JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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Karen B. DeSalvo, MD, MPH
National Coordinator for Health Information
    Technology
Office of the National Coordinator for Health Information
    Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Suite 729D
Washington, DC 20201

Dear Dr. DeSalvo:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to submit our comments on the Office of the National Coordinator for Health Information Technology's (ONC) Nationwide Interoperability Roadmap—Draft Version 1.0. We thank ONC for its focus on interoperability as it is a critical component to improving health care quality, reducing costs, and supporting delivery and payment reform. It will take all stakeholders working together to remove the current barriers to interoperability, and we hope that our comments facilitate improvements in data exchange, electronic health records (EHRs), and other health information technology (health IT). While the Roadmap extends out through 2024 we believe that the primary focus should be on the immediate needs of physicians and patients and to reassess other goals later on. We have therefore constrained our comments to the years 2015-2017 of the Roadmap.

Physicians are at the forefront of a transforming health care system that is experiencing rapid growth of digital capabilities, genetic and genomic breakthroughs, and new tools that are driving changes in the way treatment is delivered to patients. The promise of a robust digital health environment hinges on the ability of physicians and patients to access information when and where they need it and in a manner that can be easily understood and acted upon. Although electronic exchange of patient information is increasing, functional interoperability—the ability for information to be exchanged, incorporated, and presented in a contextual and meaningful manner— is still lacking. It is through this lens that we offer the following high-level recommendations to improve interoperability. Our comments on specific recommendations contained in the Roadmap can be found in Appendix 1.

1. **Prioritize "cornerstone" interoperability issues and high-value use cases;**
2. **Forego using a punitive approach on providers to achieve interoperability;**
3. **Address cost and EHR usability barriers to interoperability;**
4. **Continue to allow private sector governance efforts to flourish; and**
5. **Acknowledge the impact Meaningful Use is having on interoperability.**

Prioritize "cornerstone" interoperability issues and high-value use cases

Interoperability Cornerstones

The AMA strongly supports ONC's focus on interoperability since this is where much of the value surrounding the use of EHRs and other digital technology lies. As physicians transition to value-based payment models, they will require technology and standards that enable data exchange and care coordination. For this to happen, not only must there be a supportive business case to drive use and innovation, but also a solid infrastructure upon which to build meaningful information exchange. The AMA believes the best way to advance interoperability is to prioritize cornerstone issues that are fundamental to information exchange and to focus on specific use cases. We fear that unless a more prioritized approach is taken, interoperability will continue to elude us.

We support ONC's intent to drive the development of patient matching, provider directories, and standardized data vocabularies. These are key resources that must be widely-available by health IT vendors, health care organizations, and health information service providers (HISPs) before robust and seamless data exchange can take place. Furthermore, we are pleased to see ONC's proposal on nationwide semantic and syntactic standards in the recent 2015 health IT certification rule. **The advancement of these fundamental building blocks, however, should be prioritized to improve health IT and functional interoperability before adding new certification and other requirements.**

The Roadmap also calls for standard development organizations, physicians, and public and private stakeholders to collaborate on developing standards. In particular, the AMA believes ONC should prioritize efforts to align standards and data vocabulary on clinical data registries. National medical specialty societies have led the way in the establishment of registries to support quality improvement, development of clinical evidence base, and other essential activities. Quality registries are also necessary for research purposes, post-market surveillance, coverage decisions, and reimbursement. **Given their importance to improving care, we believe that registry interoperability is a critical challenge and must be further highlighted by the Roadmap.**

Taking steps to improve data captured in EHRs and registries is another interoperability cornerstone that is needed to advance medicine. Uniform definitions should be developed through a consensus process that includes all specialties and practitioners who understand the clinical context of the data elements based on their patients. Semantic interoperability, syntactic interoperability, and functional standards are key to establishing the consistency needed across health IT to drive data exchange. Any future benefits from alternative payment models and value-based payments are premised on registries, vendors, and payers working with medical associations to establish this level of standardization. In particular, we urge the following:

- **Interoperability between registries and EHRs -** There are specific formats to move data and discrete program language to exchange data. Yet, not all registries are operating on the same standards. ONC should encourage registries, such as qualified clinical data registries (QCDR), to exchange data with EHRs through a uniform standard. Currently, the Centers for Medicare & Medicaid Services (CMS) requires QCDRs to submit their data in one format, which should be used as a starting point for also harmonizing data exchange.

- **Clinical Data Definitions -** Uniform clinical data definitions ensure that when a data element is captured/exchanged it means the same thing across registries and EHRs. Some registries, large health systems, and third-party vendors have begun this work; however, if these efforts are not aligned, the standards are likely to vary significantly. The AMA believes that federal funding is necessary to support this collaborative effort and would welcome the opportunity to collaborate with ONC to launch and maintain this work within the private sector.

- **Functional Standards -** EHR data is stored in an unstructured free text format. To enhance quality, a third party and/or an individual needs to scrub and clean this information to make it meaningful. For example, when a patient complains of shortness of breath, this is simply typed into the EHR, but for performance improvement physicians need to determine exactly what the patient means by shortness of breath. Is it shortness of breath because the patient just walked a mile or due to a particular condition? These functional status types of definitions, while important for quality improvement activities, are not widely defined because it is neither needed nor relevant for payment. To begin this work, physician-led stakeholders must start with the most universal data elements and the most commonly used standards. The AMA-convened Physician Consortium for Performance Improvement® is well positioned to support this level of work.

- **Provider Directories -** A major stumbling block to information exchange is the lack of provider directories, which serve as a "yellow pages" to identify physicians and other health care providers. To address this problem, the AMA supports proposal N1, #6, in the proposed certification rule for 2015 that calls for a provider directory standard.

- **Patient Matching -** Exchanging information requires a consistent, reliable mechanism for matching patients to their records. Without a national patient matching strategy there are serious safety risks that could arise from attributing a medical record to the wrong individual. We urge ONC to prioritize this issue and seek innovative solutions to this problem.

- **Security -** To improve the security of patient and health information, the AMA strongly supports the efforts by the National Strategy for Trusted Identities in Cyberspace and the Identity Ecosystem Steering Group. This work is aimed at helping securely identify individuals in cyberspace and should be supported by ONC.

High-value use cases

In addition to a strong emphasis on cornerstone interoperability issues, the AMA urges ONC to work with the industry to coalesce around a discrete and limited set of high value use cases. There are 56 use cases listed in Appendix H of the ONC Roadmap. We fear that if the industry attempts to accomplish too much too fast—especially before resolving the aforementioned cornerstone issues—that this will hinder rather than advance interoperability efforts.

One key area that we believe ONC should highlight is providing data, not in raw form, but in context with other information. While most acknowledge that a key tenant to a learning health system is having the right data, at the right time to impact care, there has been far less emphasis on providing that information in the *right context*. We believe this is necessary to drive demand and use of interoperable technology.

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We also believe, and agree with ONC remarks, that attention should focus on chronically ill patients. Addressing patients with multiple chronic conditions can have a profound impact on health care utilization and associated costs, as well as outcomes. [1] As of 2012, among adults with at least one chronic condition, more than half (approximately 60 million) had multiple chronic conditions.[2] These cases are challenging and expensive to treat, with just five percent of the population responsible for almost 50 percent of all spending.[3] Treatment for these patients could be greatly enhanced by interoperability since care requires coordination inside and outside traditional care settings. One of the AMA's key focus areas is preventing two of the most pervasive chronic diseases—cardiovascular disease and type 2 diabetes—that cost our health care system more than $500 billion annually. [4] Beginning with a focus on risk factors for these conditions, the AMA is helping physicians and care teams to control high blood pressure and prevent diabetes. Other key areas associated with high-cost patients that ONC could prioritize may include behavioral health and a focus on socioeconomic factors such as poverty or racial minorities.[5]

The AMA supports highlighting use case #39, which would close the referral loop. This use case focuses on a task that is very common across physicians, as many patients are transferred between sites of service. Ensuring their medical records, lab results, and office notes are transferred to the appropriate people not only supports the wellness of the patient but also reduces cost and waste. We urge ONC to prioritize this high-use scenario and avoid creating overly complex requirements, checklists, and other measures that may create confusion rather than simplifying this process.

