December 18, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C., 20201

Submitted electronically via www.regulations.gov

RE: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking [Docket No. RIN 0955–AA05]

Dear Secretary Becerra:

Premier Inc. appreciates the opportunity to submit comments on the Department of Health and Human Services (HHS) notice with request for comments titled "*21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking,"* which was published in the Nov. 1, 2023 Federal Register. The proposed rule would establish disincentives for healthcare providers participating in the Medicare Promoting Interoperability Programs (MIPS) or in the Medicare Shared Savings Program (MSSP) that are found to have committed information blocking. The proposed disincentives in this rulemaking would not apply to all healthcare providers included in the Public Health Service Act (PHSA) definition; rather, the disincentives would apply to those healthcare providers participating in the relevant Medicare programs.

Premier strongly supports the goals of the proposed rule to deter information blocking and further the appropriate sharing of electronic health information (EHI) to improve care coordination and support safer and better care. Premier is seriously concerned, however, that the proposed disincentive for providers participating in the MSSP program imparts an extreme penalty in the form of banishment from the MSSP program for at least one year following the investigation decision. In addition, the rule focuses on the punishment of healthcare providers, without commensurate discussion of education or technical assistance. While Premier believes penalties are reasonable for willful violators, we consider that an approach that emphasizes education and technical assistance first before resorting to penalties is likely to result in better outcomes. This is particularly the case as the information blocking regulation is still relatively new and untested, and there are still many situations where providers would benefit from additional guidance.

Premier has outlined these specific concerns and suggested alternatives in further detail below.

I. BACKGROUND ON PREMIER INC

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 2.7 billion hospital outpatient and clinic encounters, and 177 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in

product sourcing and contracting and assure access to the highest quality products. Premier runs the largest population health collaborative in the country, the Population Health Management Collaborative, which has worked with well over 200 Accountable Care Organizations (ACO) and is currently comprised of more than 70 ACOs.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

I. EFFECT ON MOVEMENT TO APMS

The Centers for Medicare & Medicaid Services (CMS) has continuously affirmed the importance of accountable care to achieving its goals of advancing health equity, supporting high-quality, person-centered care and promoting affordability and sustainability in Medicare. Premier supports this move to accountable care and has worked diligently with our members through our Population Health Management Collaborative, which has worked with well over 200 ACOs since its inception. Given this premise and the fact that CMS has set a goal of having 100 percent of people with traditional Medicare in accountable care relationships with providers who are responsible for the quality and total costs of their care by 2030, Premier is at a loss to understand why a disincentive has been crafted that would create a chilling effect upon future ACO participation in the MSSP program.

Under the proposal, a healthcare provider that the Office of Inspector General (OIG) determines has committed information blocking may not participate in the MSSP for at least one year. This arbitrary penalty does not address the underlying reasons for any actions that have been deemed to constitute information blocking nor does it provide a path forward to alter any such actions that have led to a guilty finding. If the aim is to deter providers from blocking the sharing of important information, it will be key to provide clear and consistent guidance and future opportunities to remediate any unsuitable actions instead of issuing a penalty that will literally prevent the greater sharing of information that is part of the ACO structure. ***Premier urges HHS to remove this MSSP disincentive and work with stakeholders to create a disincentive framework that provides educational and technical assistance first and then appropriate penalties if corrective action is not taken.***

II. INVESTIGATION CLARITY

This negative effect on the movement to accountable care would be exacerbated by the lack of sufficient detail regarding the investigation process. While Premier appreciates that healthcare providers will be held to a “knowledge” standard which would require that healthcare providers must know that their alleged information blocking practice is likely to interfere with access, exchange or use of EHI to be found in violation, it remains to be seen how “knowledge” will be defined in these cases, leading to uncertainty and concern.

In connection with OIG’s final rule, OIG provided guidance describing its planned investigative process for entities subject to information blocking civil monetary penalties (CMP); however, OIG stated in its final rule that its guidance of its anticipated enforcement priorities and investigative process was limited to those entities subject to CMPs, and not applicable to healthcare providers that may be referred for appropriate disincentives. Although the proposed rule discusses OIG’s enforcement priorities for healthcare providers, it does not provide sufficient detail regarding the underlying investigative process, including whether OIG’s process will similarly include an opportunity for healthcare providers to discuss an OIG investigation and explain why their conduct was determined to be noncompliant. This is notable given the absence in the proposed rule of any appeal mechanism by which healthcare providers could challenge OIG’s information

blocking determination.

Premier is concerned about the proposed rule's omission regarding how the OIG would engage with the healthcare provider to perform a reasonable investigation and what, if any, reasonable opportunities healthcare providers would have to appeal before penalties were implemented. ***Premier urges HHS to issue clear, definitive guidance on the investigation process, how the knowledge standard will be interpreted and what opportunities exist for appeal.***

III. PUBLIC POSTING

Premier is also concerned about the proposal to list the names of actors determined to have engaged in information blocking on ONC's public website. This provision will do little to advance transparency regarding the impact of information blocking on the nationwide health information technology (HIT) infrastructure but will result in public shaming of actors who have already been penalized for their conduct. Public repudiation for a possible inadvertent act could have severe unintended consequences especially since, as we state above, there is also a great deal of unease with a provision that publicly posts bad actors without a clear, detailed path regarding the investigation and appeal process.

An efficacious alternative could include issuing a warning after an investigation finds concerning practices with some type of remediation process before escalating to a severe penalty such as is currently included in this rule.

IV. GRACE PERIOD

Premier wants to ensure that HHS fosters an environment of collaboration and education for information blocking, rather than one of enforcement. To help achieve that situation, in addition to our suggestions above, Premier recommends that any guidance, FAQs, or other materials that change or illuminate HHS's interpretation of information blocking disincentives carry with it a minimum of a twelve-month grace period on enforcement. This will provide healthcare providers sufficient time to ensure that they have a clear understanding of what constitutes a violation of information blocking and to institute appropriate structures that focus on information sharing that lead to improvements in care delivery.

V. CONCLUSION

In closing, Premier appreciates the opportunity to share recommendations and considerations as HHS develops the information blocking disincentives and Premier looks forward to working with the HHS and other stakeholders to craft future disincentive frameworks.

If you have any questions regarding our comments or need more information, please contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.