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The Honorable Joe Biden
Vice President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Via facsimile to 202.456.3463

RE: Follow-Up to A Conversation on Patient Access to Health Data

Dear Vice President Biden:

It was an honor to represent Trinity Health at the January 6, 2017 "A Conversation on Patient Access to Health Data". Trinity Health greatly appreciates your personal commitment to leveraging health information technology to advance progress against the scourge of cancer, and we pledge to remain a committed partner in this essential work.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 92 hospitals, 120 continuing care programs — including PACE, senior living facilities and home care and hospice services that provide nearly 2.5 million visits annually. We employ approximately 97,000 full-time employees, including more than 5,300 employed physicians, and have 13,800 physicians and advanced practice professionals committed to 19 Clinically Integrated Networks across the country.

Across our system, Trinity Health has 5 different inpatient electronic medical record (EMR) systems and literally dozens of ambulatory EMR systems. It is a common misconception that a hospital's EMR is one single information system spanning all departments and providers. Despite this plethora of different systems, Trinity Health has patient portals well established across our facilities. We take seriously our February 2016 "interoperability pledge," and we are fiercely committed to the principles of consumer access, no information blocking and implementation of federally recognized national interoperability standards.

In our meeting, you asked for recommendations. At Trinity Health, we believe that interoperability is essential to allowing individuals to have access to their electronic health information and to enabling health care personnel to access a patient's full electronic health record regardless of patient or provider location. Interoperability will additionally increase the efficiency of care delivery; reduce the cost of care delivery, and improve the health of populations. National leadership and immediate action steps are needed to move the nation more expeditiously to interoperability. While the Medicare and Medicaid Electronic Health Record (EHR)

Incentive Program (the Meaningful Use Program) did successfully drive adoption of EHRs, the program is government-driven rather than patient-centered, which has led to "tick the box" government requirements that have failed to advance patient care, improve clinician workflow, or make the substantial progress toward interoperability that was envisioned when the program was enacted.

Following are our specific recommendations on which the Department of Health and Human Services (HHS) can provide leadership, in concert with the private sector, to advance progress toward interoperability:

1. **Accelerate public and private sector efforts toward the consistent implementation of uniform national standards for health information technology.** Adherence to open-source, consensus-based, transparent standards that are sufficiently mature should be an essential aspect of certification of electronic health record technology. While great progress has been made on standards, there is significant additional work to be done; for example, existing standards in areas such as lab, vital signs, and clinical documents need to be deepened. New areas such as scheduling, pathology reports and patient-reported data are needed. That said, it is important that we make use of existing standards whenever possible; we should not start over. For example, the nation should follow Argonaut standards for Fast Healthcare Interoperability Resources (FHIR). However, an area in great need of attention is standards based on specific use cases. Usability remains a major problem. HIT vendors often provide tools designed to help with interoperability but too often providers are required to develop new workflows that add time without patient or other benefit. Vendors should be required to build new tools within existing workflows. Vendors should also be required to have easily available metrics to measure outcomes. Certification should also test EHRs for usability in a broad array of settings, from complex academic medical centers to rural critical access hospitals. Post-installation testing should confirm that installed systems work as intended. The work of private sector efforts including CommonWell, Care Quality and CARIN should inform our shared path forward.

2. **Align Meaningful Use and Advancing Care Information requirements for physicians and hospitals.** Parity in program requirements is essential. Although Trinity Health physicians and hospitals have enjoyed significant success in the Meaningful Use program, the tremendous effort required to meet established Meaningful Use goals has diverted clinician and staff attention as well as considerable resources away from activities with greater direct patient benefit, away from activities with more significant clinician benefit, and away from efforts to advance interoperability.

While physicians are transitioning effective January 1, 2017 to "Advancing Care Information" in the new Merit-based Incentive Payment System (MIPS), hospitals remain in the flawed Meaningful Use program. While Trinity Health joins the American Hospital Association in calling for cancellation of Stage 3, in the near-term, if that is not immediately possible, alignment of physician and hospital EHR requirements should be a priority for HHS. Further, Trinity Health believes that accelerated movement toward value-based care rather than prescriptive government EHR requirements relating to functionality would more effectively drive interoperability and innovation. This would allow, for example, application programming interfaces (APIs) to flourish. Today's APIs need to be more robust and need to expand both deeper and more broadly. For example, medication list APIs need to be bi-directional so that if a patient notes in Medisafe that he is not taking a medication as prescribed, this information will go back to the native EMR with an alert that the patient changed a medication. Increased movement to value-based payment and removal of prescriptive government EHR requirements (including Meaningful Use and electronic clinical quality measure reporting) would facilitate an open ecosystem where APIs could access EMRs and other data sources via common standards. This is just one example of how technology and innovation could flourish.