Forego using a punitive approach on providers to achieve interoperability

ONC notes on page 40 of the Roadmap that:

> HHS will pursue a natural lifecycle of policies to drive interoperability beginning with incentives, followed by payment adjustments and then conditions of participation in Medicare and Medicaid programs. HHS is now pursuing ways to promote interoperability as a core element of delivery system reform for providers across the country. An important recent policy demonstrating this commitment is the separately billable payment for chronic care management, finalized under the 2015 Physician Fee Schedule. In order to bill for these services, physicians will be required to utilize certified health IT to furnish certain services to beneficiaries.

[1] Zulman DM, et al., "Quality of Care for Patients with Multiple Chronic Conditions: The Role of Comorbidity Interrelatedness." *Journal of General Internal Medicine.* March 2014, Volume 29, Issue 3, pp 529-537. Accessed March 2015. Available at http://link.springer.com/article/10.1007/s11606-013-2616-9/fulltext.html.
[2] Ward BW, Schiller JS, Goodman RA., "Multiple Chronic Conditions Among US Adults: A 2012 Update." Accessed March 2015. Available at http://www.cdc.gov/chronicdisease/overview/#ref1
[3] Schoenman JA, Chockley N., "Understanding U.S. health care spending." Washington (DC): National institute for Health Care Management Research and Educational Foundation; 2011 Jul., Accessed March 2015. Available at http://www.nihcm.org/images/stories/NIHCM-CostBrief-Email.pdf.
[4] The American Medical Association., "Improving health outcomes strategic focus." Accessed March 2015. Available at: https://download.ama-assn.org/resources/doc/about-ama/x-pub/improving-health-outcomes.pdf.
[5] Bates DW, et al., "Big Data In Health Care: Using Analytics To Identify And Manage High-Risk And High-Cost Patients. *"Health Affairs*. July 2014. Available at: http://content.healthaffairs.org/content/33/7/1123.full.

Later, on page 118 the Roadmap states:

> Within entry-level pay for value and pay for performance programs with individual practices, payers can make use of certified health IT a condition or link payments to other programs referencing IT requirements, such as medical home certification. Private plans can mirror Medicare policy to support chronic care management and require use of certified health IT.

Here, ONC makes the assumption that a punitive approach, focusing on penalizing physicians and other providers for not using certified systems, will help achieve interoperability. This is simply a flawed and misguided means of removing the current barriers to interoperability. In short, this approach will not work.

First, the threat of a penalty is unnecessary as physicians have a documented pattern of inventing and using technology in their medical practices when it works well and improves patient care. Indeed, the overwhelming majority of physicians have already adopted EHRs and implemented these systems into their practices. Physicians want to use EHRs to exchange data and improve patient care. Even more importantly, this approach looks to solve a problem (interoperability) for which the solution is not controlled by physicians and other care providers. Vendors and other entities are responsible for developing systems that are technologically capable of exchanging data. While in a normal market physicians would be able to drive demand for interoperability, the reality is that the penalty program implemented by the government has created an artificial marketplace that requires physicians to use poor performing systems that do not facilitate data exchange.

The AMA recognizes that there could be other forces that may deter physicians from moving data, such as costs, and discuss these challenges in more detail below. Nonetheless, tying physician reimbursement or participation in Medicare to interoperability, while limiting market power and ignoring the role of other stakeholders, is simply not going to incentivize or motivate physicians to exchange more data. The root causes behind interoperability, including the cornerstone issues described above, must be addressed first. **The AMA strongly opposes predicating reimbursement, whether it is from Medicare, the states, or private payers, to physician's use of certified EHRs to drive interoperability.**

Address cost and EHR usability barriers to interoperability

Costs

There is a growing awareness that the cost to exchange, extract, and analyze data from an EHR is a key factor that impedes interoperability. These costs represent significant additional expenses above and beyond the initial EHR purchase price and may not be clearly conveyed to physicians. **We applaud ONC's proposal in the Version 2015 certification rule to require all vendors that are seeking certification to publish their fees online and in marketing material. In addition to this step, we urge ONC to work with CMS to publish the costs of data transmission using a HISP in a central online location that is easily accessible and understandable to physicians.**

Even if these proposals are adopted, costs still remain a major barrier to interoperability. Many physicians are incurring significant fees, of upwards of tens of thousands dollars, to transfer data from one

EHR product to another. Others are being charged extra fees to set up portals or interfaces to facilitate data migration. Still others are reporting excessive upfront costs levied by their EHR vendor when trying to connect their EHRs to clinical registries. In these instances physicians must pay the quoted amount just to meet certain MU objectives and requirements.

A Government Accountability Office (GAO) report from March 2014 noted, "Several officials estimated various amounts between $50,000 and $80,000 that providers spend to establish data exchange interfaces. Other stakeholders we interviewed or who responded to HHS' March 2013 RFI also identified costs associated with participation in health information exchanges (HIEs) and maintaining EHR systems as a challenge for providers."[6] Overall, these costs are prohibiting data exchange and limiting the usefulness of interoperability for both physicians and patients. Since EHRs are currently the main method for physicians to access and share information, it is necessary that connection points and interfaces are cost effective, reliable, and flexible enough to support a wide array of business needs.

With the current state of interoperability, the Direct Project serves as a stop gap for moving messages securely, as discussed in the Roadmap. Yet, even with this more basic technology, we are hearing a growing number of concerns from physicians that using Direct can be costly. Given that data exchange is still expensive even in this primitive form, we are concerned that this price will continue to rise as more innovative technology is developed. In addition, the ability to collect, interpret, analyze, and display the information in a meaningful manner to a physician is still a challenge when using most products. Unless ONC and other stakeholders directly address and seek to mitigate the costs of interoperability, we will not be able to improve data exchange and use it to promote alternative payment and delivery models and improve patient care.

Usability of EHRs

In addition to costs, another barrier that we believe will persist unless systematically addressed is the usability of EHRs. To date, EHRs focus mainly on meaningful use (MU) requirements and are designed to meet the needs of payers first, with the needs of physicians and their patients a distant second. By trying to replicate a paper-based system, EHRs are widely seen as cumbersome and inefficient instead of time-saving tools that support the safe care of patients.

The ability to enhance the visualization of complex data sets is a hallmark of many other consumer electronic products. EHRs, however, have not yet achieved tools to improve the understanding of patient data. The advent of templates, macros, favorite lists, document scanning, and free text boxes are in many ways "advanced" features not offered by most products on the market. EHRs also face additional challenges as the amount of data collected locally or externally makes it difficult to identify meaningful patterns in patient information.[7] While ONC's Roadmap attempts to stipulate how interoperability should be adopted and used, our view is that it is the combination of well-developed systems utilizing the right data and displaying information in an actionable way that will drive the use of health IT, improve quality, and reduce costs. A strong business case coupled with tools centered on the physician's needs is what is

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[6] GAO (GAO-14-242), "Electronic Health Records HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones" March 2014.

