April 8, 2015

The Honorable Michael Burgess, MD
2336 Rayburn House Office Building
Washington, DC 20515

RE: Comments on Discussion Draft "Ensuring Interoperability of Qualified Electronic Health Records."

Dear Representative Burgess:

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 your demonstrated interest in the critical area of achieving interoperability within the healthcare system. We appreciate the invitation to comment on the discussion draft legislation entitled Ensuring Interoperability of Qualified Electronic Health Records released for comment by your office on March 6, 2015, and thank you for the opportunity to provide input on these very important issues. We hope that you will find value in our responses.

Included with the discussion draft was a series of questions that you asked interested stakeholders to consider. Below are our responses to a number of your questions.

We begin with a summary of our key concerns and recommendations for action.

- Rather than the proposed definition of interoperability, we recommend starting with the ONC definition, "An interoperable health IT ecosystem that is person-centered makes the right electronic health information available to the right people at the right time across products and organizations, in a way that can be relied upon and meaningfully used by recipients."
- The current health information exchange environment involves multiple interfaces to and from every system, greatly increasing costs and the difficulties involved in exchange. We recommend moving to a hub and spoke approach for public reporting initially, followed by other use cases.
- We must avoid predefining what is important, based on what we know today. Future changes in technologies and policies will be hampered by overly restrictive terms and concepts.
- The goal should not be to make all data available to all. Beyond the obvious privacy and security concerns, relatively few data are needed for any particular purpose. Also, not all data have to be moved. In most cases data should stay where they are and be available to authorized queries.
- Interoperability criteria should ensure that a disproportionate share of the costs is not falling on those who deliver care.

- What is always needed by the clinician, although other stakeholders do not value it, is the narrative – the story of the patient and the reasoning of the physician or other clinician in unstructured text.
- The quickest way to get where we want to go would be to modify the HITSC charter and governance process rather than setting up a new organization.
- Decertification is not a workable penalty.

Questions and responses

1) This discussion draft is intended to establish baseline mandates for qualified EHR to be considered interoperable through the "criteria" that begin at page 1, line 14.
a) These criteria are intended to set basic tenets of how users must be able to access, share, use, and consume health information. Further, these criteria will be used to identify certain activities relating to EHR that are prohibited. ***What criteria should be included to achieve these goals?***

The ACP does not recommend having mandated process measures for interoperability. This approach has been tried before with meaningful use, and leads to unintended consequences and stifles innovation. We believe that the best way to promulgate meaningful interoperability is to have each exchange of information be meaningful and solve real problems. It should then be self-promulgating, as long as standards are in place to serve as guardrails.

Interoperability within this discussion draft is defined as including "open access." The 24/7 availability to the entirety of a patient's record is a separate issue, and should not be considered as interoperability, which is already defined quite appropriately by ONC, in the "Principle-Based Interoperability" found in *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*.[1] "An interoperable health IT ecosystem that is person-centered makes the right electronic health information available to the right people at the right time across products and organizations, in a way that can be relied upon and meaningfully used by recipients." Interoperability is further defined within the discussion draft as including "complete access to health data." Again, complete access to all health information, even including narrative information that is not structured form, should not be considered as interoperability. Requiring interoperable EHRs to offer 24/7 availability to everything in a patient's health record is not reasonable or useful.

Rather, interoperability is an attribute of infrastructure, and not a solution per se. Increased interactions and communications in a thoughtfully designed healthcare system will be more accurate and less costly; however, 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. While data liquidity is important, sharing information with patients and providers that is meaningful and not misleading is more important.

Therefore, ACP recommends as an alternative approach that this legislation facilitate the creation of a hub and spoke type of model. To meet federal reporting requirements, federal and/or state agencies should be required to have their registries and clinical quality measure (CQM) data collection tools aligned with Meaningful Use and EHR certification requirements, and further required to build and maintain a public health hub and a CQM hub – then physicians and other participants in the Medicare

[1] http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf

and Medicaid programs would only be required to output information to a federal hub, to a state hub, etc. to meet all governmental reporting requirements. Third party hubs, such as clinical registries operated by medical societies, would use the same architecture. This approach would make prescriptive legislation with specifications as to the number of registries to which a provider has to connect and manage unnecessary. Also, this would put the burden of establishing/maintaining connections on data subscribers and not providers. The current system requires that each practice or provider purchase and operate many separate interfaces – each costing thousands of dollars. This alternative approach would dramatically reduce the costs to all healthcare providers.

