



April 2, 2015

Karen DeSalvo, MD, MPH, MSc
The Office of the National Coordinator for
Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Re: Connecting Health and Care for the Nation; A Shared Nationwide Interoperability Roadmap; Draft Version 1.0

Dear Dr. DeSalvo,

The American College of Physicians (ACP), the largest medical specialty organization and second-largest physician group in the United States, representing 141,000 internal medicine specialists (internists), related subspecialists, and medical students, applauds the ONC's development of this living document that takes a first step towards detailing the actions and roles needed for ONC's 10-Year vision to achieve interoperability. We appreciate the invitation to comment on how we can collectively achieve this shared goal, and thank you for the opportunity to provide input on these very important issues. We hope that you will find value in our responses. Attached to this letter is a side-by-side of comments from the College's Medical Informatics Committee members on selections from the draft roadmap that are relevant to practicing Internists. Some of the key themes from the Committee's comments include:

- Our actions should move towards market needs and away from artificial incentives, penalties, and mandates on physicians and other providers as a way to drive interoperability.
- The physician's and provider's role in the learning health and healthcare system should not be limited to merely data entry - they should not be left out of the formulation of the learning health system. It is important to not only focus on what happens outside of the care delivery process, and involve those at the front lines of care delivery.
- Only a very small set of common use cases should be chosen for the initial work involved in mapping interoperability throughout the health care system.
- The proposed common data set is overly lengthy and untenable. Physicians and other health care providers should determine what information should go into any common data set for clinical information at point of care.
- Improving interoperability through payer mandates should address excessive administrative and financial burdens in healthcare operations at the physician and provider level.

- Incentivizing the adoption and use of interoperability to create interoperability is a display of circular logic that is unnecessary and counter-productive – especially if the data are interoperable but inaccurate.

We hope that these comments will aide in developing future versions of the Shared Nationwide Interoperability Roadmap. In addition, we hope that there will be regular opportunities for us to be involved in future deliberations, as this plan is developed. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'P Basch', with a long horizontal flourish extending to the right.

Peter Basch, MD, MACP
Chair, Medical Informatics Committee
American College of Physicians

Excerpts from ONC's Nationwide Interoperability Roadmap; Draft Version 1.0	ACP Medical Informatics Committee Comments
<p>Letter from the National Coordinator Achieving that better care system and better health for all will, through health IT interoperability, require work in 4 critical pathways: 1) Requiring standards; 2) Motivating the use of those standards through appropriate incentives; 3) Creating a trusted environment for the collecting, sharing and using of electronic health information; and 4) aligning the interoperability infrastructure with the shift from pay-for-volume towards pay-for-value.</p>	<p>Incentivizing vs. Business Needs: ACP strongly recommends that we stop thinking about incentivizing the use of a standard, or interoperability in general. Instead, we must move towards a sustainable business case for appropriate use of an effective interoperable infrastructure. Incentives, penalties, mandates, and structural and process measures are inappropriate for this purpose and only point out that the business case for exchange in many situations is lacking. If there are real and visible benefits to exchange in a particular situation, there will be no need for incentives, penalties, mandates, and measures. The focus should be on identifying supportive business cases for exchange, and then reducing the current barriers and friction points that are impeding implementation. Measurement must focus on outcomes for this approach to succeed</p>
<p>Questions on the Roadmap As you review the Roadmap, please consider the following questions and submit your responses during the public comment period.</p> <p>1. General</p> <p>1. Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning healthsystem in the long term?</p>	<p>Learning Health and Healthcare System: The outlined approach to a learning healthcare system appears to enfranchise providers only as data input personnel; but not as professionals otherwise engaged in helping to move the country towards improving health and healthcare. The formulation of the learning health system appearing in this document leaves physicians and other health care professionals feeling left out. Health professionals provide massive amounts of data prescribed by others, and then they are instructed to change their practice behaviors based upon decisions made by others. The clinical data alone will not provide the policy makers with answers to what needs to be changed. The clinical data will only suggest where outcomes appear to be better than elsewhere. This is only a starting place for a thorough investigation of what differences among practices might account for different outcomes. The only way we will move from suppositions to supportable recommendations is through the essential ongoing involvement of those at the front lines of care delivery.</p>

<p>2. What, if any, gaps need to be addressed?</p>	<p>One significant gap relates to support for migration from system to system by practices and other providers. There is no cost effective way to move the majority of patient data from one system to another. This prevents or hampers a practice’s ability to select appropriate tools and migrate from system to system over time as we all do in every field.</p>
<p>2. Priority Use Cases</p> <ol style="list-style-type: none"> Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications. 	<p>Use Cases: The first, and possibly one of the hardest tasks that will be faced by any governance process will be to identify the very small set of initial use cases to be addressed. All previous attempts at governance in this space have found it impossible to identify the small simple starter set of objectives. Every stakeholder group insists that its needs be addressed as a condition of participation.</p> <p>It will be very difficult for stakeholders to agree to go forward with initial projects that do not address their data desires. We will need to find ways to convince all stakeholders that their data requirements will be addressed within a reasonable timeframe.</p> <p>A very small set of reality-based use cases must be chosen for initial work. There are finite limits to the availability of critical resources – especially human expertise. There are already far too many initiatives underway, and the lack of results proves this. If most stakeholder groups are not disappointed by the initial set, then the initial set is still too large.</p> <p>We recommend starting with very common use cases (e.g., longitudinal care of a patient with 2 chronic disorders, a patient with a chronic illness receiving pre-operative evaluation through a surgical procedure into the post-operative recovery/rehab period, a healthy person with occasional intercurrent illnesses receiving preventive services for most of their life.) If we cannot map out just the complexities of these three, as a start, we are doomed from both the generalizability and scalability perspectives.</p>

<p>3. Supportive Business, Cultural, Clinical and Regulatory</p> <p>1. How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?</p>	<p>Incentivizing vs. Business Needs: Enhancing incentives for data/information sharing equals incentivizing sending data. Thus, incentives provide for data dumping rather than intelligent use and re-use – which is why the driver for this should be the payment system, rather than artificial incentives, penalties, and mandates. Where there is a supportive business case for USING these mobilized clinical data, artificial incentives will not be required. Without the supportive business case, no amount of incentivizing will overcome the key barrier to having interoperability improve care and support reducing redundant testing / care.</p> <p>Private health plans and purchasers can incentivize providers to purchase and use interoperable systems by accepting their output and stop requiring duplicative documentation onto paper or digital forms or the development of a parallel administrative system.</p> <p>This phrase, “send, receive, find and use clinical data,” is used repeatedly. What is the meaning and significance of “find?” Our concern is that this appears to be a new requirement for physicians and other clinical staff to go on a hunt for data that may or may not be available, and may or may not be of use. Unless there are automated tools that perform the “finding,” this requirement would be inappropriate.</p>
<p>Executive Summary</p> <p>Health information technology (health IT) that facilitates the secure, efficient and effective sharing and use of electronic health information when and where it is needed is an important contributor to improving health outcomes, improving health care quality and lowering health care costs – the three overarching aims that the U.S. is striving to achieve.</p>	<p>Interoperability: The first principle of interoperability is the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p> <p>The most important action is how anyone can most cleverly use health IT to improve care. This is always true in all circumstances. Not everyone sees multiple providers, and algorithms based on diagnosis, BP, weight, etc., determine some health and healthcare decisions. By putting information</p>

	<p>sharing first, ONC is falling into the trap that many policy makers now believe - that sharing of information has never occurred before, isn't occurring now, and that once it occurs, everything gets better.</p> <p>(Pham et al. Primary Care Physicians' Links to Other Physicians Through Medicare Patients: The Scope of Care Coordination. <i>Ann Int Med</i> 150: 236-242, 2009)</p> <p>It is important that we all keep in mind that there is little evidence of any benefits attributable to Health Information Exchange (HIE). (Saurabh Rahurkar, Joshua R. Vest and Nir Menachemi. Despite The Spread Of Health Information Exchange, There Is Little Evidence Of Its Impact On Cost, Use, And Quality Of Care. <i>Health Affairs</i>, 34, no.3 (2015):477-483.)</p>
<p>Health IT can help health care providers recommend treatments that are better tailored to an individual's preferences, genetics and concurrent treatments; it can help individuals make better treatment decisions and health-impacting decisions outside of the care delivery system; and can help reduce care delivery redundancy and cost by allowing test results to be reused while supporting analyses to pinpoint waste. To achieve this, however, the health IT community must expand its focus beyond institutional care delivery and health care providers, to a broad view of person-centered health.</p> <p>This shift requires a high degree of information sharing between individuals, providers and organizations and therefore a high degree of interoperability between many different types of health IT, such that systems can exchange and use electronic health information without special effort on the part of the user. The goal of this shift is to a nationwide learning health system—an environment that links the care delivery system with communities and societal supports in "closed loops" of electronic health information flow, at many different levels, to enable continuous learning and improved health. This kind of system allows individuals to select platforms and apps to share and use their own electronic health information to meet their needs without undue constraints.</p>	<p>It is curious why these items appear in this order. In healthcare, preferences would not come before genetics and treatments. Clinicians think first of demographics and diagnoses, and then tailor those with preferences – rather than going to preferences first.</p> <p>Learning Health and Healthcare System: We are concerned that, by using the term “Health” instead of “Healthcare” as used by the IOM, the focus is on all that happens outside of the care delivery process. Clarity would be added if Joseph Kanter’s definition of Learning Health System were adopted. "One in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care." http://www.prnewswire.com/news-releases/joseph-h-kanter-family-foundation-convenes-historic-learning-health-system-summit-stakeholders-collaboratively-work-toward-realizing-a-national-scale-learning-health-system-153255845.html).</p>

