify leading candidate standards and drive the adoption of a minimum number of compatible standards where competing standards exist;
2. When competing standards are shown to be incompatible, ONC should develop a migration strategy complete with a timeline and benchmarks towards a single standard;
3. Congress should enable private sector-run test-beds for users and developers of standards as an intermediate step between draft standard for trial use and consensus standard;
4. The government should fund pilot programs to enable providers and software developers to test and enhance implementation guides;
5. Establish clear maturity criteria that determine when a standard/implementation guide can be endorsed;
6. The government should enable the development of national licenses for all widely-used clinical terminologies so that they are more affordable for provider organizations and support the sustainability needs of Standards Development Organizations (SDOs).

Challenge: ONC Certification does not guarantee health IT systems are interoperable.

Solution: Congressional action is needed to ensure that ONC dutifully reexamines its certification program and incorporates more robust interoperability testing in future Certified EHR Technology (CEHRT) Edition updates.

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. Congress should view ONC’s Certification Program as a lynchpin for interoperability and acknowledge voluntary certification as the only current means to enforce technology developers’ compliance to federal law. To date the program has not achieved its stated goal of giving “providers and patients’ confidence that the HIT products and systems they use are secure and can work with other systems to share information (interoperability).”¹ Instead, ONC’s Certification Program has demonstrated limited success in “assuring purchasers and other users that an EHR system offers the necessary technological capability, functionality, and security to help them meet MU objectives and measures.”²

To help ONC pivot its Certification Program towards interoperability, Congress should:

1. Require changes to ONC’s approach to testing;
2. Enhance ONC’s ability to enforce adherence to certification program requirements;
3. Establish mechanisms to bring more transparency to the performance of Certified EHR Technology (CEHRT) especially related to interoperability.

Testing

Congress should enable ONC to acknowledge and leverage private-sector testing bodies requiring potential CEHRT to pass robust interoperability tests using common standards. Congress should enable ONC to employ a range of conformity assessments to products that claim to use those standards.

Enforcement

Congress should enable ONC to enhance its enforcement tools meant to ensure health IT functionalities are effective and they adhere to interoperability standards in the following ways:

1. Further develop post-certification surveillance program managed by ONC
2. Establish a process to address bad actors in a way that holds harmless those providers who use CEHRT found in violation of ONC’s Certification Program vis-à-vis program requirements tied to the use of CEHRT

Transparency

Transparency metrics around CEHRT performance should be developed in conjunction with the private sector, with special attention given to interoperability performance. These metrics would be additive to ONC’s Certification Program requirements.

- Vendors should be able to accommodate multiple transport mechanisms, in both the input and output fashion;

¹ About the ONC HIT Certification Program, <http://bit.ly/1G0FHJa> accessed 26 Feb. 2015

² Ibid.

- Metrics could include ability to connect with multiple HISPs and multiple HIEs, compliance with private-sector testing requirements, etc.

ONC's Certification Program was not built with a full understanding 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.

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 sectors establish a learning health system, characterized by continuous improvement and consistent accountability.

Empowering Patients

Challenge: Providers and hospitals have been unable to demonstrate the value of patient portal function mandated by the Meaningful Use Program.

Solution: Encourage innovation in CMS' policies to represent the patient interests in mandated engagement.

Due to the rigidity of existing policy stipulating how providers should conduct patient engagement under the Meaningful Use Program, we remind policymakers that future efforts to build on this flawed approach to patient engagement will be met with continued resistance from providers and will divert the industry's focus from fostering true patient engagement. This is because the patient action requirement has taken care providers away from patients and reassigned them to the role of email collectors; it has created an array of information silos for patients to aggregate and new passwords for patients to remember; and new research indicates the proliferation of portals could lead to greater health disparities³.

Under the current requirement, our members tell us that many of their patients are not willing to sign up for their portals, a necessary step to gaining access to their health information, citing data security concerns. In other cases, it is simply unreasonable to expect patients being treated by multiple providers to access the portals of all of these providers. We are deeply concerned about objectives and measures that make providers accountable for patient unwillingness or inability to complete certain actions, given the all-or-nothing construct of the patient engagement measure. Further, to the extent that policy makers wish patients to take specific actions, should policy should focus on incenting the desired behavior in patients, not holding providers accountable for behavior over which they have no control.