[7] West VL, Borland D, Hammond WE., "Innovative information visualization of electronic health record data: a systematic review." *J Am Med Inform Assoc.,* October 2014. Accessed March 2015. Available at http://jamia.oxfordjournals.org/content/early/2014/11/07/amiajnl-2014-002955.

required in the very short-term. **The AMA believes that more consideration should be given to how EHRs facilitate clinical understanding rather than meeting MU requirements and billing for services.**

We are encouraged that ONC's proposed Version 2015 EHR recognizes the need for Application Programming Interfaces (API) capability in EHRs. We believe that APIs are the next logical step to enhancing patient engagement, data reporting, and data visualization or as a possible method to facilitate EHR to EHR migration. APIs and other technology must still follow certain procedures designed to minimize inaccurate and incomplete data. Moreover, the structure and definitions of metadata (data that describe data) may need to be standardized. Technologies such as Fast Healthcare Interoperability Resources (FHIR), which rely on metadata schemes, are gaining more attention and platforms such as, Substitutable Medical Applications & Reusable Technology (SMART) on FHIR, are becoming more mature. **We urge ONC to continue to explore new technologies and their role in improving EHRs throughout the Roadmap.**

Continue to allow private sector governance efforts to flourish

The AMA is committed to promoting interoperability through properly coordinated collaboratives and complementary actions by the public and private sectors. We believe that this coordination will achieve a greater level of sophistication and ultimately more ubiquitous data sharing than one that is too heavily driven by the federal government and excludes necessary participants. As noted, many stakeholders are already working together to address EHR interoperability challenges. In particular, the AMA is a founding member of Healtheway and a member of Carequality, efforts devoted to improving interoperability and data exchange. Specifically, Healtheway is comprised of several federal agencies and private partners who have implemented health information exchange according to a single Data Use and Reciprocal Agreement (DURSA) under the Nationwide Health Information Network (NwHIN) and is expected to continue expanding.

To achieve a Learning Health System in the future, organizations must develop trust among stakeholder groups and a collaborative spirit between stakeholders and the federal government. ONC and other federal agencies should be active partners with industry in governance across the various domains, such as standards development, rules of the road, and testing. No single network, organization, or process will be able to provide and manage the full interoperability life cycle. We therefore do not foresee a unitary and monolithic governance process, but rather processes that require some coordination but can operate independently as long as the overall scope, focus, and direction is well understood and shared.

We urge ONC to work with stakeholders to establish such a lean framework to support a small set of high-value use cases that can benefit from improved interoperability. At the same time, prioritization should in no way hinder industry and market efforts to develop and implement standards and technologies for other use cases or needs. As we review the draft Interoperability Roadmap, we are struck by the tone that suggested the various initiatives underway are a problem to be solved. Instead, we see all of this work as a resource to be leveraged, and as a reflection of the different domains within governance.

A coordinated approach that takes advantage of the efforts already underway will provide the level of sophistication needed to meet the data sharing and health information exchange requirements of a

Learning Health System. Working together with ONC and other federal partners we believe is the right way to make strides toward achieving interoperability.

Acknowledge the impact Meaningful Use is having on interoperability

The MU program has spurred rapid adoption of EHRs. Unfortunately, it is not possible to divorce the lack of an interoperable health care infrastructure from the prescriptive nature of the MU program. There is widespread recognition in the health care field—including vendors themselves—that the numerous set of MU mandates required to obtain EHR certification stymies innovation, limits resources, and prioritizes the wrong efforts to improve usability, safety, and interoperability. Accordingly, certified systems are created with the MU requirements as the first priority. The end result is an environment in which physicians must attempt to thrive in an era of significant transformation without the tools to improve care coordination.
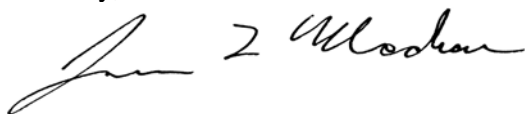
The challenge physicians are experiencing with a lack of interoperability is evidenced by their low participation in the MU program and the high level of dissatisfaction with these products. According to the most recent data made available by CMS, while as many as 70 percent of eligible professionals (most of whom are physicians) have met the MU requirements at some point in time, 46 percent did not participate in 2014.[8]

Instead of facilitating interoperability, many MU requirements to date simply assume EHRs are fully capable of exchanging data. This is not the case, and, as a result, thousands of physicians may face MU penalties. A new approach is clearly needed if successful adoption and utilization of EHRs remain our shared goal. Unfortunately, after an initial review of both the Stage 3 proposed rule and the ONC proposed certification rule, we believe that the Stage 3 rule retains a construct that is overly prescriptive and will continue to hinder interoperability. We look forward to submitting our detailed comments in the near future.

Conclusion

The AMA appreciates the opportunity to offer these recommendations and looks forward to working collaboratively to address the interoperability concerns we outlined above. If we can be of any further assistance, please contact Matt Reid, Senior Health Information Technology Consultant, Federal Affairs, at (202) 789-7419 or matt.reid@ama-assn.org.

Sincerely,

James L. Madara, MD

Enclosure

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[8] According to the CMS proposed Stage 3 MU rule, there are 675,000 EPs (up from an initial estimate of 576,000). Of these 256,000 received a financial penalty for non-participation in 2014 and another 56,000 received a hardship.

Appendix

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A1. Establishment of Coordinated Governance	1. ONC will define a nationwide governance framework with common rules of the road for trust and interoperability and a mechanism for identifying compliance with common criteria. These rules will first focus on interoperability of a common clinical data set for purposes of treatment. 2. ONC will identify a mechanism for recognizing organizations that comply with the common rules of the road. 3. Call to action: Public and private sector stakeholders across the ecosystem should come together to establish a single coordinated governance process to establish more detailed policies regarding business practices, including policies for identifying and addressing bad actors and to identify the technical standards that will enable interoperability for specific use cases (see Appendix H for Priority Interoperability Use Cases). 4. Call to action: Federal agencies that provide or pay for health services should align their policies for interoperability with the nationwide governance framework. 5. ONC and stakeholders participating in the coordinated governance	The AMA is committed to promoting interoperability through properly coordinated actions by the public and private sectors. We believe any governance structure will benefit from including broad membership to avoid excluding necessary participants. As noted, many stakeholders are already working together to address EHR interoperability challenges. In particular, the AMA is a founding member of Healtheway and a member of Carequality, efforts devoted to improving interoperability and data exchange. ONC should consider the progress being made by these groups. In particular, Healtheway is comprised of several federal agencies and private partners who have implemented health information exchange according to a single Data Use and Reciprocal Agreement (DURSA) under the Nationwide Health Information Network (NwHIN) and is expected to continue expanding. ONC and other federal agencies should build upon these existing stakeholder groups. No single network, organization, or process will be able to provide and manage

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	process should establish metrics for monitoring and assessing nationwide interoperability and methods for data collection.	the full interoperability life cycle. Instead, we urge the adoption of focused bodies that can operate independently as long as the overall scope, intent, and direction are well understood and shared. We urge ONC to work with stakeholders to establish such a lean framework to support a small set of high-value use cases that can benefit from improved interoperability. At the same time, prioritization should in no way hinder industry and market efforts to develop and implement standards and technologies for other uses cases or needs.
A2. Policies & Operations	1. Governance entities and data holders should align their policies with the nationwide governance framework. 2. ONC, in collaboration with stakeholders, should define a policy framework for exchange of patient-generated health data and pilot it.	See A1 comments.
A3. Standards	1. The coordinated governance process should support three main functions related to technical standards: prioritization of use cases for which standards are needed, selection of standards to support priority use cases based on ONC's Interoperability Advisories and coordination across SDOs and implementers as standards	See A1 comments.

