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Kaiser Foundation Health Plan
Program Offices

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Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Submitted electronically on *www.HealthIT.gov*

RE: ***Proposed Interoperability Standards Measurement Framework***

Kaiser Permanente offers the following comments on the ***Proposed Interoperability Standards Measurement Framework*** ("Framework")**,** posted April 27, 2017 at the Office of the National Coordinator for Health Information Technology ("ONC") webpage.[1]

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with over 11.8 million members in eight states and the District of Columbia.[2] Kaiser Permanente is committed to providing high-quality, affordable health care services and improving the health of our members and the communities Kaiser Permanente serves.

Kaiser Permanente appreciates the opportunity to provide our feedback.

GENERAL COMMENTS

Kaiser Permanente recommends that ONC modify the Framework to measure the results of interoperability in health care as well as the use of different interoperability standards. Multiple alternative methods for shared access to data are available today in addition to older transactional models that move duplicated data extracts between databases. These newer data sharing methods may use remote authentication of systems or users to allow access, or they may use standard or nonstandard Application Programming Interfaces ("API"); ONC should recognize all

[1] https://www.healthit.gov/sites/default/files/ONCProposedIOStandardsMeasFrameworkREV.pdf

[2]Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members

One Kaiser Plaza, 27th Floor
Oakland, CA 94612

methods that share data to achieve intended health care purposes in the standards measurement Framework.

Historically, many information sharing models used standard transactions to move copies of data from one entity to another, where duplicate data were stored alongside local data. Although these methods are still widely used, they are inefficient because they require multiple copies of the same information to be managed and protected by many organizations. They also increase the burden on providers, potentially heighten cybersecurity risks and may require managing workflows for consents and amendments to the data. This approach may implicate patient safety whenever the amended/corrected information is not propagated fully among duplicate data holders downstream.

Newer technical models include virtualization, which allows data to remain with the organization that created it, thus minimizing security risks of duplicate copies and ensuring data provenance, while providing authorized access and integration. Private virtual data sharing rooms can allow one organization to view another organization's data and use it when authorized, while managing permissions for obtaining duplicate copies when legally required. This can minimize or eliminate information blocking concerns. Interoperable data sharing also can be accomplished by adopting the principles of a logical data warehouse. According to Gartner, "between 8% and 14% of organizations have adopted this concept."[3] The data do not need to be restructured or remapped multiple times for duplicate copies, which saves time and money and may help achieve the ultimate goal of interoperability.

ONC also should shift its focus towards requirements for data stewardship and ensuring longitudinal record integrity. Record integrity requires greater emphasis on content standards for data capture, representation, and meaning (i.e., standard terminology, coding systems, and value sets). With these standards in place, shared access models support Value Based Purchasing more effectively and at lower cost than transactional exchange. Innovative new models and the evolution of alternative technologies should be supported and must coexist with legacy data exchange methods.

[3] "Five Ways to Evolve Traditional Approaches to Data and Analytics — Gartner Keynote Insights," Gartner, accessed July 10, 2017, https://www.gartner.com/document/3354718?ref=solrAll&refval=187228462&qid=9d6df2d57ccd0e0409251a4156a2c015#.

We offer our responses to the questions presented in the Framework:

1) *Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system's value to stakeholders?*

   A voluntary, industry-based measure reporting system may be the best way to implement measurements of interoperability standards and minimize reporting burdens. This approach should be open to evolution and refinement to meet the changing needs of various stakeholders.

2) *What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?*

   The value of surveys may be limited; biased in favor of responses from those who are willing and able to participate. Some type of industry seal/accreditation may serve to create and foster consumer confidence and should be considered as an alternative mechanism.

3) *Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?*

   The Framework proposes measuring the use of transactional technology standards as a way of documenting the achievement of interoperability. We argue that a better and more comprehensive measurement framework would encompass the larger goals that interoperability is intended to serve – delivery of data-driven, coordinated, continuous quality care, population health initiatives, better care transitions, and ultimately more informed decision-making at the point of care delivery. At the same time, adoption and use of standard terminology, vocabulary, and coding systems is required to achieve interoperability. Developing and implementing measures that assess the level of this standardization of information content should be prioritized over measuring the transactional technology standards. The Framework should be substantially modified to emphasize more appropriate measurable standards that address interoperable health information.

   Simply measuring elements such as 1) the frequency of data exchange transactions, such as the number of Consolidated-Clinical Document Architectures ("C-CDA") exchanged between providers; 2) the degree of use of transactional technology standards, such as clinical data exchange standards, Clinical Decision Support ("CDS") standards, ePrescribing standards, or Clinical Lab Ordering standards; or 3) the usage level of certain health information technologies *per se*, such as Direct email technology, are **not** sufficient, appropriate, or valuable in determining whether interoperability was actually achieved.

   Usability of information is different from system usability that concerns user interface design and functionality. The usability of information across systems involves the degree to which the information accessed by a provider while delivering patient care is useable for clinical

decision making and effective care delivery - as well as whether the information was actually used. The usability of information is critical in determining whether interoperability was achieved. We urge ONC to help strengthen and broaden the concept of interoperability and to define performance in terms of information availability, the usability of information, and clinical outcomes, rather than just transactional processes, technologies, and methods.

