Trinity Health

December 20, 2023

Micky Tripathi, National Coordinator for Health IT
Office of the National Coordinator
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: RIN 0955-AA05; 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Submitted electronically via http://www.regulations.gov

Dear Mr. Tripathi,

Trinity Health appreciates the opportunity to comment on policies set forth in RIN 0955-AA05. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high-quality care for all, especially among vulnerable populations such as those covered by Medicaid.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 121,000 colleagues and nearly 36,500 physicians and clinicians caring for diverse communities across 27 states. Nationally recognized for care and experience, the Trinity Health system includes 101 hospitals, 126 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. In fiscal year 2023, the Livonia, Michigan-based health system invested $1.5 billion in its communities in the form of charity care and other community benefit programs. Trinity Health is committed to serving as a critical provider in our communities and coordinating care across settings and the care continuum, with 41% of our revenue coming from Medicare and 18% from Medicaid and uninsured patients.

Trinity Health is a strong proponent of value-based care delivery. We have 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 11 markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participate in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we participated in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

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.

**We urge the ONC and CMS to provide technical support and advice to help providers avoid information blocking and take corrective action rather than—or prior to—imposing a penalty.** For example, in the inpatient and outpatient quality reporting programs for hospitals, CMS frequently offers webinars, provides resources (guides, tools, checklists), and publishes Q&A. In addition, the ONC has a website through HealthIT.gov, where providers are able to submit questions for obtaining technical assistance. However, as the ONC website is still relatively new, we do not have information on the claims that have been made or how the determination of information blocking was made.

Trinity Health is concerned the rule as outlined creates a complicated penalty structure and unfair appeals process. In addition, the penalties proposed for ACOs may impede progress for delivering care based on outcomes rather than volume by removing providers from ACOs or disincentivizing providers enrolling in them.

Trinity Health recommends that:

- ONC provide clarity and education, including more FAQs and examples of actions that will be deemed information blocking.
- The applicability of claims for which “health care provider” information blocking determinations can be made be limited to the period of time that begins when the rule is implemented.
- Only those providers who exhibit a pattern of information blocking should be penalized. For other instances, HHS should work with the provider to provide education and remediate the issue. HHS and ONC should consider tiered penalties.
- Any penalties related to interference with patient access should mirror the penalties that exist for HIPAA. Both sets of regulations deal with access to patient information, so there is an opportunity for natural alignment.
- HHS should clarify that only one participant may be found at fault for an instance of information blocking and should detail in the final rule the process for determining the responsible party.
- An approved hardship application should protect a hospital or provider from incurring a downward payment adjustment, regardless of information blocking determination.
- HHS should not penalize participation in value-based care models and should instead partner with ACOs in identifying instances of information blocking and help flag such instances for ACOs to remediate.
- OIG investigate instances of information blocking but turn the action over to the ONC or CMS to make the determination. Further, we recommend OIG priorities, as they relate to investigations into complaints of providers who have committed information blocking, focus on ‘intent’ versus ‘outcome’.
- HHS should clearly detail an equitable appeals process for providers and get feedback from stakeholders prior to finalizing the rule.

Education Needed

Per existing regulations, to have been found guilty of information blocking providers must have knowingly taken actions that are unreasonable and likely to interfere with the exchange, access, and use of electronic health information. **Prior to implementing the proposed rule, it is critical the OIG provide significant education and examples of the types of actions that would be deemed to be information blocking so there will be no surprises for providers.** What is proposed is an entirely new framework and this is the first time the OIG will be enforcing the requirement; examples will help clarify how the OIG will define "knowingly."

There may be clinically appropriate circumstances for providers not to share information in reliance on an exception, such as at the request of a patient or in connection with a determination as permitted by HIPAA that sharing would create a risk of harm. In addition, there may be instances out of a provider's control—for example, if an electronic health record (EHR) system is out of service, rendering providers unable to exchange or provide records in a timely fashion. Clarity on the parameters will help providers ensure they aren't inadvertently taking actions that may be information blocking. **Further, we recommend limiting the applicability of claims for which health care provider information blocking determinations can be made to the period that starts when the rule is finalized.**

Penalties

If determined to have committed information blocking, hospital and provider penalties as proposed would differ depending on which Medicare quality program they participate in:

- Those in Medicare Promoting Interoperability Program would see a reduced payment of 75% of the Medicare market basket update, and critical access hospitals (CAHs) would receive 100% of its reasonable costs instead of 101%.
- Merit-Based Incentive Payment Systems (MIPS) eligible clinicians would receive a zero score for the promoting interoperability performance category; the amount of funding lost would depend on the performance category weight for that year. (This category is currently weighted at 25%.)
- Providers in the Medicare Shared Savings Program (MSSP), including ACOs and ACO participants, would be prevented from participating in the MSSP for at least 1 year. (CMS could bar them from the program for longer if there are subsequent OIG determinations of information blocking).

Consideration of cooperation and remediation actions should be included in the penalty assessment.

Penalties currently are proposed to be applied a significant time after a corrected violation, whereas correction of the violation would appear to be the primary goal.

