April 3, 2015

Dr. Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Connecting Health and Care for the National, A Shared Nationwide Interoperability Roadmap ("the Roadmap")

Dear Dr. DeSalvo,

DrFirst is a healthcare information technology company specializing in applications that promote and utilize standards-based secure communication between healthcare stakeholders. We are best known for our success in e-prescribing and e-medication management and in particular our most recent EPCS accomplishments. We also provide acute-care products including medication history, secure messaging and communications applications, data hosting/distribution for healthcare payers, and strong identity proofing and authentication for healthcare providers. We appreciate the work the Department of Health and Human Services is directing towards interoperability, as we believe this is one of the most important issues facing successful advance of a learning health care system.

We at DrFirst are seriously committed to promoting a learning health care system, and have been deeply involved in the standards process, including but not limited to original development of the Continuity of Care Record (now advanced to the Consolidated CDA), NCPDP SCRIPT, and security and transport standards as a member of the Healthcare Information Technology Standards Committee (HIT-SC) Security and Transport Workgroup. We also worked directly with NIST to enhance the 800-63-1 Level of Assurance and identity proofing recommendations to include healthcare institutional options for the first time. That series of conversations and documentation led to SP 800-63 version 2.

We applaud the insight evident in the Roadmap especially regarding the following issues

- Need for buy-in by all stakeholders
    - Payment reform to enhance the advantage of value-based care
    - Encouragement for payers to participate in incentives
- Current disincentives toward interoperability, including
    - Desire of entrenched HIT vendors to prevent clients from "defecting"
    - Lack of enthusiasm by end-users due to perceived lack of value

- Common Clinical Data Set
- Movement of focus from meaningful use to the desired outcome of interoperability and a learning health system
- Integration of patient-generated data into the shared record
- Recommendation to establish common identity proofing practices at the point of care, not only for health care providers but for staff and patients, too
- Consider requirement of multi-factor authentication for all patient and provider access to health IT systems

There are several **issues** we believe would further advance our shared goals of interoperability and development of a learning health care system (addressed just below):

1. Accurate identification of patients
2. Understanding real-world challenges with patient-control of records
3. Working with the limits of some current standards
4. "Incentives" that include unfunded requirements and penalties could derail support by organized medicine toward this process (p39)
5. Data overload could create severe issues

1. Accurate Identification of Patients
   As a vendor of e-medication management systems, we understand the critical importance of matching the correct patient. We have developed complex algorithms to accurately match patients based on all available data, but unfortunately there is often not enough data available on both sides (the data we have and the data we receive) to assure a perfect match. This is especially problematic in heavily populated areas and with common names, but can be an issue anywhere. The solution is a national patient identifier, and we believe the resistance to this important patient-safety factor is diminishing. We urge HHS to reevaluate ways to begin at least exploring development of a national patient identifier.

2. Understanding real-world challenges with patient-control of records
   We agree that in the best of all possible worlds, patients would control who can view, edit, and transfer each part of their medical record, and today some patients have both the interest and the ability to do that, if their providers' EHRs would let them. But many patients lack either that interest or the capability, and from my personal experience, they may say they are concerned about privacy but are not willing to put forth even minimal effort to manage their records. Hopefully, this will change in the near future, but we believe

that any requirements should address the fact that many patients will not access their own privacy controls, and a default allowing interoperability should be defined. In addition, we hope you keep the stipulation that *treating* providers can communicate and transfer patient health information freely without requiring complex permission. Along these lines, under "Individual Choice" on p32, the Roadmap states

- An individual shall not be denied access to health care services based on whether they have documented their choice regarding electronic health information exchange.

As advocates of practicing physicians, we feel this is unfair and unreasonable. A patient who denies any data sharing both increases their own risk and likely the cost of their care, and also dramatically reduces the efficiency of the process of caring for them. Providers should be allowed to refuse to care for a patient who will not allow interoperable data sharing. Exceptions to this would be reasonable, such as emergencies or very urgent problems, , and reasonable limits regarding behavioral health care data substance abuse treatment (although either could put the patient and possibly the provider at risk) and certain sensitive conditions particularly if protected by local statutes.

