



2800 Rockcreek Parkway
Kansas City, MO 64117
816.201.1024 ^{Tel}
816.474.1742 ^{Fax}

February 6, 2015

Karen DeSalvo, MD
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: *Comments on Federal Health IT Strategy Plan 2015-2020*

<Submitted Electronically>

Dear Dr. DeSalvo,

The Cerner US Client Regulatory Council is pleased to respond to the proposed updates to the Federal Health IT Strategy Plan for 2015-2020. We applaud the ONC for its remarkable efforts convening such a large number of federal agencies through the Federal Health IT Advisory Council and offer congratulations on facilitating this Plan as the outline for the federal government's advancement of health information technology (IT) in the second half of this decade.

As the world's largest publicly-traded health information technology company providing leading-edge solutions and services for health care organizations worldwide, Cerner's mission is to contribute to the systemic improvement of health care delivery and the health of communities. Our solutions are used by more than 463,000 providers and are licensed at more than 18,000 facilities in 30 countries.

Cerner has partnered with 16 health care organizations who use the Cerner CEHRT systems, creating the Cerner US Client Regulatory Council. Our mission is to create a collaborative partnership amongst health care providers and software solutions that are powering the future of the health care industry with a focus on regulatory matters. The health care providers represented in our Council cover a spectrum of health care organizations including academic hospitals, multi-state organizations, state health plans, ambulatory providers, critical access hospitals, children's hospitals and specialty providers. Collectively, these organizations are responsible for over 10 million patient healthcare records across the United States.

Health IT has the potential to enhance the flow of information across the health care system to improve quality, efficiency and safety, while serving as the infrastructure to enable care transformation. From our perspective as a health IT innovator creating technology solutions alongside some of the nation's most forward-thinking providers and health systems, we offer for your consideration several generalized observations as well as specific feedback for objectives, goals and strategies included in the proposed Plan.

General Observations

- Interoperability is critical, period. Future models of care will not be effective without interoperability, and the return on billions of dollars being invested in digitizing health care will be limited without it.

Cerner is committed to true semantic interoperability and having the most open electronic health record (EHR) system.

- The Plan recognizes various roles of the federal agencies with a participatory role in health IT as payer, provider, researcher and regulator. These roles set the distinction that is critical to understanding specifically what each agency is expected to do and will do, as well as defining expected deliverables.
 - We request that the Plan include clearly identify the role each agency is meant to play as it pertains to the agency's expectations under each outcome.

- Overall, the Plan attempts to identify the "Who," "What" and "When," but largely is silent on the "How."
 - We request that the Plan include specific measurements of accountability for each agency, for each outcome – and its related goal, objective and strategy(ies).

- As outlined on p. 6 of the proposed Plan, "Federal partners...will implement the Plan and review progress for each goal, identifying milestones, measurement and reporting tools, and risk mitigation. Each department and agency listed under an outcome will report on progress measures or milestones annually through the Federal Health IT Advisory Council."
 - We strongly urge public communication of the supporting implementation details (milestones, measurements, etc.), as well as transparency into the ongoing activities within the Federal Health IT Advisory Council to allow for public view into the progress of the Plan's implementation. Successful implementation of the Plan will require input from and coordination with stakeholders across the health industry, including private sector actors, on a continued and consistent basis. This is abundantly made clear in the expectations for private sector and commercial entities in the Nationwide Interoperability Roadmap published as a supporting roadmap to this Plan. This will ensure the Plan is able to evolve as the health IT marketplace matures as well as provide the public with a better understanding of the federal government's direction to improve health care, individual and community health, and research through the collection, sharing, and use of interoperable health information.

- The Federal Health IT Principles as outlined on p. 7 of the proposed Plan begins with, "Federal agencies will collaborate with one another and with state, local, tribal, and private stakeholders..."
 - We request that the Plan include further details around the purpose, nature, expectations and expected outcomes of Federal agency collaboration with state, local, tribal and private stakeholders. Much of the Plan's successes will hinge on this collaboration. Clarification of how the federal agencies plan to incent and hold accountable non-federal public and private sector participants in the plan implementation is critical for those participants to understand.

- We strongly affirm the cross-agency focus on interoperability, privacy and security, patient safety, public health, and quality reporting.
 - We suggest focus on these areas instead of on the functional attributes of health IT, as this enables the market to develop and innovate products that meet and exceed their customers' needs for support of their businesses without dictating what the products must do and how they must do it. An important step in the evolution will be to ensure that the advances in these areas have a clear line of sight to the outcome to be achieved.

- We endorse the expanded definition of health IT beyond what is established under the HITECH legislation as covered by the EHR Incentive Program.
 - One barrier that currently limits the effectiveness of interoperability efforts is the lack of engagement with all the necessary stakeholders who must share data to complete the end-to-end process being automated, such as labs, long term care facilities, registries, public health agencies, and patients.
 - We also find the Veteran's Administration is missing from the initial list and encourage ONC to include the VA as a stakeholder in the Plan.

