June 3, 2019

Alex M. Azar, II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: RIN 0955-AA01 21st Century Cures Act: Interoperability, Information Blocking; and the ONC Health IT Certification Program; submitted electronically via http://www.regulations.gov

Dear Secretary Azar,

Trinity Health appreciates the opportunity to comment on policies outlined in the proposed Office of the National Coordinator for Health Information Technology (ONC) information blocking rule. Our comments and recommendations reflect a strong interest in improving interoperability and improving patient access to data to improve care coordination in our people-centered health system.

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 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs).

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.

Information Blocking Exception Criteria

Current law prohibits health care providers, health IT developers, networks and exchanges from engaging in information blocking, as defined by the 21st Century Cures Act. ONC proposes seven exceptions that would not be considered information blocking. Trinity Health supports these exceptions; however, existing challenges with the lack of alignment of requirements under the Health Insurance Portability and Accountability Act (HIPAA) across agencies, and between HIPAA and 42 C.F.R. Part 2 will affect the compliance and implementation of the proposed rule. In addition, incorrect patient matching and duplicate registrations remain an issue on a national level and will further reduce effectiveness of the proposed rule prohibiting information blocking until addressed.

HIPAA Regulations

The proposed information blocking exceptions make allowances for HIPAA regulations without any acknowledgement of the complexity of these regulations—the broad reference to HIPAA allows for great subjectivity in the interpretation of the rule. Specifically, the proposed rule requests feedback on "provisions that require access, exchange or use in situations that HIPAA does not" and implies that HIPAA regulations provide a blanket acceptance requirement of any data sharing not designated as a restriction. HIPAA regulations contain many nuances and the proposed rule language is not an accurate reflection of the intent or the courts' and agencies' interpretation of HIPAA regulations.

Current policies and procedures of different entities are reflective of their own interpretation of HIPAA. For example, many covered entities will request an authorization to share data even if HIPAA permits disclosure. This type of variation is problematic when determining the proposed dis-incentives and creates complications in complying with HIPAA, ONC, and Centers for Medicare and Medicaid Services (CMS) operationally when the goals and enforcement of these agencies are not aligned. **We recommend the ONC and CMS take more time for comprehensive review and analysis of existing HIPAA policies and procedures to determine a national standard and clarify language prior to finalizing this rule.**

42 C.F.R. Part 2

Current 42 C.F.R. Part 2 substance abuse regulations often require patient consent prior to any exchange of data. The U.S. opioid crisis has resulted in many patient diagnoses that include both substance abuse and behavioral health. The current electronic health vendors do not have functionality to effectively separate type of patient information subject to 42 C.F.R. Part 2 and, out of an abundance of caution for patient privacy and the technical limitations, this important data is not shared on electronic data sharing platforms. State laws also require consents that are broader than 42 C.F.R. Part 2 and are impediments to information sharing, especially for treatment, care, and coordination. **Trinity Health continues to recommend Part 2 be aligned with HIPAA with regard to permitting the disclosure of protected health information for treatment, payment, and health care operations purposes (TPO) including care coordination. In addition, care providers would benefit from additional focused education on the appropriate criteria needed for permitted sharing of information with family members.**

Inaccurate or corrupted data

Trinity Health appreciates CMS seeking comment on how to improve patient data matching in the proposed interoperability regulation (CMS-9115-P). However, the proposed ONC rule does not take into account that there are no existing national patient identification standards and the challenges this creates in data sharing. **Trinity Health recommends ONC acknowledge this issue in the final rule and work with CMS to address how challenges in patient data matching could impact effectiveness of the proposed rule.**

Updates to the 2015 Edition Certified EHR Requirements

ONC proposes to adopt a standardized approach to open application programming interface (APIs) by requiring the use of the Fast Healthcare Interoperability Resources (FHIR) standard as well as identifying the United States Core Data for Interoperability (USDCI) Version 1 as a standard.

FHIR API Standard

Trinity Health supports empowering our patients to access their health information and incorporate it into any tool of their choice. Finalizing FHIR APIs as the interoperability standard will allow patients and care teams to send, receive, collate, and integrate data regardless of the source.