<p>Principles of Interoperability:</p> <ul style="list-style-type: none"> • Build upon existing health IT infrastructure • Maintain Modularity • One size does not fit all • Consider the current environment and support multiple levels of advancement • Empower Individuals • Simplify • Protect privacy and security in all aspects of interoperability • Leverage the market • Focus on Value • Scalability and universal success <p>...Specifically, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017.</p>	<p>Interoperability: The first principle of interoperability is the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden. This one principle obviates the need for many on this list.</p> <p>“Modularity” seems more related to architectural choices. We agree that is preferable for practices to be able to assemble modular components rather than be forced to use whatever their primary EHR vendor supplies. It is not clear why this is a principle of interoperability. It may be a preferred architectural approach in appropriate situations, but it does not belong in a policy document. A more appropriate formulation might be that services may be modular. If modularity becomes policy, we can expect providers to be required to adopt modularity even where inappropriate and to report on measures of modularity.</p> <p>Common Data Set: We are concerned that the proposed “common data set” is too close to the overly lengthy and existing set in the Summary of Care Document (SoCD). This set is excessive for any specific use, and yet it is incomplete for any specific use. Physicians and other clinicians with direct patient care need to be the ones determining what key information should be in the common data set. We encourage ONC to ensure that the data set be aligned with the best knowledge/evidence/current clinical guidelines, and have input from key stakeholders, including (perhaps most importantly) practicing clinicians.</p> <p>Narrative information is critical: A common data set is not a complete solution. Much of the rich clinical patient data exist in the narrative form that provides context and meaning to the</p>
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	<p>structured data. It is not feasible or desirable to require structured entry of all significant elements. Secondary data users, in the mistaken belief that structured data represent more accuracy than narrative, may desire only structured data elements. Even structured data have greater value when viewed in the context in which they were captured. Taken out of the context, the structured data may be interpreted incorrectly. For this reason, the provenance (origin) of the data is highly important to encourage appropriate use and understanding. For care delivery, on the other hand, the elements that the doctor or other clinician wants to see first are the narrative assessment and the plan. One of the key lessons we have learned thus far in our move to computerized records is that the narrative, the patient's story and the clinician's reasoning, must be maintained.</p>
<p>...several barriers continue to inhibit nationwide interoperability despite these arrangements and must be overcome rapidly to achieve a learning health system. These barriers include:</p> <ol style="list-style-type: none"> 1. Electronic health information is not sufficiently structured or standardized and as a result is not fully computable when it is accessed or received. That is, a receiver's system cannot entirely process, parse and/or present data for the user in meaningful and useable ways. It is also difficult for users to know the origin (provenance) of electronic health information received from external sources. Workflow difficulties also exist in automating the presentation of externally derived electronic health information in meaningful and appropriately non-disruptive ways. 	<p>Narrative information is critical: A common data set is not a complete solution. Much of the rich clinical patient data exist in the narrative form that provides context and meaning to the structured data. It is not feasible or desirable to require structured entry of all significant elements. Secondary data users, in the mistaken belief that structured data represent more accuracy than narrative, may desire only structured data elements. Even structured data have greater value when viewed in the context in which they were captured. Taken out of the context, the structured data may be interpreted incorrectly. For this reason, the provenance (origin) of the data is highly important to encourage appropriate use and understanding. For care delivery, on the other hand, the elements that the doctor or other clinician wants to see first are the narrative assessment and the plan. One of the key lessons we have learned thus far in our move to computerized records is that the narrative, the patient's story and the clinician's reasoning, must be maintained. (For specific recommendations see: Kuhn T, Basch P, Barr M, Yackel T. Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper From the American College of Physicians Clinical Documentation in the</p>

<p>2. Even when technology allows electronic health information to be shared across geographic, organizational and health IT developer boundaries, a lack of financial motives, misinterpretation of existing laws governing health information sharing and differences in relevant statutes, regulations and organizational policies often inhibit electronic health information sharing.</p>	<p>21st Century. <i>Annals of Internal Medicine</i>. 2015;162(4):301-3. http://annals.org/article.aspx?articleid=2089368#ACPPositionStatementsandRecommendations)</p> <p>Sharing, by itself, does not suggest any value. The information must be able to be put to effective use to have value. The first principle of interoperability is the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p>
<p>Critical Actions for Near Term Wins</p> <p>The four most important actions for public and private sector stakeholders to take to enable nationwide interoperability of electronic health information through health IT in the near term are: (1) establish a coordinated governance framework and process for nationwide health IT interoperability; (2) improve technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhance incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarify privacy and security requirements that enable interoperability.</p> <p>Below are more detailed near-term actions for each of these high priority areas:</p> <p>2) Improve technical standards and implementation guidance for sharing and using a common clinical data set. This basic set of electronic health information must be accessible via clinical documents (for example, in a care summary) and as discrete data elements (for example to plot blood pressure over time). It is unlikely that the care delivery system will stop using clinical documents for specific purposes in the near term (or perhaps the long term) and mobile technologies and applications will need to simultaneously access specific data elements to support individuals in the near term. The purpose for which electronic health information is shared and used must drive the</p>	<p>Incentivizing vs. Business Needs: Enhancing incentives for data/information sharing equals incentivizing sending data. Thus, incentives provide for data dumping rather than intelligent use and re-use – which is why the driver for this should be the payment system, rather than artificial incentives, penalties, and mandates. Interoperability aside, the incentives for consultants and imaging centers to share their findings should be that, if they don't send the information, practices should have the freedom not to use the facilities.</p> <p>While we understand that the proposed list is meant to start a conversation, the inclusions and exclusions say a lot about underlying assumptions. Preferred language is helpful but the Learning Health System (LHS) should address language literacy to assure patients understand health information, and language literacy should address learning style. Also, a clear definition of care team members and roles is essential to address successful interoperability. Laboratory tests and values" must be clarified, for example. This cannot mean all available tests and values, but only those that the sender feels</p>

<p>technical standards and methods selected for nationwide adoption through a coordinated governance process.</p> <p>While coordinated governance processes are established, public and private stakeholders should advance standards that are scalable, high performing and simple. These standards should enable sharing a common clinical data set, further constrain implementations of the C-CDA and define standards for data provenance at the document and data element levels and implement standards in a manner that makes sharing and receiving electronic health information easy for users.</p>	<p>are appropriate for a specific purpose. For any given purpose, this list is both excessive and incomplete.</p> <p>Common Data Set: This common data set has caused undue burden because it is overly described and one-size fits all. Valid use of the C-CDA has led to information overload and buried headlines.</p> <p>Narrative information is critical: A common data set is not a complete solution. Much of the rich clinical patient data exist in the narrative form that provides context and meaning to the structured data. It is not feasible or desirable to require structured entry of all significant elements. Secondary data users, in the mistaken belief that structured data represent more accuracy than narrative, may desire only structured data elements. Even structured data have greater value when viewed in the context in which they were captured. Taken out of the context, the structured data may be interpreted incorrectly. For this reason, the provenance (origin) of the data is highly important to encourage appropriate use and understanding. For care delivery, on the other hand, the elements that the doctor or other clinician wants to see first are the narrative assessment and the plan. One of the key lessons we have learned thus far in our move to computerized records is that the narrative, the patient’s story and the clinician’s reasoning, must be maintained.</p>
<p>3) <i>Advance incentives for sharing health information according to common technical standards, starting with a common clinical data set.</i> While the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) have been a primary motivator for the adoption and use of health IT, these programs alone are insufficient to create economic incentives that lead to interoperability across the care continuum and, over time, a learning health system. Experience has demonstrated that current fee-for-service payment policies often deter the exchange of electronic health information, even when it is technically feasible. To ensure that individuals and providers can</p>	<p>This proposes to incentivize exchange of a common data set. As discussed above, we do not believe that the common data</p>

