June 3, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD, 21244

Re: RIN 0938-AT79 Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers; submitted electronically via http://www.regulations.gov

Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the proposed policies outlined in CMS-9115-P. Our comments and recommendations reflect support of interoperability and patient access to data to improve care coordination in our people-centered health system. This includes our comments on CMS' requests for information on interoperability across the continuum of care and in innovation models, and recommendations for improving patient data matching.

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).

Interoperability is a key strategic imperative for Trinity Health. To this end, we are implementing the largest single instance of Epic in the country and are working to move all of our hospitals and continuing care facilities to the platform over the next four years to thoroughly integrate care for all of our patients across the continuum of care. In the meantime, we are actively pursuing interoperability between the various EHRs we utilize, as well as aggressively pursuing health information exchange with other organizations. We believe that interoperability is essential to a high-performing People-Centered Health System, as it allows the widespread exchange of structured and standardized health

information. Further, we are committed to helping 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.

Hospital Requirement to transmit Admit, Discharge and Transfer (ADT)

CMS is proposing to modify the conditions of participation (CoPs) for hospitals to require transmitting ADT notifications. Everyday Trinity Health facilities are transmitting more than 200,000 ADTs. We believe that sharing the real-time information included in these notifications is essential for care coordination and our People-Centered Health System, particularly as it pertains to handoffs. However, not all providers across the continuum have the infrastructure necessary for a meaningful exchange. **Trinity Health recommends requiring the use of FHIR to share this information. In addition, we recommend regulatory guidance require that all participating providers attest annually that they are transmitting ADT notifications to established community-wide, regional or state-wide health information exchanges or similar repository that act as vehicles for disseminating information. We recommend requiring hospitals and providers develop a plan to be submitted to CMS for approval outlining steps they will take to obtain the capacity necessary to be able to transmit ADT notifications within a 3-year timeframe**. Based upon review of industry compliance and adherence to an attestation standard, CMS can determine if more extensive regulatory requirements—such as tying this to conditions of participation—are necessary.

We believe requiring such transmission is reasonable when a community resource is available and capable of receiving the transmissions; however, we are concerned some of the intended recipients of this information do not have the technological capabilities to make the exchange useful. **CMS should place requirements on all providers, including post-acute providers, to ensure they have the technological capacity to send and receive this information.**

We strongly urge that providers be accountable for *transmission only*, as it is not realistic to hold them responsible for assuring receipt of such transmissions, nor to hold them accountable to transmit to specific providers. We are concerned with the accuracy of any list of providers receiving ADT notification, and recommend CMS develop a complete directory of organizations who are recipients and ensure this information is properly maintained and updated. Trinity Health believes that care coordination for patients is most effective when community-wide capabilities are available to all providers. **We recommend providers will be considered to have satisfied the condition of transmitting ADT notifications if such information is sent to a community information exchange.**

Lastly, CMS should provide clarity on how transmission of ADT information would or would not apply to 42 CFR Part 2 and identify criteria to use if hospitals need to remove patient data before it is transmitted.

Hospital Attestation of Promoting Interoperability

The proposed rule would require hospitals and providers to attest annually that they do not engage in information blocking; CMS would publicly report on Physician Compare and Hospital Compare the names of clinicians and hospitals who do not attest.

We are fiercely committed to the principles of consumer access, no information blocking, and implementation of federally recognized national interoperability standards. Trinity Health fully supports requiring hospitals and providers to attest they are promoting interoperability.

Open APIs

CMS proposes to require establishment of open APIs using technical and vocabulary standards set forth by ONC to provide individuals access to their data held by Medicare Advantage organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan issuers in federally facilitated exchanges. The information to be made available includes patient claims and encounter data, provider directory data, clinical data (including lab data) held by the organization, and drug benefit data, including pharmacy directory, and formulary data. CMS proposes to make these requirements effective in 2020.

Trinity Health supports consumer interoperability standards that help consumers easily access all of their information, free of charge, and incorporate it into any tool they wish to use. Further, patients should be able to easily obtain data from multiple sources to provide information that is easy to share with their care team and families. Finalizing FHIR APIs as the interoperability standard as proposed in the ONC regulation 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 the 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.

Request for Information on APIs

1. *CMS seeks comment for possible consideration in future rulemaking on the feasibility of providers being able to request a download on a shared patient population, and whether such a process could leverage the APIs.*

   If implemented correctly, it would be incredibly beneficial if providers could download a shared patient population through APIs. However, revisions are necessary for this to work in any meaningful way—the initial design of FHIR APIs is consumer access to data, it is not designed for system interoperability. Additional specs need to be added to the API to ensure

providers can see necessary data. In addition, ensuring there are underlying standards in any reformed API that providers would use would lessen the burden on health systems and software vendors, as there would be coding to one API spec.