Additionally, ACP strongly recommends that this legislation address several current policy issues that are barriers to achieving meaningful, relevant, and valid data exchange. These include ensuring:

- The provision of complete and up-to-date directories of clinician contact information.
- Reliable and accurate patient identification and matching of the right records with the right patients.
- 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. As a patient's records move from system to system, the patient's consent information must not be lost.
- Support for the development of new quality measures that track patients across care settings and track their outcomes..
- Accurate data cleaning and standardization services provided by data recipients.
- Active management of longitudinal patient care records by the clinical care team, with the patient at the center.
- The creation and/or improvement of data analytics, alerts and public reporting services.
- The creation of data hubs for federal quality reporting programs and for state public health and disease registries (as outlined above).

Addressing these issues would ensure that the focus will be on making the functions that care providers really want more accurate, usable, transparent, and cost-effective—before we move on to longer term goals.

ii) Alternatively, should definition of certain terms or phrases be recommended by the Charter Organization and adopted through the process in this draft so that they can continue to develop over time? (E.g. are there benefits to a definition of "patient's data" that evolves over time?)

We must avoid predefining what is important, based on what we know today. Future changes in technologies and policies will be hampered by overly restrictive terms and concepts.

b) These criteria are not intended to establish any technical standards or definitions that could become outdated over time and serve to inhibit or slow the development of technology. Does any of the current language pose risks of this nature? If yes, how?

Legislation should address intent and guiding principles, and legislation does not have to specify more than that. The proposed interoperability definitions fail to address many other forms of exchange that are already underway, let alone new forms of exchange of which we are not yet aware.

2) The criteria of "open access" beginning on page 1, line 14, is intended to ensure that any authorized user who has reason to access a patient's health information, can obtain a sufficient understanding of that patient's medical history for the purpose underlying the user's need to access that information. Further, it is intended to ensure that user's access is not burdened by any restrictions or requirements. ***Should all information in a patient's medical record be accessible to all providers?***

No, ACP does not recommend making all information in a patient's record be accessible to all clinicians, as this would inevitably lead to HIPAA violations. Furthermore, it is important to note that only certain information is valuable as structured data (problems, medications, allergies, etc.); whereas other information is better able to create and convey context when kept in narrative form. Therefore, the focus should not be on the volume of data exchanged, particularly if these data do not add sufficient value, 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. There is no 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. There is a major difference between the amount data needed by a physician to care for a patient and the data needed by all of the other stakeholders in health and healthcare. We need to ensure that the care delivery process is not overwhelmed with data not needed for that purpose.

c) Certain laws, at the Federal and State levels, may restrict access to certain information; should they be addressed in this legislation?

ACP recommends that this legislation conform to existing federal and state health information privacy laws.

3) The criteria for "complete access to health data" beginning on page 1, line 18, is intended to ensure that the user accessing EHR can view such data in a manner conducive to understanding the patient's medical history. ***Is this accomplished by the language provided?***

ACP does not believe this goal is accomplished by the language provided. The complexity of a patient's health and healthcare status cannot be significantly understood through the collection of data points. In some cases, what one needs to know is only a piece of information to complement other information – such as a CT result added after a visit with a history and physical exam. In other cases, such as when seeking a second opinion, rarely are the data enough. What is always needed by clinicians, although other stakeholders do not value it, is the narrative – the story of the patient and the reasoning of the physician or other clinician in unstructured text. We are concerned that the push to structure all clinical data will harm the care delivery process and put patients at risk.

4) The criteria requiring that an interoperable EHR "not block access" beginning on page 2, line 3, is intended to ensure that a qualified EHR can be accessed by any authorized user, regardless of the particular software or technology from which they are accessing the EHR. ***Is this language sufficient to incorporate any activity that might accomplish the blocking of health information?***

ACP believes that this language is insufficient to address he complexities of the problems.

a) If no, how can it be revised to do so?

ACP recommends that "blocking" only be addressed as an affirmative action taken by a vendor or provider to prevent sharing. It should not be defined as the inability of an end-user to obtain data, where the problem could be something as simple as a down line or switch, or an inappropriately formatted query.

b) Are there additional activities that burden the free flow of health information that should be prohibited (e.g. contracting terms that lead to de facto data blocking?)

Yes, vendor lock-in is a burden due to excessive costs imposed by the vendors to migrate data from one system to another, which restricts free-flowing communications and prevents practices from being able to switch vendors. Vendors often charge a practice as much as $10,000 for each communication and reporting interface, as well as further charges for each message sent–therefore, ACP views this as another form of "blocking?"

5) This discussion draft is intended to define criteria of interoperability that ensures appropriate users will be able effectively and efficiently access, share, use, and consume medical records. The brackets for "other criteria" at page 2, line 5, are intended to solicit this information from stakeholders across the industry. ***What other criteria should be defined to ensure that these goals are accomplished?***

Interoperability criteria should ensure that a disproportionate share of the costs is not falling on those who deliver care. The current state of interoperability requirements place the collection and communication effort and costs on providers while the data collection costs of payers and government are decreasing. Any established criteria should be easily integrated into clinician workflows and not require any additional burdens or time taken away from patient care.