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	are developed and refined (see Appendix H for Priority Interoperability Use Cases). 2. The coordinated governance process should support a holistic lifecycle process for technical standards that enable care providers and individuals to send, receive, find and use a common clinical data set. This involves establishing clear feedback loops between SDOs and implementers, as well as supporting non-certification-related testing of technical standards.	
B1. Federal Actions	1. CMS will aim to administer 30% of all Medicare payments to providers through alternative payment models that reward quality and value, rather than volume, by the end of 2016. Alternative payment models may increasingly require a baseline level of health IT adoption or other provisions reinforcing interoperability. 2. Federal agencies will begin to incorporate technical standards and certification requirements in new grants and contracts that fund health IT adoption and Medicaid financing of IT systems. 3. CMS will encourage states to emphasize provider networks' health IT adoption and interoperability to support care coordination as a component of state oversight of Medicaid Managed Care	We recognize that CMS is now pursuing ways to promote interoperability as a core element of delivery system reform for providers across the country. While we agree that interoperability is necessary to achieve a learning health system, we are discouraged that CMS is seeking to reinforce this effort by applying penalties and conditions of participation on physicians and other Medicare providers.

As discussed in our cover letter, the threat of additional penalties is unnecessary as physicians have a documented pattern of inventing and using technology in their medical practices when it works well and improves patient care, and the overwhelming majority of physicians have already |

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	required quality strategies, performance measurement reporting, etc. 4. ONC will reinforce the ability of individuals and providers across the care continuum to send, receive, find and use a common clinical data set through its funding programs.	adopted EHRs and implemented these systems into their practices. Rather, ONC should focus on key interoperability solutions, resolving the lack of usability of EHRs, and mitigating costs that prevent data exchange. Such efforts should not target physicians but should focus on the stakeholders that control whether systems are technologically capable of exchanging data.
B2. State Actions	1. Call to action: All states should have an interoperability roadmap articulated in their health-related strategic plans (including their Annual Medicaid Health IT Plan). 2. Call to action: All states should take appropriate steps to implement policies that are in alignment to the national, multi-stakeholder approach to coordinated governance for interoperability. 3. Call to action: Roughly half of states should have proposed and/or implemented strategies to leverage Medicaid financial support for interoperability. 4. Call to action: Roughly half of states should enact state-autonomous policies to advance interoperability that go beyond their current efforts. 5. Call to action: All states should utilize health homes or	See B1 comments.

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	other new models of care and payment to integrate behavioral health with physical health and incentivize health information exchange.	
B3. Private Payer/ Purchaser Actions	1. Call to action: A growing number of private payers should implement provisions supporting interoperability within value-based payment arrangements covering commercial populations. 2. Call to action: Purchasers should consider health plans' commitment to the use of interoperable health IT and health information exchange among network and non-network providers in their purchasing decisions.	See B1 comments.
C1. Cultural change for individuals including demanding and using their electronic health information	1. Call to action: A majority of individuals and their caregivers should demand access to their electronic health information in a format they can use to manage their health or that of others.	We strongly agree that patients should have access to their health information and that ideally it should be in an electronic format. We also believe that it is important to recognize that there is a persisting misconception that doctors are the barrier standing between patients and their medical information, when often it is the technology that prevents access. Technology, including EHRs, needs to do a better job of supporting multiple patient portals and contextualizing data so that it is easily understood by patients. These issues, however, are outside of the scope of the average physician's capability. Access

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		problems are also rooted in ongoing misunderstanding and complexities with respect to HIPAA and other privacy and security laws. Physicians and other providers need clarification regarding when information can be shared and under what circumstances.
C2. Providers and technology developers supporting individual empowerment	ONC, government and the industry will identify best practices for the incorporation of patient-generated health data in health care delivery. 2. Call to action: Providers should encourage their patients to access their health information online and will enable patients to view, download and transmit that information to a destination of the patient's choice. 3. Call to action: Providers and technology developers should provide a majority of individuals with the ability to send and receive their health information and make decisions with the providers of their choice, including but not limited to their existing care team based on their preferences 4. ONC will work with the technology community to increase the use of Blue Button through implementation of a portfolio of standards to support consistency in the way that individuals receive information.	We agree that there is a need to study best practices for incorporating patient-generated data (PGD) into medical records. To date, there is no way to segment sensitive patient data in the EHR, nor is there a way to identify PGD from provider-created data. While ONC's proposed 2015 Health IT Certification rule does add a data segmentation for privacy (DS4P) standard, it has not been widely piloted, and EHR vendors will not be required to incorporate this technology until 2018. This raises security and provider liability concerns that need to be addressed in the short-term and before incorporating this information. Prior to or concurrent to studying best practices for incorporating PGD, we believe a prudent first step would be to examine what types and sources of PGD providers think will help them to manage their patients' conditions. There still is a

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	5. ONC and government ensure that patients understand their ability to access, send and receive health information.	dearth of information on what data will be actionable. Yet, CMS has included PGD, without further consideration, as a recommended measure for meeting Stage 3. We are unaware of any studies that have assessed the value of PGD or considered the potential problems to medical records on a national or wide scale. In terms of Blue Button, we would welcome more information on how this effort is progressing. For example, how many Medicare patients have downloaded their information? How many after downloading it have acted upon it? How many have returned to the site? Is the information correct in the record? Currently, Blue Button is an amalgamation of claims data, which may not be clearly understood by patients. While we recognize that the efforts to provide patient access to data must begin somewhere, an evaluation of the existing progress in using Blue Button could elicit valuable information that could inform future action. We are aware, for example, of Blue Button recommending preventive services for patients which were inaccurate.
C3. Privacy and Security for	1. Call to action: Public and	We seek clarification on how

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Individuals	private sector stakeholders should assess whether people understand how to safeguard their health information and the need for resources related to this topic. 2. Call to action: Providers should provide individuals with secure access to their own behavioral health information in a manner that is easy to use and enables them to make choices about disclosure of specific information that is sensitive to the individual and/or legally protected.	providers should offer secure access to behavioral health information when EHRs are not yet equipped to segment and produce this data. Without this capability, physicians may be reluctant to incorporate and share this information for fear it could be inappropriately accessed or released. For example, to date, there still is no way to identify services that are paid out-of-pocket by the patient, (this data receives greater privacy protections under the ACA), from other data in the EHR. How are providers expected to provide secure access when the systems do not yet support this functionality?
C4. Education and digital health literacy for individuals	1. Call to action: Consumer advocacy groups in collaboration with government agencies, associations and payers should develop and disseminate resources (toolkits and best practices) based on consumer needs to assist individuals with increasing their digital health literacy. This supports consumer participation in shared decision-making with their care team based on more complete and accurate information.	We generally agree with this call to action. AMA policy recognizes that limited patient literacy is a barrier to effective medical diagnosis and treatment. It is also the policy of the AMA to support efforts to address the economic and cultural barriers patients face, including barriers in utilizing information technology.