<p>send, receive, find and use a common clinical data set, federal, state and commercial payers will need to evolve policy and funding levers. These levers should incentivize information sharing according to technical standards designated through ONC's HIT Certification Program in the near term and standards identified through the coordinated governance process over the longer term. See the Supportive Business and Regulatory Environment that Encourages Interoperability requirement for more detail on payment policy actions.</p> <p>Footnote: Vitals in particular should be expanded to include – patient's body height, body weight measured, diastolic and systolic blood pressure, heart rate, respiratory rate, body temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index (ratio).</p>	<p>set will be the right data set to exchange in many circumstances, and its use should not be universally required and incentivized. This proposal predetermines a common data set that is not subject to the LHS. Will it remain mandated even if experience with it shows little value? We encourage ONC to ensure that the data set be aligned with the best knowledge/evidence/current clinical guidelines, and have input from key stakeholders, including (perhaps most importantly) practicing clinicians. Where data sharing makes sense, it will be self-reinforcing. The purpose of this schema seems not to support what makes clinical sense, but rather to have providers contribute data for government, payers, app developers, and others.</p> <p>This is a good example of a one-size fits all statement that makes little clinical sense. Where is the evidence that all patients need a pulse ox? It is not possible to define a set of vitals that is universally applicable. Incentivizing or mandating the use of such a set is clinically inappropriate.</p>
<p>Interoperability Vision for the Future An interoperable health IT ecosystem makes the right data available to the right people at the right time among disparate products and organizations in a way that can be relied upon and meaningfully used by recipients.</p> <p>By 2024, individuals, care providers, communities and researchers should have an array of interoperable health IT products and services that support continuous learning and improved health. This "learning health system" should also result in lower health care costs (by identifying and reducing waste), improved population health, truly empowered consumers and ongoing technological innovation.</p>	<p>We agree with this statement, however it is counter to many proposals in this document that would require the collection and exchange of irrelevant data.</p> <p>Improving Interoperability by Reducing Payer Requirements: This statement fails to mention the desperate need to address excessive costs in healthcare operations. There is no mention of reducing administrative burden in healthcare delivery, reducing waste in excessive documentation requirements, or comprehension of what new burdensome requirements are being mobilized via interoperable platforms.</p> <p>The outlined approach to a learning healthcare system appears to enfranchise providers only as data input personnel; but not as professionals otherwise engaged in helping to move the</p>

<p>For example, all individuals, their families and health care providers should be able to send, receive, find and use electronic health information in a manner that is appropriate, secure, timely and reliable. Individuals should be able to securely share electronic health information with care providers and make use of the electronic health information to support their own health and wellness through informed, shared decision-making. An interoperable health IT ecosystem should support critical public health functions, such as real-time case reporting, disease surveillance and disaster response, as well as data aggregation for research and value-based payment that rewards higher quality care, rather than a higher quantity of care.</p>	<p>country towards improving health and healthcare. The formulation of the learning health system appearing in this document leaves physicians and other health care professionals feeling left out. Health professionals provide massive amounts of data prescribed by others, and then they are instructed to change their practice behaviors based upon decisions made by others. The clinical data alone will not provide the policy makers with answers to what needs to be changed. The clinical data will only suggest where outcomes appear to be better than elsewhere. This is only a starting place for a thorough investigation of what differences among practices might account for different outcomes. The only way we will move from suppositions to supportable recommendations is through the essential ongoing involvement of those at the front lines of care delivery.</p> <p>There is no mention of whether the information is understandable and actionable. A good example is the way Amazon combines and makes fully transparent the cost of goods plus the costs of shipping and handling as well as the estimated delivery window. All of the proposals in this document, taken together, will not ensure that patients and physicians will have all of the information they really need to make the best decisions. There is no proposal to address the lack of transparency, lack of complete information, and imposition of transaction friction, administrative procedures that impede efficiency) that prevents informed decision making.</p>
<p>Guiding Principles for Nationwide Interoperability</p> <p>1. Build upon the existing health IT infrastructure. Significant investments have been made in health IT across the care delivery system and in other relevant sectors that need to exchange electronic health information with individuals and care providers. To the extent possible, we will encourage stakeholders to build from existing health IT infrastructure, increasing</p>	<p>The current health IT infrastructure is not suitable. Rather than a hoped-for hub and spoke approach, our current scheme requires every end-point to establish a unique connection to each additional end-point with which it must interact. A typical practice requires dozens of distinct interfaces to communicate</p>

<p>interoperability and functionality as needed.</p> <p>2. One size does not fit all. Interoperability requires technical and policy conformance among networks, technical systems and their components. It also requires behavior and culture change on the part of users. We will strive for baseline interoperability across health IT infrastructure, while allowing innovators and technologists to vary the usability in order to best meet the user's needs based on the scenario at hand, technology available, workflow design, personal preferences and other factors.</p> <p>4. Leverage the market. Demand for interoperability from health IT users is a powerful driver to advance our vision. As delivery system reform increasingly depends on the seamless flow of electronic clinical health information, we will work with and support these efforts. The market should encourage innovation to meet evolving demands for interoperability.</p>	<p>with every lab, quality measurement organization, public health organization, and other practice with which it must communicate. A typical hospital system may require dozens of interfaces just for quality reporting. There is no plan to simplify and merge these unique and expensive interfaces into a smaller set.</p> <p>Of course we agree that one size does not fit all. Unfortunately, while this document takes this approach with regard to the exchange infrastructure, it does not recognize the same need regarding the content inside the envelope..</p> <p>Interoperability, as in movement of patient data from one place to another, is not what is being demanded by health IT users. While the cry may be for “interoperability, users are not interested in volume. They want value. What is needed is exchange of specific data for specific purposes. Calling for the “seamless flow” of health information equates health data with water. Unlike with water molecules, one health data element is not like any other. Also, unlike water, volume is not a relevant measure of value. Patients and their data are more like snowflakes – each is different in significant ways. Attempting to move patient data in bulk, such as with genomic data, risks damaging the unique aspects. Additionally moving too much patient data risks privacy and inappropriate information being sent. With large data sets, such as imaging or genomics, it makes far more sense for many reasons to leave the data in place and access as needed through tools such as Picture Archiving and Communication Systems (PACS.)</p>
<p>5. Simplify. Where possible, simpler solutions should be implemented first, with allowance for more complex methods in the future.</p>	<p>This is a crucial principle that has been ignored thus far in all of our attempts to exchange healthcare data. There seems to be a natural tendency among S&I work group participants to load up requirements documents with every conceivable use case.</p>

6. Maintain modularity. A large, nationwide set of complex systems that need to scale are more resilient to change when they are divided into independent components that can be connected together. Because medicine and technology will change over time, we must preserve systems' abilities to evolve and take advantage of the best of technology and health care delivery. Modularity creates flexibility that allows innovation and adoption of new, more efficient approaches over time without overhauling entire systems.

7. Consider the current environment and support multiple levels of advancement. Not every individual or clinical practice will incorporate health IT into their work in the next 3-10 years and not every practice will adopt health IT at the same level of sophistication. We must therefore account for a range of capabilities among information sources and information users, including EHR and non-EHR users, as we advance interoperability. Individuals and caregivers have an ongoing need to send, receive, find and use their own health information both within and outside the care delivery system.

8. Focus on value. We will strive to make sure our interoperability efforts yield the greatest value to individuals and care providers; improved health, health care and lower costs should be measurable over time and at a minimum, offset resource investment.

The requirements documents become supersets of all of the individual use cases of the participants. If this issue is not tackled with dedication our historical lack of progress is likely to continue. Suggested early topics for focus include standardizing vocabulary for laboratory and imaging reports, immunizations, and preventive screenings.

“Modularity” seems more related to architectural choices. It is not clear why this is a principle of interoperability. It may be a preferred architectural approach in appropriate situations, but it does not belong in a policy document. A more appropriate formulation might be that services may be modular. If modularity becomes policy, we can expect providers to be required to adopt modularity even where inappropriate and to report on measures of modularity.