3. Working with the limits of some current standards
   DIRECT as an interoperability standard has issues. It is not a strict standard in that vendors often need to communicate with one another to implement DIRECT messaging, and even then, communication is by messages, rather than interfacing. Messages are more easily scaled nationwide, but are inferior for workflow and keeping records up to date. For example, consider an email string between 2 parties. If the parties' messages get out of sync ("crossing in the mail" so to speak) the resulting record of emails will be clumsy.

   There is no guarantee of delivery of a DIRECT message, and in fact DIRECT Trust providers often don't or can't communicate with one another. As an example (this may have been corrected) just a year ago, DIRECT messages had difficulty passing from a practice in Massachusetts over the boarder to Rhode Island, because they used different DIRECT Trust providers who did not communicate with one another. A final issue with DIRECT is cost, which at more than $100.00 per year per provider is not appreciated by small practices and solo providers.

   We believe that ONC should allow more flexibility and options with the DIRECT protocol. We believe you should immediately introduce and encourage exploration of so called

"Privacy on FHIR", Open ID Connect, and the two factor authentication protocols being developed within the FIDO Alliance. DIRECT is obsolete, very limited and web unfriendly. It was okay when initially introduced, but its adoption has been hampered in part by its rigidity versus the newer more web friendly protocols. Hopefully the HEART project with the involvement of ONC, MIT, NIST and the Open ID Foundation will lead to a much better vehicle for secure patient Identity, Authentication and communication

4. "Incentives" that include unfunded requirements and penalties could derail support by organized medicine toward this process
   For interoperability to be successful, there will need to be "buy-in" from multiple stakeholders. Providers should be encouraged to participate by positive incentives, not by penalties that will sour their feelings about the process.

5. Data overload could create severe issues
   With interoperability comes the possibility of data overload. If a provider is inundated with unfiltered data, they may be both unable to find the necessary data in a timely fashion, and also open to legal risks related to data present but unread. For example, a physician is referred a new patient with multiple medical problems in their history, but many of them resolved. All historical data on that patient is available, but some of it is in scanned PDF form. The data encompasses approximately 200 pages. It is unlikely the physician will have time to review all of the data, and because it is unfiltered and some is unstructured, it will be difficult for them to find relevant information even when looking for it in a time-limited appointment. There is also legal risk – picture the physician on the stand, with the plaintiff's attorney stating, "why didn't you see this alarming test result, doctor? I was able to find it and I'm not even a doctor!" Therefore, in addition to availability of data there needs to be research into filtering the data sent as well as organizing or indexing data such that it can be searched and easily evaluated.

In addition, there are several issues that specifically should be addressed
Transparency: The 2nd and 3rd bullets on p32 state:

- Data holders and entities should provide clear descriptions of decision tools that may be used to match individual identifying information, share individually identifiable information, or withhold individual identifying information sharing.
- Data holders and entities should provide clear information to health information trading partners about technical error rates (e.g., for improper individual matching) and other information (for example results of independent audits of security controls) about information interoperability that may have diverged from expected practices.

This neglects the fact that few end-users or their administrators understand either the practices or the

very complex algorithms used for data matching, nor know the technical error rates (which at best are "estimates"). In fact, these are constantly changing as technology improves. While we understand the limitations recent law places on a national patient identifier, this is the time for address that issue, perhaps starting with a voluntary national patient identifier.

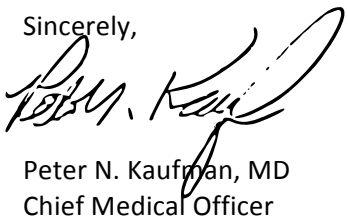
The 1st bullet under *Standards* on p33 states:

- Where available and appropriate for the desired exchange of health information federal vocabulary, content, transport and security standards and associated implementation specifications are used.

This is not always the best solution. When writing standards for the Structured and Codified SIG as part of the e-prescribing SCRIPT standard, we were constrained to use Federal Medication Terminology because it was available, even though it was less complete than other available and free vocabularies. To be most efficient, the best available standard should be allowed.

We agree with the goal of a nationwide learning health system, and we believe the Roadmap and outlined plans to monitor progress are steps in the right direction. Thank you for your work, and for the opportunity to comment on this important process.

Sincerely,



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