

Testimony of Dr. Thomas H. Payne, Medical Director, IT Services, UW Medicine, University of Washington School of Medicine, and Chair-Elect of the AMIA Board of Directors before the U.S. Senate Committee on Health, Education, Labor and Pensions

Hearing on "Health Information Exchange: A Path towards Improving the Quality and Value of Health Care for Patients" June 10, 2015

OPENING REMARKS

Good afternoon, Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee. My name is Dr. Thomas Payne. I am Medical Director of IT Services at UW Medicine and the University of Washington School of Medicine, and I am Chair-elect of the AMIA Board of Directors. The American Medical Informatics Association represents more than 5,000 doctors, nurses, clinicians, researchers and other informatics professionals, who develop, implement and study ways to manage information for patients, professionals in their clinical practice, public health and clinical research.

It is an honor to appear before you today, alongside this distinguished panel. My comments will focus on positive, near-term action items policymakers can take to capitalize on the increased adoption of electronic health records, and utilize a burgeoning trove of health data to improve the quality and value of healthcare for Americans.

Recommendations, which I will describe in my comments, are derived from a recent report published by a multidisciplinary Task Force chartered by the AMIA Board of Directors. The EHR 2020 Task Force was established to develop recommendations on how we, as a Nation, can resolve challenges related to EHRs – challenges this Committee has examined through a host of recent hearings. This report was developed over the course of 12 months by a diverse group of informatics professionals representing a wide range of perspectives.



Broadly, the report's 10 recommendations fall into four categories, which I will briefly summarize as a need to:

- 1. Improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information;
- 2. Refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem;
- 3. Increase transparency to improve usability and safety of EHRs; and
- 4. Foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the "learning health system."

Congress can and should play a vital role towards encouraging better EHR usability, improved interoperability and more meaningful patient engagement. For example, relatively simple steps could be taken to improve documentation requirements, such as encouraging regulatory guidance that clearly delineates who is and who is not eligible to enter data into the record for compliance and reimbursement purposes. A more impactful and coordinated undertaking would include the refinement and adoption of standards meant to integrate clinical data from patients, medical devices and other external sources into the EHR. Longer-term, Congress should develop policies that require CMS to revisit the entire billing and coding system that drives documentation for reimbursement and compliance purposes. Congress should also continue to promote broad adoption of alternative payment models, such as value-based purchasing, so that reimbursement is contingent on outcome-oriented measures, supported by less prescriptive and more flexible requirements for documentation.

Documentation – and the burdens associated with it – are only one piece of a larger, more complex puzzle. The EHR 2020 Task Force also recommended that policymakers refocus the varied set of regulations and policies shaping the development of the health IT market and its use within healthcare. The simple message resonating among the Tasks Force's recommendations: slow down regulation to accelerate progress. Ensuring CMS does not rush to get to the next stage of meaningful use, but rather works to help the private sector accelerate optimization of the tools and regulations that are already in place; reorienting ONC's certification program to test true



interoperability by testing how systems both send AND receive information are among the key steps HHS should take in the near-term. Should the regulatory pressure continue, stakeholders may look to Congress to intervene.

While these steps will help the private sector make advancements towards more interoperable, safer health IT systems, Congress would engender genuine and lasting impact by enabling all patients to have their medical record, not just a summary of their record, available in standardized, machine-readable formats. It is unconscionable that in 2015, with the widespread adoption of electronic health records, a patient must still print and scan their medical record when they change to a new physician. The future of healthcare will be characterized by an electronic, transportable record of care that provides customizable views and varied amounts of context depending on what the care team needs to deliver care, and according to patient preference. The record will have the ability to incorporate data from different sources, including patient generated data, population data and community context into an EHR. Once the complete medical record is available in an electronic form, patients can more fully participate in clinical research, precision medicine, and other activities in which they control who can use their data. The first step towards this future is to enable patients to have access to their entire record in a computable, electronic form, not just a summary of their record. The electronic standards are ready, and this is perhaps the single, most important work Congress can engage to help turn the page from our current state problems.

Should this Committee take up legislation during this or the next Congress, and should you focus on the areas described in the AMIA EHR 2020 Task Force report, I am confident that we can turn the page from the frustrations of today's technology to realize the promise of a truly integrated, modern healthcare experience for all patients and their care providers.

A more detailed explanation of recommendations and a copy of the EHR 2020 Task Force report will be submitted as part of the written record.

Thank you.



DETAILED TESTIMONY FOR THE RECORD

The remainder of my comments will detail the action items policymakers can take to improve the quality and efficiency of care delivery, optimize patient safety, and improve interoperability of health IT.

Recommendation 1: Improve documentation requirements and functionality to empower patients so that all members of the care team can contribute their perspectives and information For the last two decades, documentation requirements for reimbursement and compliance purposes have increased dramatically in healthcare. Rather than diminish the burdens associated with documentation, as information technology has done for countless other industries, EHRs have magnified the amount of time physicians and nurses spend away from the bedside, increasing their workload and contributing to worsened professional satisfaction. Because EHRs are expected to serve the dual purpose of capturing data for clinical and billing purposes, as well as envisioned to fulfill a myriad of quality reporting requirements, EHRs do not inherently promote sensible workflows. Quite the contrary, in many cases EHRs dictate workflows to users in order to generate reports and satisfy documentation requirements, creating a classic "tail wagging the dog" situation.