Unfortunately, accommodating both EHR and non-EHR users often means no administrative benefit for either, and no convenience for EHR users. Thus, the largest payer in the Mid-Atlantic has a PCMH program, where the PCP has to complete a clinical form with weight, BMI, BP, lipids, smoking status, cancer screenings, etc. To accommodate both EHR and non-EHR users, there is a paper form to complete, even though all of the elements required are in the EHR. The policy should require data receivers to accept electronic transmissions and allow a paper form as well.

Every lab, public health agency, quality reporting agency, HIE, Direct HISP, etc. requires a separate interface. For example, simply adding scheduled drug ordering functionality to an EHR's e-prescribing system is costing each practice \$10,000 with a major vendor. Given the huge investment in interfaces required of practices, we expect that practice resource investment will be a primary target to offset. Consider reduction of administrative burden as a sure way to ensure that interoperability yields real value. Reducing the cost of

	<p>administrative waste, such as separate payer, quality, and public health reporting formats, provides a clear offset.</p>
<p>How the Roadmap is Organized: Business and Technical Requirements for a Learning Health System Rules of engagement and governance</p> <p>A. Shared governance of policy and standards that enable interoperability: Nationwide interoperability across the diverse health IT ecosystem will require stakeholders to make collective decisions between competing policies, strategies, standards in a manner that does not limit competition. Maintaining interoperability once established will also require ongoing coordination and collaborative decision-making about change.</p> <p>Supportive business, clinical, cultural and regulatory environments</p> <p>B. A supportive business and regulatory environment that encourages interoperability: Rules that govern how health and care is paid for must create a context in which interoperability is not just philanthropic, but is a good business decision.</p> <p>C. Individuals are empowered to be active managers of their health: A learning health system is person-centered, enabling individuals to become active partners in their health by not only accessing their electronic health information, but also providing and managing electronic health information through mobile health, wearable devices and online services.</p>	<p>A. The first, and possibly one of the hardest tasks that will be faced by any governance process will be to identify the very small set of initial use cases to be addressed. All previous attempts at governance in this space have found it impossible to identify the small simple starter set of objectives. Every stakeholder group insists that its needs be addressed as a condition of participation. All stakeholders must be willing to accept that their proposed use case may not be in the initial set.</p> <p>B. We fully support this approach. We are concerned that this requirement is often ignored in the rest of this document. If there is not a business case for a proposed action, then a different action, where the case exists, should be taken.</p> <p>C. There appears to be an unaddressed tension between personalized care and the push for population-based care and reducing variation in care delivery. This tension is not discussed. This is a very important point that must not get lost. How will we address the true needs of the individual patient (using personalized or precision medicine) if we are attempting to stamp out variation in the treatment of patients who may, on the surface, appear to share a common condition? Population-based care is a whole other cost center for a practice requiring new computer savvy administrative/clinical personnel. Its workflows may be at odds with patient-centered care. Also as documentation requirements are increasing. Office visits for patients are becoming less “person centered” and more “computer centered” care. We must address the fact that guidelines and</p>

	<p>providers to be required to adopt modularity even where inappropriate and to report on measures of modularity.</p>
<p>Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability</p> <p>A1. Establishment of Coordinated Governance</p> <p>4. Call to action: Federal agencies that provide or pay for health services should align their policies for interoperability with the nationwide governance framework.</p> <p>7. ONC and stakeholders will use nationwide interoperability metrics to assess the success of governance activities and make or recommend changes, as needed.</p> <p>9. ONC and stakeholders should continue to use nationwide interoperability metrics to assess the success of governance activities and make or recommend changes, as needed.</p> <p>A2. Policies & Operations</p> <p>3. ONC will work with the established coordinated governance process to identify or modify criteria and implementation specifications to address an expanded data set and uses of health information beyond treatment including but not limited to payment and health care operations and patient-generated health data.</p>	<p>4. Federal agencies that require health information from providers should develop methods that permit e-submission and/or abstraction of that information from interoperable EHRs, and only require paper submissions from providers not using EHRs.</p> <p>7, 9. Process metrics such as measures of volume are inappropriate for health data exchange.</p> <p>Physicians and other healthcare providers must be part of this process. Otherwise, the result will be everyone else dictating additional data collection burdens for those who deliver care. Thus far, through multiple attempts at governance since the founding of ONC, physician and provider input has been insufficient.</p>
<p>Supportive Business, Clinical, Cultural and Regulatory Environments</p> <p>While the Medicare and Medicaid EHR Incentive Programs have been a primary motivator for the adoption and use of certified EHR technology, these programs alone are insufficient to overcome barriers to our vision of information sharing and interoperability as outlined above. Current policies and financial incentives often prevent such exchange, even when it is technically feasible. To ensure that individuals and care providers send,</p>	<p>Excellent. This is the only valid approach to expanding</p>

<p>receive, find and use a basic set of essential health information across the care continuum over the next three years, we need to migrate policy and funding levers to create the business imperative and clinical demand for interoperability and electronic health information exchange.</p> <p>A Supportive Business and Regulatory Environment that Encourages Interoperability LHS Requirement A supportive business and regulatory environment that encourages interoperability: Rules that govern how health and care are paid for must create a context in which interoperability is not just a way to improve care, but is a good business decision.</p> <p>Policy and funding levers that create the business imperative for interoperability are pivotal for helping to ensure that individuals, caregivers and providers can send, receive, find and use a common clinical data set across the care continuum in the near term. Policy levers related to other learning health system stakeholders such as public health, social and human services and research communities must also be addressed. Additionally, a cultural shift at both the individual and provider levels is necessary to empower individuals to participate in their health and care.</p>	<p>interoperability. The first principle of interoperability is the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p> <p>Excellent. This is the only valid approach to expanding interoperability</p> <p>This phrase, “send, receive, find and use a common clinical data set,” is used repeatedly. What is the meaning and significance of “find?” Our concern is that there appears to be a new requirement for physicians and other clinical staff to go on a hunt for data that may or may not be available and may or may not be of use. Unless there are automated tools that perform the “finding,” this requirement would be inappropriate.</p>
<p>Background and Current State: Despite strong agreement on the need for interoperability to enable higher quality, more efficient, person-centered care, the demand among providers, consumers and purchasers of health care has not yet translated into seamless interoperability across the health care system. Countervailing market forces and structural attributes of the health care system make it costly to move away from the status quo of fragmented care and silos of health information, inhibiting widespread adoption of interoperable systems. One key barrier to interoperability arises from the way in which health care in the U.S. has traditionally been reimbursed (typically “fee-for-service” payment models.) Economic gains from interoperability are realized in the form of greater efficiency in the delivery of health care-for instance, laboratory and imaging tests are often duplicated when an existing image that might obviate the need for a test is not available or not accessed, contributing to wasteful health care spending that could be allocated more efficiently. While the effective use of</p>	<p>We are concerned that “policy levers” will be resorted to when adoption fails to meet arbitrary metrics. Practices should not be faced with penalties for non-compliance with mandated</p>

<p>interoperable systems has the potential to address this waste by allowing providers to share test results, there are few incentives to adopt these systems under the fee-for-service system, which can actually incentivize providers to deliver a greater volume of services and disincentives the reuse of prior lab tests.</p>	<p>practices. The policy levers should be used to remove barriers and reduce friction points that impede practice's abilities to use health data exchange effectively and efficiently.</p> <p>Adoption is not the only roadblock. As long as it is in the business interest of the labs to make it difficult to switch, no amount of incentivizing physicians will result in the efficiencies that interoperability can deliver. If interoperability gave providers the ability to easily share results, then the notion of there being an incentive to re-test will be shown to be a red herring. This is a clear case where the regulatory focus should not be on the physician but on the lab.</p> <p>Interoperable systems will not eliminate all duplication (so-called "waste"). Lab blood tests are fairly reliable, but the quality of other diagnostics (office spirometry performed below technical standards for acceptability or reproducibility, CT scans with motion artifact or volume averaging obscuring a nodule, studies with false negative rates like sleep studies and HIDA scans, echocardiograms that do not measure/capture pulmonary artery pressures or comment upon right ventricular function, etc.) sometimes mandate repeating a study in an individual patient. These cases are not wasteful, but patient-centric examples of where a prior study with a general interpretation may be inadequate to answer a very specific clinical question.</p>
<p>...However, paying for outcomes alone will not be sufficient to change the way providers deliver care. The transition to value-based payment is a long-term, incremental process and providers will need to master new tools and ways of working together before they are willing to take on more substantial levels of risk. Payment policy should encourage incremental steps toward interoperability and address those disincentives that stakeholders perceive as making the transition to interoperability too costly.</p> <p>... As HHS continues to test and advance new models of care that reward providers for outcomes, it will help to create an environment where</p>	<p>CMS recently announced targets of 2016 and 2018 to have significant shift to pay for value. The business case for interoperability is now real and within the medium term horizon.</p>

