## Introduction

The Massachusetts Medical Society (MMS) represents over 25,000 physicians, residents and medical students in the Commonwealth. An essential part of our mission is “playing a leadership role in developing a sustainable model of health care delivery that will preserve the integrity of the doctor-patient relationship, and ensure the best care for patients, which is at the core of patient centered care[[1]](#footnote-1). To that end, we wish to express the opinion of our members regarding implementation of the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH), particularly the Meaningful Use (MU) provisions. We are encouraged by many recent changes in reporting and reimbursement requirements. But we remain concerned about several remaining features of the Act.

## Interoperability

We appreciate the potential benefits of health information technology. We agree that Electronic Health Records (EHRs), at least in theory, hold forth the promise of improved health care delivery and improved health outcomes. We are concerned, however, that EHR technologies and the mandates regarding their use, were pushed out to providers and patients before these constituencies were prepared to use them for the promised purpose.

A major reason why providers and patients were not ready for EHR technologies is the “interoperability problem”. Interoperability, for our purposes, means the ability of electronic systems and devices to transfer and share data and health information. In general, we’re cautiously optimistic about moves in the right direction regarding interoperability, but we continue to see substantial difficulties for our members.

### A Problem of Definition

One possible explanation for the interoperability problem is that the term “interoperability” was not defined precisely by HITECH. As a result, vendors and programmers were free to define the term as they wished. The result was a large number of commercially-available EHRs that did not transfer patient data between one another and did not interface with laboratories and pharmacies[[2]](#footnote-2)

The language of the Meaningful Use Stage 3 statute, including revisions, refers to interoperability repeatedly without defining the term. Several agencies, both governmental and non-governmental, have convened to deal with the problem. None have emerged with a workable definition of interoperability, leaving the medical community with a great deal of uncertainty over compliance with the mandate.

### A Problem of Technology

Adoption of MU standards, particularly Stage 2, has proven difficult for providers and patients alike: the “end-users” of EHRs.

Many providers, including “early adopters” who already had computerized offices and EHRs in place, felt unprepared for the documentation and reporting requirements imposed by HITECH[[3]](#footnote-3). Our physicians’ concerns include work-flow impediments imposed by documentation requirements, and a general concern that EHRs were designed primarily to satisfy MU and only secondarily to serve patients[[4]](#footnote-4).

Hospitals as well encountered problems with EHRs. It became apparent early on that medical devices such as telemetry units and fetal monitors did not interface with hospital EHR systems. This adds countless hours of wasteful data entry time on the part of nurses and ancillary staff. A mismatch between hospital and JCAHO requirements and MU reporting standards adds further wasteful documentation time. Patient care suffers as a result[[5]](#footnote-5).

If doctors and hospitals were unprepared to meet the mandate, patients were even less prepared for the transition to HIPAA-compliant, MU-mandated communication with providers. Many patients, particularly elderly and non-English speaking, have found adoption of electronic communication difficult if not impossible. Even younger, English-speaking patients, who are accustomed to electronic communication (including secure electronic communication) find mandated communication channels difficult to navigate. All these factors create disincentives for patients to use electronic interfaces to transfer information and data with providers.

### A Problem of Language

Despite numerous conventions and meetings of agencies, both governmental and non-governmental, the healthcare information technology industry has been unable (or unwilling) to create a standard “EHR Language” that would permit the kind of interoperability mandated by the relevant statutes. Privacy concerns (real and imagined) on the part of the public have also impeded the creation of standards that are required for interoperability of EHR systems.

Many observers believe that privacy concerns of patients and the special characteristics of the healthcare industry make the prospect of adoption of an industry-wide EHR language standard an impossibility. This assertion does not stand up to scrutiny. The banking industry encountered similar privacy concerns during the transition to a universal standard of communication that gave rise to the 100% interoperable automatic teller machine system, to cite only one example. Similarly, the telecommunications industry, in the context of vigorous competition, also developed a completely interoperable network that permits the communication network we enjoy today. The presence of governmental regulation cannot be advanced as an excuse to delay implementation of interoperability. Both banking and telecommunications are heavily-regulated industries, as is healthcare.