2. *Requirements for patient notice and consent, and applicable legal and regulatory requirements, and whether or how this data transfer could be cumulative over time and between various providers:*

Consent is important; however, adding a consent requirement when providers access your health information through an API creates additional complexity in delivering care. It can also be challenging for vendors to utilize and track consent flags given complexity of existing privacy rules. Any consent criteria placed on this data sharing needs to align with HIPAA and we recommend HHS develop national standard consent language that is the same across all providers in all settings and evaluate it with a large industry work group.

3. *Input on the utility to providers of obtaining all of their patients' utilization history in a timely and comprehensive fashion,*

As stated above, it would be incredibly helpful if providers were able to obtain all patient utilization history—doing this through API would enable systems to connect and pull in patient data friction-free. This would especially useful for patients who see multiple providers and would lead to improved care coordination. However, HHS needs to improve patient-matching for this to be effective.

4. *Input on potential unintended consequences that could result from allowing a provider to access or download information about a shared patient population from payers through an open API, and*

HHS should ensure payers are able to adopt FHIR and upload information as quickly as possible—payer data tends to be older and illustrates where a patient has been in their health journey, but not where they are real-time. Perhaps one of the most significant cautions is that this will not be effective if HHS does not find a remedy to the issue health providers and payers are having with patient matching.

Request for Information on Advancing Interoperability Across the Care Continuum
The proposed rule requests feedback for how CMS can advance interoperability across the care continuum. We note that long-term care and PAC providers were ineligible for EHR Incentive Programs under the HITECH Act, and this is a contributing factor to many of these providers not adopting EHR capabilities at the same rate as eligible hospitals and physicians. Trinity Health applauds HHS' commitment to interoperability and supports advancing interoperability across the continuum of care; below are our responses to the specific questions included in the RFI.

1. *How HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and PAC, behavioral health, and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services.*

Interoperability within health IT systems begins with organizations' willingness to adopt standardized data to feed EHR systems. Trinity Health acknowledges that the long-term care and PAC providers are years behind EHR and standardized data adoption as compared to

the acute care hospitals and physician practices. As such, Trinity Health would support a phased approach to EHR and standardized data adoption with higher, front-loaded incentives similar to the Medicare and Medicaid EHR Incentive Programs offered to acute care hospitals and physician practices. The reluctance of EHR and standardized data adoption in the long-term and PAC sectors is likely due to limited funding and the insular characteristics of these settings, factors that need to be considered carefully during the development of the incentive program.   Additionally, a phased incentive approach needs to allow vendors who provide EHRs in this sector the time to develop, test, and roll out systems in support of the set of standardized patient assessment data elements proposed by CMS.

2. *What implementation timeline would be most appropriate for requiring adoption of these data elements in provider and hospital systems under the ONC Health IT Certification Program and on the administrative, development, and implementation burden that may be associated with adopting these data elements.*

Dependent upon the development and approval timing of standardized data elements within the long-term care and PAC providers, adopting those standardized data elements into provider and hospital systems under the ONC Health IT Certification Program would require a minimum of three years based on previous experience during the acute care and provider certification process.   EHR vendors will require time to evaluate, plan, and implement the standardized data elements into upcoming EHR releases which are usually programmed 6-12 months prior to general release to their customers.   Further, acute care and provider organizations, based on vendor EHR general release dates, will need to plan the implementation/upgrade of their EHR platforms.   Depending upon the complexity of the release, upgrades usually require 6-9 months to incorporate into hospital and provider settings.

Request for Information on Advancing Interoperability in Innovative Models
The proposed rule indicates CMS plans to use CMMI to test ways to promote interoperability and is seeking comments on general principles around interoperability within Innovation Center models. Trinity Health believes CMMI could play an important role in testing interoperability, particularly given all models implemented by CMMI each have their own interoperability requirements that must be enforced. In addition, CMMI can promote interoperability by sharing data with providers across all models consistently—there should be a shared infrastructure and data components both within and across model teams.

If CMMI is interested in testing and evaluating interoperability, we recommend providing incentives in episode based payment models as they are 90-day episodes of care that include various DRGs and bundles. Optimal success in these model requires coordination of patient care across the continuum—from acute to the post-acute setting—and presents a good opportunity to test and evaluate patient access to their records and being able to create interoperability across providers and settings.   Further, as our patients are transitioned to post-acute care, we need access to their data for the duration of the 90-day episode. This should be structured as an incentive and not a penalty in these models.

In addition, interoperability within the BPCI Advanced model will affect our system's ability to access savings. For the first two model years, the program savings amount may be adjusted by up to 10% based on the composite quality score, which includes an advanced care planning (ACP) measure.

CMMI has indicated that ACP will be measured using CPT codes that can only be billed by physicians or advanced practitioners (CPT codes are typically billed in the ambulatory setting or by geriatricians in post-acute care settings). Interoperability would provide access to advanced care plans across the continuum and ensure we are able to meet the quality measure.