- We applaud the steps ONC is currently taking toward ensuring the certification process justifies the means and its cost and impact on downstream activities, such as the Kaizen meetings.
 - We encourage ONC to take a fresh look at solving perceived challenges associated with health IT solely through the current certification process.

- Both government payers (such as Medicare, Medicaid, Veterans Affairs and Department of Defense) and private payers hold valuable data relative to cost, quality and utilization. Claims-based data can also help employers, providers and hospitals know, manage and ultimately improve the health of their populations more effectively. Oftentimes, payers are reluctant to release data related to their patients, plans and providers, or the availability of the data is hindered by proprietary technology or expensive business requirements.
 - *We strongly believe that, like HIPAA-mandated provider-captured data, payer data should also flow unimpeded for treatment and payment purposes, including population health activities.*

Specific Comments

Introduction: Overview

- The term "health IT" as defined in paragraph 2 on page 4 includes both software applications and various types of technologies used to deploy software. We suggest refinement of this statement.

Introduction: Background

- Illustrating the success of the EHR Incentive Programs by the number of providers that have received incentive payments is only one factor in EHR adoption. We encourage ONC to emphasize outcomes improved or costs reduced as measures of success may be better suited to demonstrate the value of the program.

Goal 1: Expand Adoption of Health IT

1A: Increase the adoption and effective use of health IT products, systems and services

- We agree that not all providers critical to the care continuum were eligible to receive incentives through HITECH's EHR Incentive Program, and we agree with the overall objective and outcomes as described.
- We believe that certification should not be a preferred solution or the principal strategy for policy implementation by federal agencies over thoughtful business case development and useful implementation guidance.
 - We pose the value is not just to "capture health information from all sources in order to obtain a more complete picture of overall health," but that meaningful, integrated use of a patient's information – the right data being available to the right provider at the right time – is a far more significant goal, and attainment of that goal as to the availability and liquidity of the patient's information must be viewed comprehensively.
- Specifically, in reference to Strategy 3, we urge an approach that focuses on modularity of requirements to suit a business need that allows providers to ask for, receive and/or exchange what is useful to them in their moment of need. To this end, we suggest a model of testing standards that provides for the following:
 - What business need does it fulfill?
 - What safety-related benefits does it provide?
 - What economic benefits does it provide?
 - What efficiency benefits does it provide?
 - What operating rules or guidance support its use?
 - What use cases does it enable?

1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services

- We recommend that the role of health IT certification be balanced with providing tools and abilities to assess the implementation based on principles of "safe use."
 - We agree that the SAFER Guides are a good start by helping stakeholders know what to do and providing evaluative tools to judge where they are and know how to get there.
- Efficiency of use is important to realize along with the safe and quality of use. Many in the industry are changing electronic health record vendors and the loss of information integration when changing systems is cumbersome and problematic.

1C: Advance a national communications infrastructure that supports health, safety, and care delivery

- Bringing broadband service to rural areas is not enough, the services and technology devices must also be affordable in low income areas. Further, there is no mention of the disenfranchised population.

- Relying on access does not cover the patient subset of elderly who are now being pushed into the technology world. We recommend the Plan acknowledges the “generational divide” as a barrier to adoption and address educational needs for the elderly.

Goal 2: Advance Secure and Interoperable Health Information

- We urge the government to develop and support policies that prohibit the restriction of data access and exchange across the industry. We are pleased to see interest in investigating ways to ensure taxpayer dollars spent on the EHR Incentive Program support certified EHRs that truly are interoperable. We distinguish *intra*-operability from *inter*-operability, meaning that the former connects and exchanges data only within its own system. We encourage these discussions to focus not just on the technical capabilities of EHRs or the certification processes by which EHRs are tested, but also on provider and vendor business practices that discourage interoperability efforts by making it too difficult or too expensive for providers to connect and exchange patient data with others in their community.
 - To this end, we strongly urge support for a common definition of interoperability, standard mechanisms to support interoperability, and in particular, use cases that illustrate successes.

2A: Enable individuals, providers, and public health entities to securely send, receive, find, and use electronic health information

- Inconsistent health exchange governance models, as well as a general misunderstanding of the applicability of HIPAA and related state laws governing certain types of health information, has created challenges for providers as they look to support data exchange among non-affiliated providers.
 - We urge the federal government to invest in providing education to providers and other key stakeholders, as well as providing safe harbor – or a “blessing” of sorts – in regard to key provisions that will facilitate key health exchange particularly related to a treatment purpose. We request adding accountability for OCR and OIG to develop this guidance.
- We feel the timeline to enable health information exchange is not aggressive enough. True interoperability requires data standardization and 6-years to develop an “expanded set of health information” is too long to wait.
 - The interoperability objective found in the Meaningful Use, Transition Summary of Care CCD document is, in its current form, an effort of collecting ‘junk’ for most providers. We cannot wait 6-years to correct this. We request ONC to speed up the federal agency adoption of interoperability by allowing the providers to decide and agree what information is truly useful.
 - We request ONC also speed up the Veteran’s Administration adoption of ‘interoperability’ as they are not under any obligation to provide data on their patients and can be a substantial barrier to patient care.

