



September 8, 2014

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: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure

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 efforts to develop a plan to address interoperability issues within the health IT infrastructure, and appreciates the invitation to comment on how we can collectively achieve interoperability across the health IT ecosystem. We thank you for the opportunity to provide input on these very important issues. Below we offer our thoughts on specific numbered questions you have raised. We hope that you will find value in our responses. 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, 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, FACP
Chair, Medical Informatics Committee
American College of Physicians

Americans are now living longer and are generally healthier because of healthier life styles, better screening and prevention, more consistent identification and treatment of key chronic conditions, and advances in heart disease and cancer treatments. We believe that there is real potential for the emerging digital healthcare system to markedly broaden those advances – leveraging electronic health

records to help further the consistent application of existing knowledge, and utilizing the EHR as a learning system to more quickly diffuse new knowledge and changes in best practices.

1. What are the 3 most important priority items that should be included in the national interoperability roadmap that will help advance interoperability nationwide?

- A clear message that interoperability is an attribute of infrastructure, and not a solution *per se*. Prior to Meaningful Use, many policy makers thought that putting a computer on a physician's desktop would automatically make care better, safer, and more affordable. The maturation of thinking by policy makers that led to the idea that value from health IT came not from the health IT by itself, but how it is used – is a lesson that should not be lost when determining policy for interoperability. While a thoughtfully designed healthcare system's operations will be more accurate and less costly when its interactions and communications are more directly interoperable, the rapid advance of technical interoperability in the absence of thoughtful healthcare operations and information flow redesign is more likely to lead to information overload and chaos. Further, as providers are just now beginning to feel both the benefits and the costs of limited and phased interoperability with the sharing of Summary of Care documents, we believe that the calls for "interoperability now" will be tempered with examples from the field – which will help to inform the roadmap as to speed and direction.
- While data liquidity is important, sharing of information with patients and providers that is meaningful and not misleading is more important. Thus, we take exception to the notion advanced in the latest PCAST report, that interoperability of data atoms is the ideal state. Rather, as internal medicine providers, we appreciate the importance of context and meta-data, and wish to point out that a standard phrase in imaging reports, "clinical correlation should be considered," also applies to mobilizing information. Thus, while it may be valid for research to create and support a data structure and mobilization platform that "atomizes" healthcare information, that is often not the case for clinical care. Thus, furthering the principle of first do no harm, we encourage more thought to interoperability architecture and format – where that thinking is patient-centric and not data centric.
- If interoperability can at best make information sharing less costly, until such time as there is a sustainable business case for health information management and quality outcomes, the business case for interoperability will be limited. Our current healthcare system makes it far more profitable to do and redo, rather than share and interpret information, and thus appropriately reduce redundancy by reusing information. Even the recent PCAST report concluded that the largest barrier for achieving interoperability is the lack of a business case.

2. What other topics should be included in the national interoperability roadmap that may not have been explicitly mentioned in the 10 year vision paper?

- Whatever was intended, EHRs at this point are seen as intrusions into healthcare that add little value and add considerable burden to providers. While the vision of interoperability may paint a picture of a healthcare system where care is more efficient, we are concerned that either the definition of efficiency does not include wasting providers' time on unnecessary administrative burden, or that the vision may be unrealizable. Bidirectional interoperability of useful, usable, accurate, and transparent information could result in a far more efficient healthcare system, but that is not occurring now. Consider the example of electronic formularies. These now flow from pharmacy benefit managers - via ePrescribing networks - to all or most all EHRs. Doctors and patients can see in real-time the most cost effective medication for a particular condition; and prescriptions are sent electronically to patients' preferred pharmacies, saving them both time and

money. With the exception of “prescriptions are sent electronically... saving them time...” this statement is a fallacy – and one that has been made worse by interoperability. Non-interoperable formularies, published as PDFs on payer websites are more accurate than electronic formularies.