<p>interoperability makes business sense. Additional policy levers across the public and private sector could also be leveraged to encourage interoperable health IT, including: 1) new incentives to adopt and use interoperable health information systems to create additional demand for interoperability; and 2) requirements/penalties that raise the costs of not moving to interoperable systems.</p>	<p>Circular Logic: This logic is circular. Incentivize interoperability to create demand for interoperability. Incentives are unnecessary and penalties are counter-productive. Value based payment models are enough to drive exchange.</p> <p>ACP strongly recommends that we stop thinking about incentivizing the use of a standard, or interoperability in general. Instead, we must move towards a sustainable business case for appropriate use of an effective interoperable infrastructure. Incentives, penalties, mandates, and structural and process measures are inappropriate for this purpose and only point out that the business case for exchange in many situations is lacking. If there are real and visible benefits to exchange in a particular situation, there will be no need for incentives, penalties, mandates, and measures. The focus should be on identifying supportive business cases for exchange, and then reducing the current barriers and friction points that are impeding implementation. Measurement must focus on outcomes for this approach to succeed.</p>
<p>Moving Forward and Critical Actions</p> <p>In the August 2013 document Principles and Strategy for Accelerating HIE, HHS articulated a commitment to leveraging appropriate authorities that go beyond HITECH implementation to accelerate interoperability and the electronic exchange of health information across the health care system. As discussed in the document, 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.</p> <p>Today, federal value-based payment programs have already begun to advance</p>	<p>This is an example of an unnecessary requirement. Providing CCM services is not cost effective without use of an interoperable health IT infrastructure. It is worth noting that this PFS has had to be revised to reflect the fact that few docs are using 2014 certified technology.</p>

the business case for improved care coordination through interoperable health IT. Accountable care programs, which encourage doctors and hospitals to reduce the growth of total cost of care for individuals in exchange for an opportunity to share in savings, are designed to reward more effective care coordination. In the next three years, HHS can look to reinforce interoperability among providers participating in these programs through measures of adoption of health IT among providers. As market capabilities around interoperability mature, programs may transition to measures more directly focused on interoperability.

...State governments are key partners in advancing a business environment that is supportive of interoperability and reinforces information exchange. Through the administration of state Medicaid programs and their ability to direct how federal Medicaid funds are spent, states have considerable opportunities to support interoperability. The Centers for Medicare and Medicaid Services (CMS) has identified a number of ways that states can use Medicaid funds to develop care coordination capacity among their Medicaid providers. Several states have already begun to use Medicaid Managed Care contracts to advance interoperability. As part of managed care organization requests for proposals (RFPs) and contracts, states can require payers to ensure that provider networks use interoperable health IT or electronically report data to support care coordination as a condition of participation. States can also emphasize use of health IT and health information exchange as part of quality strategies for managed care plans.

This is unnecessary. If interoperability solves problems, there is no reason for new regulations to further define and measure interoperability adoption and use. Process metrics such as measures of volumes of data are inappropriate for health data delivery. The focus must be placed on the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.

Improving Interoperability by Reducing Payer Requirements:
This is unnecessary, and, more importantly, inappropriate. If a state has any authority over payers, the states should mandate that the payers provide interoperability-enabled solutions for healthcare documentation and reporting burdens. Myriad forms and complex prior authorization processes should be replaced with automated submission of routinely collected data from EHRs. This is a real business case for providers. States can create free CQM reporting platforms – such that end-users can report CQM data at no cost. Going in the other direction to define interoperability process measures can only cause problems.

Private Payers

Much like public payers, commercial health plans have an important role to play in driving accountable care and value-based payment. Interoperability among provider networks can offer important competitive advantages to payers seeking to ensure members have access to high-value, coordinated

Improving Interoperability by Reducing Payer Requirements:
Payers have consistently limited the effectiveness of market drivers for interoperability. For example, existing reference labs, a key source of interoperability benefit and pain for providers, have never been able to compete for business – as most lab services are tied to an insurance contract. A practice

care. These attributes of provider networks are also attractive to health care purchasers seeking to partner with networks that can deliver the most efficient care for employees.

In parallel with public sector efforts over the past several years, commercial payers have developed and deployed a wide range of value-based payment programs within their provider networks that offer new opportunities to focus attention on and generate demand for interoperability. For instance, payers can make adoption of certified health IT systems or demonstration of interoperability a condition of participation for providers that wish to take part in these programs. In markets with more advanced infrastructure for health information exchange, such as an active health information organization, payers could consider partnering with a health information organization and requiring participation by providers seeking to join these programs.

Purchasers

Private purchasers of health care, including large employers, can also contribute to a supportive environment for interoperability. Purchasers can selectively contract with plans that demonstrate a commitment to the use of interoperable health IT and health information exchange among network and non-network providers (e.g., certain percentage meeting meaningful use requirements or engaging in health information exchange). Purchasers can also commit to sponsoring benefit plans that encourage employees to choose providers that are using interoperable health IT and support individual access to electronic health information.

should be able to tell a lab to either connect to us electronically for ordering and results, or we will shift our business elsewhere. Payer contracts impede interoperability.

Payer mandates are unnecessary and inappropriate. Mandates and use requirements do not generate demand for true interoperability. We would improve interoperability by eliminating paper forms and supporting the automatic sharing CQM data without the need for duplicative data entry.

Encouraging employees to choose interoperable healthcare providers will accomplish little as long as those with whom the provider interacts do not become more transparent. For example, MIPPA requirements on Part D providers require the inclusion of medication history, formularies, and substitutions. However, there is no requirement that the formulary is accurate, or that substitutions appear where expected. The regulations on payers and purchasers are such that they still permit nontransparent, inaccurate, and non-actionable information. Interoperability will accomplish nothing if the information exchanged is not of value. The College strongly believes that the optimal solution is not just to make prior authorizations easier to resolve, but to avoid them wherever possible. This approach, which utilizes technology to bring transparent, accurate, and actionable cost and insurance coverage information to patient and clinician before and at the point-of-care not only reduces administrative burden; it facilitates informed value-based shared decisions about treatments and testing.

Table 2: Critical Actions for a Supportive Business and Regulatory

All of these actions, in themselves are not a sufficient reason

<p>Environment that Encourages Interoperability</p> <p>B2. State Actions</p> <p>6. Call to action: States with managed care contracts should routinely require provider networks to report performance on measures of standards-based exchange in required quality strategies, performance measurement reporting, etc.</p>	<p>for adoption and use of interoperable health IT. If interoperability solves problems, there is no reason for new regulations to further define and measure interoperability adoption and use. Process metrics such as measures of volumes of data are inappropriate for health data delivery. The focus must be placed on the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p> <p>This action is unnecessary and inappropriate. All actions should make standards based exchange make sense. Attempts to force behavior are a clear acknowledgment of a market failure. Artificial attempts to move data do nothing to create a sustainable movement to meaningful information exchange. Creating interoperability process measures will be a continuation of the ugly and messy world of MU today.</p> <p>The College strongly recommends that we stop thinking about incentivizing the use of a standard, or interoperability in general. Instead, we must move towards a sustainable business case for appropriate use of an effective interoperable infrastructure. Incentives, penalties, mandates, and structural and process measures are inappropriate for this purpose and only point out that the business case for exchange in many situations is lacking. If there are real and visible benefits to exchange in a particular situation, there will be no need for incentives, penalties, mandates, and measures. The focus should be on identifying supportive business cases for exchange, and then reducing the current barriers and friction points that are impeding implementation. Measurement must focus on outcomes for this approach to succeed</p>
<p>Moving Forward</p> <p>While the concept of “patient-centered health care” has been emerging over</p>	<p>There appears to be an unaddressed tension between personalized care and the push for population-based care and reducing variation in care delivery. This tension is not</p>

the past decade, there is vast distance between that concept and a truly “person-centric” vision that embraces the value of the individual inside and outside the health care system for improving both health and care. There needs to be a greater focus on incorporating patient-generated health data and ensuring the availability of tools for individuals to use this information to manage their health and make more informed health-related decisions. In the future, there will be increased numbers of at home and community-based services and information from these sources will need to be incorporated or connected with institutionally based clinical information. **Changing the paradigm to a person-centered ecosystem is vital to improving health given that an individual’s actions greatly impact health outcomes. The person-centered care vision is that, “the power of each individual is developed and unleashed to be active in managing their health and partnering in their health care, enabled by information and technology.”**

discussed. This is a very important point that must not get lost. How will we address the true needs of the individual patient (using personalized or precision medicine) if we are attempting to stamp out variation in the treatment of patients who may, on the surface, appear to share a common condition? Population-based care is a whole other cost center for a practice requiring new computer savvy administrative/clinical personnel. Its workflows may be at odds with patient-centered care. Also as documentation requirements are increasing. Office visits for patients are becoming less “person centered” and more “computer centered” care. We must address the fact that guidelines and quality measures fail to address the individuality of each patient.