On the hardware side, the electronics industry convened and created the USB standard that proved essential to interoperability of electronic components, and to mutual survival of the several players in the industry.

Finally, concerns over patient privacy have blocked efforts to create a unique identifier for patients, that would be essential for creation of a fully interoperable healthcare network[[6]](#footnote-6). The automobile industry created such a standard with the vehicle identification number (VIN) standard, despite initial resistance. This move has benefited both the consumer and the automobile industry.

Therefore, for the healthcare industry, it makes eminent sense that we should not rush to mandate interoperability until the industry decides on its own, or is compelled by government, to create standards.

### HL7 is Inadequate to Solve the Interoperability Problem

In response to the interoperability problem, a “bridging” mechanism has evolved that today is known as “Health Level 7” (HL7). HL7 refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers. These standards focus on the application layer, which is "layer 7" in the “open systems interconnection” model[[7]](#footnote-7).

As a tool for permitting devices and EHRs to exchange patient data, HL7 has proven less than adequate. Both logistical and financial burdens are imposed that have made MU attestation more time-consuming and expensive for doctors and hospitals, while doing little to improve healthcare delivery and outcomes[[8]](#footnote-8).

HL7 “patches” and the like are offered by vendors and other third parties. For example, commercial or hospital laboratories use HL7-based mechanisms to transmit results reporting data to hospitals and provider offices. Such mechanisms often do not work as promised. They do however impose financial burdens on providers and hospitals that have proven onerous, especially to small practices.

An illustrative example: a small pediatrics practice in Massachusetts purchased an EHR system that permitted full compliance with MU. However, the providers needed to input manually all laboratory data that they received from both a commercial and a hospital lab. The commercial lab offered to purchase a patch based on HL7, but never fulfilled the promise. The hospital did not even make an offer. The practice had neither the means nor the knowledge to locate, purchase, and install a patch. As a result, the practice continues to perform manual input of data, at enormous cost in terms of work-flow and administrative time.

The HL7 standard and the logistical and financial burdens it imposes are powerful reasons to delay mandate of MU reporting until these interoperability problems can be addressed adequately.

### Data Blocking

“Data Blocking” refers to efforts, direct and indirect, to restrict or impede the transfer of patient data between practices and across systems. Both vendors and providers are incentivized currently to engage in data blocking, whether or not they do so consciously and deliberately.

Vendors have a proprietary interest in their EHR systems, which entail substantial research and development costs, as well as marketing and operating costs. There are currently no incentives to cause vendors to create products that “play nice” with others. Many vendors, including the largest and most prominent, possess the capability to make their systems interoperability. But such systems are essentially glorified HL7 interfaces. These cost extra money for hospitals and providers and do not often deliver the interoperability functions they promise.

Providers as well have their own proprietary interest, that being in retention of patients, either in a provider network or a private office. Many networks and providers are content to continue providing disincentives to patients seeking care out of network or out of the practice.

If health information were truly portable, meaning that EHRs were truly interoperable, we believe data blocking would pose much less of a barrier to patient-centered care. Such care would be based on individual preference, unconstrained by limitations imposed by data blocking.

## Patient Engagement

The third stage of Meaningful Use requires a substantial amount of electronic interaction between patient and provider. In addition, there are significant penalties imposed on providers if certain thresholds of patient engagement are not met. We believe that such requirements place hurdles in front providers in Massachusetts that may prove insurmountable.

For example, many providers serve populations that do not speak English. While many providers themselves are bi- and multi-lingual, the EHRs and their interfaces are all written in English[[9]](#footnote-9). For these populations, electronic communication is difficult or impossible. It may not be enough to provide written patient information in more than one language in order to satisfy MU3 requirements. Even if so, translation and production of language-specific materials presents a financial and logistical burden on our members, particularly small practices. We would request clarification on this issue before moving forward with the mandate.