- Furthermore, information flow is not structured for optimizing use. Thus, where payer coverage policies are most often either not published or if published, not actionable, a usable segment of coverage policies, visible to the provider and patient at the point-of-care, could help to shape testing and treatment decisions, and therefore speed access to care and eliminate most after-the-fact prior authorization requests. And where prior authorization requests are needed, information that should be interoperable (captured as structured information in an EHR) is not accepted by payers, employers, or health plans.
- We are concerned that, while the government is focusing on the goal of an information-rich healthcare environment, the formats that are being pushed are too often “data rich but information and knowledge/insight poor.” The focus should not be on the volume of data exchanged if these data do not add sufficient value or if they are difficult to find and separate from a large collection of less valuable data, or if the external data are delivered in formats that cannot be easily compared to local data and accurately reconciled. Specifically, a 2103 HHS RFI states, “HHS envisions an information rich, person-centered, high performance health care system where every physician has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes.” This statement contains the underlying assumption that there is a correlation between physicians having a larger quantity of clinical information about each patient, and patients having improved health. In fact, it is possible that such data overload could result in adverse consequences for patient care. More importantly, value-based goals for HIE should focus on the delivery of services, such as those mentioned, that facilitate decision-making, facilitate care coordination, and effectively measure and track health outcomes.

3. What aspects of BUILDING BLOCK #1: CORE TECHNICAL STANDARDS AND FUNCTIONS are the most important to address?

- Although there may be a research need to develop a method for representing granular data, researchers have been largely silent about it. More importantly for healthcare delivery, there must also be a clinical model for representing data requiring context for clinical utility – and this could include consideration of data clusters, where meaning of granular data plus metadata is deemed unable to be interpreted or even misleading below a certain level.
- Physicians want and need the ability to use data to learn and to perform better. It is self-evident to thoughtful physicians that data exchange per se does not improve care, and that too much data exchanged too broadly may make it harder to provide good care, and can lead to confusion due to “data overload” and potential misuse and/or misinterpretation of the data.
- Structured and coded data have value, but not in every circumstance. There is growing concern among physicians and other health care providers that critical narrative components of the patient record are being reduced to unsatisfactory structure or are being ignored in the exchange of patient data. The narrative elements of the record, including the patient’s story and the physician’s reasoning, are critical to the safe and effective delivery of health care. Standards must preserve and protect critical narrative elements through the exchange process.

4. And what are your recommended solutions or tactics for effectively addressing this building block?

We want to see the government use the levers available to facilitate the kinds of exchange that matter most to patients, and thus to physician efforts to maximize quality, safety and value, such as those listed in the next paragraph. Policies must minimize the number of connections and protocols that practices

will have to establish and manage. Currently, many EHR vendors are charging each practice thousands of dollars to establish each connection, and to exchange each document type. Vendors are also signaling that there will be ongoing maintenance charges for each connection for each practice. In addition, vendors are so overwhelmed with work that they are unable to respond to the needs of small practices in a timely manner. There is nothing to be gained from policies that encourage exchange if the exchange partners do not have cost-effective and readily available connections.

There are many opportunities for valuable exchange that should be encouraged through policy. These include:

- Directories of provider contact information – complete and up-to-date.
- Reliable and accurate patient identification and matching.
- Rapid notifications of patient care activities such as emergency department arrivals, and admission and discharge notifications to ambulatory physicians.
- Cross-system management of patient consent.
- Support for quality measures that track patients across care settings.
- Data cleaning and standardization services.
- Management of longitudinal care records.
- Data analytics, alerts and public reporting services.

5. What aspects of BUILDING BLOCK #2: CERTIFICATION TO SUPPORT ADOPTION AND OPTIMIZATION OF HEALTH IT PRODUCTS AND SERVICES are the most important to address?

The current certification program has failed to deliver usable interoperability. Where we have implemented usable standards that address real clinical needs, such as e-prescribing, we have still not seen all of the possible benefits, because they have been implemented in ways that impair accuracy, transparency, and usability. The standards and certification criteria for clinical summary documents have backfired – resulting in practices being deluged with unusable, bloated documents. Standards plus certification will not yield the desired benefits unless all of the players involved are required to use the standards as intended.

6. And what are your recommended solutions or tactics for effectively addressing this building block?

ONC should increase its focus on improving usable end-to-end interoperability, and decrease its focus on requiring the authoring and sending of bloated, unusable documents. Rather than continuing to add more and more interoperability requirements, the focus should be on making the functions that care providers really want more accurate, usable, transparent, and cost-effective. We should fix what we have before moving on to other functions of dubious value.