Another option is for CMMI to use its authority to test incentives to encourage post-acute providers to build infrastructure and share data. Hospital stays could be reduced if post-acute providers shared data with hospitals; however, many of these providers have not invested the same amount of time or resources as hospitals to develop interoperability capabilities. Options include allowing post-acute providers to share in savings in value-based programs if they meet certain metrics or CMS could provide other incentives for the exchange and communication of data.

Request for Information on Policies to Improve Patient Matching

Consistency in patient data matching is foundational to interoperability and is essential to patient safety and ensuring the information in a patient's electronic medical records actually belongs to that patient and includes all available information. Further, the lack of consistent patient matching strategy is one of the primary challenges impeding the safe secure electronic exchange of health information. Trinity Health is supportive of CMS examining this issue; however, expenses associated with improving data matching should not be borne by providers. In addition, care should not be denied based on the inability to patient match. Below are Trinity Health responses to the RFI.

1. *How and in what way patient matching does or does not present the same security and privacy risks as a UPI.*

   Trinity Health supports the use of UPIs for all providers and payers. However, relying on UPIs alone would present a security and privacy risk and would not be a sufficient solution for improved patient matching. If HHS were to move to UPI's, we recommend requiring an additional piece of patient verification. We caution that we do not believe many of our consumers and patients would support the use of a UPI.

   In addition, transitioning to the use of UPIs will have an expense across the health care system; CMS should consider appropriate levels of funding and incentives necessary to ensure successful implementation.

2. *Ways for CMS to continue to facilitate private sector work on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information for future consideration.*

   Relying solely on a UPI could complicate the free flow of information, as there could be a "contamination" of records if there is an erroneous UPI. However, requiring a UPI *in addition* to other demographics could address this issue. CMS can facilitate patient matching by standardizing patient fields, including demographics—matching algorithms should be required to handle simple inconsequential demographic differences (such as using "st" rather than "street"). In addition, CMS could require vendors to return close matches for human discernment to minimize the chance of a false negative. We also recommend CMS consider standardizing the use of referential patient matching software, some HIEs use this technology already.

   In thinking through the effectiveness of patient matching, CMS should consider how to incentivize the use of vendors who use the above recommended standards.

3. *How CMS may leverage program authority to provide support to those working to improve patient matching, specifically:*
   - *Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs (not including SADP issuers), use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3rd party?*

     Consistency in patient data matching is foundational to interoperability and is one of the primary challenges impeding the safe and security electronic exchange of health information. Trinity Health strongly believes that improved data matching should occur for *all* patients and consumers, regardless of payer--ensuring medical providers have identified and are treating the correct patient and avoiding duplicate records is critical for patient safety. In addition, HHS should promulgate guidance as necessary so that patient matching does not conflict with HIPAA.

     CMS should require whatever software is used have a specific success rates and make sure any tests encompass environments where similar surnames are concentrated.

   - *Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party?*

     Similar to our answer above, Trinity Health strongly believes that improved data matching should occur across *all* patients, regardless of payer. We are in favor of not requiring a particular software, but suggest HHS require software to have a specific success rate. HHS can borrow from the PI Program CEHRT review process to determine this.

   - *Should CMS expand the recent Medicare ID card efforts by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in health care programs under CMS administration and authority?*

     Trinity Health is supportive of ways to improve patient matching; however, we refer to our response to question 2 of this RFI and caution relying solely on a CMS-wide identifier.

   - *Should CMS complement CMS data and plan data in Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP managed care entities, MA Plans, and QHP issuers in an FFE (not including SADP issuers) with one or more verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?*

     We believe one or more verifying data source for identity proofing would be useful (see our earlier responses to the RFI). However, a patient's inability to produce or remember this data should not be used as an excuse for not delivering care.

- *Should CMS support connecting EHRs to other complementary verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?*

  Trinity Health is supportive of connecting EHRs to other complementary verifying data sources for identity proofing, such as driver's license and phone databases. CMS should pilot this prior to broad implementation to evaluate its effectiveness--one suggestion is to provide grants or additional funding to those who use this technology.

  By October 2020, States must issue identification that meets increased security standards for state-issued driver's licenses and identification cards (real ID). We recommend CMS and the ONC evaluate real ID to identify how successful it is in record matching. However, we caution real ID is only for individuals 16 and older and who have a driver's license or state ID, so it will not be all-inclusive of the population.

- *To what extent should patient-generated data complement the patient-matching efforts?*

  Patient generated data may be less reliable than other data, as patients can easily forget passwords, dates of birth, and other information. There are more reliable options for verifying identity, more innovation ideas include biometric data such as palm and retina scans. In addition, patients should be educated to treat all of their identifying information for purposes of patient matching, as well as any UPI, as secure information and not share it with others.

Conclusion

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 patients' health. Thank you for the opportunity to comment on this proposed rule and we 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,
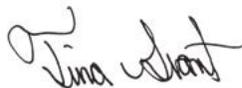
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