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D1. Organization/ Governance	1. Call to action: Providers should participate in governance of interoperability at all levels, from regional efforts to nationwide coordinated governance.	See A1 comments.
D2. Providers embrace a Culture of Interoperability and work with vendors and other supporting entities to improve interoperability	1. Call to action: Providers should routinely expect electronic access to outside information in the provision of care and engage with other providers to send, receive, find and use health information for their patients. 2. Call to action: Providers should recognize that valuable clinical information about their patients may reside with patients or caregivers themselves and that they may need to incorporate that information into their decision making. 3. Call to action: Providers and their organizations should embrace the use of enabling technologies such as publish/subscribe and query-based exchange with single sign-on to minimize workflow barriers to interoperability. 4. Call to action: Providers and their organizations should ensure contracts and agreements that they sign and re-sign with technology developers include necessary requirements for interoperability, to ensure they can share and incorporate patient information	We agree with D2, #1 and would be willing to promote efforts to achieve this goal. We also agree with D2, #2, however, there must be a way to meaningfully incorporate this data, as we discussed above in item C2. Concerning D2, #3 single sign-on has the potential to improve physician's access to health IT by reducing the number of authentication steps needed. However, we do not believe this is the optimal solution to resolve multiple access points. The major issue that must be addressed is that physicians are accessing multiple data hubs because patient information is spread across multiple systems. To remedy this, it is vital that cornerstone interoperability issues, such as patient matching, provider directories, security, and data vocabularies, are addressed to support query-based exchange. With respect to D2, #4 we believe ONC should publish model contracts for physicians

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		and should prohibit the use of gag clauses for products certified by ONC.
D3. Accurate Measurement	1. Call to action: Providers should leverage data beyond their internal systems for population health analytics and quality measurement (eCQMs) including supporting value-based payment models.	Physicians would be supportive of using other data sources but would need for this information to be developed in a way to minimize workflow barriers and costs. Existing EHRs have not yet incorporated these functionalities. Again, we urge that the necessary technology changes be developed, tested, and evaluated before asking physicians and other providers to achieve these goals.
D4. Interoperability of processes and workflows	1. Call to action: Providers should routinely leverage standards-based health IT to support prioritized workflows including: o Closed loop transitions of care o Secure clinical communications o Prior authorizations, medication co-pays and imaging appropriateness o CPOE for services and diagnostic testing o e-prescribing of controlled substances with concurrent availability of PDMP data	Physicians are desperate for interoperable systems that improve rather than hinder their workflows. Physicians assumed that the investments they made in EHRs would give this level of functionality but have been disappointed in the current state of interoperability. We would note that D4 calls on providers to take action; however, before providers can act they need EHR vendors and other stakeholders to make workflow and interoperability processes a priority. One of the highest value use cases that we believe would improve interoperability and physician workflow is closing the transition of care information loop. The AMA

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		participated in a Closing the Referral Loop pilot project that involved physician-to-physician referrals in the ambulatory setting. During the pilot project we learned that the current vendor systems do not facilitate sharing of patient information, only the ability to request a referral. This is leading to extensive customization (and cost) within each vendor system for a function that should be considered a standard operating practice, since it often occurs many times a day. To date this functionality does not exist or is not implemented well within EHRs. With respect to prior authorization, these policies are very burdensome on physicians and patients, requiring delays in care and diversion of resources to administrative tasks. Specifically, the results of a May 2010 American Medical Association (AMA) online survey of 2,400 physicians found that 63 percent of respondents typically wait several days for a response to private insurers' prior authorization requests, while 13 percent generally wait *more than a week*. To the degree that prior authorization is required by payers, we

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		believe that there needs to be a standard way to perform these requests to mitigate administrative burdens. Importantly, this process should be standardized across all payers and seamlessly incorporated into EHRs.
D5. Training and maintenance of certification for providers	1. Call to action: Public and private stakeholders should incorporate interoperability into the training of new providers and continuing professional education. 2. Call to action: Professional specialty boards and other certifying bodies should agree on standards for interoperable registries and maintenance of certification.	We agree that best practices and training on new technology should be included as a part of physician education, and we are working to facilitate these training programs. In particular, the AMA recently awarded $11 million in grants to support transformations in physician education. We encourage all stakeholders involved in the health IT space to support and promote new opportunities to educate the future health care workforce.
D6. Innovation and Generation of New Knowledge and Evidence	1. Call to action: Providers currently engaged in clinical research and quality improvement should work together with research institutions and other public and private stakeholders to establish a strategic plan for research and the generation of new knowledge.	The Patient Centered Outcomes Research Institute (PCORI) was created to handle such a recommendation. If ONC feels there is a hole in this space they should specifically state how PCORI has failed to meet their needs and who is best suited to coordinate such action. Without a convening entity and funding to coordinate and draft a strategic plan for research and the generation of new knowledge, there may be overlap of multiple entitles trying to

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		address this recommendation.
D7. Transparency of Value and engagement of patients, families, and caregivers	1. Call to action: Providers should work together with purchasers of care to have access to patient out-of-pocket costs and those of payers and purchasers. Providers are engaged in regional efforts to measure quality and maximize value. 2. Call to action: Providers should offer and encourage access to medical records and secure communications with all patients and any family and caregivers who are authorized to engage in such communications. 3. Call to action: Providers should support consumers in downloading or transmitting their health information to a destination of their choice.	On D7, #1, we agree with and actively support providing cost information to patients. However, we note that physicians are reliant on payers for accurate and timely information on patient financial responsibility at the point of care. For medical services, it is imperative that payers provide accurate and current information regarding patient out-of-pocket costs in eligibility responses. For pharmacy benefits, physicians are often unable to access accurate and granular data about patients' drug coverage at the point of prescribing due to deficiencies in formulary data in EHR systems, making it difficult (or impossible) to provide patients with this information. In short, if payers do not provide accurate data to physicians, physicians will not be able to give patients accurate out-of-pocket cost information. D7, #2 concerns problems with HIPAA and privacy laws and the use of patient portals. Physicians continue to report a number of challenges with the use of portals. First, they are costly to purchase and can exceed the cost of the EHR itself, running between $8,000-$10,000 for a small practice. Second, patients

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		complain that they are hard to navigate. The format of a portal and the way the information is organized is generally controlled by the physician's vendor, not the practice. Third, as we have noted in the past, several practices have reported to us that patients are not interested in using the portal and/or they have had to hire or repurpose clinical staff to convince patients to use them. In addition, it would be helpful if the Meaningful Use requirements counted patients accessing, scheduling, and billing use of the portals. We believe this could help drive greater demand of these systems and that there would eventually be a natural progression from using them for administrative purposes to clinical tools.
E1. Cybersecurity	1. ONC will work with OCR to release an updated Security Risk Assessment tool and hold appropriate educational and outreach programs. 2. ONC will coordinate with the Office of the Assistant Secretary for Preparedness and Response (ASPR) on priority issues related to cyber security for critical public health infrastructure. 3. HHS will continue to support, promote and enhance the establishment of a single health and public health	The AMA is deeply concerned that our nation's health care providers have been insufficiently prepared to help meet the cybersecurity challenges of an increasingly digital health care system. We firmly believe that this is a national priority and that physicians and other providers need tools to secure sensitive patient information in the digital sphere. We strongly agree that ONC should work more closely with OCR to release an updated

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	cybersecurity Information Sharing and Analysis Center (ISAC) for bi-directional information sharing about cyber threats and vulnerabilities between private health care industry and the federal government. 4. ONC will work with NIST and OCR to finalize and publish the NIST Critical Infrastructure Cybersecurity Framework and Health Insurance Portability and Accountability Act (HIPAA) Security Rule Crosswalk. 5. HHS will work with the industry to develop and propose a uniform approach to enforcing cybersecurity in healthcare in concert with enforcement of HIPAA Rules.	risk assessment tool and additional educational tools for physicians. We also agree that ONC should work with ASPR to make cyber security a national priority. We additionally agree that collaboration between ONC and NIST will be helpful. We would also note that small physician offices that do not have stand-alone IT departments will need extra help in navigating cybersecurity challenges. We urge a specific tool focused on small physician practices to help them prepare and ensure patient data remains confidential and does not land in the hands of criminals.
E2. Encryption	1. ONC will work with OCR and industry organizations to develop "at rest" standards for data encryption and provide technical assistance. OCR will consider whether additional guidance or rulemaking is necessary. 2. ONC will work with OCR and industry organizations to develop "in transit" standards for data encryption and provide technical assistance. OCR will consider whether additional guidance or rulemaking is necessary. 3. ONC will develop guidance	We strongly urge ONC and OCR to work together to develop information on encryption for physician practices—particularly small to medium size ones—that is scalable for their needs and helps to deploy these tools. We also seek clarification as to how physicians and other providers can ensure privacy and security when they are working with products that are not covered by HIPAA and are not required to sign a business associate agreement. In particular, how can

