

February 25, 2011

Department of Health and Human Services Office of the National Coordinator for Health Information Technology Attention: Joshua Seidman Mary Switzer Building 3330 C Street SW, Suite 1200 Washington, DC 20201

### **RE:** Request for Comments Regarding Meaningful Use Stage 2

Dear Dr. Seidman:

On behalf of AMIA (the American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced request for comment (RFC). AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

AMIA thanks the HIT Policy Committee (HITPC) for issuing this RFC to solicit feedback on the preliminary set of recommendations for Stage 2 meaningful use (MU) objectives. We understand that, as called for by the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), such rules are to take effect for payment years 2013 and 2014. We applaud the very rapid pace at which the HIT Policy and HIT Standards Committees have worked to advise the Department of Health and Human Services (HHS) as it implements the electronic health record (EHR) incentive program. AMIA appreciates that, in addition to taking public testimony in a series of hearings, the HITPC has initiated a more formal public comment process in advance of its final Stage 2 recommendations. In providing input, we will respond to the queries posed regarding proposed Stage 2 objectives and discuss as well some of the broader questions relating to EHR functionalities included in the RFC.

### **General Comments**

AMIA strongly believes that three principles are essential to achieving meaningful use of certified EHR technology: 1) we must invest in people, as well as in technology; 2) users need EHR systems that provide cognitive support and evidence-based functionalities; and 3) adoption of EHR systems requires a balancing of benefits and burdens that users will accept.

### 1. The need to invest in people, as well as technology:

The use of health information technologies and information science principles, tools and practices will, ultimately, enable clinicians to make healthcare safer, more effective, efficient, patient-centered, timely and equitable. This goal can be achieved only if such concepts and technologies are fully integrated into clinical practice and education. In addition to a substantial investment in capital, technology and resources, the successful implementation of a safe electronic platform to improve healthcare delivery and quality will require an investment in people across a broad range of expertise levels. That is, we must ensure that healthcare providers not only invest in EHR systems, but obtain the competencies required to work with electronic records, including basic computer skills, information literacy, and an understanding of informatics and information management capabilities. In brief, achieving "meaningful use" will be a matter not only of providing financial assistance to eligible providers and hospitals to purchase qualified systems and then expecting technology vendors to provide adequate training and support for the use of those systems, but also to assist providers in obtaining the competencies necessary to select and use EHR systems effectively, and it will mean developing the clerical, administrative and technical staff necessary to support a healthcare enterprise built on electronic platforms. Importantly, developing a real "meaningful use" pathway for EHRs will also require supporting the basic and applied informatics science needed to address issues of design safety, change implementation, error monitoring and reduction, and the like.

# 2. The need for cognitive and decision support as well as evidence-based functionalities to improve patient safety and minimize potential harm:

Under the current (and future) payment rules of the electronic health record incentive program (42 CFR Parts 412, 413, 422 and 495), achieving meaningful use goals and objectives is, ultimately, the responsibility of eligible professionals (EPs) and hospitals. But, while EHR certification criteria include requirements for enabling or demonstrating functionalities, they do not include requirements for evidence that those functionalities work as intended under real-time conditions of use. While we are enormously supportive of the financial incentives afforded to eligible providers and hospitals under the payment incentive program, we are concerned that EHRs will continue to serve as large, costly receptacles of data with the potential for decision support but may not enable clinicians to achieve the desired levels of continuity, quality, and safety of care.

In our view, many of the Stage 1 MU criteria and measures (on which the Stage 2 recommendations build) seemed to be somewhat arbitrary "add-on" functionalities that may or may not support valid use of the EHR by clinicians under practice conditions. We believe that MU criteria and quality measures should be carefully designed and tested to minimize the burden required to process and connect new pieces of information cognitively with the existing clinical record. Showing that a user can record, modify, and retrieve a single piece of information or measure it effectively is very different from demonstrating that the EHR fully supports the user's need to apply that information in a way that meaningfully affects the delivery and the quality of care.

We continue to be concerned that the rule issued by ONC for certification of EHR technology, while including directions for testing of complete EHRs and EHR modules that integrate standards and criteria, may still fall short of ensuring HIT systems that provide not just information but effective cognitive support to users in the clinical setting. Put another way, given the current state of EHRs it is critical that payment and certification rules support "meaningful use" that is genuinely achieved, and are not just one more set of documentation standards that bring little value at the point of care. Planned and systematic testing and evaluation are needed to demonstrate achievement of meaningful use, interoperable health systems, and attainment of the desired effects on improved quality of care.