Patient engagement presents a challenge to the elderly and non-computer savvy population, to say nothing of the visually-impaired[[10]](#footnote-10). Providers who see a primarily elderly population (Geriatricians) and Ophthalmologists are disproportionately challenged by the patient engagement mandate. Similarly, public health centers that serve the homeless and indigent population face a similar struggle to engage. We seek guidance on behalf of our members as to how to comply with MU3 with regard to patient engagement in these relatively non-connected populations.

Patient-generated health data (PGHD) capture is a concept that is mandated by the Meaningful Use Stage 3 Final Rules. Eligible providers must incorporate PGHD from more than 5% of unique patients during the reporting period[[11]](#footnote-11). However, this recommendation is made in the absence of evidence that sufficient numbers of patient-generated devices exist and that they are capable of transmitting relevant or useful data to clinicians. We await guidance from CMS on this issue.

Finally, and most concerning, MU3 imposes penalties on physicians for failure to achieve these patient-engagement goals[[12]](#footnote-12). In an era when we champion patient-centered care and value patient autonomy, we believe it is unfair to penalize physicians for patient behavior over which our members have no control. We ask that these penalties be removed or transferred to the responsible parties (patients) until such time as use of PGHD capture is clinically relevant and widely-adopted.

## Meaningful Use Does Not Address Important Concerns of Patients, Providers, and Vendors

### The Promise of Big Data

As with all organizations that care about population health, our members are concerned that Meaningful Use, as currently constructed, fails to deliver on the promise of Big Data[[13]](#footnote-13). In a truly interoperable healthcare world, data could be accessed securely while observing patient privacy and autonomy. These data are crucial for solving population health problems that are currently accessible only through lengthy and expensive epidemiologic studies. For example, medical device and drug safety analysis could be performed quickly and efficiently, promising potential enormous savings in reducing morbidity and mortality, to say nothing of costly litigation. Another forestalled potential is the leveraging of an interoperable system to perform large-scale clinical trials. Our members look forward with anticipation for the day when they will be able to offer their patients the benefits of Big Data.

### Concerns from Behavioral Health Providers

Clinicians who care for patients suffering from addiction and mental illness are also concerned about reporting requirements, but from an entirely different perspective. For obvious reasons, behavioral health clinicians and their patients worry that information will be shared too widely, as opposed to not widely enough. Our members are concerned that insufficient consideration has been paid to the particular privacy concerns of this vulnerable population. We ask that full deployment of these reporting requirements be delayed until such time as privacy safeguards for behavioral health patients can be developed.

### Burdens on Providers

The logistical difficulties of installing and managing an EHR are considerable enough. However, the financial burdens imposed by MU reporting requirements may prove insurmountable, particularly to small practices[[14]](#footnote-14). The incentive payment provided by the MU program do offset many of the start-up costs involved in setting up an EHR and integrating it with hospitals, pharmacies and laboratories. However, there are considerable on-going costs associated with HL7 patches, service contracts, and per-provider licensing fees, to name only a few. These costs add to the already high cost of doing business in our state. Our smaller providers are desperate for relief from pressures to sell their practices or to consolidate with other providers. We are encouraged by efforts on the part of CMS to incentivize clinicians to provide excellent care to our patients. The recent adoption of MACRA is a move in this direction.

### Burdens on Vendors

When asked by end-users to help solve their interoperability problems, vendors often complain that they would like to, but too many of their resources are consumed by creating and maintaining products that satisfy MU requirements[[15]](#footnote-15). Whereas we have no independent means for verifying this claim, we have no reason not to accept it at face value. Perhaps the vendors underestimate the amount of resources and time they can devote to interoperability? If so, a freeze or delay in MU implementation might reorient the incentives in the industry. Historically, in other industries, the market has always incentivized reluctant participants to implement interoperability. We see no reason why healthcare will be different. Therefore, our members ask that EHR vendors be engaged and become active participants in the process of developing a truly interconnected healthcare information infrastructure.