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	for implementing encryption policies. 4. ONC will work with payers to explore the availability of private sector financial incentives to increase the rate of encrypting, starting with discussions with casualty insurance carriers who offer cybersecurity insurance.	physicians ensure the privacy and security of mobile applications, portals, and other health information technology beyond EHRs. Concerning E2, #4 we are unclear whether the incentives referenced are intended for payers or providers? We believe these would be very helpful for physicians who, as described previously, are facing cost barriers to implementing new technology.
F1. Policies and Best Practices	1. Policies established through the coordinated governance process will adopt the concept of multi-factor authentication for all roles that access health information, subject to contextual appropriateness and consistency with the HIPAA Security Rule.42 2. ONC will identify and undertake (where necessary) work to harmonize other standards with those adopted for multi-factor authentication. 3. Through coordinated governance, stakeholders (with input from OCR) will establish and adopt best practices for identity proofing that are consistent with standards already adopted for other, comparable industries and with the HIPAA Security Rule.	We believe policies and best practices through governance processes will need to be user-friendly and scalable for physician practices. Physicians support the use of e-prescribing of controlled substances (EPCS). However, the current two-factor authentication process has limited the utility of EPCS forcing physicians to default to paper for a portion of their prescriptions. We believe that more attention should be paid to improving these processes. As two-factor authentication requires "something you know and something you have," we support efforts (which are acknowledged on page 59 of the Roadmap) by the National Strategy for Trusted Identities in Cyberspace (NSTIC) and

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		the Identity Ecosystem Steering Group (IDESG). We encourage ONC to explore the notion that an individual's trusted identity be used as the second factor (i.e., something you have) in authentication.
F2. Standards	1. Health IT developers will leverage existing mobile technologies and smart phones to provide efficient, effective paths for patient or provider identity authentication. 2. SDOs will work with health IT developers to conduct Pilots using RESTful approaches for authentication.	See F1 comments.
G1. Improve Health IT stakeholders' understanding of existing HIPAA rules and how they support Interoperable exchange through permitted access, use and disclosure for TPO	1. Through education and outreach, federal government/Office for Civil Rights (OCR) will consider where additional guidance may be needed to help stakeholders understand how the HIPAA Privacy Rule permits health information to be exchanged (use and disclosure) for TPO without consent. 2. Federal and state governments, in coordination with organizational health information privacy policymakers, conduct outreach and disseminate educational materials and OCR guidance to LHS participants about Permitted Uses and Disclosure of health information and Individual Choice. 3. ONC will brief key	The AMA strongly supports the following to ensure patient privacy and security of their data: 1. Public investments to assist health care providers in protecting patient information in an increasingly digital world. 2. Updating existing privacy guidance. HIPAA privacy rules, despite being enacted for more than a decade, are widely misunderstood by health care providers of all sizes. Real life examples should highlight when physicians can share patient information and the pitfalls of new technologies. 3. The AMA strongly urges that HHS engage in a provider education campaign that breaks what are nuanced and complex rules into easily

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	stakeholders, possibly including NCSL, NGA, privacy advocates and Congress on findings regarding the complexity of the rules environment, especially the diversity among more restrictive state laws that seek to regulate the same concept, impedes computational privacy. 4. ONC, in collaboration with states, national and local associations, and other federal agencies will convene a Policy Academy on Interoperability with a particular focus on privacy as an enabler of interoperability.	digestible information. Physicians need boots on the ground training and tools relevant to their practice size to meet ongoing privacy and security concerns. 4. Physicians also need more information on how to remedy or mitigate a breach involving health IT. Corrective actions typically focus on notification of those affected without explaining what mitigating factors can be taken to prevent further disclosures.
G2. Align stakeholder adopted policies with existing HIPAA regulations for health info that is regulated only by HIPAA	For information that is regulated by HIPAA only, ONC will 1. adopt at a policy level a standard definition of what is "Basic Choice" 2. adopt technical standards regarding how to ensure individuals are offered Basic Choice in a manner that can be captured electronically and in a manner in which the individual's choice persists over time and in downstream environments, unless the individual makes a different choice.	The AMA is unclear how these recommendations would work and believes a wider policy discussion is needed to explore this proposal. For example, some health information exchanges (HIEs) are further along with their policies on sharing patient information. Policies can also vary state-by-state as noted by ONC on page 63.
G3. Align regulations and policies for electronic health info that is protected by laws in addition to HIPAA	1. State governments standardize existing laws pertaining to "sensitive" health information, particularly those regarding clinically sensitive and age-based rules, so that	We believe that the scope of what is being proposed is extremely extensive and will need to be handled through a separate effort. An HHS request for information (RFI)

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	those laws mean the same things in all U.S. jurisdictions, without undermining privacy protections individuals have today. 2. Federal government, a majority of state governments and stewards of health information (health care organizations, HIEs, etc.) begin revising regulations, policies and programs for granular choice to align with the consensus categories of sensitive health information and rules for granular choice that establish consensus background rules for the nation.	may be needed to explore this matter in greater depth.
G4. Technical standards for basic choice	1. ONC, standards development organizations, health IT developers and appropriate stakeholders harmonize technical standards and implementation guidance for consistently capturing, communicating and processing basic choice across the ecosystem. 2. Technology developers begin implementing harmonized standards that document and communicate an individual's basic choice.	See comments for G3.
G5. Associate individual choice with data provenance	1. ONC, standards development organizations, health IT developers, health care providers and appropriate stakeholders harmonize technical standards and develop implementation guidance for associating	See comments for G3.

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	individual choice with data provenance to support choice 2. Technology developers begin to implement technical standards for associating individual choice with data provenance to support choice.	
H1. Develop New Policies and Regulations	1. ONC will convene workshops or listening sessions on the types of data sharing that may be required, by role, to support value-based purchasing. A major goal of the workshops will be to evaluate how close the nation can come to achieving its goals of the three-part aim using existing privacy rules.	We agree and appreciate ONC's efforts to provide these educational tools.
H2. Clarify Existing HIPAA Requirements	1. The HHS Office for Civil Rights will consider where additional guidance may be needed to help stakeholders understand how HIPAA Privacy and Security Rules apply in an environment where ACOs and other multi-stakeholder entities permeate the landscape in support of value-based purchasing.	We agree.
I1. Testing Tools	1. ONC, NIST and other health IT stakeholders will provide testing tools necessary to support the criteria in ONC's certification program. 2. Health IT developers, SDOs and government will explore and accelerate a suite of testing tools that can be used by implementers post-implementation to ensure continued interoperability while health IT is in use.	For I1, #1 the AMA agrees. In a January 21, 2015 letter sent by the AMA and 36 other medical societies and organizations, we made a number of recommendations on testing methods to improve the functionality of certified EHRs. While we appreciate that ONC proposed a number of changes to the health IT certification process in their