#### 3. The need to find a balance of benefits and burdens:

Explaining its rulemaking approach for Stage 1 MU, CMS stated: "In defining meaningful use through the creation of criteria, we have balanced competing considerations of proposing a definition that best ensures reform of health care and improved health care quality, encourages widespread EHR adoption, promotes innovation, and avoids excessive or unnecessary burdens on healthcare providers, while at the same time recognizing the short time-frame available under the HITECH Act for providers to begin using certified EHR technology." AMIA supports the Department's goal of developing MU criteria and payment policies that will in fact improve health care quality and promote innovation in care delivery and patient involvement, but we remain concerned about the wide range of goals that the Stage 1 (and now proposed Stage 2) objectives seem to be aimed at, from changing physician and other stakeholder behavior to shaping and in some instances dictating HIT functions and performance. Simply, we are concerned about the use of EHR incentives that may create significant burdens for providers and are only indirectly related to advancing processes of care or improvements in quality, safety, or efficiency.

AMIA suggests that only mature technology applications should be included as a MU criterion for stage 2 or 3. There seems to be an underlying assumption by ONC that if a technology exists

and is in use that it should be made a requirement for everyone. We think there should be an emphasis on technologies that are mature and have been demonstrated to be efficacious. Process change takes time and resources, and incremental progress is preferable to wholesale process change. Further, we encourage the HITPC to continue to consider MU objectives that reflect the inter-disciplinary nature of care delivery and care coordination beyond the walls of the hospital and beyond the current spectrum of EPs.

### Answers to Specific Questions Posed By the HITPC

1. <u>How can electronic progress notes be defined in order to have adequate specificity?</u>

Because the content and structure of progress notes need to reflect the care of diverse patients by an interdisciplinary care team, and thus varies across specialties and subspecialties, AMIA does not believe that the structure or specific elements of progress notes should be prescribed in MU objectives. However, we do think it would be useful to separate the documentation of time-dependent factors (e.g., history of present illness) from the static (or infrequently updated) factors (e.g., past medical history (PMH); family history (FH)) and to emphasize "type-once – use everywhere" coded or structured documentation. Part of the policy challenge is to align any documentation changes with reimbursement and payment requirements among other requirements. In fact, it is not clear to what extent any MU objectives that relate to documentation requirements can or will be harmonized with other clinical documentation requirements (such as those included as part of Medicare Conditions of participation; the Joint Commission accreditation standards; third party payers; state laws; and/or performance measures).

2. For patient/family access to personal health information, what standards should exist regarding accessibility for people with disabilities (e.g., interoperability with assistive technologies to support those with hearing, visual, speech, or mobile impairments)?

Various federal standards already exist in this area. These should be evaluated for feasibility and applicability for a Stage 3 time frame. Many operating systems have disability accessibility features and it would not seem efficient to require PHR/ EHR vendors to duplicate that functionality.

3. <u>What strategies should be used to ensure that barriers to patient access – whether secondary</u> to limited internet access, low health literacy and/or disability – are appropriately addressed?

This question perfectly illustrates our concern that EHR objectives are being asked to carry burdens – in this case relating to educational, health status and socioeconomic factors – that are far beyond the scope of health information technology implementation. While AMIA would be very pleased to be part of a dialogue on the issue of barriers to patient access, we do not believe that such a question is within the scope of "meaningful use" as defined by ARRA. We strongly

believe that the MU objectives must not become yet another stand-alone set of reporting requirements that, through well-meaning attempts to correct a wide variety of problems that exist in our healthcare system and in our society, impede the acceptance and effective application of EHRs in the delivery of quality and effective healthcare.

4. <u>What are providers' and hospitals' experiences with incorporating patient-reported data (e.g., data self-entered into PHRs, electronically collected patient survey data, home monitoring of biometric data, patient suggestions of corrections to errors in the record) into EHRs?</u>

While various positive examples of patient-reported data can be cited in general we believe that , hospitals and physicians have very limited experience in this area and AMIA would suggest going slowly until there is a better understanding of potential benefits, risks, and burdens of incorporating patient-reported data into the electronic health record. We do think the domain of patient-reported outcomes measures is an extremely important one and that there should be increased federal support for research in this area, but it would be premature to begin to require use of these as part of MU. AMIA previously submitted comments to ONC about personal health records and has voiced there our concerns and recommendations in this area.

5. For future stages of meaningful use assessment, should CMS provide an alternative way to achieve meaningful use based on demonstration of high performance on clinical quality measures (e.g., can either satisfy utilization measures for recording allergies, conducting CPOE, drug-drug interaction checking, etc, or demonstrate low rates of adverse drug events)?