## On Provider Penalties

The Massachusetts Medical Society emphatically enjoins CMS from imposing penalties on its members related to Meaningful Use reporting regarding issues over which the physicians and institutions have no control. These include, but are not exclusive to, interoperability mandates and patient-engagement metrics.

Our members are fully committed to providing high-quality care and services based on best practices and evidence-based medicine. We were “early adopters” of EHR technology. We were among the founding members of the Massachusetts EHealth Collaborative (MAeHC). According to our 2016 MMS member survey, over 90% of Massachusetts physicians currently use EHRs, with a significant percentage having used them for nearly 10 years. Despite this fact, only 20% of these same physicians have been able to meet Meaningful Use Stage 2 including some of our most tech-savvy and enthusiastic providers. We believe the inherent problems with the design of the EHRs and the meaningful use program must be acknowledged and corrected before penalties can be reasonably distributed.

### Where Penalties Properly Belong

The Massachusetts Medical Society, on behalf of its members, recommends substantial financial penalties levied on vendors who do not provide, and health care organizations that do not allow, for full interoperability features with their products. Interoperability is the cornerstone of the health information exchange infrastructure. Without true interoperability between and among systems, the full promise of health information technology cannot be realized. We assert that the burden for meeting this standard rests with vendors and healthcare organizations that our members rely upon. We are grateful for steps some players in the industry have already taken but we implore them to finish the task and provide complete interoperability, on the scale achieved by the banking and telecommunications industry.

## The Benefits of MACRA

The membership of MMS acknowledges with gratitude the recent adoption of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We appreciate that the new proposal offers features that would make it easier for physicians to benefit from implementing EHR systems. In contrast to the previous Meaningful Use incentive system, our members will have more flexibility with the new system, and it better aligns with other Medicare reporting programs.

We recognize that the reporting and reimbursement system remains complex, but we are encouraged by the progress that MACRA represents, and look forward with great anticipation to further reforms and improvements. We are particularly grateful to CMS for listening to physician and patient advocate voices and making appropriate adjustments to the law as a result.

1. http://www.massmed.org/About/Mission-and-Priorities/MMS-Mission-and-Strategic-Priorities/#.VyYpDKMrLBI [↑](#footnote-ref-1)
2. Modern Healthcare. August 3, 2015 [↑](#footnote-ref-2)
3. Modern Healthcare April 7, 2014 [↑](#footnote-ref-3)
4. AMA town hall [↑](#footnote-ref-4)
5. Modern Healthcare May 11, 2015 [↑](#footnote-ref-5)
6. Modern Healthcare. January 25, 2016 [↑](#footnote-ref-6)
7. HL7 Wikipedia [↑](#footnote-ref-7)
8. “Swivel chair”, IBID [↑](#footnote-ref-8)
9. http://www.healthcareitnews.com/blog/meaningful-use-workgroup-recommendations [↑](#footnote-ref-9)
10. http://gettingpaid.kareo.com/gettingpaid/2014/04/3-ways-to-get-elderly-patients-to-use-a-patient-portal/ [↑](#footnote-ref-10)
11. https://www.mwe.com/en/thought-leadership/publications/2015/11/meaningful-use-stage-3-final-rules [↑](#footnote-ref-11)
12. http://www.cmanet.org/news/detail/?article=cms-rule-reduces-meaningful-use-burdens-cma [↑](#footnote-ref-12)
13. Modern Healthcare January 19, 2015 [↑](#footnote-ref-13)
14. http://www.ca-hie.org/site-content/2015/09/Stage-3-MU-NRPM-Comments\_final.pdf [↑](#footnote-ref-14)
15. Big data learning curve. Ibid [↑](#footnote-ref-15)