When it comes to interoperability standards, we have seen that a disproportionate share of the cost has fallen on those who deliver the care. Ambulatory practices have no mechanism for recovering the costs of implementing each transaction channel for each end-point, let alone ongoing costs for use of the communication channel. It will be difficult to encourage use of an interoperability function where the intended user is forced to pay out of pocket for each use.

9. What aspects of BUILDING BLOCK #4: SUPPORTIVE BUSINESS, CLINICAL, CULTURAL, AND REGULATORY ENVIRONMENT are the most important to address?

- We are concerned that health plans consider healthcare efficiency as “spending less money on a unit of care,” and that burden to the provider or provider office is then not viewed as an issue to

be addressed. We, of course, believe the opposite. Providers and staff have limited time, and if that time is wasted because of poor information flow, or adequate information flow of inaccurate, unusable, or nontransparent /nonactionable information, there is less time to focus on patients, and the important work of making our care delivery consistently better, safer, and more value laden. A winning business case for providers and patients would be real interoperability of useful information to reduce unnecessary process friction in healthcare operations. Thus, having formularies presented by e-prescribing systems be required to be accurate, usable, and transparent as to their make-up (e.g., if a brand name drug is most preferred because of a 3 month rebate or special pricing deal, doctors and patients should know this), would result in less time spent on writing appropriate prescriptions for patients. Everybody wins. Further, if medications requiring prior authorization were displayed such that what was similar and did not require prior authorization was clearly visible; most prior authorization situations could be avoided. Again, less burden and rework for the provider, less processing for the plan, and no delay for the patient.

- The current MU-mandated exchange of patient summaries presents a clear warning about the risks of pursuing a policy of expansive and inadequately organized data exchange that too often “buries the headline” such that the most important information is so difficult to find that it is missed. What was once more typically a carefully crafted page-and-a-half of relevant information has, through the requirements of MU, expanded to 7 or more pages – too much of which is not helpful to the receiving physician, who now has to scan through this bloated document to try to determine what matters (diagnosis and thought processes) and what has changed (medications, test results, treatment plans). The government should refrain from incentives that encourage exchange without conciseness and high usability.
- Data users such as research, public health, and quality measurement will benefit enormously from the automated delivery of EHR data. These data users invariably want data to be in formats other than the way they are stored in EHR systems. Further, they want data that exists in narrative text to be extracted and coded. They also insist that practices collect additional data that are not needed for the proper delivery of health care. Those who are interested in each disease and condition are anxious to get data flowing to their repositories each time an encounter relates to their concern. The current process encourages each group to develop their data and reporting requirements independently. Unless this process is rationalized, the data collection system will soon become unmanageable.

10. And what are your recommended solutions or tactics for effectively addressing this building block?

- When it comes to interoperability standards, we have seen that a disproportionate share of the cost has fallen on those who deliver the care. Ambulatory practices have no mechanism for recovering the costs of implementing each transaction channel for each end-point, let alone ongoing costs for use of the communication channel. It will be difficult to encourage use of an interoperability function where the intended user is forced to pay out of pocket for each use.
- A supportive business and regulatory environment must also take into account the effect of data input requirements on physicians and inability to re-use data for healthcare operations. It creates an interoperable environment with more pain than gain for physicians, which means less use by physicians and less focus on patients and patient care.
- Where data users such as research, public health, and quality measurement will benefit enormously from the automated delivery of EHR data, these users must also pay to support the additional work they are requiring of practices.
- Having formularies presented by e-prescribing systems be required to be accurate, usable, and transparent as to their make-up (e.g., if a brand name drug is most preferred because of a 3

month rebate or special pricing deal, doctors and patients should know this), would result in less time spent on writing appropriate prescriptions for patients. Everybody wins.

- The view of the Health IT Ecosystem (figure 1, page 2) is missing payers, PBMs, and others who dictate many of the rules of the road for healthcare operations. Without consideration of their importance, we are creating a “write many times – use once” health IT ecosystem – one that doctors will always (justifiably) complain, “feels like more work and less gain.” EHRs and other physician-facing health IT cannot fix inefficiencies in healthcare operations without cooperation from both public and private payers. Meaningful Use requirements only address physician use of health IT. This imbalance in addressing the healthcare ecosystem has led to this paradox – what should make physicians more efficient (and thus lead to more time spent in patient care) has instead led to more administrative work and less face time with patients. Health IT would be able to achieve far more in terms of driving recommended care if this imbalance was addressed and fixed.