3. **Promote an effective national strategy for accurately matching patients to their data.** One of the primary challenges impeding the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. Consistency in patient data matching is foundational to interoperability and remains conspicuously absent. Consistency in patient matching is also essential to patient safety and to ensuring that the information in a patient's EMR actually belongs to that patient and includes all available information.

4. **Establish common national standards for privacy and security.** This will improve the appropriate and secure flow of health data. The current patchwork of state laws impedes information flow.

5. **Require consumer interoperability standards so that it is easy for consumers to access all their information, free of charge, and incorporate it into any certified tool they wish to use.** Make it easy for patients to collate data from multiple sources, creating useful information which is easy to understand and share with their care team. Consumer interoperability standards must be prioritized, and they should be a part of the government's certification program. Improvement in authentication standards for consumer applications is needed; for example, consumers should not be forced to sign in each and every time they access information.

Trinity Health is working assiduously to advance interoperability, which we view as fundamental to achieving success in our drive toward a People-Centered Health System. This is because it is impossible to accurately ascertain the patient's story without sharing information. Some of the work we are doing includes development of an interoperability proving ground in Ohio, working in collaboration with athenahealth, Cerner, Epic, and CommonWell to establish optimal work flows and tools to efficiently and effectively share information across the care continuum. To date, this work has led to new tools in both athenahealth and Cerner. Trinity Health is committed to continuing to partner to develop highly usable tools that enhance workflow and remove impediments to the smooth functioning of care teams.

To further interoperability on a national level we established an Advisory Group that includes Stan Huff from Intermountain Healthcare, John Glaser and David McCallie from Cerner, Ed Park from athenahealth, Steve Posnack from the Office of the National Coordinator (ONC), and Trinity Health. This group is working to develop use cases that will lead to standards development for all EHR vendors to adopt. ONC's certification program is a vital tool for moving the nation to the consistent implementation of common national standards, particularly as use of certified EHR technology (CEHRT) is required beyond the Meaningful Use program.

Another advancement that we were pleased to be asked to share at the January 6 meeting is the progress Trinity Health, Cerner, athenahealth, and Medisafe have made in a test environment with a safe medication list incorporating medications from multiple electronic health record (EHR) vendors including NextGen, athena, Cerner and Epic. We expect to load code into our production domains this month, which will enable functionality for current patients in the near-term. As I noted during our discussion, this pilot was designed to meet the ONC challenge to use APIs to connect EMR source system medication lists, aggregate these lists, and present them on a consumer application. The ability for a patient to have an accurate, aggregated, continuously updated medication list at their fingertips is priceless. Rest assured we will continue to innovate with medication lists and other consumer-facing technologies, which are an integral aspect of Trinity Health's commitment to becoming a People-Centered Health System.

Trinity Health has also developed a new consumer digital strategy, which truly focuses on the needs of known patients and consumers who have never touched our system (verified, known, and unknown). We are developing new APIs to assist in open scheduling, asynchronous and synchronous e-visits, readmission

prevention, and smoking cessation. We are partnering with vendors on open source clinical decision support (CDS). As we work toward a People-Centered Health System, we will continue robust advocacy work to promote the highest quality, safest, and most efficient care to our patients and consumers.

With respect to the recently enacted 21st Century Cures Act:

