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Re: Comments on Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap version 1.0

I am pleased to submit this letter in response to the request for comments on Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap version 1.0. I am currently the Principal in Leading Edge Policy & Strategy and work on health information technology policy in various ways. Previously, I worked as staff on the Energy and Commerce Committee including work on H.R. 4157, the Health Information Technology Promotion Act of 2006 in the 109th Congress. That bill passed the House 270 to 146 and went to Conference, but the Conference was not able to resolve differences. Nonetheless, that bill language has some explicit focus on interoperability. There are some concepts in the bill that would be useful as ONC moves forward. I think reference to the bill is also a measuring point for asking the question what progress has been made on interoperability policy front since 2006.

Since I left the Hill, I have since worked for a couple of health information technology vendors, consulted on health information and health care policy, and been active as a volunteer with the Health Information Management Systems Society (HIMSS) on many policy issues related to the roadmap. In light of this background and long term thinking on the subject, I wanted to offer ONC both any assistance and also provide some comments and insights that may be useful.

There is a lot of good material in the draft roadmap. Some of the comments below focus on some areas of concern and others just refinement or addition of concepts. The discussion on consent issues in the draft roadmap stand out as a discussion with significant problems.

A. <u>ONC should proceed with the focus on addressing interoperability in significant use cases without further delay or distraction</u>

The call for determining priority use cases in the draft roadmap is an effort to focus and take steps to get concrete steps done. This is laudable. Similarly, there are other statements in the draft documents designed to maintain focus. See page 10 of the draft regarding the intersection of administrative and clinical information and other aspects beyond interoperability.

I suspect many public comments will include discussions elaborating on a variety policies and agendas to tie them to the interoperability roadmap. There are some discussions in the draft roadmap that also appear to distract from the central focus of getting software relevant to significant use cases to be technically interoperable. As a general matter, distractions of marginal relevance to core interoperability effort will simply keep progress from occurring.

H.R. 4157, in 2006, asked ONC to identify and "endorse a subset of core interoperability guidelines for significant use cases". These terms are defined in the bill. The draft roadmap uses the term "priority use cases" and "core technical standards and functions." It is emblematic that it is 2015 and the step of selecting priority use cases and core technical standards and functions has not yet occurred.

I note there seems to be little discussion on how prior Federal Health IT Strategic Plans actually played out moving forward on interoperability. That type of review provides for accountability and improvement in government programs and strategic efforts. There at least two prior strategic documents. The ONC Federal Health IT Strategic Plan 2008-2012 had strategies and milestones that included:

- advancing use of specified date and technical standards for interoperability
- use by federal government entities of interoperability standards
- testing tools an criteria, and certification criteria are available

Unless I missed something, ONC's Federal Health Information Technology Strategic Plan 2011-2015 contained no statements to focus on core interoperability standards for significant use cases as a strategy. That was probably a mistake.

There are a number of factors that could be used for selection priority use cases, but the most important thing is to move forward on this strategy or step. I suspect transition from the hospital to ambulatory post-acute care might be a very good use case.

As a suggestion on a possible factor consider, CMS has data on what types of providers are seen by the same patient in the Medicare population, including what services were billed for. It would seem possible to get some information on the types of transition or coordination of care events that are most frequent, at least in the Medicare population.

Another factor to consider is what areas are likely to constitute a core platform for communicating clinical information.

B. Common technical standards or formats should be a desired capability for certain health information system software under some use cases but there should not reflect efforts to restrict additional, alternative formats when coupled with common format capability

The draft roadmap discusses common technical standards, starting with a common clinical data set. It would be useful to further clarify and understand the policy objectives and terminology. Interoperability, and particularly using common formats, is an objective with qualifications. There are competing policy objectives and policy tensions need to be understood. It is not, for example, the objective that all health information software and transmissions only use National common formats. Such an overregulated state of affairs would damage the competing objectives of innovation, competition, and tailoring. There are also additional policies in play, such as data security. Static formats can pose security risks and the relationship between the two policies has not been adequately discussed.

It is inappropriate to prohibit any two parties from communicating information in the format they think best. Government should not prohibit a means of communication among willing parties.

The strategy should be to encourage that transmission of certain types of information either (1) be in the National common format or (2) contain the capability to be read and subsequently used consistent with the common format. The actual transmission may be in a manner that provides for both the National common format and alternative formats. If the alternative format is the preferred format for two parties, nothing should discourage that approach, as long the information is also amenable to or has the necessary features to be read and subsequently used by software based on the National common format for the use case. Such a policy maximizes innovation, competition and tailoring.