11. What aspects of BUILDING BLOCK #5: RULES OF ENGAGEMENT AND GOVERNANCE OF HEALTH INFORMATION EXCHANGE are the most important to address?

There is one important clinical area that has not been addressed in any way thus far. This is the need for standardized metadata needed to support clinical processes. For example, there is a standard rule that if someone orders something, that person is responsible for obtaining the result, interpreting it, acting upon it, and communicating that to the patient. Rules of engagement could continue this safe practice by including meta-data – who ordered a test, if it was seen, if it was acted upon, etc. Failure to consider this meta-data is more likely to lead to confusion and perhaps errors, as multiple providers may appropriately react differently to the same result. As we move from intra-institutional to inter-institutional workflows, the patient safety risks of not tracking these metadata will grow. While there is an S&I Framework project dealing with provenance metadata, these data address legal record requirements but do not provide the metadata needed to track and manage distributed workflows.

12. And what are your recommended solutions or tactics for effectively addressing this building block?

Adding metadata will be of limited value if there are not universally agreed-upon rules governing how the data are to be managed and interpreted by systems. We need a process that starts the building of rules of engagement, or rules of interconnectivity, which makes technical interoperability meaningful and more likely to result in better care, and not information overload. Medical specialty societies should have a central role in developing and managing the rules.

13. What priority use cases should be considered for the 0-3 year agenda in the national interoperability roadmap?

Reference is made to a “basic set of essential health information” – which is based upon the Summary of Care document – which we would argue is bloated and aside from being mandated, has not been shown to be useful to recipients. Further, an example of the 3-year agenda includes sending the Summary of Care record to specialists and closing the loop by returning that document from a specialist. Again, we may be codifying something built by committee that is not necessarily helpful to either the PCP or specialist, and more importantly, not necessarily helpful to the patient. In multi-provider interactions, not all referrals are created equal: not all loops need to be closed (where the referral is more “elective”); and not all loops should be closed (ongoing diagnostics or ongoing chronic care). While handoffs in medicine are occasionally simple and linear, they are most often complex and nuanced. Making a

lynchpin of the 3 year agenda “closing the loop on referrals,” without recognition of that complexity and nuance, would be a mistake.

14. What priority use cases should be considered for the 3-6 year agenda in the national interoperability roadmap?

The 6-year agenda supports team-based care; does our payment system recognize team-based care? Without a business case that exists and is sustainable, this notion is merely aspirational. There is also mention of remote monitoring and home-monitoring devices supplying information to become part of the healthcare technology ecosystem – all true – but no mention of the payment system to support health information management and quality outcomes. The issue is similar for patients, caregivers or family members contributing information to their EHR. While there are some technical issues, the barriers for use and optimization are more workflow change and payment policy.

15. What priority use cases should be considered for the 6-10 year agenda in the national interoperability roadmap?

We strongly support their use case of sharing information and best practices in a learning system, with “rapid advancement in methods for deriving meaning from data without sharing PHI.”

We also support the inclusion of a highly regarded practice in medical safety – a pause or time-out – where the work to date is evaluated such that what seemed to make sense in a PowerPoint actually is making sense in the field, and that it is contributing to quality, safety, and value –not just adding documentation and a reporting burden. For example, it is clear to us that team-based care is a laudable construct that will become real and better, based on technology, workflow redesign, and supported by payment policy. A mandated pause would force ONC to evaluate what has been done to date, and not allow us to be misled by the appeal of a faster Internet, or mobile devices with a more appealing user interface.

16. Do you have any general suggestions or feedback?

Yes – interoperability is an attribute of infrastructure, and if healthcare operated more like a free market, then interoperability *might* make everything work better and faster. However, healthcare does not behave like a free market, and just like it was naïve to imagine that computers per se would fix all that is broken in medicine, it is also naïve to think that of technical interoperability. We have already seen examples of unhelpful interoperability in note bloat, inaccurate information leading to information overload, and inaccurate decision-making.

We ask that ONC, even though it does not have jurisdiction over stakeholders other than providers in the healthcare ecosystem, at least considers that a healthcare ecosystem exists. Continuing to add requirements and partially baked solutions where an imbalance of information and control already exists may actually worsen that imbalance, and in addition to adding burden to providers may result in no value to patients.