Table 3: Critical Actions for Individuals That Are Empowered, Active Partners in the Health and Health Care

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.**

5. Call to action: **Individuals should regularly access and contribute to their health information in health IT, send and receive electronic health information through a variety of emerging technologies and use the information to manage and participate in shared decision making with their care team.**

C2. Providers and technology developers supporting individual empowerment

1. **ONC, government and the industry will identify best practices for the incorporation of patient-generated health data in health care delivery.**

Why is the word, “demand” used here? This supposes that all that is needed is for individuals to make the demand. To whom should individuals address their demands for information? Encouraging individuals to demand is not necessary or helpful. Currently practices are struggling with getting patients interested in viewing their health information, signing up for portals, and sending online requests. This wording suggests a new and inappropriate process measure is being considered.

This wording suggests a new and inappropriate process measure is being considered. Will physicians be responsible for the actions of their patients? This action assumes and requires that there are fundamental changes in how we pay for health care. There is an existing evidence base around how best to engage patients in shared decision-making and this call to action does not seem to take that into account.

Patients, providers, and the Learning Health System must also be included.

<p>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.</p> <p>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</p>	<p>This is happening now – and depending on specialty and scope of practice, it’s either easy or nearly impossible.</p> <p>This seems to expand on the current Stage 2 View/Download/Transmit measure requirement; which has proven so problematic for practices. This wording suggests that a new, broader, and inappropriate process measure is being considered. Providers cannot provide technologies. They must rely on the technology developers, as must individuals.</p> <p>Glucose levels may be a poor example. They are measurable and mobilizable. However, in most circumstances, the value of mobilizing all discrete data points is limited, and may in fact contribute to data clutter.</p>
<p>6. Call to action: Providers and technology developers should support the incorporation of patient-generated health data in health care delivery, which may include advance directives, remote monitoring, glucose levels and other data individuals are tracking</p> <p>7. Call to action: Technology developers should deploy innovative aggregation platforms and tools that allow individuals and caregivers to receive and compile health information from multiple sources in one place, send their data to a destination of their choice and find and use the information they need (as determined by the individual), to support for example, the individual participating in shared decision-making with their care team.</p>	<p>This is far more complicated than supporting a technology; as the incorporation of data streams into healthcare delivery is not a neutral event; it carries with it obligations to analyze and treat. Thus, pacemaker interrogation is a remote billable service, but diabetes management is not. Governance in section A1 is called upon to identify “bad actors” but not the health delivery implications of interconnectivity of information. Also, patients may choose for their own reasons to track all sorts of things; such as daily steps, minutes per mile each day; basal body temperature for optimizing fertility efforts, etc. Individuals should always be free to track whatever they believe to be important to them – but that should not necessarily be an obligation upon providers to incorporate and help manage such information.</p> <p>Deploying innovative platforms will fail to move us forward unless there are fundamental changes in the healthcare world that will make it possible for practices and patients to absorb and use these technologies appropriately.</p>

<p>8. Call to action: Providers should welcome and use information from other providers to avoid duplication of tests and ensure coordinated care.</p>	<p>This is not a call to action, but an aspirational statement. If there is a business case for any particular exchange, the information will be welcomed and used. If what is made available is useful, usable, relevant, and actionable, instead of a “call to action,” this becomes a metric of success.</p>
<p>Care Providers Partner with Individuals to Deliver High Value Care LHS Requirement</p> <p>Care providers partner with individuals to deliver high value care: Providers share and use information from multiple sources as they transform the way they provide care and engage with patients to routinely assess and incorporate patient preferences and goals into care plans that achieve measurable value for individuals and the population.</p>	<p>This should never be a requirement, as patients don’t always see multiple providers. The way this proposal is worded, it suggests that a new and unnecessary process measure unfolding.</p>
<p>Moving Forward and Critical Actions</p> <p>...In a learning health system, data will be created and collected automatically during the routine provision of care, alleviating the need for duplicate entry of data into registries and other parallel systems. This data will not only seamlessly enable improvement in the quality of care but also, as enabled by individual permission, will support secondary uses of data that help to achieve important advances in population health management, public health and the generation of new biomedical knowledge. Close integration of CDS into health IT systems will enable the rapid dissemination of new knowledge to support the use of best evidence in the care of all patients, including those with multiple, complex or rare conditions.</p> <p>... In a learning health system, integrated cost and quality data will be widely available to all stakeholders. Providers will use cost and quality data to help patients choose their preferred treatments. Consistent information on health care outcomes and transparency of health costs will assist individuals in making care decisions; providers in improving care; and purchasers in moving from pay for volume to pay for value. This will require standards</p>	<p>While this statement seems acceptable on its face, the rest of the paragraph suggests that much of the data collected during routine care will be unnecessary for care delivery. With the exception of data received from devices, no data are “collected automatically.” The data are entered into systems by physicians and other health care providers. If a data element is desirable for some secondary use, and the physician or other health care provider is required to enter it, then the burden is even greater than “duplicate entry.” There seems to be an assumption among all stakeholders other than those delivering care that the only place to get their data is the EHR system. This is often inappropriate, as the desired data could be collected more accurately from another source.</p> <p>We need clarity on definition of cost data - relative cost, patient copay ‘cost’, payer preferred cost? Further, payer contracts may interfere with decision making that suggests going outside of narrow networks. Currently, the primary experience physicians have with cost data is with eFormularies, which cannot be trusted for accuracy, and thus</p>

<p>improvements, policy changes, coordinated governance and infrastructure investment.</p> <p>... A continuous cycle of improvement will emerge, in which information gathered and decisions made during the normal course of care will be transformed in real-time into computable data and knowledge that will inform clinical decisions, report on notifiable conditions or events, measure quality of care and provide evidence for patient-centered outcomes research. This rapid and actionable feedback, when implemented in care delivery workflows optimized for usability, safety, quality and respect for patient preferences, will continuously improve the interactions and decisions of providers, care teams and patients/individuals.</p>	<p>cannot be used. Having similar data on lab and imaging costs will not be as helpful as we would hope. Unless the cost data are accurate, up-to-date, complete and fully transparent, their use will be little more than another burden. As for patients, is societal cost relevant to shared decision making, or their cost / copay?</p> <p>This is a good reason to broaden the definition of a learning health system to include providers as participants and not just data entry clerks. The outlined approach to a learning healthcare system appears to enfranchise providers only as data input personnel; but not as professionals otherwise engaged in helping to move the country towards improving health and healthcare. The formulation of the learning health system appearing in this document leaves physicians and other health care professionals feeling left out. Health professionals provide massive amounts of data prescribed by others, and then they are instructed to change their practice behaviors based upon decisions made by others. The clinical data alone will not provide the policy makers with answers to what needs to be changed. The clinical data will only suggest where outcomes appear to be better than elsewhere. This is only a starting place for a thorough investigation of what differences among practices might account for different outcomes. The only way we will move from suppositions to supportable recommendations is through the essential ongoing involvement of those at the front lines of care delivery.</p>
<p>Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value Care</p> <p>D1. Organization/Governance</p>	<p>Physicians and other providers must have a say in modifying the required minimum data set.</p>

<p>1. Call to action: Providers should participate in governance of interoperability at all levels, from regional efforts to nationwide coordinated governance.</p> <p>3. Call to action: Providers should continue to provide input on the evolution of coordinated governance to support a learning health system.</p> <p>4.</p>	<p>“Continue to provide input” suggests that providers have already had meaningful input. It is our perception that practicing physicians are the most under-represented group in the existing and preceding deliberative bodies. This must be remedied.</p>
<p>D2. Providers embrace a Culture of interoperability and work with vendors and other supporting entities to improve interoperability</p> <p>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.</p> <p>5. Call to action: Providers should routinely access and use health information from other sources, including individuals, when making clinical decisions</p> <p>6. Call to action: Providers should routinely populate key data when E-</p>	<p>2. Providers recognize the value. We suggest rewording this call to action. It is not necessarily providers, but the "IT infrastructure should provide better mechanisms for sharing information with patients and engaging patients to directly participate in their care and decision-making."</p> <p>5. Providers routinely access and use health information from all available sources. Providers would access data from other sources if only the data were easy to access and truly interoperable. We suggest rewording this call to action. It is not necessarily providers, but the "IT infrastructure should provide better mechanisms for sharing information with patients and engaging patients to directly participate in their care and decision-making." The first principle of interoperability is the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p> <p>6. This call appears to redefine an E&M service without consulting CMS. This also calls for duplicative data entry.</p>