Yes. If the goal of having MU criteria is improved outcomes, then demonstration of improved outcomes should be sufficient to demonstrate MU. That said, we again express our concern that the MU objectives must not become yet another stand-alone set of reporting requirements that impede the delivery of quality and effective healthcare. We urge the HITPC to harmonize requirements across existing and contemplated reporting programs.

## 6. <u>Should Stage 2 allow for a group reporting option to allow group practices to demonstrate</u> <u>meaningful use at the group level for all EPs in that group?</u>

Our answer is, Yes, definitely – in many ways, group reporting would more accurately capture the "meaningful use" of an EHR system at the actual point of care across a target population in this way. This would also substantially decrease provider burden.

7. In stage 1, as an optional menu objective, the presence of an advance directive should be recorded for over 50% of patients 65 years of age or older. We propose making this objective required and to include the results of the advance-directive discussion, if available. We invite public comment on this proposal, or to offer suggestions for alternative criteria in this area.

This is a very high proportion and there is no there is no explanation for why ONC believes that this is the correct proportion. See our comment on the attached table.

## 8. <u>What are the reasonable elements that should make up a care plan, clinical summary, and discharge summary?</u>

While standardizing elements to be included in care plans, clinical summaries, and discharge summaries definitely need to be pursued, the topic should be supported and agreed upon before it should be included in MU. This should represent a high priority for ONC and perhaps a subgroup of the Standards Committee could be tasked with how to meet this goal.

# 9. <u>What additional meaningful-use criteria could be applied to stimulate robust information</u> <u>exchange?</u>

On the positive side, HIE for laboratory values is within reach with current HL7 standards and HIE regional pilots/networks. The development of HIE policies and MU criteria surrounding medication data (fills, active medications, recent changes) would potentially contribute to large benefits to clinical care. On the whole, however, the key for "robust" information exchange will be hardware and networks that do not go down without immediate fail-over backup. Today, the Internet is robust but may not be sufficiently reliable for medical needs in real time. AMIA would urge the development of information exchange standards in relation to specific objectives, such as the transmission of laboratory values, rather than as a broad but vague conceptual goal.

### **Additional Comments**

AMIA notes that current Stage 1 MU criteria and functionality measures are focused entirely on the delivery and measurement of clinical care. We believe that MU criteria specific to research should be included during Stage 2 – for instance: "create and aggregate de-identified data and limited data sets for quality and research, by diagnosis, treatment, medication, etc.; utilize CDISC (Clinical Data Interchange Standards Consortium) or other agreed-upon standards to allow 'automatic' adverse drug event reporting".

The Stage 1 measure for ensuring adequate privacy and security protections is to conduct or review a security risk analysis per 45 CFR 164.308(a)(1) and implement security updates as necessary. Requiring a HIPAA Security Rule review by all EPs and hospitals constitutes a large, but important, compliance task – we are concerned, however, that the "<u>additional</u> [emphasis added] privacy and security objectives under consideration via the HIT Policy Committee's Privacy & Security Tiger Team" will make that compliance task genuinely burdensome for EPs and EHs.

We recommend that the HITPC continue to consider options for Population Health / Public Health Criteria for Meaningful Use stages 2 and 3 and in an ongoing effort to advance quality outcomes and improvements. We support the ultimate goal of electronic case reporting from EHRs for public health reporting.

Please see the annotated Table of the HITPC proposed Stage 2 and Stage 3 objectives for our additional comments. We have for example, noted specific instances where we believe additional definition and clarification of terms and terminology is warranted.

### **Concluding Comments**

As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, uses and protection of clinical and personal health information, and public health considerations, AMIA appreciates the opportunity to submit these comments. Again, we thank the HITPC for soliciting public input to help inform the next stage of MU recommendations so that eligible providers and hospitals and technology vendors can prepare to demonstrate meaningful use of EHR and qualify for payment incentives under the Medicare and Medicaid programs. Please feel free to contact me at any time for further discussion of the issues raised here.