The EHR 2020 Task Force concluded that much of the information relevant to the diagnosis and treatment of a patient could more effectively be entered by other members of the care team, captured automatically by devices or other information systems or captured and entered by patients themselves. Further, the Task Force noted that moving away from the current evaluation and management (E/M) billing structure would free EHR developers to support more novel methods to collect important data. In order to help the care team get back to the bedside, Congress should:

- Encourage regulatory guidance clearly delineating who is and who is not eligible to enter data into the record for compliance and reimbursement purposes;
- Adopt standards meant to integrate clinical data from patients, medical devices and other external sources with the EHR;



- Encourage and support Federal agencies, such as AHRQ, NIH, NLM, NSF and NIST to study alternative approaches to documentation using different media and data sources to identify more efficient documentation;
- Finally, Congress should support and encourage further adoption of alternative payment models, such as value-based purchasing, so that reimbursement is contingent on outcomeoriented measures, supported by less prescriptive and more flexible requirements for documentation. This will focus attention on documenting outcomes and clinically relevant information (rather than processes and procedures), and will speed the adoption of better ways of capturing and documenting clinical care.

Recommendation 2: Refocus regulations so that patients and their caregivers can derive the most benefit from a networked healthcare ecosystem

Over the last five years, the federal government has been much more proactive in shaping the market for health IT and informatics. The federal government's centerpiece legislation, the HITECH Act, has driven significant efforts by public and private stakeholders, resulting in undeniable gains for the public good. The CMS EHR Incentive Program has enabled a remarkable rise in the adoption of EHRs and ONC's certification program has provided a long-overdue framework to identify, harmonize and drive the adoption of health IT standards across the fractured healthcare landscape. The impact of HITECH is undeniable, but so too are the burdens associated with compliance – and not just to meaningful use, but a host of other programs dependent on the use of IT and informatics tools. The growth in adoption and use of health IT has not been without its challenges.

Following completion of meaningful use Stage 1 and adoption of the 2011 Edition of Certified EHR Technology, many developers struggled to produce upgraded versions – 2014 Edition CEHRT – and many providers struggled to meet Stage 2 – more rigorous – requirements for meaningful use. Seeing these challenges, policymakers turned to a flurry of regulatory responses with exceptions, flexibility, and extended attestation periods. The challenges faced by healthcare stakeholders has also led to proposed legislation to increase flexibility in the program. These changes suggest that the



EHR incentive programs should take a different approach to leverage the gains already made and prevent further erosion of the program. Further, the federal government needs to refocus the wider set of health IT and informatics policies across agencies and programs.

The EHR 2020 Task Force recommended federal health IT regulations focus on 1) clarifying and simplifying MU regulations for providers and vendors; 2) improving data exchange and interoperability; and 3) Reducing duplicative quality measurement while prioritizing patient outcomes over new functional measures.

Clarify and simplify MU regulations for providers and vendors

In order to provide vendors with clarity on how to meet the MU certification criteria, ONC provides precise instructions for each MU functional objective. The advantage of this approach is that vendors know with certainty how to qualify for MU certification. An unintended consequence is that vendors believe their customers must follow the workflow they programmed into the certified function and built into the automated calculation of the MU threshold determination. This predetermined workflow built into EHR products significantly affects usability of the products, often in a negative way. The goal of certification should be to assure that standards are consistently used in vendor products, in how systems interact with each other, and how quality is measured. Properly used, standards can lead to *more* flexibility as best of breed and modular products allow customization. The certification program, however, has led to preprogrammed workflows that are intended only to meet the conditions of certification, and not the needs of health care providers. Near-term action items for Congress include:

- Ensuring CMS does not rush to get to the next stage of MU, but rather works to help the private sector accelerate optimization of the tools and regulations that are already in place;
- Create flexibility in the certification program by encouraging vendors to develop testing methods that focus on demonstrating a functional capability instead of adherence to a predetermined, prescriptive test procedures.

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Improve data exchange and interoperability

New certification requirements should focus on technical requirements that will improve interoperability and data exchange, support better quality measures, and provide for safer and more secure care. To do this Congress should:

- Engage with HHS to ensure that ONC's certification program tests not just conformance to the standards, but true interoperability. This means testing both how systems send information and making sure that they are flexible in how they receive information.
- Require that health IT vendors provide all patients with their entire medical record in a standards-based computable format;

Reducing duplicative quality measurement while prioritizing patient outcomes

Quality measurement and reporting has become the primary focus of many FTEs within any given healthcare system due to a proliferation of quality reporting programs, such as the Physician Quality Reporting System (PQRS) Program, Inpatient Quality Reporting (IQR) Program, meaningful use quality reporting requirements and a host of quality reporting regimes applied by state-level health officials or private-sector insurers and accreditation bodies. Many, if not most of these quality reporting requirements befall providers simultaneously and call for slightly different specifications of quality measures, rendering multiple uses of the same measures impossible. As federal legislators look to quality measures as the basis for future reimbursement models and consumer comparison efforts, federal regulators are looking to require submission of electronic clinical quality measures, which are incomplete and inaccurate without the addition of manual abstraction with current EHR systems.