Such a policy may entail greater burden in certain ways. It may entail less of a commitment to the common formats. The market may reflect preferences in this regard. Regardless, systems that maintain information in both a common format and an alternative format should be viewed as an acceptable measure of successful interoperability.

In this light the following statement on page 24 at least needs clarification. The draft plan states that the fewest number of protocols necessary to fulfill the needs of learning health system participants is most desirable. There are several reasons that the statement appears to have problems. Additional or alternative protocols can exist to provide additional security and provide tailored or innovative additional information with additional value. ONC should not concern itself with the number of protocols or the number of lines of codes or any other similar construct.

C. Modularity, like exchange and common format capability, is important, but stakeholders must also assess the value and approaches to modularity under competing objectives and practical considerations

ONC statements regarding modularity in the draft roadmap are important and useful. As outlined in the draft report, Modularity is not simply interoperability or common formats. As discussed, modularity includes an ability to divide systems into independent components that can be connected together. Interoperability can occur within a vendor product suite and external to that product suite and that product suite may still not provide for modularity.

In the discussion of application program interfaces (APIs) the draft roadmap states:

> Diverse systems can share algorithms, features and capabilities by relying on these shared services rather than reproducing this functionality each time it is needed. Users do not need to know or be concerned about the existence of an SOA within the systems they are using. Using an SOA can dramatically reduce the cost and complexity of building and adapting systems to changing needs and environments.

The above is true, but the expectation that a vendor or a system operates through shared algorithms or in a modular mode can be a case-by-case issue. It is unclear whether or how the draft roadmap applies to objectives in this area. Just like interoperability as an objective, modularity is also an objective that works under competing factors that vary by circumstance.

Among the values of modularity are the promotion of a competitive market, innovation, creation of additional value, and flexibility. Modularity has some practical downsides as well. Modularity, in practice, makes the number of permutations of software and software vendors greater. Functional integration is harder with modularity. Maintaining modularity means multiple vendors potentially responsible for interoperability and given aspects of functionality. This may mean complexity in the health information architecture and also complexity in federal programs. It is also inherently important to define where the expectations of modularity apply. Vendors design software products to accomplish broad objectives for customers and cannot always be held to a standard that their product must be designed in a way that a different vendor might substitute its software related to a given function or for refined sets of functions. The draft roadmap explains the expectation that there be consistent and standardized points of contacts between software systems, but whether a system is divisible or should be divisible is also at the heart of the modularity construct.

Perhaps one way to visualize the issue is from several questions:

1) What sets of software form a core platform where there is an expectation that other value added software should receive core information in a common format?
2) Under what circumstances is it reasonable to expect software comprising the core platform to have the capability to be further divided into modular functions?
3) Under what circumstances is it reasonable to expect vendors to design with the potential for additional or competitive modular software in mind?
4) Under what circumstances and where should vendors design software to provide for an API?

As a basic point, the construct of modularity, like common formats, should be viewed as a capability, but that in practice software at a facility or among facilities may also be part of integrated product suite and not modular. Software need not be sold in modular modes. Better functional integration is a value and vendors will and should be able to design and market with this point in mind. The possibility of best of breed competition, better tailoring, and new, value added software and functions from other vendors represent some of the competing values. Still, given the potential complexity of the policy, it is hard to know whether modularity and the answer to the above questions are answered by market expectations or also enhanced by some sort of consensus discussion or process.

D. <u>The Roadmap should try to articulate where there are separate transitional burdens from generally competing policy factors which include the value of innovation, competition, and tailoring products</u>

One of the themes of these comments is to encourage accurately breaking down what factors apply in determining what should be subject to common format capability, modularity expectations, or other policies. Working from figure 1 on page I it would be useful to explain the relationship of these principles. At least two principles of figure 1 involve the consideration that we want to get from point A to point B in a practical way. These are:

- Build upon existing health IT infrastructure
- Consider the current environment and support multiple levels of advancement

However, even in some future state 30 years from now, there should be zones where common formats, modularity, individual empowerment or patient consent are not expected. The task is to determine where the lines are or at least what factors and processes go into drawing the lines. That discussion is based on a tension that flows from the values of common formats, modularity, or other constructs and the competing values that may arise from market competition, innovation, tailoring, information security, practicality or other factors. The draft roadmap makes the case that common formats, modularity, service oriented architecture, and other ideas will increase innovation and tailoring in various ways. Those points are correct, but only to a degree. Those points do not obviate the point that burdening the system with just National commonality across the board is not good.