Sincerely,

Edward & Shortliffe

Edward H. Shortliffe, MD, PhD President and CEO, AMIA

Meaningful Use: Stage 1 Final Rule and Proposed Objectives for Stages 2 and 3

| Stage 1 Final Rule                               | Proposed Stage 2  | Proposed Stage 3  | <b>ONC Comments</b>  | AMIA Comments   |  |  |  |
|--|---|---|--|---|--|--|--|
|  | Improving Quality, Safety, Efficiency & Reducing Health Disparities   |   |  |   |  |  |  |
| <b>CPOE for medication</b><br>orders (30%)       | CPOE (by licensed professional) for<br>at least 1 medication, and 1 lab or<br>radiology order for 60% of unique<br>patients who have at least 1 such<br>order (order does not have to be<br>transmitted electronically) | CPOE (by licensed professional) for at<br>least 1 medication, and 1 lab or radiology<br>order on 80% of patients who have at<br>least 1 such order (order does not have to<br>be transmitted electronically)  |  | If meaningful users can meet the objective of 30% in 2011,<br>AMIA believes that the goals of 60% in Stage 2 and 80% in<br>Stage 3 represent reasonable expectations for deployed<br>systems that are being incentivized  |  |  |  |
| Drug-drug/drug-<br>allergy interaction<br>checks | Employ drug-drug interaction<br>checking and drug allergy checking<br>on appropriate evidence- based<br>interactions  | Employ drug-drug interaction checking,<br>drug allergy checking, drug age checking<br>(medications in the elderly), drug dose<br>checking (e.g., pediatric dosing,<br>chemotherapy dosing), drug lab<br>checking, and drug condition checking<br>(including pregnancy and lactation) on<br>appropriate evidence- based interactions | Reporting of drug interaction<br>checks to be defined by quality<br>measures workgroup   | AMIA assumes that "appropriate" evidence-based<br>interactions" means "relevant" evidence-based interactions<br>here. We suggest that further definition is needed for<br>"appropriate" evidence-based interactions".   |  |  |  |
| E-prescribing (eRx)<br>(EP) (40%)                | 50% of orders (outpatient and hospital discharge) transmitted as eRx  | 80% of orders (outpatient and hospital discharge) transmitted as eRx  | If receiving pharmacy cannot<br>accept eRx, automatically<br>generating electronic fax to<br>pharmacy OK   | Presuming an objective of 40% at Stage 1, AMIA suggests that 60% of outpatient and hospital discharge orders be transmitted as eRx in Stage 2   |  |  |  |
| Record demographics<br>(50%)                     | 80% of patients have demographics<br>recorded and can use them to produce<br>stratified quality reports   | 90% of patients have demographics<br>recorded (including IOM categories) and<br>can use them to reports<br>produce stratified quality reports   |  | We are confused by the language here – we presume that the actual objective is that EPs and EHs can produce "stratified quality reports" not that individual patients can do so.<br>Multiple studies show that there are pitfalls in properly collecting useful and comparable demographic data.<br>Assuming that this functionality is to some extent outside of the clinician's control, should not this objective properly be a certification criterion? |  |  |  |
| Report CQM<br>electronically                     | Continue as per Quality Measures<br>Workgroup and CMS   | Continue as per Quality Measures<br>Workgroup and CMS   | The HIT Policy Committee's<br>Quality Measures Workgroup<br>issued a request for comment in<br>December; new measures will be<br>considered after review of public | We recommend submission of patient-level quality data via<br>the Quality Reporting Document Architecture (QRDA)   |  |  |  |

| Stage 1 Final Rule                                  | Proposed Stage 2  | Proposed Stage 3  | ONC Comments   | AMIA Comments  |
|---|---|---|--|--|
|   |   |   | comments   |  |
| Maintain problem list<br>(80%)                      | Continue Stage 1  | 80% problem lists are up-to-date  | Expect to drive list to be up-to-<br>date by making it part of patient<br>visit summary and care plans | Given the high expected objective of Stage 1, AMIA<br>supports this continuation. However, we continue to be<br>concerned about the lack of standards for problem lists. For<br>example, the definition of "up-to-date" is problematic: do<br>we mean up-to-date as of the last visit, the last encounter<br>within the ACO or HIE, the last time when a patient entered<br>a change in his/her non-network PHR, etc? We recommend<br>that further clarification be provided for the term "up-to-<br>date," and that research be supported to assess what sort of<br>definition would be beneficial. |
| Maintain active med<br>list (80%)                   | Continue Stage 1  | 80% medication lists are up-to-date   | Expect to drive list to be up to date via medication reconciliation                                    | We recommend that further clarification be provided for the term "up-to-date".   |
| Maintain active<br>medication allergy list<br>(80%) | Continue Stage 1  | 80% active medication allergy lists are up-to-date  | Expect to drive list to be up-to-<br>date by making it part of patient<br>visit summary                | We recommend that further clarification be provided for the term "up-to-date".   |
| Record vital signs<br>(50%)                         | 80% of unique patients have vital signs recorded  | 80% of unique patients have vital signs recorded  |  | AMIA supports this increase from the Stage 1 objective to the Stage 2 objective.   |
| Record smoking<br>status (50%)                      | 80% of unique patients have smoking status recorded   | 90% of unique patients have smoking status recorded   |  | AMIA supports this.  |
| Implement 1 CDS rule                                | Use CDS to improve performance on<br>high- priority health conditions.<br>Establish CDS attributes for purposes<br>of certification: 1. Authenticated<br>(source cited); 2. Credible, evidence-<br>based; 3. Patient-context sensitive; 4.<br>Invokes relevant knowledge; 5.<br>Timely; 6. Efficient workflow; 7.<br>Integrated with EHR; 8. Presented to<br>the appropriate party who can take<br>action | Use CDS to improve performance on<br>high- priority health conditions.<br>Establish CDS attributes for purposes of<br>certification: 1. Authenticated (source<br>cited); 2. Credible, evidence-based; 3.<br>Patient-context sensitive; 4. Invokes<br>relevant knowledge; 5. Timely; 6.<br>Efficient workflow; 7. Integrated with<br>EHR; 8. Presented to the appropriate<br>party who can take action |  | AMIA supports implementation of CDS. We note, however, that it has been much more effective for some conditions than others.   |
| Implement drug                                      | Move current measure to core  | 80% of medication orders are checked  | What is the availability of  | Implied in this requirement is that insurers and PBMs be   |