<p>prescribing in support of unambiguous prescription for verification, counseling, monitoring and activities of comprehensive medication management.</p>	<p>Providers should not have to populate any data when e-prescribing. All of the data required for e-prescribing should have already been collected during the encounter or at other times. The decisions to e-prescribe and what to e-prescribe should always be made based upon data collected prior to prescription ordering.</p>
<p>D3. Accurate Measurement</p> <p>5. Call to action: Public and private stakeholders should objectively measure and value interoperability and information sharing as an indicator of care coordination, quality and efficiency.</p> <p>5. Call to action: Public and private stakeholders should objectively measure and value interoperability and information sharing as an indicator of care coordination, quality and efficiency.</p>	<p>Every data exchange requires at least two participants. The practice or healthcare provider is only one. We need measures for all of the other participants, or useful exchange cannot happen. We need measures of interoperability for vendors, payers, quality organizations, researchers, public health, and other governmental data users and suppliers.</p> <p>Circular Logic: This call is self-referential and uses circular logic. This says that all information is somehow more valued if it is somehow measured as interoperable, even if it is wrong. Without trusted identifiers, external information may be useful or a distraction, and accuracy should be valued above the vehicle with which the information was delivered.</p> <p>This call is self-referential and uses circular logic. This says that all information is somehow more valued if it is somehow measured as interoperable, even if it is wrong. Without trusted identifiers, external information may be useful or a distraction and the truth should be valued above the vehicle with which the information was delivered.</p> <p>How is efficiency defined? There are many competing definitions. To a payer, it is cost of providing a service. To a provider, it is time and resources to provide that service. And to a patient – it is time to get something done. Now efficiency will be newly defined as an attribute of information sharing. We are concerned with attempts in this paper to redefine care coordination, quality, and efficiency to support a push for interoperability.</p>

	<p>What do these metrics look like? Process metrics such as measures of volumes of data are inappropriate for health data delivery. The focus must be placed on the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p>
<p>D4. Interoperability of processes and workflows</p> <p>1. Call to action: Providers should routinely leverage standards- based health IT to support prioritized workflows including:</p> <ul style="list-style-type: none"> 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 	<p>Every data exchange requires at least two participants. The practice or healthcare provider is only one. We need measures for all of the other participants, or useful exchange cannot happen. We need measures of interoperability for vendors, payers, quality organizations, researchers, public health, and other governmental data users and suppliers.</p> <p>Improving Interoperability by Reducing Payer Requirements: Providers would love to have interoperability-enabled solutions for prior authorizations, imaging appropriateness, etc. If they work, they do not need to be incentivized or required. The College strongly believes that the optimal solution is not just to make prior authorizations easier to resolve, but to avoid them wherever possible. This approach, which utilizes technology to bring transparent, accurate, and actionable cost and insurance coverage information to patient and clinician before and at the point-of-care not only reduces administrative burden; it facilitates informed value-based shared decisions about treatments and testing.</p> <p>E-prescribing of controlled substances: There must be consideration of the costs involved in each of these activities. For example, adding the functionality to support e-prescribing of controlled substances to the existing e-prescribing function of one of the most popular EHR systems costs each practice \$10,000.</p>

<p>D5. Training and maintenance of certification for providers</p> <p>1. Call to action: Public and private stakeholders should incorporate interoperability into the training of new providers and continuing professional education.</p> <p>4. Call to action: Professional specialty boards and other certifying bodies should receive most of the information required from their diplomats through information exchanged in a standard format.</p>	<p>How do you train providers in interoperability? If a new provider has a need to exchange information, it will happen. If training is needed in interoperability, then the fault is with the systems being used. The College strongly recommends that we stop thinking about incentivizing the use of a standard, or interoperability in general. Instead, we must move towards a sustainable business case for appropriate use of an effective interoperable infrastructure. Incentives, penalties, mandates, and structural and process measures are inappropriate for this purpose and only point out that the business case for exchange in many situations is lacking. If there are real and visible benefits to exchange in a particular situation, there will be no need for incentives, penalties, mandates, and measures. The focus should be on identifying supportive business cases for exchange, and then reducing the current barriers and friction points that are impeding implementation. Measurement must focus on outcomes for this approach to succeed</p> <p>Provide examples. Is there a problem with the current process? This appears to be an example of feeling the need to sprinkle interoperability everywhere, without an assessment of the need.</p>
<p>D6. Innovation and Generation of New Knowledge and Evidence</p> <p>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.</p>	<p>If providers are taking seriously the shift to pay-for-value, then we hope that all providers are engaged in QI work. How do all providers establish a strategic plan for research and generation of new knowledge?</p>
<p>D7. Transparency of Value and engagement of patients, families, and caregivers</p> <p>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</p>	<p>How might this happen? Providers currently have no opportunities to work with purchasers on this. Neither providers nor purchasers knows and has access to the information.</p>

value.

4. Call to action: Providers should routinely utilize cost and quality data to make shared diagnostic and treatment planning decisions.

6. Call to action: Providers should support consumer-facing services such as:

- o Online scheduling
- o Medication refill requests
- o Electronic/ Telehealth Visits
- o Patient provided device data, screenings and assessments
- o Informed consent and education modules
- o Integration of patient- generated health data in the medical record
- o Patient-defined goals of care
- o Shared care planning

7. Call to action: Providers should demonstrate the value of their care to those who receive and pay for it using objective, trusted metrics.

8. Call to action: Providers and individuals should work together to substantially reduce the burden of care coordination through patient-centered tools and sharing and use of electronic health information.

9. Call to action: Individuals should interact easily and seamlessly with their

We agree, but this presupposes that such data exist. They do not exist today. Significant effort will be required to motivate the sources of these data to provide them in usable form. The regulations on payers and purchasers are such that they still permit nontransparent, inaccurate, and non-actionable information. Interoperability will accomplish nothing if the information exchanged is not of value. The College strongly believes that the optimal solution is not just to make prior authorizations easier to resolve, but to avoid them wherever possible. This approach, which utilizes technology to bring transparent, accurate, and actionable cost and insurance coverage information to patient and clinician before and at the point-of-care not only reduces administrative burden; it facilitates informed value-based shared decisions about treatments and testing.

We assume that these visits are not free. What is meant here by “Telehealth” is likely different than what Congress has incentivized as Telehealth, given the variability of these definitions. eVisits, even by private payers, are now typically limited to real-time video visits. We support reimbursement for appropriately structured synchronous or asynchronous telemedicine that are clinically comparable to the face-to-face encounter.

Assuming this is a covered service or part of bundled payments, this is appropriate. Technology capabilities cannot

<p>care team as they transition into and out of the health care system, communicating remotely with their care team as needed over time, rather than only in face-to-face care situations.</p>	<p>lead where there is no business case.</p>
<p>Table 7: Critical Actions for Consistent Representation of Permission to Disclose Identifiable Health Information</p> <p>G3. Align regulations and policies for electronic health info that is protected by laws in addition to HIPAA</p> <p>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.</p> <p>G4. Technical standards for basic choice</p> <p>3. Technology developers implement technical standards and implementation guidance for consistently capturing, communicating and processing individual choice. Adoption has begun, with 5% of exchangers using the standards regularly.</p> <p>G5. Associate individual choice with data provenance</p> <p>3. Technology developers implement harmonized technical standards for associating individuals' choice with data provenance; adoption has begun, with 5% of exchangers using the harmonized standards regularly.</p>	<p>This work will also have to be informed and guided by ethical practice and medical liability. Thus, if a patient has an allergy to an HIV drug but does not want the diagnosis, meds, or drug allergies sent to another provider – that could be done. But new conventions of conveying information that make it clear that certain information was redacted, and that the provider is held harmless for following a patient's wishes to withhold information, need to be developed.</p> <p>We do not need more process measures of interoperability. The data produced by a measure such as this tells us nothing about the spread of useful exchange. If interoperability solves problems, there is no reason for new regulations to further define and measure interoperability adoption and use. Process metrics such as measures of volumes of data are inappropriate for health data delivery. The focus must be placed on the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p>
<p>Core Technical Standards and Functions</p> <p>Over time (and for a learning health system to rapidly innovate), it will be necessary for the industry to converge and agree on the use of the same content and vocabulary standards to satisfy each specific interoperability</p>	<p>Narrative information is critical: Structured data will always provide an incomplete and inaccurate view of a patient or an encounter. Rather than trying to shove narrative into fielded data, we should focus on making appropriate use of the full</p>

purpose. The use of multiple data formats over the long term is not sustainable and retains systemic costs and burdens that could otherwise be removed from the health care system for health IT developers, providers and individuals.