There needs to be a principle reflecting the ability to innovate, compete, and tailor without the constraints of common formats or public disclosure of formats or expectation to design toward modular additions. Specifically, there should be a principle called market competition, innovation, and tailoring in the Roadmap discussions.

Initially, ONC has suggested a focus on a common set of clinical information. That sounds pretty good as a starting point for what constitutes elements of a core platform. Still, there are going to be questions and areas that need further guidance and understanding. What if I have a proprietary image taking device that increases resolution and can identify cancer more quickly? Is that part of the common set of clinical data set lab result? The discussion on p. 12 of the draft appears to reflect more narrative material and not necessarily material where different levels and types of diagnostic devices an computer assisted diagnostic devices are in

play and in motion. What types of clinical information might be presented in more advanced formats and, in practice, not be interoperable with other systems? Would it be sufficient that parts of the more advanced diagnostics can be sent in a common format, albeit with less data or less refined data as the alternative format?

The draft roadmap has addressed the point that the intersection of administrative and clinical information is a topic for another day. However, it is worth asking about derivative information from core clinical information. This might include software that incorporates multiple pieces of diagnostic information for a more complete diagnostic. This might include information from clinical decision support that uses core clinical information. For now, I take it the roadmap is talking about core clinical information and not derivative information. At some point, there will need to be more of a discussion of derivative information. The common formats, modularity, or personal access discussions in the draft roadmap may not be the same for derivative information.

E. <u>Some type of National survey or other approach to measuring the current and future level and means of interoperability would be useful</u>

We are trying to achieve a sort of core platform where core health information can be shared and used interoperability. The core interoperability platform might support software beyond the core that involves derivative information or functions that are or are interoperable. The problem is the core platform itself is very complicated. It is an architecture made by many vendors, providers, and other organizations in modular formats that vary. It is going to be hard to assess and realize the expectations of achieving a core platform.

A National survey or other approach to measuring the current and future level and means of interoperability would be useful. First, it would be very helpful to get an assessment of where we are and where systems have achieved element of interoperability. Any roadmap is an assessment of what it takes to get from point A to Point B and this roadmap does not have sufficient information to have much of an assessment. Clearly there are places where we are getting greater care coordination and interoperability. There may be information on how this occurred and whether vendors or providers worked together. These might be models. The future may simply be a matter of using the best strategies of today.

Actual exchange and interoperability may be quite a different construct than what bench testing a given piece of software entails. We need ways of measuring success. That may be

something like providing a model record for Jane Doe and seeing if one provider can alter part of the record in a manner that can be picked up an used by software for another provider.

A second feature of a survey is that it might produce market pressure by highlighting those organizations including providers and vendors that find ways of being in interoperable systems

H.R. 4157 had a specific section calling on ONC to conduct one or more surveys designed to measure the capabilities of entities to exchange electronic health information by appropriate by appropriate use case. It might be that such information reporting could be part of the meaningful use program today. We would probably be much further along if we had conducted such a survey earlier, but it remains of great value today and might be a basis for (1) measuring progress; (2) highlighting capacity for the public; (3) creating a roadmap to look for solutions.

F. Federal Agencies should commit to follow interoperability guidelines

H.R. 4157 guidelines did not have mandatory enforcement mechanisms for the private sector. The idea was to work on the guidelines and survey and then, possibly take additional steps. However, H.R. 4157 made the guidelines mandatory for Federal activities. On page 40 of the draft ONC states "Other federal partners that purchase health care, such as the Department of Defense and the Office of Personnel Management, can also advance interoperability by promoting use of measures of health IT adoption and interoperability in a consistent fashion across contracted payer organizations' provider networks." On page 114 there is, again, a reference to federal contracts. The federal commitment needs to be more concrete. DOD and VA electronic health record systems do not communicate with one another let alone with commercial enterprises. There should be a specific commitment that DOD, VA and other federal health information systems commit to the objectives of addressing common format capabilities, measurement requirements, and other basic interoperability standards within a reasonable time frame.