\*Indicates Menu (Optional) Item

| Stage 1 Final Rule   | Proposed Stage 2  | Proposed Stage 3   | ONC Comments   | AMIA Comments   |
|--|---|--|--|---|
| formulary checks   |   | against relevant formularies   | formularies for eligible<br>professionals?   | required to furnish up-to-date formularies to EPs and EHs,  |
| Record existence of<br>advance directives<br>(EH) (50%)*                   | Make core requirement. For EP and<br>EH: 50% of patients >=65 years old<br>have recorded in EHR the result of an<br>advance directive discussion and the<br>directive itself if it exists | For EP and EH: 90% of patients >=65<br>years old have recorded in EHR the<br>result of an advance directive discussion<br>and the directive itself if it exists                                    | Potential issues include: state<br>statutes; challenges in outpatient<br>settings; age; privacy; specialists;<br>needs to be accessible and<br>certifiable; need to define a<br>standard | We support making this a core requirement, but question the investment of resources that would be necessary to meet a 50% of patients (for stage 2) and then 90% at stage 2 fro some EPs.   |
| Incorporate lab<br>results as structured<br>data (40%)*                    | Move current measure to core, but<br>only where results are available   | 90% of lab results electronically ordered<br>by EHR are stored as structured data in<br>the EHR and are reconciled with<br>structured lab orders, where results and<br>structured orders available |  | We support moving this measure from 'optional' to 'core'<br>but do want to note that adding the necessary proviso that the<br>measure is required "only where (when) results are<br>available" will make actual certification of the objective<br>more subjective than objective. |
| Generate patient lists<br>for specific<br>conditions*                      | Make core requirement. Generate<br>patient lists for multiple patient-<br>specific parameters   | Patient lists are used to manage patients<br>for high-priority health conditions   |  | We agree that meaningful use should include this capability<br>as a core function. The phrase "High-priority health<br>conditions" needs further clarification.   |
| Send patient<br>reminders (20%)*   | Make core requirement.  | 20% of active patients who prefer to<br>receive reminders electronically receive<br>preventive or follow- up reminders   | How should —active patient    be defined?  | "Active" patient must be defined before this can become a core requirement.   |
| (NEW)  | 30% of visits have at least one electronic EP note  | 90% of visits have at least one electronic<br>EP note  | Can be scanned, narrative, structured, etc.  | AMIA supports this objective.   |
| (NEW)  | 30% of EH patient days have at least<br>one electronic note by a physician,<br>NP, or PA  | 80% of EH patient days have at least one electronic note by a physician, NP, or PA   | Can be scanned, narrative, structured, etc.  | AMIA supports this objective.   |
| (NEW)  | 30% of EH medication orders<br>automatically tracked via electronic<br>medication administration recording  | 80% of EH inpatient medication orders<br>are automatically tracked via electronic<br>medication administration recording   |  | AMIA supports this objective.   |
|  | ·   | Engage Patients and Fa   | amilies in their Care  |   |
| Provide electronic<br>copy of health<br>information, upon<br>request (50%) | Continue Stage 1  | 90% of patients have timely access to<br>copy of health information from<br>electronic health record, upon request   | Only applies to information<br>already stored in the EHR   | AMIA supports this objective, but we believe the CMS regulation must provide guidance regarding the issue of the specific electronic medium (flash drive, e-mail attachment,  |

