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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.
Washington, D.C. 20201

RE: *Comments on Federal Health IT Strategy Plan 2015-2020*

<Submitted Electronically>

Dear Dr. DeSalvo,

Cerner 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. For more than 30 years, Cerner has been executing its vision to make health care safer and more efficient. We started with the foundation of digitizing paper processes and now offer the most comprehensive array of information software, professional services, medical device integration, remote hosting and employer health and wellness services. Cerner systems are used by everyone from individual consumers, to single-doctor practices, hospitals, employers and entire countries. Taking what we've learned over more than three decades, Cerner is building on the knowledge that is in the system to support evidence-based clinical decisions, prevent medical errors and empower patients in their care.

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.
- Accurate patient identification is crucial to ensuring the right health data is available to the right people (providers, organizations *and* consumers) at the right place, and at the right time. Fundamental to safely and uniquely identifying patients in support of true information liquidity across geographic and technical boundaries is the notion of a single, national patient identifier. Cerner feels so strongly about the need for strong patient identity management that in March of 2013, Cerner co-founded the CommonWell Health Alliance. Since then, CommonWell has been aggressively facilitating the exchange of clinical data across EHR systems and care providers. A key feature of CommonWell's offering is a national patient identity management service, facilitated by a patient's voluntary decision to allow CommonWell providers to use one of the patient's "strong identity cards" (such as a driver's license) as the key to link the patient's encounters together, no matter which provider he or she receives care from. CommonWell Health Alliance is one example of a private market initiative striving to overcome the obstacles inherent in the lack of a national patient identifier. At CommonWell, together with our service provider and members, we are creating and executing a vendor-neutral platform that breaks down the technological and process barriers that currently inhibit effective health data exchange, and we are committed to defining and promoting a national infrastructure with common standards and policies. We strongly urge the federal government to recognize the significant investments made in the private industry and to avoid implementing mechanisms, including requirements on governance or standards, that would hinder or penalize these types of efforts.
- 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 clearly identifies the role each agency is meant to play as it pertains to the agency's expectations under each outcome. In addition, we ask that the federal government recognize that while its own agencies may be subject to specific restrictions and standards, it may not make sense to impose these same restrictions and standards to private market entities.
- 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 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, and 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. *Cerner strongly believes 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

- We suggest rather than illustrating the success of the EHR Incentive Programs by the number of providers that have received incentive payments, emphasizing outcomes improved or costs reduced as measures of success are 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 are not convinced that specialties such as behavioral health, post-acute care and long-term care services necessitate specific health IT certification. Further, we posit 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." To that end, 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.
- We also take this opportunity to remind the Agencies of established FDA processes focused on safety, including the FDA's MedWatch reporting mechanism, and we encourage alignment with these processes where appropriate to reduce redundancies and minimize cost.

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

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

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

- Specific to strategy 1, which states, "Work with partners to reduce regulatory and business challenges that impact health information exchange," we urge the federal government to better understand the practices of states and state health information exchanges and to ensure that these entities are not creating barriers to health exchange or duplicating efforts/cots in that regard. In particular, we provide two examples. The state of Minnesota has enacted statutory requirements for a state certificate of authority required to operate as a health information exchange service provider, which requires significant effort, duplicative of other national efforts, as well as an additional fee. The state of Missouri's state-designated entity for health information exchange, the Missouri Health Connection (MHC), in our experience, has not participated in sub-national/regional intra-state HIE activities with regional health information exchange organizations. Further, the state of Missouri is now exchanging Medicaid data with only MHC, and this data is only available to Missouri providers willing to pay connection fees directly to MHC. Missouri providers are not able to access Medicaid clinical data and must use a legacy tool to access claims data if they choose to maintain their connections to regional health information exchange organizations.
- 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, have created challenges for our clients as we 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. To this end, we suggest adding accountability for OCR and OIG to develop this guidance.
- Specific to Strategies 4 & 5: We repeat our thoughts regarding "transactional modularity" by defining the business cases that support this goal (see comments on Objective 1A), and point toward CAQH CORE'e efforts that have informed rule development for the HIPAA Operating Rules for EFT/ERA, which identify the business cases supported by the standards and specifications and promote the appropriate use of them through implementation guidance that is, part of the model requirement.

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

- Transport and payload standards, by themselves, are not sufficient to drive wide-scale health information sharing, as we've learned from years of local and regional HIE efforts. Scalable trust, legal and financial frameworks must also be in place in order for information to be seamlessly available whenever and wherever it's needed.
- We suggest that tighter coordination between federal agencies as it relates to certification requirements viz a viz implementation requirements will increase the opportunity for "out-of-the-box" interoperability, subsequently promoting higher confidence in its use.
- Our health IT ecosystem must be encouraged to innovate with technical standards by introducing them alongside value-based use cases that exercise the standards' broadest capabilities. As we've learned with the rollout of Direct, using a document submission use case ripped from the IHE playbook has encouraged little innovation.
- 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 adoption of an open API, specifically HL7's FHIR. We urge the Plan's authors to encourage this mechanism to drive industry-wide adoption, or at a minimum, to ensure that those who are moving forward at an accelerated pace are not penalized. Cerner is already testing and implementing FHIR to much great success.
- We take this opportunity to repeat our concern regarding the lack of a nationwide unique patient identifier, voluntary or otherwise.

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. Cerner urges 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. The difficult and onerous technical requirements that must be implemented in order to support integration of sensitive data in EHRs introduce great potential to adversely affect provider productivity and usability, which we strongly suggest the federal government to keep at the forefront of their policymaking in this regard.
- 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 that 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

- Cerner wholeheartedly agrees 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 across the continuum of care. 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 generally agree with the objective, outcomes and strategies as defined and offer no substantive comments.
- 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

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

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.
- We recommend the inclusion of predictive analysis in the Plan.
- Platforms such as Facebook and Twitter allow individuals to reach across geographical boundaries to share and access information that may indicate or affect an individual's health or a community/public health occurrence. Providers are increasingly monitoring their patients through social media, leveraging it as an additional communication mechanism and source of data. Further, community events such as the Boston marathon bombing or public health occurrences such as Lyme disease outbreaks can be identified and monitored for impact to health resources and individuals.

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. We encourage the federal government to support innovative strategies aimed at facilitating a single access point for consumers to access all of their health information, regardless of source.

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.

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

non-PHI data related to costs, trends and processes, 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 de-identified 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.

Cerner 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 me if we can be of further assistance.
Sincerely,

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