*Lack of Alignment with HIPAA*

Currently, ONC is not proposing any scaling for the information blocking penalties in connection with patient access and use or provider corrective actions. For example, a provider who is found to have committed information blocking one time for one patient will receive the same penalty as a provider who is deemed to be engaged in information blocking for multiple patients for a longer time period. We urge HHS to rethink this. **If the rule is finalized as proposed, only those**

**providers who exhibit a pattern of information blocking should be penalized. In other instances, HHS should work with the provider to provide education and remediate the issue.**
The proposed rule is silent on the interaction with HIPAA. Given the intersection between the two regulations, we strongly recommend that HHS better align the requirements and penalties and address the potential overlap. **We urge CMS and ONC to more closely mirror the penalties related to patient access to the penalties for HIPPA rather than finalize the proposed disincentives. Both sets of regulations deal with access to patient information, so there is natural alignment.**

Under HIPAA, the penalty structure for a violation is tiered, based on the knowledge a covered entity had of the violation; these violations range from Tier 1 (Lack of Knowledge) to Tier 4 (Willful Neglect). OCR then sets the penalty based on several "general factors" and the seriousness of the HIPAA violation. Most importantly, OCR attempts to resolve HIPAA violations using non-punitive measures, such as voluntary compliance or technical guidance to help covered entities address areas of non-compliance. Financial penalties are then applied only if the entity fails to enact remediations or if the violations are severe and longstanding.

*Multiple Disincentives*
It is possible for multiple participants to be penalized by one instance of information blocking. For example, there could be an instance in which a single provider employed at an eligible hospital blocks the sharing of patient information. The proposed rule lacks clarity around who would be penalized in such instances—would it be the hospital or provider? **Trinity Health urges ONC to clarify that only one participant may be penalized for an instance of information blocking and to detail the process for determining the party that will be penalized in the final rule.**

*Hardship* Exceptions
Participants in the Medicare Promoting Interoperability Program and Quality Payment Program can apply for hardship exceptions if there are circumstances out of their control that make it challenging to meet program requirements. For example, a health system switching vendors for their EHR system may experience a delay in obtaining critical information for reporting and might need to request a hardship exception while the new EHR is implemented.

Similar circumstances may make it challenging for a hospital or provider to comply with information sharing requirements. **Trinity Health recommends HHS align exceptions and hardships so that an approved hardship application be allowed to protect a hospital or provider from incurring a downward payment adjustment, regardless of information blocking determination.**

*Targeted Concerns for ACOs*
ACOs found to have been participating in information blocking by the OIG will be removed from MSSP for at least one year. We are concerned that, as drafted, the rule would reduce the number of providers participating in risk-bearing arrangements, which could impede progress for delivering care based on outcomes rather than volume. In addition, the ACOs themselves would not be the entity involved in information blocking; the proposed penalty is, therefore,

inappropriate. **Trinity Health urges HHS not to implement penalties that penalize participation in value-based care models, as these are meant to improve care for patients.** ACOs cannot manage providers if they are removed from the ACO, so the rule has potential to disrupt patient care and safety. **CMS should instead partner with ACOs to identify instances of information blocking and help flag instances for ACOs to remediate.**
The proposed rule doesn't address the complexities involved with suspending a provider's ACO participation. For example, what happens to patients who are attributed to that provider and who will bear responsibility for their care? How would a provider operationally be removed from MSSP? Such clarity is critical for stakeholders. There are also complexities that would render implementation of these policies challenging. These include the double penalties applied to clinicians via the MIPS PI as well as MSSP. Given the way MSSP is structured, there would be no way for HHS to prohibit an individual's participation and, therefore, would need to exclude a full TIN, which is overly punitive.

Many EHRS are in use across large ACOs. For example, Trinity Health ACOs works with about 120 EHRs. Each EHR functions differently and, without the proposed rule providing more detailed examples of what the OIG would deem to be information blocking, ensuring the functionality is in place for all of the different instances of EHRs to prevent information blocking is challenging.

OIG Investigative Process and Limited Appeals Process

It is critical HHS outline in more detail the review process. As proposed, OIG would make a determination of information blocking and refer to CMS. **We recommend OIG investigate instances of information blocking but turn the action over to the ONC or CMS to make the determination. Further, we recommend OIG priorities, as they relate to investigations into complaints of providers who have committed information blocking, focus on 'intent' versus 'outcome' – particularly given that if the practice (information blocking) is conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI. Thus, we recommend prioritizing on themes of intent. For example, actions that discourage competition among providers, prevent a patient from accessing care or health data they may need to make care decisions independently, etc.**

Although the proposed rule discusses OIG's enforcement priorities for health care providers, it largely omits discussion of the underlying investigative process, including whether the OIG's process will similarly include an opportunity for health care providers to discuss or challenge an OIG investigation and to explain why its conduct either did not implicate the information blocking prohibition, met an exception, or was otherwise lawful. **Such an appeals process should be aligned with the information blocking final rule for developers/vendors, who have appeal rights to the OIG after the agency makes a determination of information blocking. We urge HHS to clearly detail an equitable appeals process for providers and obtain feedback from stakeholders prior to finalizing the rule.**

Conclusion

Trinity Health is 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.  Trinity Health looks forward to working with you to advance patient access and exchange of health information.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health