However, some of the API data requirements included in the proposed ONC information blocking and CMS will require providers to share data through API that they have yet to build capability for—such as formulary data. While we can provide data for episodic care through APIs in 2020, other requirements would take engineering and architecture work. **Trinity Health recommends allowing for two years after HHS makes the HL7 resources available to implement and select vendors.** In addition, the API standard is still evolving and HHS needs to better define this standard.

The ONC proposed rule changes how providers and health systems look at security data for patients. Trinity Health is concerned that some of the uncertified vendor products offered directly to patients may include consents that allow for greater use of personal data than the patients realize. **Enhanced privacy protections will be necessary with more data flowing to relatively unregulated third party applications—HHS should clarify how they will address these security concerns in both the ONC and CMS final rules. At a minimum, patient education materials are necessary to provide cautionary guidance on over-permissive consent terms prior to implementation and explain the differences between HIPAA vs. FTC protections (including that FTC protections are based on the privacy terms and conditions of the application, not the federal government).** Patients should be made aware that once shared, their data can be shared with other actors or used to generate advertisements. Data may also be at risk if third-party vendors are not required to encrypt patient's data, leaving the data vulnerable to hacking.

Absent requiring APIs be HIPAA compliant, APIs should be required to notify patients and receive consent prior to using personally identifiable data for any purpose.

USCDI as a Standard

Trinity Health supports using USCDI as a standard and we are especially pleased that clinical notes have been added, as they maintain the chronologic and relational aspects of data as well as relative importance of various data.

In looking at standardization, the ONC and CMS need to consider the value of standardization to migration as providers are required to change electronic health systems. As systems change, it is challenging to map to the new system and bring data in, creating challenges for clinicians.

Trinity Health recommends ONC do studies to see how frequently each of the required elements are used and remove those that are not proving useful. We also recommend incorporating the ability to transmit text clinical notes, as these are created as a normal part of workflow and don't require specific software manipulation. Text clinical notes can be used as a stepping stone to XML documents/C-CDA templated clinical notes, and can continue to be transmitted as part of the C-CDA notes along with more discrete elements.

Trinity Health recommends better coordination of LOINC, HL7, and ONC on the approach to clinical documents to improve standards across organizations. There should be more granularity of LOINC codes so exchanged document types can be uniformly and easily recognized by the querying organization—providers currently rely on non-standard naming conventions that are vendor and organization specific.

Trinity Health recommends generated notes always be assigned a LOINC code that matches the content of the note and ONC needs to clarify how the document title/LOINC name should be displayed for the user in the receiving system. In addition, we encourage the Interoperability Standards Advisory (ISA) to include clinical documents as a code set/terminology standard and specify how they are to be represented.

Trinity recommends that ONC investigate whether vendors may be inadvertently or intentionally blocking information through lack of cooperation with other vendors and resistance to the creation and use of standards. It would also be beneficial for ONC to participate in the standards meetings of the major interoperability platforms (CareQuality and CommonWell), as well as become more active in encouraging vendors to settle on standards, mandating them as necessary if voluntary action by vendors does not occur or is slow.

<u>Disincentives vs. Penalties</u>

The Cures ACT authorizes the Office of Inspector General (OIG) to assess significant penalties of up to $1 million per violation—adjusted from time to time for inflation—against certain health IT developers, health information exchanges and health information networks that engage in information blocking and to refer certain health care providers to an appropriate agency for "appropriate disincentives." We note that clinicians and hospitals participating in the Medicare Promoting Interoperability Program (PIP) must already attest they do not participate in information blocking to avoid payment penalties. While the proposed rule seeks comments on "appropriate disincentives ", the NPRM specifically notes that the 21st Century Cures Act shall to the extent possible not duplicate penalty structures that would otherwise apply with respect to information blocking in effect before the

enactment of Cures. For this reason, we recommend clinicians and hospitals participating in PIP be exempt from additional penalties or disincentives.