2B: Identify, prioritize, and advance technical standards to support secure and interoperable health information

- Standards by themselves are not sufficient for achieving interoperability, as we learned from the rollout of Direct. A trust, legal and financial framework must also be in place in order for information to truly be shared across entities.

- Cerner is a member of the Argonaut Project, launched by Health Level Seven (HL7) in December to advance the work of the JASON Task Force by pushing for adaption of an open API, specifically HL7's FHIR. We urge the Plan's authors to encourage this mechanism to drive industry-wide adoption. Cerner is already testing and implementing FHIR to much great success.
- We have concerns regarding the use of nonstandard information. The use of free text information and unstructured data is a lofty and unmeasurable goal and seems counterintuitive to Objective 2A.

2C: Protect the privacy and security of health information

- We generally agree with the objective, outcomes and strategies defined. We strongly urge heightened focus toward developing standards and guidance for managing sensitive health information exchange – especially practical implementation models. The DS4P Pilot was a good start, but as it was limited to behavioral health, more development needs to occur to provide practical guidance to the industry and to inform potential certification standards and implementation specifications.
 - We urge the support for the integration and exchange of *all* types of health information. Inconsistencies in various state and federal privacy laws pertaining to sensitive health information, such as that protected under 42 CFR Part 2, 38 CFR Part 1, emancipated minor-related data such as reproductive health, and other common sensitive data types and conditions, are obstacles to widespread health information exchange. A nationwide, privacy-focused legal framework is needed to create true interoperability across all venues of care and all types of health information.
- We encourage policymakers to explore ways to deter data misuse rather than prescribing specifically how and when health IT must be able to block or hide sensitive data.
- We suggest the federal government tackle the angst associated with patient privacy, including de-identification, by focusing on how such data *should* and *should not* be used (and the penalties for misuse). As stated previously, we strongly encourage activities that associate penalties with the misuse of data. The Genetic Information Nondiscrimination Act of 2008 (GINA) follows a similar approach, in that the focus is on appropriate use and penalties of protected data. We believe technology will continue to advance and it will become harder to appropriately de-identify data, but we support rigid constraints on how de-identification is performed and with strictures and penalties for inappropriate attempts at re-identification. Further, we urge federal government to look outside the United States toward current efforts in the United Kingdom to create “Accredited Safe Havens” to license organizations to hold data for secondary uses beyond direct clinical care.
- We suggest it may be appropriate to accelerate the 3- and 6- year outcomes. This is a critical issue affecting current adoption and will hinder success of many other goals if not addressed appropriately and quickly.

Goal 3: Strengthen Health Care Delivery

- We agree that the current fee-for-service model contributes toward waste and friction and must be replaced as quickly as possible by value-based models that emphasize the quality of care and the value of good outcomes. Health IT will play a central role in the success of this transition by supporting the ability to measure outcomes for purpose of reporting to the responsible oversight agencies and payers both at a state and federal level and also in the private sector. Providers shifting from fee-for-service to value-based models will be successful only if they are able to leverage additional capabilities that increase connectivity at the community level to share real-time data and ultimately reduce costs, manage risk and improve quality. Further, the shift in payment incentives provides a business driver that encourages timely exchange of information in support of efforts toward nationwide interoperability.

3A: Improve health care quality, access, and experience through safe, timely, effective, efficient, equitable, and person-centered care

- We feel a need for targeted incentives to improve the health of populations are needed. World health issues, such as obesity and infant mortality, prevalent in our populations should be an immediate goal.
- Federal initiatives need to keep in mind that health literacy issues are very specific to local populations and are affected by primary local languages and diversity of communities. One of the technology tools necessary to fulfill this objective is a personal health record that is collaborative with patient portals. Many patients in today's society have several patient portals, and if these portals could integrate with one patient health record, we could see true patient-centered care with the patient leading their health team.
- Specific to Strategy 2, we remind the Plan's authors that this must not be solely about certification, but also about implementation guidance, business justification, and reference points to help guide stakeholders toward success and appropriate measurement.
- Specific to Strategy 5, while we agree with the need to integrate critical self-reported data, we caution that practical strategies to educate and encourage consumer adoption of such tools will help overcome a vast number of adoption challenges. The U.S. consumer health economy is being inundated with wearable health devices, the longevity of any given type, brand, platform, etc. is uncertain, and if not addressed appropriately, may create even more data sets at risk of data decentralization and orphanage.