Caution should be taken as to specifying criteria for effective and efficient access to clinical data, as we do not yet know what the ideal end-state should look like. The current state, where every system must establish a separate interface to every other system is not sustainable. We need to move to entirely new approaches, such as more use of a hub and spoke approach (described earlier).

a) For instance, should technology that generates health information in an automated fashion (e.g. medical devices) be specifically addressed to ensure that the health information that technology contributes to an EHR meets the standards of interoperability established under this legislation?

Yes, ACP believes that these technologies should be addressed; however, these devices must meet certain standards for data format and nomenclature. There will be significant costs for the new interfaces that will be required to move the data into clinical systems. Finally, time will be required for physicians or other clinicians to review all of the data and selectively import relevant portions into the patient record.

6) This discussion draft is intended to create a Charter Organization responsible for establishing the standards necessary to achieve widespread interoperability with members drawn entirely from non-government entities. ***What groups should be represented? Providers, patients, standards development organizations, vendors, software developers, others?***

It appears from the discussion draft that a new FACA organization will govern mandated interoperability definition and measurement, and that this new organization will replace the HITPC and HITSC, which are to be sunset with the adoption of this legislation. It is understandable as to why the HITPC might be eliminated, as its purpose is unclear in a post-meaningful use world; but the same is not true of the HITSC. Their standards recommendation mission must continue to be addressed. However, within these organizations to date, each stakeholder group argues for its desires with limited compromise occurring. Additionally, physician representation in these groups has always been insufficient, resulting in processes and requirements that are not well informed by practicing clinicians and ultimately become burdensome rather than aligned with realistic workflows. This organization must be focused initially on an exceedingly small set of critical use cases. Most of the stakeholder groups will have to be convinced to accept that their needs may not be addressed in the first round, or even the second round, but they will be addressed. We need simple successes that can be implemented quickly before we start adding complexity. If we do not take this approach, a future Congress will be considering a replacement organization. The quickest way to get where we want to go would be to modify the HITSC charter and governance process rather than setting up a new organization.

a) Achieving widespread interoperability will require coordination of technological standards as well as common clinical terminology and vocabulary. ***Should all members of the organization develop standards for both of these areas? Alternatively, should there be two discrete branches under the organization, one that develops standards for technology, and another that develops standards for common clinical terminology?***

We believe that clinical content and terminology standards have to work first for clinicians. This will require significant participation by clinicians of all sorts in their development. Thus far there has not been sufficient clinician involvement in these standards, and the results are clear. Clinical data standards such as C-CDA and all of the public health standards reduce the accuracy and value of the clinical data being reported.

7) Applicability of the certification criteria in this discussion draft would begin in 2018, while the current policy and standards committees would sunset 6 months after the date of enactment. ***Should the current standards continue to apply to certification until 2018? Should there be a method by which new or modified standards can be applied during that time?***

This bill appears to continue the meaningful use incentive program under both Medicare and Medicaid, starting with an additional requirement beginning in 2018. There are no Medicare incentive dollars after 2016 and Medicaid dollars for meaningful use run out in 2021. Thus the focus is on penalty avoidance. That said, any new standards developed should be voluntary until 2018 with waivers for Meaningful Use regulations, the recommended requirement is simply an attestation. Meaningful Use should sunset in a way that leads towards outcomes based payments with no further incentives or penalties based on meeting or not meeting process thresholds.

8) ***In the event that a qualified EHR is determined to not be in compliance with the standards for interoperability, should there be a process by which the vendor will have an opportunity to bring that EHR into compliance before being subject to decertification?***

Yes, ACP believes that interoperability should never be defined by process measures; and decertification of previously certified EHRs carries severe burden and unintended consequences to providers and their patients. If an EHR were to be decertified, all practices that had invested in the product would be forced

to begin an immediate search for a replacement. The cost and disruption caused by decertification of a major product would have devastating consequences on the entire system. Decertification is a "nuclear option." It cannot be used because of the devastation it would cause. What are needed are other less devastating penalties that would be felt by the vendors rather than the clinicians, who had nothing to do with the problem. One suggested penalty is to remove certification from any new systems that the vendor may wish to install.

We hope that these comments help you in determining the most appropriate way to achieve interoperability throughout the healthcare system. We recommend starting with the description of interoperability found in ONC's discussion of "Principle-Based Interoperability" found in *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*. We believe that the existing HITSC could work at least as well as any replacement if its mission and charter were better focused and it was required to focus on tightly-constrained and simple projects that could be executed quickly. In addition, we hope that there will be opportunities for us to comment as this draft is developed.

Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org

Sincerely,

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American College of Physicians