The EHR 2020 Task Force recommended that quality measurement should focus on outcomes that are consistent with national priorities while also being relevant to patients, their communities and clinicians' specialties. And, again, working with payers and other stakeholders to develop payment alternatives that depend less on documentation and more on quality and value is likely to promote EHR innovation and uses that support these goals. In order to reduce duplicative quality measurement and prioritize patient outcomes over functional measures, Congress should:



- Develop a special committee dedicated to harmonizing quality measurement across federal, state and private sector stakeholders;
- Encourage development of accurate, complete and reusable electronically specified electronic CQMs, by building quality measures from a consistent set of data "building blocks".
- Study the value of complex versus simple quality measures, and use the results of those studies to simplify data collection and quality measure calculations. Complex quality measures will lead to complex data collection requirements, and simple, high quality measures may achieve the same goal at a lower cost.

Recommendation 3: Increase transparency to improve usability and safety of EHRs

Currently, purchasers of EHRs often do not have visibility into how applications work. This lack of transparency inhibits an effective, competitive marketplace. Those choosing EHRs need clear knowledge of what commercial EHR systems offer and, importantly, what workflows are incorporated into their use for frequent tasks such as creating notes, entering data, reconciling medications, responding to decision support, and extracting data for reports or research—so they can make more informed choices.

However, transparency in how EHRs perform during certification conformance testing is only one aspect of transparency. Users of health IT also need transparency in how systems perform after they're deployed in a live environment. Moreover, patients and their care providers should have a clear understanding of the safety performance of health IT and informatics tools. In order to improve usability and safety and to foster innovation, health care organizations, providers and vendors should be fully transparent about unintended consequences and new safety risks introduced by health information technology systems, including EHRs, as well as best practices for mitigating these risks. In order to create the most transparent market for health IT, Congress should:

 Encourage ONC to modify its certification program to streamline the certification process – as outlined previously in my comments – and better convey the process by which developers program common functionality and frequent tasks;



- Make all the results of testing and how each vendor satisfies the certification requirements open to the public for review. This should include not just summaries, but videos, screen shots and details of the workflow used to satisfy the certification requirements;
- Move forward with recent Food and Drug Administration Safety and Innovation Act (FDASIA) report recommendations to develop a public-private Health IT Safety Center that would promote health IT as an integral part of patient safety with the ultimate goal of assisting in the creation of a sustainable, integrated health IT learning system;
- Encourage a more inclusive "culture of safety," by affording similar safe harbors to vendors that are afforded to providers that participate with Patient Safety Organizations (PSOs)

Recommendation 4: Foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the "learning health system."

Given the complexity of our healthcare system, the incomplete state of several national efforts to modernize care, harness health data and empower patients, a clinician could be forgiven for being overwhelmed. But the future is bright and the possibilities are great. As a Nation, we are closer than any other point in history where every patient encounter could present an opportunity for patients and clinicians alike to contribute to our understanding of health care and participate in research and clinical trials. This is the essence of the learning health system.

In addition to enabling the incorporation of research knowledge into practice to support evidence based medicine, EHRs can enable evidence generating medicine thereby creating a virtuous cycle of rapid evidence generation and evidence-based care delivery, an essential element needed to create a learning health system and to advance precision medicine.

Although we don't know what the next generation EHR will look like, we know that it will likely be very different than the systems that we have now. If we want to have the same successes that we've seen in the internet, we need a stable base of standard building blocks that allows us to create new technology to benefit patients. Unfortunately, there is a disconnect between the promise of what we can do and the real-world infrastructure required to actually make it operational and scalable.



In order to foster innovation so that we can build toward the next generation of EHRs and realize the benefits of the learning health system, Congress should:

- Support the adoption of standards for connecting different systems together, such as Application Program Interfaces (APIs),
- Require standards that allow patients to have a copy of their entire medical record, not just a summary as previously described;
- Fund research on how to best capture data, integrate data and design new user interfaces utilizing the best computer and human-computer interaction science available; and
- Support innovation in precision medicine by making it easier to get information out of the electronic health records and into the hands of patients who wish to participate in precision medicine.

We know that the IT sector has in many other domains driving significant economic development and job growth. We believe the same is possible in Health IT, but we must create the innovation ecosystem that will allow everyone, not just the largest companies thrive in the expanding marketplace.

Together, we are confident these recommendations will improve the landscape for better, more usable EHRs that will lead to greater interoperability, more engaged patients and improved clinical outcomes. Congress can take tangible steps towards the improved future of health IT by reducing documentation burden, requiring vendors to give patients an electronic copy of their entire record, and by streamlining certification so the process is more flexible and transparent. These actions will enable advances in population health, precision medicine and capitalize on the progress made to-date.

Lawmakers have a vital role in determining the next evolution in EHRs, and AMIA stands ready to support Congress in this important work.