ONC should collaborate with the National Institute of Standards and Technology ("NIST"), the National Library of Medicine in the National Institutes of Health ("NLM"), the National Center for Health Statistics in the Centers for Disease Control and Prevention ("NCHS"), accreditation bodies such as the Joint Commission ("TJC"), and quality measurement organizations such as the National Quality Forum ("NQF") to expand existing measures and develop new measures that capture the availability and usability of information in the context of decision-making by patients and clinicians. In order to minimize the reporting burden on providers, these measures should be well integrated and highly automated. In the long term, if the underlying purpose of interoperability is to improve decision making, then the quality of decisions should be measured instead of any data or technical measures.

4) *What, if any gaps, exist in the proposed measurement framework?*

Kaiser Permanente offers the following recommendation to address gaps that currently exist in the Framework:

Define interoperability in broader terms
As we explain in our general comments, the measures identified in the Framework stress whether and which transactional data standards have been implemented. This approach does not allow measuring the achievement of care goals and whether interoperability has led to care improvements.

Measure shared access
The Framework does not measure the use of shared access methods, only transactional technology models of sending and receiving duplicate copies of health information across the care continuum. Counting sending/receiving events does not indicate whether a patient's care team has been able to successfully access data to provide and improve care.

Focus on interoperable content standards
A framework intended to promote interoperability should focus on content standards, i.e., the terminology and coding standards required for data to be integrated and processed with precise meaning and common understanding among many entities. Measuring technology standards such as standardized XML formats, transport mechanisms, application choreography, or physical data models, limits innovation and is not a valid proxy for measurement of interoperability.

Adopt a voluntary approach
As discussed in our response to Question #1, the measurement reporting system should be voluntary. Even a voluntary approach may become unduly burdensome for clinicians and

health systems, but increased automation and attention to systems design may help to reduce the reporting burden.

Identify critical stakeholders
Those who can say whether the goals of interoperability were achieved – patients and their representatives, clinical decision makers, and all members of a care team – should be included in the process.

5) *Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?*

Systems connectivity can be assessed through the measurement of technology standards use, but the effective use of interoperable health IT and information in health care will require different concepts and measures that are not transactions based. Measuring whether the right information about the right individual was available to the provider at the right time means going beyond the transactional technology standards to look at information content and clinical care delivery.

In measuring the results of interoperability to deliver usable information for care decisions and care delivery, a more narrowly defined set of stakeholders should be involved – patients and their representatives, clinical decision makers, and all members of a care team.

6) *Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?*

IT developers and exchange networks generally are not and should not be responsible for interoperability measures described in the Framework. When these types of organizations act as data holders, the risk of unauthorized reuse of data and potential breaches increase, as do the growing challenges associated with cyber threats. The shift away from measuring exchange of duplicate copies of health information toward an environment that promotes shared access to data requires rethinking the appropriate set of stakeholders.

Growing calls for individual access and control of health records data will alter the role of EHR vendors and HIE organizations in interoperability measurement. Models of bulk data accountability involving employers, payers, and other authorized stakeholders may further diminish reliance on vendors and HIEs for interoperability solutions, as will other innovative methods of information sharing such as data virtualization. The Framework should also not rely on data holders that are not HIPAA covered entities or business associates. Transactional intermediaries cannot measure achievement of interoperability and a results-focused measurement framework should be designed to bypass such intermediaries unless they also operate in an end user interface model to present a complete set of clinical information for patient and provider decision-making with control of the user interface.

7) *Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which*

publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

Implementation and use of interoperability standards is no guarantee of interoperability that results in useable data at the point of care, so the value of publishing this measurement is questionable. Kaiser Permanente supports reporting measures of interoperability on an annual basis as a mechanism for tracking evolution of the standards, but not as a regulatory mandate for patients, providers, or other stakeholders.

The health IT standards lifecycle typically proceeds over a time frame of multiple years in SDOs. Measures should undergo a rigorous vetting process. Development, review, selection, testing, and implementation cannot occur at a fast pace (e.g., within one year).

8) *Given that it will likely not be possible to apply the measurement framework to all available standards; what processes should be put in place to determine the standards that should be monitored?*

The Framework does not advance a concept of interoperability that supports the goal of getting the right information to the right person at the right time for delivering quality care, based on a patient's interoperable health records. ONC should collaborate with other stakeholders to first define the outcomes and results that will demonstrate the achievement of interoperability, then determine the content, terminology, and coding standards that are required to support specific outcomes. These are the standards that should be measured in the Framework.

9) *How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?*

Please see our responses to Questions #6 and #8.

10) *What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?*

Measures used to track conformance or customization of transactional standards do not measure the success of interoperability and should be eliminated in favor of measures that assess achievement of the goals of interoperability. Therefore, Kaiser Permanente recommends developing measures of interoperability that can assess the completeness, quality, and usability of health information that is available for health decisions. Measuring how well health records content conforms with the most important content standards, i.e., Systematized Nomenclature of Medicine -- Clinical Terms ("SNOMED CT"), Logical Observation Identifiers Names and Codes ("LOINC"), and RxNorm, would be helpful. We

suggest ONC work with NIST, NLM, NCHS, accreditation bodies, and quality measurement organizations to develop and maintain a national assessment of these standards.

CONCLUSION

Kaiser Permanente hopes these comments and recommendations will help contribute to a stronger, more practical, realistic and achievable version of the Framework. Thank you for considering our input. Please contact Jamie Ferguson (510-271-5639; email: jamie.ferguson@kp.org) or Lori Potter (510-271-6621; email lori.potter@kp.org) with any questions or concerns.

Sincerely,

Jamie Ferguson
Vice President
Health IT Strategy and Policy

Lori Potter
Senior Counsel
Government Relations