\*Indicates Menu (Optional) Item

| Stage 1 Final Rule   | Proposed Stage 2   | Proposed Stage 3  | ONC Comments   | AMIA Comments   |
|--|--|---|--|---|
|  |  |   |  | e-mail message), the format of the information (e.g.,<br>machine-readable vs. PDF), and the respective obligations of<br>providers and patients regarding privacy and security of<br>health information.  |
| Provide electronic<br>copy of discharge<br>instructions (EH) at<br>discharge (50%) | Electronic discharge instructions for<br>hospitals (which are given as the<br>patient is leaving the hospital) are<br>offered to at least 80% of patients<br>(patients may elect to receive only a<br>printed copy of the instructions)  | Electronic discharge instructions for<br>hospitals (which are given as the patient<br>is leaving the hospital) are offered to at<br>least 90% of patients in the common<br>primary languages (patients may elect to<br>receive only a printed copy of the<br>instructions)                | Electronic discharge instructions<br>should include a statement of the<br>patient's condition, discharge<br>medications, activities and diet,<br>follow-up appointments, pending<br>tests that require follow up,<br>referrals, scheduled tests [we invite<br>comments on the elements listed<br>above]  | AMIA supports this objective. Again, however, we believe<br>the CMS regulation must provide guidance regarding the<br>issue of specific electronic medium (flash drive, e-mail<br>attachment, e-mail message), the format of the information<br>(e.g., machine-readable vs PDF), and the respective<br>obligations of providers and patients regarding privacy and<br>security of health information.   |
| EHR-enabled patient-<br>specific educational<br>resources (10%)                    | Continue Stage 1   | 20% offered patient- specific educational<br>resources online in the common primary<br>languages  |  | While we strongly support the availability of patient-specific<br>educational resources, AMIA is concerned that by having<br>MU objectives related to patient education/teaching EHRs<br>are apparently being seen as a panacea for all that ails the<br>current health care system. "Common primary languages"<br>needs further clarification.   |
| (NEW for EH)   | 80% of patients offered the ability to<br>view and download via a web-based<br>portal, within 36 hours of discharge,<br>relevant information contained in the<br>record about EH inpatient encounters.<br>Data are available in human readable<br>and structured forms (HITSC to<br>define). | 80% of patients offered the ability to<br>view and download via a web-based<br>portal, within 36 hours of discharge,<br>relevant information contained in the<br>record about EH inpatient encounters.<br>Data are available in human readable and<br>structured forms (HITSC to define). | Inpatient summaries include:<br>hospitalization admit and<br>discharge date and location; reason<br>for hospitalization; providers;<br>problem list; medication lists;<br>medication allergies; procedures;<br>immunizations; vital signs at<br>discharge; diagnostic test results<br>(when available); discharge<br>instructions; care transitions<br>summary and plan; discharge<br>summary (when available);<br>gender, race, ethnicity, date of<br>birth; preferred language; advance<br>directives; smoking status. [we<br>invite comments on the elements<br>listed above] | As a new requirement, we are concerned that many hospitals,<br>especially small and rural hospitals, may not be able to put<br>into place web-based portals that allow access to this much<br>specific information within 36 hours, without engendering<br>significant risks to compliance with the Privacy and Security<br>rules, given a very short two-year timeframe for<br>implementation. The requirement for access to a web-based<br>portal, along with the objectives related to "clinical<br>summaries", discharge summaries, and discharge<br>instructions" should be reconciled and/or harmonized as<br>appropriate. We suggest that additional clarification is<br>needed about how patients' ability to assess the internet will<br>be documented and determined. |