³ S. G. Smith, R. O'Connor, W. Aitken, L. M. Curtis, M. S. Wolf, M. S. Goel. **Disparities in registration and use of an online patient portal among older adults: findings from the LitCog cohort.** *Journal of the American Medical Informatics Association*, 2015; DOI:[10.1093/jamia/ocv025](https://doi.org/10.1093/jamia/ocv025)

As our industry continues the discussion of how best to engage patients through technology and how best to measure these efforts, we encourage the Committee to direct CMS to think more innovatively around the concept of patient engagement; namely, how to differentiate between those that do it well and those who do not, and how to encourage improvements. A 2014 study done by the National Partnership for Women and Families concluded that consumers want more robust functionality and features of online access than are available today, including the ability to email providers (56 percent), review treatment plans (56 percent), doctors' notes (58 percent) and test results (75 percent), schedule appointments (64 percent), and submit medication refill requests (59 percent)⁴. Unfortunately, the existing Meaningful Use requirement does not allow providers to capture refill requests, appointment scheduling or reminders in the patient engagement measure, despite these being patient priorities. Congress should consider the discrepancy between HHS' priorities for patient engagement, and patients' self-indicated priorities.

IT Resources to Improve Patient Safety

It would be incorrect to state that exchange and interoperability of health data is completely absent, but failures related to the health IT market and the government program dictating IT product functionality must be addressed. 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 those Summary of Care Records will not likely integrate with existing patient information. A recent study outlines the various errors seen when exchanging Summary of Care Records, which could have grave consequences for downstream patient safety.⁵ One key take away 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 an adverse patient safety event based on incomplete or inaccurate data.

We reiterate the value a national patient-matching strategy will have on improving patient safety by enabling healthcare providers to make informed care decisions.

Protect Patient Privacy

Challenge: Inconsistencies in consent policies and state privacy laws hinders the exchange of health information.

Solution: Congress should 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 reexamining or providing clear guidance on certain provisions of HIPAA.

⁴ "Engaging Patients and Families: How Consumers Use Health IT" *National Partnership for Women & Families* December, 2014.

⁵ D'Amore, J., Mandel, J., et al. "Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative" *J Am Med Inform Assoc* doi:10.1136/amiajnl-2014-002883
<http://jamia.bmj.com/content/early/2014/06/26/amiajnl-2014-002883.full>

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 to 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’s vision for a longitudinal healthcare record supported by widely adopted standards, includes an improvement to patients’ ability to manage consent privileges and diminish privacy concerns related to the digitization of PHI.

The multi-level consent requirements – including health systems, HIEs, and state law – confound a provider’s ability to exchange data with any confidence that they are not breaking the law. In fear of liability, many providers and provider organizations choose not to share patient data. CHIME is currently unaware of any technical solution or policy approach agreed to 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 behavioral and mental health PHI. However, from a technical perspective, these solutions are years away from scaling and they do not solve the problem of varied and sometimes conflicting state privacy laws.

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 the Health Insurance Portability and Accountability Act (HIPAA).

EHR Incentive Program

CHIME would like to close with recommendations intended to preserve the integrity of the EHR incentive program, enabling this innovative program to deliver the anticipated return on investment to the federal government and to our tax payers. The EHR Incentive Payments program has been a vital and successful driver of health IT adoption, which sets a foundation for better population health, better healthcare delivery and lower costs. However, challenges with program implementation and future participation must be addressed.

CHIME calls on the Committee to consider the following recommendations:

1. Delay the production of Stage 3 final rules until the completion of the 2016 program year.
2. Refocus the program on outcome measures that measure improvements in patient care, not physician actions.
3. Revisit the “all-or-nothing” or “all-or-penalty” structure currently employed under current law.
4. Develop policies to recognize the timelines associated with safely implementing health IT systems:
 - Hardship exemptions should be granted for hospitals and physicians implementing new systems or incorporating new systems resulting from a movement in practice or acquisition.

- Providers should be allowed to take a 90-day reprieve during any program year for upgrades, planned downtime, bug fixes related to new technology or optimizing the use of new technology within new workflows.

CHIME, once again, commends the Committee on their continued leadership on health IT policy and appreciates the opportunity to provide comments on this important work. If there are questions about CHIME's comments or more information is needed, please contact Leslie Krigstein, Interim Vice President of Public Policy, at lkrigstein@chimecentral.org or (202)507-6158.

Sincerely,



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