3B: Support the delivery of high-value health care

- Specific to Strategy 2, "simplify participation and reporting requirements". This must be acted on immediately and is absolutely necessary to achieve this objective. There have been many promises from ONC and CMS regarding this strategy, however, that has been a small amount of alignment happening and it is not progressing quickly enough.

3C: Improve clinical and community services and population health

- We have no substantive comments toward this objective and the stated outcomes/strategies.

Goal 4: Advance the Health and Well-Being of Individuals and Communities

- We stress the importance of making relevant information accessible and usable to people.

4A: Empower individual, family, and caregiver health management and engagement

- We agree with and support this objective, and its outcomes and associated strategies as described. However, we urge the Plan's authors to accelerate the 3- and 6-year outcomes. This is a critical component to the overall success of health IT. We feel that a patient population not adequately educated on the benefits of or engaged to leverage health IT will greatly hinder the success of the Plan.
- Patients need access to cost, quality and safety data related to the providers and hospitals in their region in order to make effective decisions and create market pressure for safer, better quality care at a lower cost. In an effort to promote transparency among providers and consumers and encourage diligent use of health care resources, physicians' fee schedules/pricing and reimbursement data should be more transparent.
- Currently the EHR Incentive Program's specifications for consumer engagement have fragmented the health information that a consumer can access since he or she is required to use a provider-specific access path to view a particular subset of their data. Just as interoperable health records enable providers to see the 'whole picture' when diagnosing and treating, they should also provide patients with the ability to view all of their information from one access point.

4B: Protect and promote public health and healthy, resilient communities

- In general, we agree with and support this objective, and its outcomes and associated strategies as described. In its implementation, however, we stress the importance of ensuring support for the appropriate data collection by the most relevant stakeholder, in a way that won't require the patient to repeatedly answer potentially embarrassing questions, or for the provider to interrupt her/his workflow to capture data not relevant to the care s/he is focused on providing.
- We agree that using health IT can identify emerging hazards and public health threats, it is important to know the states sometimes do not align with federal programs. The most recent instance of this is the syndromic data submission to public health agencies as part of the Meaningful Use program. While important to submit, some states do not accept the data, making this measure unable to obtain. Mandating or encouraging states to align with the federal initiatives is important to achieving this objective.
 - Furthermore, in Meaningful Use Stage 3, the ONC recommendations to CMS appears this measure will be retired; allowing for all to stop submission of this data for eligible professionals. This data is necessary to identify emerging health threats.

Goal 5: Advance Research, Scientific Knowledge, and Innovation

- We strongly agree with and support this goal and its objectives. However, we question how effective its implementation will be without a unique patient identifier or other nationwide patient matching mechanism, and suggest acceleration of the 6-year outcomes.
- We also urge the federal government to continue to promote open access to federal health care data. One way this can be done is to expand on the Department of Health and Human Services (HHS) Health Data Initiative (HDI) open data and strategy execution plan, which focuses on making a large volume of data available from various agencies in multiple formats for public consumption and innovation. While the initiative has facilitated the release of valuable health data from federal agencies, a similar initiative is needed to unleash data held in the private industry.
- We encourage the federal government to release anonymized clinical data collected by government agencies in a timely manner, as this information could facilitate more comprehensive clinical research. Further, the progress that the government has made in releasing its own data needs to be continued so that non-clinical data such as socio-demographic, environment and education data can be linked to clinical data.
- We suggest that the federal government urges private payers to be more forthcoming in releasing data in a timely manner. Payer information plays an important role in population health improvement and wellness incentive activities. We challenge payers to shift their business models to take every possible opportunity to share information captured in support of advanced care models, including accountable care.
- We suggest the federal government support the mandatory reporting of patient safety events and near misses and work to coordinate a nationwide reporting structure. The FDA Maude database and national efforts to aggregate data by Patient Safety Organizations capture similar data with little to no coordination as to providers or vendor reporting. This data is crucial in helping to monitor therapies effectively, but also helpful for consumers, provider and payers as they look to choose safe and effective providers.

The Cerner US Client Regulatory Council compliments the federal government's efforts and willingness to approach this critical topic thoughtfully and comprehensively by considering comments from interested stakeholders. As you continue to consider the challenges and obstacles, we encourage you to seek a solution that *will set the nation on a sustainable course that benefits every citizen, provider and employer, while fundamentally changing the health experience of every Medicare recipient.*

Please do not hesitate to contact us if we can be of further assistance.
On behalf of our Council Members,

Cheri Whalen, CHTS-IM, CHC
Engagement Leader, Regulatory Compliance



Cerner Corporation
cheri.whalen@cerner.com
816.201.7586