Content standards should continue to accommodate the exchange of structured and unstructured data, but developers and end-users should design and subsequently implement systems with a very intentional movement and bias toward increased exchange of more structured, standardized and discrete information.

At a minimum, we must as a nation agree to a standardized common clinical data set that is consistently and reliably shared during transitions of care (and with individuals and their caregivers) to achieve our near-term goal of establishing a foundation of interoperability that can be expanded over time.

Footnote: Vitals, in particular, should be expanded to include – patient’s body height, body weight measured, diastolic and systolic blood pressure, heart rate, respiratory rate, body temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index (ratio). Vitals should also include date and time of vital sign measurement or end time of vital sign measurement and the

story that can be found only in the narrative. Much of the rich clinical patient data exist in the narrative form that provides context and meaning to the structured data. It is not feasible or desirable to require structured entry of all significant elements. Secondary data users, in the mistaken belief that structured data represent more accuracy than narrative, may desire only structured data elements. Even structured data have greater value when viewed in the context in which they were captured. Taken out of the context, the structured data may be interpreted incorrectly. For this reason, the provenance (origin) of the data is highly important to encourage appropriate use and understanding. For care delivery, on the other hand, the elements that the doctor or other clinician wants to see first are the narrative assessment and the plan. One of the key lessons we have learned thus far in our move to computerized records is that the narrative, the patient’s story and the clinician’s reasoning, must be maintained.

Common Data Set: We are concerned that the proposed “common data set” is too close to the overly lengthy and existing set in the Summary of Care Document (SoCD). This set is excessive for any specific use, and yet it is incomplete for any specific use. Physicians and other clinicians with direct patient care need to be the ones determining what key information should be in the common data set. We encourage ONC to ensure that the data set be aligned with the best knowledge/evidence/current clinical guidelines, and have input from key stakeholders, including (perhaps most importantly) practicing clinicians.

This is a good example of a one-size fits all statement that makes little clinical sense. Where is the evidence that all patients need a pulse ox? It is not possible to define a set of vitals that is universally applicable. Incentivizing or mandating the use of such a set is clinically inappropriate.

<p>measuring- or authoring-type source of the vital sign measurement.</p> <p>... Over the long-term, document-centric ways of exchanging electronic health information will likely be overtaken by more specific, tailored, data-centric ways of exchanging information – meaning that individual data elements are exchanged (e.g., medications or allergies) rather than an entire document with multiple information sections about a patient.</p>	<p>The use cases for document sharing in clinical care will not go away. Care delivery cannot operate properly with information stripped of meaning.</p> <p>Narrative information is critical: A Structured and atomized data not a complete solution. Much of the rich clinical patient data exist in the narrative form that provides context and meaning to the structured data. It is not feasible or desirable to require structured entry of all significant elements. Secondary data users, in the mistaken belief that structured data represent more accuracy than narrative, may desire only structured data elements. Even structured data have greater value when viewed in the context in which they were captured. Taken out of the context, the structured data may be interpreted incorrectly. For this reason, the provenance (origin) of the data is highly important to encourage appropriate use and understanding. For care delivery, on the other hand, the elements that the doctor or other clinician wants to see first are the narrative assessment and the plan. One of the key lessons we have learned thus far in our move to computerized records is that the narrative, the patient’s story and the clinician’s reasoning, must be maintained.</p>
<p>Table 12: Critical Actions for Consistent, Secure Transport Techniques</p> <p>L2. Send</p> <p>2. Providers (including hospitals, ambulatory providers, long-term care centers and behavioral health providers) should adopt and use DIRECT to reach critical mass.</p>	<p>Why should we mandate use of an exchange protocol? We should allow the business and clinical cases to drive protocol selection.</p>
<p>Measurement and Evaluation Proposed Framework: Defining Success</p> <p>Examples of Measures Available in the Short-Term (2015-2016)</p>	<p>Every data exchange requires at least two participants. The practice or healthcare provider is only one. We need measures for all of the other participants, or useful exchange cannot</p>

Information Flow and Usage

Proportion of:

- Providers and individuals who send, receive, and find electronic health information
- Providers who routinely have necessary clinical information from outside sources electronically available
- Providers who can easily integrate health information received electronically
- Individuals who use their online medical record
- Providers who experience various types of barriers
- Individuals who experience gaps in information exchange
- Transitions where TOC summary record sent electronically
- Volume of "Directed" transactions

happen. We need measures of interoperability for vendors payers, quality organizations, researchers, public health, and other governmental data users and suppliers.

This phrase, "send, receive, find and use clinical data," is used repeatedly. What is the meaning and significance of "find?" Our concern is that this appears to be a new requirement for physicians and other clinical staff to go on a hunt for data that may or may not be available, and may or may not be of use. Unless there are automated tools that perform the "finding," this requirement would be inappropriate.

Only the providers can determine what is "necessary." Existing processes and governance structures have defined "necessary" inappropriately. It is not "necessary" to send all historical lab results with every SoC.

This looks more like a vendor measure than a provider measure. The measure should be "use" rather than "Integrate."

Individuals should use their record if it makes sense for them to use it.

This is too vague to evaluate.

This is too vague to evaluate.

There are two problems with this measure. The TOC as it currently exists is not useful, and it should not be required. Second, the denominator definition is too vague to be useful; many transitions are self-directed.

What is the value in measuring how much one of the available protocols is being used? Why not measure use of all protocols? The market and business use cases will determine protocol winners and losers. ONC should not be a cheerleader for one.

<p>Defining Success: Measurement and Evaluation Domains</p> <p>The next section describes the key domains of the measurement and evaluation framework for tracking national progress. As noted earlier, many of the data sources currently available are largely based upon self-reported data from a subset of providers along the care continuum. Given the limited nature of data sources in the near-term, many of the domains listed in the framework are likely to be measured in the long-term. There are also a number of issues that will need to be considered, including: at what level(s) nationwide measurement should occur (e.g., encounters or patients; users; organizations; or health care system or network-wide) and whether a subset of nationwide core measures should focus on certain subpopulations or use cases where the value of exchanging data using interoperable health IT is and that may be prioritized as part of the Roadmap.</p>	<p>Yes to value based measurement.</p>
<p>Examples of Measures to Consider for the Long-Term (2017 and beyond)</p> <p>Information Flow and Usage</p> <ul style="list-style-type: none"> • Exchange activity • Availability of information to inform decision-making • Usage: rates of accessing available data • Interoperability of data, EHRs and other systems • Uses of interoperable data • Ability to easily integrate data across multiple sources • Reliability, trustworthiness, and utility of information exchanged • Barriers to exchange and interoperability 	<p>This is putting focus and incentives (or lack of penalties) on processes that may in some cases be helpful, but depending on the measurement, not helpful; and in other cases, unnecessary, yet forced to occur because of the need to meet process measures. We should look to outcomes as the measures to matter, and information flow as necessary for some measures, but not for others. What do these metrics look like? Process metrics such as measures of volumes of data are inappropriate for health data delivery. The focus must be placed on the delivery of timely, transparent, accurate, and actionable information to patients and providers before and at the point-of-care – such that patients and providers can make better value based decisions, and prior authorizations avoidance can be a successful approach to reducing administrative burden.</p>

Linking HIE to Conditions of Participation for Payment Programs

The federal government sets extensive requirements for organizations paid under the Medicare program that address core quality and safety expectations for any organization participating in the program. Ultimately, as electronic, interoperable exchange of health information becomes more ubiquitous, conditions of participation required for Medicare could be linked to electronic processes when consistent with clinical and safety statutory requirements. For instance, electronic sharing of summary care records between hospitals, skilled nursing facilities (SNFs) and home health agencies could be established as the routine standard for transmitting the information these facilities are required to share across care settings.

Incentivizing vs. Business Needs: This could be done, but the requirements are already over-specified. If the barriers that stand in the way of a compelling business case are removed, the activity will occur.

Require as a condition of participation, acceptance of C-CDAs as clinical attachments and as the sole source of clinical information for questions on claims and prior authorizations.

Require administrative interoperability that works, such as timely, transparent, accurate, understandable, and actionable information on costs and coverage for Medicare Part D providers.

Require DME suppliers to accept C-CDAs as sufficient clinical information for supplies.