- Cures includes important provisions that seek to reduce the administrative and regulatory burden of using EHRs, including reducing providers' reporting and documentation burden, and improve patient care. We believe the Meaningful Use program should be re-oriented to focus on the uniform implementation of common national standards. Indeed, cancellation of Stage 3 would allow providers and vendors to focus on standards, moving to interoperability, and maximizing current systems would be very welcome relief – even for those of us who have enjoyed consistent success in the Meaningful Use program. If that does not occur, then HHS should, at minimum, afford parity between the Advancing Care Information requirements for physicians and the Meaningful Use requirements for hospitals. In 2017, physicians who report any data at all for any length of time avoid the MIPS negative payment adjustment of -4% and those physicians who submit partial data for at least 90 consecutive days may potentially earn a positive adjustment. Contrast this scoring methodology with Meaningful Use for hospitals, in which hospitals that miss one Meaningful Use requirement by even a negligible amount flunk the entire program and incur significant penalties. The enormous disparity between the two programs is fundamentally unfair. Trinity Health wholeheartedly supports the American Hospital Association's (AHA's) December 2, 2016 call for the Administration to "cancel Stage 3 of meaningful use by removing the 2018 start date from the regulation". We also support the AHA's call for the Administration to "suspend all regulatory requirements that mandate submission of electronic clinical quality measures", which presently are unable to accurately measure the quality of care provided.
- We applaud the definition of interoperability in Section 4003 of Cures, which reads in part: "The term interoperability with respect to health information technology, means such health information technology that…enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology *without special effort on the part of the user*…." (emphasis added). Key to this goal of smooth exchange will be the consistent implementation of common national standards. This is an area where federal leadership, in concert with the private sector, is essential. Requiring vendors to implement common standards will enhance usability. The Certification process must include testing partners for each vendor in multiple settings, from large academic medical centers to small critical access hospitals. Further, EHR technology should be required to demonstrate usability *prior* to certification. While Trinity Health agrees with the emphasis on current API standards, broader and deeper development is needed.
- Trinity Health would be honored to serve on the Health Information Technology Advisory Committee called for in the Cures legislation. We have not yet served on either the current HIT Policy Committee or HIT Standards Committee and believe we have a wealth of experience to bring to the federal HIT policy table. Further, given that we stretch from coast to coast and have facilities that span the care continuum in 22 states and, perhaps more importantly, given our commitment to innovating and collaborating as we move purposefully toward a "People-Centered Health System," we believe we could be a significant contributor. More importantly, though, Trinity Health very strongly encourages broad and significant representation from providers on the new HIT Advisory Committee. One serious shortcoming of the HIT Policy Committee was inadequate representation from those who actually have to implement Meaningful Use requirements and use EHRs in patient care. We should not expect recommendations that work in a clinical setting from a committee that lacks real world implementation and use experience and that doesn't well represent providers.

- Trinity Health applauds the measures in Cures that deter and penalize true information blocking. We also believe that the cost of APIs, Direct Messaging, and health information exchanges are presently too expensive and that providers should not be charged for APIs.
- We applaud Cures' call for a Government Accountability Study on methods for securely matching records to the correct patient and the directive to the new HIT Advisory Committee to make priority recommendations that allow for the "electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records". Indeed, as our healthcare system moves toward nationwide health information exchange, this essential core functionality – consistency in identifying a patient – remains conspicuously absent. Patients and care providers are missing opportunities to improve health and welfare when information about care or health status is not easily available. As data exchange increases among providers, patient data matching errors and mismatches will become exponentially more problematic and dangerous. Accurately identifying patients to their data is essential to coordination of care and is absolutely foundational to health system transformation and national interoperability.

While considerable progress has been made, regretfully - and as you know only too well from personal experience - consumers continue to struggle to access and share the information in their electronic medical record in a user-friendly, seamless, and secure manner. In many ways, it seems we remain in the early days of this journey. Comprehensive information is still not shared with patients and it is often not easy to share any information at all. Patient portals and the functionality within them are still not consumer focused. We need additional and better consumer applications that providers are able to support rather than additional applications from providers that consumers must figure out how to access. While progress is being made, it remains extremely difficult and sometimes impossible to accurately and completely tell the patient story. Today, for example, patients and care teams may receive much data in the Consolidated Clinical Document Architecture (C-CDAs) that are required by the Meaningful Use program, but the data often cannot be queried, lacks context and fails to enable the reviewing provider to fully interpret the patient's story.

In order for EMRs to better tell the patient's story to the clinicians involved in their care, strong public and private sector leadership is needed to ensure common standards. For example, clinical Logical Observation Identifiers Names and Codes (LOINC) should be used to label all narratives so that care teams and consumers can easily find the information they need. Greater use of APIs to tell the patient narrative would be helpful.

Trinity Health is committed to working across the health care continuum to advance interoperability and to help consumers easily and securely access their electronic health data, direct it to any desired location, and be assured that their health information will be effectively and safely used to benefit their health and the health of their community. As Trinity Health works toward a People-Centered Health System, we are also working to provide appropriate opportunities for patients to capture, use and share their health data electronically with providers through the use of personal health devices, personal health tracking tools and more traditional medical devices for remote monitoring. This is part of our commitment to putting the people we serve at the center of every behavior, action and decision.

Thank you for the opportunity to submit our views. America's healthcare system should ensure access to high quality health care at affordable costs, and health information technology plays a major role as providers tackle spending and aim to improve care and patient safety. Without interoperability, the potential of health information technology will not be fully realized and patients will continue to be stymied in their efforts to access their own electronic medical records.

We look forward to working together to achieve our shared vision for the nation's health care delivery system. If you have any questions about our comments, please feel free to contact me at 734-343-1696 or hartzce@trinity-health.org or Tonya Wells at (313) 378-3477 or wellstk@trinity-health.org.

Sincerely,

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