G. ONC has not yet demonstrated a feasible model for requiring or managing the use of interoperable IT tools through Medicare payment programs or Conditions of Participation

It is important to recognize that ONC has not yet suggested a model that easily works with payment systems or conditions of participation as levers for interoperability. The relative responsibilities of vendors and providers remain unclear. Recall that the ONC National Health

Information Network proposals were not well received and withdrawn. Proposals to hold providers accountable for transmissions to different vendor platforms under meaningful use did not work. Interoperability in practice may be a function of multiple vendors, providers, and other groups.

Surveys are one thing, but statements in the draft roadmap pointing to payment levers for use of interoperable health IT tools or even to use conditions of participations are not well described and would require much greater understanding and consideration. Any government mandated healthcare program requirements must be justified based on evidence of benefits considering costs, cumulative burdens, limited resources, and competing priorities. These have not been set out, even as an example, by ONC. Premature or unwarranted statements on new requirements pose danger.

It maybe that interoperability may only be measured by multiple organizations and the capabilities of multiple vendors. Would penalties directly addressed at providers advance this agenda, and at what cost and burden? What is the condition of participation? Is it that a provider must own something or do something? If other providers in the area are not on common format, is that held against the provider? What if the vendor for one module does not maintain common formats? Is that a strike against the provider? How would interoperability be measured in practice? If a provider had a qualifying piece of software but in practice the provider was not establishing interoperable communication would that matter? There needs to be actual standards that could work in these programs and none of that has been adequately described. The discussions in Table 2 on page 43 should be revised. When it comes to more regulations on providers—who are already subject to a plethora of new regulatory changes it would be advisable to figure out the proposal and explain it before just committing to regulatory requirements or conditions of participation which may or may not be practical.

The broad general discussion on alternative payment models and value models should not be focused on an interoperability objective. These programs are driven by other factors in care delivery. The HIT system is a tool not the objective for these programs.

H. <u>The draft discussion on consent issues, including those on basic and granular choice, poses many problems and should be withdrawn except that consideration of developing comment consent mechanisms to facilitate consent where required under existing laws or other arrangement would be useful</u>

The draft roadmap accurately recites many of the basic constructs of HIPAA that provide for use and disclosure use without patient consent, including the treatment, payment and operations (TPO) exclusion. Yet, key statements in the draft roadmap appear to fly in the face of the legal status quo. A particular problem is on p. 55 where the draft states—

> Participation in and use of a learning health system will be highly dependent upon reliable mechanisms to ensure that…. (4) users have access only to data they are authorized to access, where authorization is determined by individual's choice, or if no choices are recorded, what the statues, regulations and consensus rules say a user may access, use, disclose and receive.

Law provides for access in many circumstances regardless of whether individual choice is or is not recorded. The interoperability roadmap should not itself include attempts to change the policy concerning where consent is or is not required under law or other arrangement. It is sufficient and more accurate to say consent mechanisms are needed as applicable in the context of law and relevant arrangements. The roadmap would need to consider these mechanisms. This statement focuses on the need for some level of interoperability and standardization where consent is operative without suggesting changes to where consent operates and without undermining the current structure. Even where consent is operative, it may be part of a complex matrix of issues.

In the discussion of the Fair Information Practice Principles FIPSS, the draft interoperability roadmap repeats the problem. It is correct that that the FIPSS makes unqualified statements regarding individual choice. However, such statements without qualification are incorrect and incompatible with a workable health information privacy system. The interoperability roadmap draft on page 64 states, in part:

> "In an interoperable learning health system, that means there must be both policies and technology that:
>
> 1. Provide individuals the opportunity to make meaningful decisions about their health information;…."

This statement suggests a potential override to the TPO exclusion or a policy statement about restricting the TPO exclusion and other features of current law.

Figure 7 on page 65 makes two statements inconsistent with existing law:

> "….4. Individual choice: Individual should be provided a reasonable opportunity and capability to make informed decisions about the collection, use and disclosure of their individually identifiable information…"

Again, these statements, on their own, are inconsistent with practical aspects of existing laws and suggest an inappropriate and impractical set of expectations. ONC should not use these aspects of FIPSS as a "touchstone" for building a privacy and security framework as suggested on page 64.

It is unclear what the draft roadmap means on page 66 regarding the following statement:

> Basic choice builds on existing standards [sic] HIPAA Privacy rule standards of "minimum necessary," role based access," and use of de-identification where possible.