Given the complexity of the proposed rule, we recommend the ONC, the OIG, and HHS delay any disincentives and/or penalties until two years after implementation of the rule to allow for learning and addressing any unforeseen challenges.

<u>**Price Transparency Request for Information**</u>

Trinity Health's People Centered Engagement strategy promotes patient access to meaningful information about the price and quality of care. We believe transparency in meaningful pricing information allows patients and shoppers to make informed decisions, minimize financial risk, and improve the overall patient experience. The proposed rule seeks comments on parameters and implications of including price information within the scope of EHI for purposes of information blocking, below are Trinity Health's responses for some of these questions.

1. *Should prices included in the EHI reflect the amount to be charged to and paid for by the patient's health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider's agreement with the patient's health plan), including for drugs or medical devices?*

   We recognize and understand the frustration of patients when shopping for healthcare, and acknowledge that changes are needed to help them better understand prices. Charge master pricing or negotiated fees will only help patients understand the magnitude of cost and not what they will be responsible for paying. Therefore, we believe publishing charges and negotiated rates with payers are of negligible value to patients and shoppers. Transparency efforts should focus on providing pertinent, current, and meaningful cost information—such as an estimate of the out of pocket expense for patients. We recommend providing an estimate using data on a patient's insurance type, copayments and coinsurance, deductible met, and in/out of network nuances. We provide all of this information to all our patients/shoppers through pull and/or push channels. The creation of an interoperable mechanism to do this will require participation by not only hospitals, but health plans, CMS, and enforcement bodies alike.

   Knowing up front what out of pocket costs are anticipated would discourage patients from selecting plans with excessive deductibles and coinsurance burdens. Simultaneously, with better out of pocket estimations, health plans should have greater clarity, options, and transparency to help consumers make better financial choices. Placing the burden on hospitals to accumulate, develop, and display individual patient's specific insurance plan information is complex—insurance plans can solve much of the transparency challenge with the actuarial data assets they already have.

   Due to the high variability in insurance plans nationwide, we believe that this should be the health plan's responsibility, not the requirement of the hospital provider.

   Including Medicare prices as a reference tool could be misleading to non-Medicare patients and shoppers. Showing the rate Medicare pays may cause patient confusion and suspicion of the hospital's pricing fairness. Hospitals with true procedure-level cost knowledge submit that Medicare reimbursement does not come close to covering their current costs. Additionally, the Medicare rate to be used would need to be well-understood—OPPS, MPFS, Local or Wage-Adjusted Rates,

National Rates, all need to be defined. This may be challenging in a complex hospital environment with multiple provider settings.

2. *For the purpose of informing referrals for additional care and prescriptions, should future rulemaking by the Department require health IT developers to include in their platforms a mechanism for patients to see price information, and for health care providers to have access to price information, tailored to an individual patient, integrated into the practice or clinical workflow through APIs?*

We believe these suggestions will only increase the already excessive costs of today's HIS platforms. The large vendors over the past decades have increased their licensing fees and implementation costs to the point of being one of a hospital's largest operating expenditures. Expecting the vendors to not pass this burden on to the client would be short sighted.

3. *To the extent that patients have a right to price information within a reasonable time in advance of care, how such reasonableness be defined for:*
- *Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care;*
- *Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization;*
- *Ambulance services, including air ambulance services; and*
- *Unscheduled inpatient care, such as admissions subsequent to an emergency visit?*

Patients and their families are in a vulnerable state when they enter an ED or need ambulance services-- point of sale notification of costs for a severely injured or sick patient will require an additional financial interaction with the patient and their families at an already challenging time. In addition, point of sale notification could lead patients to make clinical decisions about their medical care simply due to the financial ramifications. Both of these would add further emotional stress on the patient and their family in the hospital environment.

In discussing a reasonable timeframe for patients to receive pricing information, particularly in an emergency situation, it is important to recognize that per EMTALA, insurance discussions cannot occur until a patient is screened and stabilized. In such situations, it is unclear when it is appropriate to provide pricing information—does this occur once a patient is stabilized? Per service? Or once an ED visit is complete? In all of these cases, services are already rendered and there is a concern patients may refuse necessary care due to concerns about costs.