| Stage 1 Final Rule   | Proposed Stage 2  | Proposed Stage 3  | ONC Comments   | AMIA Comments   |
|--|---|---|--|---|
| Provide clinical<br>summaries for each<br>office visit (EP) (50%)  | Patients have the ability to view and<br>download relevant information about<br>a clinical encounter within 24 hours<br>of the encounter. Follow-up tests that<br>are linked to encounter orders but not<br>ready during the encounter should be<br>included in future summaries of that<br>encounter, within 4 days of becoming<br>available. Data are available in<br>human- readable and structured forms<br>(HITSC to define) | Patients have the ability to view and<br>download relevant information about a<br>clinical encounter within 24 hours of the<br>encounter. Follow-up tests that are linked<br>to encounter orders but not ready during<br>the encounter should be included in<br>future summaries of that encounter,<br>within 4 days of becoming available.<br>Data are available in human readable and<br>structured forms (HITSC to define) | The following encounter data are<br>included (where relevant):<br>encounter date and location;<br>reasons for encounter; provider;<br>problem list; medication list;<br>medication allergies; procedures;<br>immunizations; vital signs;<br>diagnostic test results; clinical<br>instructions; orders: future<br>appointment requests, referrals,<br>scheduled tests; gender, race,<br>ethnicity, date of birth; preferred<br>language; advance directives;<br>smoking status. [we invite<br>comments on the elements listed<br>above] | This requirement seems to seek to influence clinical and<br>administrative workflow, as much as to drive standards for<br>meaningful use of EHRs. 24 hours may not be a reasonable<br>requirement of an EP or EH. It is likely to be too aggressive<br>and potentially unattainable for many EPs.   |
| Provide timely<br>electronic access (EP)<br>(10%)  | Patients have the ability to view and<br>download (on demand) relevant<br>information contained in the<br>longitudinal record, which has been<br>updated within 4 days of the<br>information being available to the<br>practice. Patient should be able to<br>filter or organize information by date,<br>encounter, etc. Data are available in<br>human-readable and structured forms<br>(HITSC to define).                       | Patients have the ability to view and<br>download (on demand) relevant<br>information contained in the longitudinal<br>record, which has been updated within 4<br>days of the information being available<br>to the practice. Patient should be able to<br>filter or organize information by date,<br>encounter, etc. Data are available in<br>human readable and structured forms<br>(HITSC to define).                      | The following data elements are<br>included: encounter dates and<br>locations; reasons for encounters;<br>providers; problem list; medication<br>list; medication allergies;<br>procedures; immunizations; vital<br>signs; diagnostic test results;<br>clinical instructions; orders;<br>longitudinal care plan; gender,<br>race, ethnicity, date of birth;<br>preferred language; advance<br>directives; smoking status. [we<br>invite comments on the elements<br>listed above]  | While we believe that EHRs should indeed be able to filter<br>or organize information along various parameters, we would<br>suggest that this requirement be facilitated for EPs and EHs<br>before we focus on the patient. Put differently, this objective<br>appears to make it a requirement that patients be able to<br>access and manipulate their health information online. Why<br>should this be a requirement of an EHR system? Might this<br>objective not be better accomplished by a PHR?<br>"Longitudinal record "needs further definition and<br>clarification. |
| This objective sets the<br>measures for<br>—Provide timely<br>electronic access (EP)<br>and for —Provide<br>clinical summaries for<br>each office visit (EP) | EPs: 20% of patients use a web-based<br>portal to access their information (for<br>an encounter or for the longitudinal<br>record) at least once. Exclusions:<br>patients without ability to access the<br>Internet   | EPs: 30% of patients use a web-based<br>portal to access their information (for an<br>encounter or for the longitudinal record)<br>at least once. Exclusions: patients<br>without ability to access the Internet.   |  | AMIA supports this objective.   |
| (NEW)  | EPs: online secure patient messaging is in use  | EPs: online secure patient messaging is in use  |  | We may well support this objective, but need more detail. Is  |

| Stage 1 Final Rule  | Proposed Stage 2  | Proposed Stage 3   | ONC Comments   | AMIA Comments   |
|---------------------|---|--|--|---|
|                     |   |  |  | this online secure messaging for making appointments, for<br>clinical consultation, for emergencies? Further, we are very<br>much concerned about the "security" of secure online<br>messaging, and wonder whether system vendors will be<br>required to meet some demonstrable standard for messaging<br>security. |
| (NEW)               | Patient preferences for<br>communication medium recorded for<br>20% of patients   | Patient preferences for communication<br>medium recorded for 80% of patients   | How should communication medium be delineated?   | AMIA supports this objective.   |
|                     |   | Offer electronic self- management tools<br>to patients with high priority health<br>conditions   | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective       |   |
|                     |   | EHRs have capability to exchange data<br>with PHRs using standards-based health<br>data exchange   | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective       | AMIA supports this objective.   |
|                     |   | Patients offered capability to report<br>experience of care measures online  | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective       | Until there is sufficient real-world data evaluating the efficacy, costs, and risks of this activity, requiring its use is inappropriate.   |
|                     |   | Offer capability to upload and<br>incorporate patient- generated data (e.g.,<br>electronically collected patient survey<br>data, biometric home monitoring data,<br>patient suggestions of corrections to<br>errors in the record) into EHRs and<br>clinician workflow | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective       | Until there is sufficient real-world data evaluating the efficacy, costs, and risks of this activity, requiring its use is inappropriate.   |
|                     |   | Improve Care   | Coordination   |   |
| Perform test of HIE | Connect to at least three external<br>providers in —primary referral<br>network    (butoutside delivery<br>system that uses the same EHR) or<br>establish an ongoing bidirectional<br>connection to at least one health<br>information exchange | Connect to at least 30% of external<br>providers in —primary referral<br>network    or establish an ongoing<br>bidirectional connection to at least one<br>health information exchange   | Successful HIE will require<br>development and use of<br>infrastructure like entity-level<br>provider directories (ELPD) | The Stage 3 objective is premised almost entirely on the development of successful HIEs. We suggest dropping the language that calls for "connect to at least 30% of external providers."   |
| Perform medication  | Medication reconciliation another   | Medication reconciliation conducted at   |  |   |