The above constructs do not rely on patient choice, and, perhaps, that is ONC's point. However, existing standards are far more than the three points cited. Moreover, HIPAA references cited do not actually suggest de-identification where possible but simply sets out the structure for de-identification.

In addition, reference to a survey of consumer attitudes such as on page 66 is not a sufficient basis to further support changes to consent structures; a survey of this nature does not capture the complications and practical issues in health care operations. In this light, the reference that states "the privacy expectations of consumers are respected" on page 4 is a reference to a construct that is not itself set out in law and has little additional basis.

It is not clear as to what is the "choice" suggested in the basic choice section and why that section is different in nature from the areas covered under the "granular choice" section. HIPAA does include areas requiring consent and, thus, granular choice need not distinguish HIPAA from other laws as suggested on page 66.

Because of the above statements there are concerns with the sentence on page 67 stating an HHS commitment:

> Consistent with the governance principle of individual choice outlined elsewhere in this Roadmap, HHS is committed to encouraging the development and use of organizational policy and technology to advance individuals' rights to make choices about the use and disclosure of their electronic health information.

If ONC means working on mechanisms to help implement choice as applicable under the context of existing law and other arrangements, this would be acceptable. However, the

document is facile with respect to terms like “policy” and the effort to “advance individual rights”, suggesting something like and agenda to broaden consent requirements. It is important that ONC neither suggest increasing areas where choice applies nor decreasing where choice applies, without a much more extensive and coherent discussion that reflects the practicality of any such proposal.

Confusion also arises in the ONC statements concerning regulation under HIPAA and basic choice. This is a problem with the chart on page 69. Simply because a state provides additional regulation does not mean that information is not regulated under HIPAA or that information is only regulated under HIPAA. That concept of this HIPAA/Non-HIPAA dividing line runs into numerous, needless problems. States can incorporate HIPAA by reference. Would that mean nothing is regulated only under HIPAA? ONC recognizes there is a patchwork including other federal laws, state laws, and other governance arrangements. Is it not better to simply focus on areas where consent is applicable under relevant law or other arrangements instead of dividing policy based on which body of laws applies?

It is also important not to oversimplify the many different circumstances addressed by law and other arrangement. Law has many complicated factors and may separate access, use, disclosure and receiving personal health information and various ways. It is not likely that simple consent mechanics will be able to address these issues. Accordingly, the statement on page 23 suggesting that permission should include the question of sharing with whom and for what purpose may reflect an oversimplification. Parties performing authorized functions under HIPAA may change after the generation or initial use or disclosure of IIHI. New specific purposes, within the general authorizations of HIPAA may also arise after initial use or disclosure.

The table on page 48 also contains certain oversimplifications. It would be incomplete to say people safeguard their own information. Privacy law depends on legal obligations of parties that access, use, disclose or receive individually identifiable health information. Thus, patients play a role but do not have real power to safeguard their information beyond what is in their control. Even in areas involving specific sensitive information as stated in the same table will not allow for individual choice to govern all elements concerning of such information.

I. **Harmonization of privacy and security law is important and cannot per se preserve the most stringent aspects of existing laws**

Activities to harmonize the complex maze of federal and state laws that apply to privacy are laudable. The following statement as a prior decision rule in the harmonization process is a problem:

> Through the course of harmonization, however, individual privacy rights as specified in state and federal laws must not be substantively eroded. For example, where a law protects reproductive health or behavioral health information (to name but two sensitive conditions), harmonization would not mean the substantive weakening of such protections.

Without reviewing a given law or existing right, it is hard to have a specific position on what the harmonization outcome should be. However, it is not practical or appropriate to view harmonization as including a one-sided test, where the most stringent state law always applies. The ultimate approach is a balanced one. A well-functioning healthcare system requires the development and maintenance of a trust framework through recognition, management, and enforcement of privacy principles and risk- based security practices which, consistent with data stewardship, also allows for appropriate access and use, appropriate information flow in care delivery, and appropriate secondary uses to promote a learning health care system. Efforts at harmonization need to be viewed in this balanced light. Federal and state privacy and security laws, regulations, and policies should be harmonized considering these factors. This must, of necessity, include regarding practical impacts of any existing law. This cannot be done with an a priori statement that preserves existing laws that meet a one-sided test.

Thank you for the opportunity to comment. Please do not hesitate to communicate with any questions or request for further discussion or assistance.

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