Hospital representatives involved in emergency care, ambulance services, and unscheduled care are not trained, skilled or equipped to discuss financial implications and are already overburdened; the added responsibility will cause significant increase in operations costs. We believe point of sale estimates makes the most sense for elective services and when provided in advance of the patient's admission or encounter.

4. *How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?*

Despite HIPAA standards, there is still some variance in codes and code structures. We believe code sets and code reporting requirements must be standardized by first disallowing 'grandfathering' of historic code sets. For example, some state Medicaid programs still utilize codes

that are either not current or unique codes not included in the HIPAA Transaction Code set, creating a burden for hospitals. Fully-transitioning to one outpatient coding version for all payers is essential for simplifying charge data and clarity for the patient.

When code structure changes for CPT-4 or HCPCS Level II coded charge items, or when CMS requires alternative HCPCS Level II coding over CPT, it creates an issue of charge structure consistency—staying current with codes and charge structure is a constant challenge for hospitals. Trying to document and publicize all payers' unique codes and coding structure rather than using Medicare as a standard would be a huge undertaking.

5. *Are there electronic mechanisms/processes available for providing price information to patients who are not registered (i.e., not in the provider system) when they try to get price information?*

State publication requirements, publication of Charge Master Files and DRG information, and a patient out-of-pocket cost estimator are options for both registered and unregistered patients.

6. *Should price information be made available on public web sites so that patients can shop for care without having to contact individual providers, and if so, who should be responsible for posting such information? Additionally, how would the public posting of pricing information through API technology help advance market competition and the ability of patients to shop for care?*

Unless price estimation software is mandated and certified to meet accuracy standards retrospectively, we do not believe publishing prices in the form of price lists or Charge Master Files is helpful. In addition, price information often can get buried deep on public facing websites.

7. *If price information that includes a provider's negotiated rates for all plans and the rates for the uninsured were to be required to be posted on a public web site, is there technology currently available or that could be easily developed to translate that data into a useful format for individuals? Are there existing standards and code sets that would facilitate such transmission and translation? To the extent that some data standards are lacking in this regard, could developers make use of unstandardized data?*

The lack of standardized Charge Master Data structure can create excessive costs for software development. As a result, hospital charges used and displayed by a variety of vendors could be incorrectly aggregated, leading to incorrect price estimates and patient assumptions.

We also have concerns about the currency of such data as negotiated insurance rates would need to be modified and hospital charges updated as they are modified. These events occur throughout the year and are not simply annual updates. When code structure changes for CPT-4 coded items, or when CMS requires alternative HCPCS Level II coding over CPT, it creates an issue of charge structure consistency. Trying to stay current with codes and charge structure will be a challenge for a price transparency effort that includes financial commitments and true patient estimates. In addition, some state Medicaid programs still utilize codes that are not current to the national quarterly code sets, creating a burden for hospitals. To simplify charge data, it is necessary to fully transition to one coding version for all payers.

If CMS determines that publication of charges is essential, we believe that the many types of different hospital charges will require standardization.

Ancillary procedures represented by CPT-4 codes seem straightforward, but some charge types have unique nuances that make comparison shopping difficult. Laboratory charges represented by CPT-4 codes would be a reasonable starting point and are one of the easier services to comparison shop. Time-based services such as many of the rehabilitative services codes would be difficult for the patient to compare as the amount of time a therapist will require for their encounter is unknown. Imaging, Cardiac Catheterization Laboratory, and other diagnostic procedures often have supply costs or additional fees charged in addition to the procedures. Further, there are often additional component codes that report the surgical interventions. This variability can lead to a great deal of confusion when a patient is comparison shopping.