\*Indicates Menu (Optional) Item

| Stage 1 Final Rule                       | Proposed Stage 2   | Proposed Stage 3   | ONC Comments  | AMIA Comments   |
|--|--|--|---|---|
| reconciliation (50%)*                    | setting of care, or from another<br>provider of care, or the provider<br>believes it is relevant) conducted at<br>80% of care transitions by receiving<br>provider (transitions from   | 90% of care transitions by receiving provider  |   | AMIA supports this increase for an optional requirement.  |
| Provide summary of<br>care record (50%)* | Move to Core<br>List of care team members (including<br>PCP) available for 10% of patients in<br>EHR   | List of care team members (including the<br>PCP) available for 50% of patients via<br>electronic exchange<br>Record provided electronically for 80%<br>of transitions and referrals  |   | AMIA supports this objective.   |
| (NEW)                                    | List of care team members (including<br>PCP) available for 10% of patients in<br>EHR   | List of care team members (including the PCP) available for 50% of patients via electronic exchange  |   |   |
| (NEW)                                    | Record a longitudinal care plan for 20% of patients with high- priority health conditions  | Longitudinal care plan available for<br>electronic exchange for 50% of patients<br>with high-priority health conditions  | What elements should be included<br>in a longitudinal care plan<br>including: care team members;<br>diagnoses; medications; allergies;<br>goals of care; other elements?  | AMIA supports this objective.   |
|  | •  | Improve Population   | and Public Health   |   |
| Submit immunization<br>data*             | EH and EP: Mandatory test. Some<br>immunizations are submitted on an<br>ongoing basis to Immunization<br>Information System (IIS), if accepted<br>and as required by law   | EH and EP: Mandatory test.<br>Immunizations are submitted to IIS, if<br>accepted and as required by law. During<br>well child/adult visits, providers review<br>IIS records via their EHR.   | Stage 2 implies at least some data<br>is submitted to IIS. EH and EP<br>may choose not, for example, to<br>send data through IIS to different<br>states in Stage 2. The goal is to<br>eventually review IIS- generated<br>recommendations |   |
| Submit reportable lab<br>data*           | EH: move Stage 1 to core<br>EP: lab reporting menu. For EPs,<br>ensure that reportable lab results and<br>conditions are submitted to public<br>health agencies either directly or<br>through their performing labs (if<br>accepted and as required by law). | Mandatory test.<br>EH: submit reportable lab results and<br>reportable conditions if accepted and as<br>required by law. Include complete<br>contact information (e.g., patient address,<br>phone and municipality) in 30% (EH) of<br>reports.<br>EP: ensure that reportable lab results and<br>reportable conditions are submitted to<br>public health agencies either directly or<br>through performing labs (if accepted and<br>as required by law) |   | AMIA supports moving this requirement from optional in<br>Stage 1 to required in Stage 2 for hospitals; we are uncertain<br>that this should be required of providers also. |

| Stage 1 Final Rule  | Proposed Stage 2 | Proposed Stage 3  | ONC Comments   | AMIA Comments   |
|---|------------------|---|--|---|
| Submit syndromic<br>surveillance data*                        | Move to core.    | Mandatory test; submit if accepted  |  | AMIA supports making this reporting a core requirement for EHs. |
|   |                  | Public Health Button for EH and EP:<br>Mandatory test and submit if accepted.<br>Submit notifiable conditions using a<br>reportable public- health submission<br>button. EHR can receive and present<br>public health alerts or follow up requests. | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective                   |   |
|   |                  | Patient-generated data submitted to public health agencies  | We are seeking comment on what<br>steps will be needed in stage 2 to<br>achieve this proposed stage 3<br>objective                   |   |
|   | <u> </u>         | nsure Adequate Privacy and Security Prot  | tections for Personal Health Inform  | ation   |
| Conduct security<br>review analysis &<br>correct deficiencies |                  |   | Additional privacy and security<br>objectives under consideration via<br>the HIT Policy Committee's<br>Privacy & Security Tiger Team |   |