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	3. SDOs begin to develop and maintain additional testing tools in support of more stringent testing of standards.	v2015 proposed rule, we are concerned that the steps suggested by ONC do not go far enough. We believe the recommendations made in the aforementioned letter are reasonable and should be incorporated.
I2. Certification programs	1. Health IT Developers, ACBs, ATLs and other stakeholders will analyze, identify gaps and provide feedback to ONC regarding certification criteria that should be added to the ONC HIT Certification Program. Specifically, criteria that would support ONC's desire to expand the scope of the certification program to support health IT used in a broader set of health care settings, such as criteria for long-term and post-acute care, home and community based services in non-institutional settings and behavioral health settings. Additionally, criteria related to accessibility and usability of health IT. 2. Other existing industry certification programs will continue to complement ONC's certification program to ensure that different aspects of health IT conform to the technical standards necessary for interoperability. 3. FACAs will make recommendations for standards and certification criteria for inclusion in ONC's	The AMA believes that, before the certification program is expanded to support other areas outside of those regulated under the Meaningful Use program, that the focus should be on improving the technology and processes in place for certifying eligible providers and hospitals. We think this prioritized approach will, in the long-term, work better than one that spreads certification and processes that have been plagued with a number of challenges.

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	certification program.	
J1. Common, list of interoperability standards	1. ONC will annually publish and update a list of the best available standards and implementation guides supporting interoperability in order to enable priority functions in a learning health system, to be used by technology developers and to inform coordinated governance efforts. ONC will create this list through an open and transparent process that facilitates competition between standards for selection. To the extent possible, the updates to this list will be done in a manner to minimize unnecessary sunk costs and to promote the entry of innovative standards. 2. Technology vendors, certification programs and governing bodies should use ONC's list of the best available standards when making decisions about the standards they will use to enable specific use cases. 3. Provider and patient-facing technology developers will update their systems to align with the list of the best available standards, in particular, C-CDA 2.0 and associated vocabulary standards and code sets that support a common clinical data set.	We agree that ONC should publish a list of best available standards and implementation specifications. We have concerns regarding downstream effects that relate to existing efforts and processes. There should also be alignment with the timeline for the annual updates of EPeCQMs.

We also have questions on the ability of the industry to make changes to standards on an annual basis. Vendors and providers have requested a need for stability in standards in order to make changes or catch up. We ask that ONC consider these concerns.

The AMA does support a list of the best available standards being published as this will allow for transparency.

Associated vocabulary standards: Regarding two data elements listed in the Common Clinical Data Set: Smoking status: as currently written this data element does not include all uses of tobacco including smokeless tobacco. We urge ONC to consider revising to "Tobacco Use" to address the broader public health effort of tobacco cessation. This would align |

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		with existing electronic clinical quality measures that include smokeless tobacco. Care team members: We believe this is an important data element to capture; however, are there existing vocabularies that can capture this information (e.g., SNOMED CT)? In the context of clinical quality measurement, the Quality Data Model standard or other data models used to support quality measurement may need revision to accommodate this element. General comments related to vocabulary The HITSC made vocabulary recommendations in 2011, including recommended vocabularies and transition vocabularies. The transition vocabularies where recommended for use until organizations could adopt vocabulary standards such as LOINC and SNOMED CT. We recommend revisiting the HITSC recommendations against current vocabulary recommendations in the Standards advisory document. In the context of eCQMs, LOINC is the recommended vocabulary to represent risk categories, however, using LOINC to capture this data

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		element has presented challenges; specifically, the request submission processes within the LOINC to address gaps for this data element. Consider SNOMED (based on versatility to address content gaps) as an alternate to LOINC for functional status (FSA) or other data elements that have complexities with addressing content gaps. With a focus on patient engagement, there is a desire to assess FSA. The HITSC recommended LOINC as the preferred terminology to capture FSA, which in several instances requires proprietary tools. The use of LOINC to represent proprietary tools introduces complexity when requesting new content in LOINC. General comment: We agree with the shift from static code lists that define a concept within a single application or organization to systematic ways of representing meaning. This shift would be helpful for quality measurement efforts. We also recommend the use of structurally defined value sets (intentional) rather than enumeration or "cherry picking" to identify individual members of values sets. This recommendation is based on

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		lessons learned to requirements for effective change management. When new versions of vocabularies, terminologies and code sets are released, the changes can present a considerable impact on maintenance processes. Intentional value sets with definitions developed from structured rules and semantics will facilitate change management and sharing information across applications and organizations.
J2. Architecture in support of standards activities	1. Through coordinated governance, public and private stakeholders will establish and maintain a prioritized set of use cases and associated functional requirements for delivery system reform and a learning health system (see Appendix H for Priority Interoperability Use Cases). 2. Through coordinated governance, public and private stakeholders will develop a nationwide technical architecture for an interoperable learning health system. 3. Through coordinated governance, public and private stakeholders will define a necessary set standards activities that support the prioritized use cases and functional requirements and the agreed upon architecture.	We believe that one of the highest value use cases that would benefit numerous physicians, other health care providers, and their patients is closing the information loop for transitions of care. The AMA participated in a Closing the Referral Loop pilot project that involved physician-to-physician referrals in the ambulatory setting. During the pilot project it was learned that current vendor systems do not have functionality to facilitate sharing of patient information, only the ability to request a referral. This is leading to extensive customization (and cost) within each vendor system for a function that should be considered a standard operating practice.

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J3. Develop and pilot new standards for priorities	1. SDOs will advance and accelerate semantic standards for lab orders, other orders and other priorities for a LHS that require updated or new semantic standards 2. Research and clinical trial communities will pilot the use of the common clinical data set. 3. SDOs will advance consumer-friendly terminologies. 4. Health IT developers and SDOs should advance systems in support of human-centered design for systems, including the ability to provide information to individuals with varying levels of health literacy so individuals can understand their electronic health information and ability to provide information in their primary language. 5. Technology developers, providers and individuals will pilot data format and vocabulary standards in order to provide feedback to the SDOs for further refinement. 6. States and other stakeholders across the ecosystem to further explore and determine the role that NIEM can serve with regards to supporting health care and human services interoperability. 7. SDOs and industry will collaborate and agree on best practices and provide	See J1 comments.

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	guidance on the exchange of unstructured data such as a physician note.	
J4. Vocabulary approach	1. Through coordinated governance, public and private stakeholders will work with SDOs to define a standard approach to federated distribution of centrally maintained code sets. 2. Health IT developers will provide accurate translation and adapter services where needed in order to support priority learning health system use cases (see Appendix H for Priority Interoperability Use Cases).	See J1 comments.
J5. Maintain and improve standards	1. SDOs will maintain and improve existing standards based on implementation feedback.	See J1 comments.
J6. New standards that support new and evolving requirements and priorities	1. Through coordinated governance, public and private stakeholders will advance the development and maintenance of data format and vocabulary standards and implementation guidance necessary to support priority learning health system use cases (see Appendix.)	See J1 comments.
K1. APIs	1. Through the coordinated governance process, health IT developers, SDOs, ONC and others should implement a coordinated approach to developing and standardizing a targeted set of public APIs for nationwide interoperability. 2. Health IT developers should work with SDOs to develop	We recognize that functional interoperability is complex and may not be achievable within the current information exchange environment, data standards, and certification constructs. We are encouraged by ONC's recently proposed v2015 EHR Certification rule in that it recognizes the need for API

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	public APIs for sending, receiving and finding a common clinical data set. 3. ONC and other certification bodies should develop approaches through certification that encourage the adoption of specific APIs or consistently functioning APIs in a manner that, while reducing switching costs, does not prevent the adoption of innovative new APIs. 4. SDOs should advance and accelerate the development of standardized RESTful APIs. 5. Health IT developers should work with SDOs to develop standards for interoperable electronic health devices.	capability in EHRs. To make data useful, it must be accurate, timely, and contextually sensitive. This strongly depends on the quality of the data submitted to registries and exchanged across health care organizations. It is vital that entities contributing to data exchange follow certain procedures designed to minimize inaccurate and incomplete data. Moreover, the structure and definitions of metadata (data that describe data) may need to be standardized. Technologies such as FHIR, which rely on metadata schemes, are gaining more attention and platforms such as SMART on FHIR are becoming more mature. We believe that APIs are the next logical step to support enhanced patient engagement, data reporting, data visualization or as a possible method to facilitate EHR to EHR migration.