Until there are mandated standard charge structures and well-publicized code combination standards, we do not believe these areas can be effectively compared by price shoppers. CMS needs to provide code pair lists quarterly as code sets change and not simply require providers to read guidelines and parenthetical notations within coding references. Guidance for charging or not charging for additional services or items provided in the course of the diagnostic procedure is essential and has continued to be a grey area for many providers—this includes prep time, post op recovery in a recovery room, "level II" or "step down" recovery, supplies, implanted items, drugs used in the procedure, and more. All potential charge components like these need to be defined for a reasonable price comparison.

Clinical Services such as bedside procedures or outpatient nurse-performed procedures currently have wide variability in charge practices, and would require standardization for the ability to comparison shop.

Implanted devices that have HCPCS Level II codes could be published, but do not seem to be valuable for patient shopping for medical care, as they are too general for comparing devices since they are not 'device specific'. The patient is often unable to understand the different implants that may be used for a procedure and comparisons at a charge item level would only cause confusion.

Injectable drugs or biologicals that have HCPCS Level II codes are also difficult to comparison shop. Drugs in hospital charging systems are structured and reported in different ways. Description standards also vary despite HCPCS codes having their own descriptors. For a patient to fully understand drug charges, more specificity would be necessary. In addition, cost data used by hospitals for pharmacy charges varies and methodologies vary dramatically. Enforcing a national standard of a reliable and well-vetted cost factor may allow greater comparison of drug prices for hospital charges.

Room & Board rates, visit charges and observation charges are difficult to compare due to the variability in charge structure and charge practices.

Surgical procedure costs would need a standardized method of charging for reasonable price comparisons as flat-rate pricing is not only unfair to the provider for many surgery types, but also could inflate the amount the patient pays, as hospitals would likely need to over-estimate the rate to avoid losses.

8. *What technical standards currently exist or may be needed to represent price information electronically for purposes of access, exchange, and use?*

CMS would need to define where and how data should be displayed with CMS Transmittals published at least 6-12 months prior to effective date with any information from FAQs or Open Door Forum sessions published as Transmittal or MLN Matters updates. CMS should identify the number of web-pages deep this information should be listed from the hospital landing page and also define clear data specifications to avoid confusion.

9. *Are there technical impediments experienced by stakeholders regarding price information flowing electronically?*

Ownership of mandated data by associations and potential costs to license new data sets that may be available by the government or its agents are a significant concern.

10. *Would updates to the CMS-managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?*

The publication, licensing restrictions and costs of certain HIPAA transaction data would need to be waived to avoid adding extensive costs to providers. If pricing data is to become transparent and more data fields become required for publication, all profit-making for HIPAA transaction code set data should be abolished.

11. *What future requirements should the Department consider regarding the inclusion of price information in a patient's EHI, particularly as it relates to the amount paid to a health care provider by a patient (or on behalf of a patient) as well as payment calculations for the future provision of health care to such patient?*

For reasons discussed above, we do not believe this information should be included in the new EHI definition.

12. *If price information is included in EHI, could that information be useful in subsequent rulemaking that the Department may consider in order to reduce or prevent surprise medical billing, such as requirements relating to:*

- *The provision of a single bill that includes all health care providers involved in a health care service, including their network status;*
- *The provision of a binding quote reasonably in advance of scheduled care (that is, non-emergent care) or some subset of scheduled care, such as for the most "shoppable" services;*
- *Ensuring that all health care providers in an in-network facility charge the in-network rate; and*
- *Notification of billing policies such as timely invoice dates for all providers and facilities, notwithstanding network status, due date for invoice payments by the prospective patient's payers and out-of-pocket obligations, date when unpaid balances are referred for collections, and appeals rights and procedures for patients wishing to contest an invoice?*

Trinity Health does not believe the above noted information should be included in the new EHI definition.

<u>Conclusion</u>

Trinity Health is fiercely committed to interoperability as a mechanism to improve the efficiency of care delivery, reduce the cost of care, and improve our patient's health. Thank you for the opportunity to comment on this proposed rule and look forward to working with you to advance the exchange of health information.

If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,
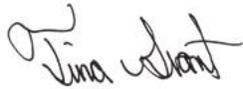
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