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L1. Common Transport Standards	1. ONC will identify, and health IT developers should adopt, a minimum set of common transport standards to enable priority learning health system functions. 2. SDOs should update standards and health IT developers should adopt standards as needed.	We agree.
L2. Send	1. Public health agencies should converge on the use of standardized web services to support data submission as well as data query from registries and other systems. 2. Providers (including hospitals, ambulatory providers, long-term care centers and behavioral health providers) should adopt and use DIRECT to reach critical mass. 3. Providers and health IT developers should provide individuals with the ability to easily and securely transport their health data to a destination of their choice.	The AMA appreciates that the marketplace is not yet capable of exchanging information in a functionally interoperable manner and that DIRECT serves as a stop gap for moving message securely. We also recognize the utility of provider directories and believe this is a cornerstone issue that should be immediately addressed. That being said, we are hearing a growing number of concerns from physicians on the frontlines that the costs to move data using DIRECT, which require use of a HISP (which can be their vendor), can be costly. We applaud ONC's proposal in the v2015 certification rule to require all vendors who are seeking certification to publish their fees online and in marketing material. In addition, we urge ONC to work with CMS to publish the costs of data transmission using a HISP in a central location online that is easily accessible and understandable to physicians.

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L3. Receive and Find	1. Health IT developers, providers and researchers should increase use of national standards for query functionality 2. Health IT developers, providers and public health agencies should increase use of national standards for publish/subscribe functionality. 3. SDOs should pilot, assess and refine standards for RESTful web services. 4. Health IT developers should widely implement national standards for query. 5. Health IT developers should widely implement national standards for publish/subscribe. 6. Health IT developers should implement national standards for RESTful web services as they are available.	As noted in the body of our letter, physicians generally do not have any control over the incorporation of functionality and standards within their EHR systems. Physicians would welcome the opportunity to use their EHRs in a manner that is consistent with sending, receiving and locating information. The AMA strongly supports vendor attention to these issues. However, we continue to harbor significant concerns with the impact of the Meaningful Use program on the ability for a viable business case to thrive in this heavily regulated environment.
M1. Standards and Best Practices	1. ONC and SDOs should standardize the minimum recommended data elements to be consistently included in all queries for patient clinical health information, and to be used to link patient clinical health information from disparate systems. 2. Through coordinated governance, public and private stakeholders should work with standards development organizations to require a set of data elements in all individual identity query and record linking transactions.	For M1,#1 the AMA believes that with respect to minimum recommended data elements, that physicians and other health care providers are best positioned to determine which data elements should be exchanged. However, ONC and SDOs have a role in helping ensure that the technology is able to capture and move this data in a uniform and functionally interoperable way. We agree with M1, #2-4.

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	3. Through coordinated governance, public and private stakeholders should establish and document best practices for the following processes: patient registration, patient verification of information and patient updates and corrections to information. 4. Through coordinated governance, public and private stakeholders should designate the API capabilities necessary to support individual identity search and individual identity linking transactions.	
M2. Pilots and Further Study	1. Through coordinated governance, public and private stakeholders should develop and pilot tools and technologies for establishing performance metrics for individual identity, query and internal individual matching/record linking. 2. ONC will coordinate with industry stakeholders and other HHS initiatives to test scenarios that represent a variety of matching settings with the purpose of providing further direction for scalable solutions, standards and best practices. 3. ONC will coordinate with industry stakeholders to study voluntary collection of additional identity attributes, which may include biometric technologies, cell phone number, email address, etc.	Generally speaking, the AMA supports efforts to pilot test innovative strategies for improving health care delivery. We also believe that ONC and CMS should work together to explore a method for providers to participate in Meaningful Use through the use of systems that are being pilot tested by vendors but which do not meet the standards for certification. If this were to occur, providers should be shielded from penalties while vendors use this opportunity to explore development of innovative technologies.
M3. Adoption	1. ONC among other	The AMA strongly agrees.

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	stakeholders should begin coordination and dissemination of best practices on identity matching.	
N1. Development of New Architecture and Standards	1. Through coordinated governance, public and private stakeholders should identify the architecture and workflow for resource location as part of a learning health system, including the individual and IT system actors, roles and access requirements. 2. Through coordinated governance, public and private stakeholders should prioritize the participants and services that are to be discoverable using resource location and identify a near-term goal for the first small set of resources to be included in an initial implementation. 3. From the architecture, SDOs and health IT developers should determine or develop standard(s) and API(s) for discovering participants and resources (including other directories if the architecture is federated), determine whether any of the current standards or legacy services already incorporated in products can be used or extended and develop a Roadmap to implementation of new standard(s) and API(s), if necessary. 4. Through coordinated governance, public and private stakeholders should identify	The AMA generally agrees with what is laid out in N1. We would note, though, that whatever process is used must be able to be implemented across multiple settings of care. Concerning N1, #4 we refer readers back to our comments under Section A.

Regarding N1, #5 we support the need for an initial prioritization of a set of resources.

Concerning N1, #6 the AMA supports the proposal in the certification regulation for 2015, which calls for a provider directory standard. |

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	rules of the road for participating in distributed management of resource location, if appropriate for the architecture and actors. This includes establishing policies and procedures for operation of resource location services, including curation of directory information to maintain data quality. 5. Through coordinated governance, public and private stakeholders should work with SDOs and health IT developers to demonstrate standard(s) and API(s) in a trial implementation, beginning with the prioritized set of resources. 6. Through coordinated governance, public and private stakeholders should develop a glide path for moving from current provider directories to future resource location techniques.	
N2. Refinement and Adoption of Standards and Best Practices	1. As an interim step, ONC will work with others to encourage initial uptake of current provider directory activities 2. ONC will recommend to CMS that NPPES implement support for the provider directory information query API and data model as specified in the IHE HPD Profile. CMS should maintain Direct addresses and ESI in NPPES 3. CMS/HRSA/OIG should	The AMA believes that the work on a provider directory should focus on the use of a common standard. Concerning N2, #2 the AMA intends to seek clarification from CMS and ONC. We want to ensure that physician information does not land in the hands of individuals intent on using it for fraudulent purposes. For N2, #3 the AMA seeks

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	advance the proposed effort to consolidate/synchronize national credentialing support systems 4. ONC and other certification bodies will determine how to support provider directories through certification processes 5. ONC will lead the effort to coordinate across federal agencies on the use of existing standards (e.g. provider directory standards) 6. ONC will support testing through its Standards Implementation and Testing Environment (www.sitenv.org)	clarification on the intent of this proposal. Is it ONC's desire that there be a central provider enrollment system for all payers? For N2, #4 the AMA supports advancing a national standard for provider directories as noted earlier. We strongly agree with N2, #5. We support N2, #6 but further recommend consolidating technical and policy information in an easily searchable site.