January 2, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Micky Tripathi
National Coordinator for Health IT
Office of the National Coordinator
200 Independence Ave NW
Washington, DC 20201

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

Dear Administrator Brooks-LaSure and National Coordinator Tripathi:

The Health Care Transformation Task Force ("HCTTF" or "Task Force") appreciates the opportunity to comment on Proposed Rule on the Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking ("Proposed Rule").

The Task Force is a consortium that supports accelerating the pace of transforming the delivery system into one that better incentivizes and pays for value-based care. Representing a diverse set of organizations from various segments of the industry – including providers, payers, purchasers, and patient advocacy organizations – we share a common commitment to transform our respective businesses and clinical models to deliver better health and better care at reduced cost. We strive to provide a critical mass of policy, operational, and technical support that, when combined with the work being done by Centers for Medicare and Medicaid Services' ("CMS") and other public and private stakeholders, can increase the momentum of delivery system transformation.

The Task Force is committed to advancing interoperability to facilitate more effective and efficient data sharing, to help consumers easily and securely access their electronic health data, direct it to any desired clinician or health care organization, and to be assured that their health information will be used effectively and safely to advance their health. All of these objectives are fully aligned with the Task Force members' interest in advancing value-based care and supporting payment models. CMS's and the Office of National Coordinator's ("ONC") joint responsibility in administering the disincentives for information blocking is important. We agree that close coordination is necessary to ensure appropriate policy lines are drawn to mitigate violations, while also ensuring that information sharing is effective and efficient.

As a general comment, any final rule should more appropriately focus on truly disincentivizing providers from information blocking, rather that penalizing providers as the Proposed Rule would do. The 21st Cures Act requires the Secretary of Health and Human Services to establish disincentives for providers that are found by the Office of Inspector General ("OIG") to have engaged in information blocking. The choice of the word disincentives is purposeful and should be adhered to. To disincentivize means the act of creating a disincentive or withdrawing a previously existing incentive. In contrast, the Proposed Rule creates penalties that impose significant punishments on providers found to have engaged in information blocking.

In this way, the Task Force believes the proposed policies go well beyond what Congress intended and may even run afoul of Supreme Court precedent on the major question doctrine, under which a court should defer to Congress and not executive agencies on matters where it perceives there to be significant impacts and outcomes if it believes Congress did not explicitly grant that power to the agency. (*See West Virginia et al v Environmental Protection Agency*, 597 U.S. ___ (2022).

The term "provider" as used in this letter is inclusive of providers, clinicians and Accountable Care Organizations ("ACOs").

I. Education is Critical to Disincentivizing Provider Information Blocking

The Task Force believes that appropriate disincentives begin with the need for educating providers on what it means to block the transfer of information. **The Task Force strongly urges the ONC and CMS to engage in an education campaign aimed at the provider community about what activities constitute information blocking and are likely to lead to OIG referrals.**

The OIG's policies regarding information blocking apply to health IT developers and vendors and are not sufficiently informative to address provider activities. A clearer picture about problematic information blocking activities by providers should be foundational to any disincentive scheme: the problems should be clearly defined before disincentives are applied.

II. Providers Should Be Able to Contest Information Blocking Determinations

The process established by the 21st Century Cures Act directs the OIG to refer determinations of provider information blocking to CMS and ONC. However, providers should have a due process right to contest the information blocking determination, especially before any onerous penalties are imposed (such as those contained in the Proposed Rule). The approach outlined in the Proposed Rule is antithetical to many other Medicare program policies where providers are given appeal rights to contest adverse determinations.

The Task Force strongly recommends that CMS and ONC establish an appeals process for providers to contest information blocking determinations that is like the process afforded health IT developers and vendors by the OIG. It seems at least inconsistent and potentially arbitrary and capricious to provide one set of stakeholders with appeal rights while denying providers a similar avenue for due process. Under any circumstance, a provider or clinician should be able to request reconsideration of the initial determination, even if that redetermination should be considered by the OIG instead of CMS and/or ONC.

III. Information Blocking Disincentives Should Be Scalable, Beginning with Corrective Action Plans

The Task Force's major concern with the Proposed Rule is the significant penalties that may be imposed for provider information blocking activities. A fair reading of the Proposed Rule is that the proposed sanctions of payment reductions on provider organizations and clinicians—or even disbarment for ACOs—would be applied in response to a first violation. **The Task Force strongly believes this approach is unreasonable.**

The Task Force believes at the very least that an effective disincentive policy should be scalable. In lieu of sanctions for a first offense, providers who have committed clear information blocking activities should be required to submit corrective action plans as an appropriate disincentive for future conduct. Preparing a corrective action plan will necessitate that a provider assesses its own policies and procedures and makes improvements to mitigate the possibility of future violations. This approach allows for a collaborative approach to improving operations over the Proposed Rule's overly punitive policies.

It may be that more significant sanctions should apply to provider organizations or clinicians that engage in patterns or practices of information blocking and are knowingly doing so. **As necessary, the Task Force urges CMS and ONC to engage in further rulemaking to better define the limited circumstances in which the Proposed Rule's penalties would be properly applied and how sanctions beyond disincentives for those circumstances are supported by the governing statute.**

IV. The Proposed Policy for ACOs Should Be Withdrawn

Even under a scalable disincentive policy**, the proposed disbarment or denial of participation of ACOs from the Medicare Shared Savings Program ("MSSP") should be withdrawn.** Under the proposal, provider organizations or clinicians within an ACO that are found to have engaged in information blocking are subject to payment reductions under various Medicare payment programs while the ACO itself may also be subject to termination from MSSP for at least one year or a denial of initial participation. The extra penalty imposed on the ACO is excessive, both because it constitutes a double penalty as well as the severity of the sanction of denying program participation based on a specific violation. **Given that individual provider organizations and clinicians are subject to enforcement, the Task Force urges CMS and ONC to withdraw their proposed policies regarding terminating ACO participation as an appropriate double penalty. At the very least, this double penalty seems clearly at odds with the governing statute passed by Congress such that it may be found illegal upon judicial review under the major question doctrine precedent referred to above.**

The Task Force is surprised that ONC and CMS would propose a policy that would harm beneficiaries by disrupting the advanced services and care coordination that ACOs provide, which is not supported by traditional fee-for-service. ACOs invest in care delivery strategies that innovate for better patient health at the individual practice level and even the individual clinician level. Denying or terminating participation of an ACO based on a single information blocking violation would harm many beneficiaries by removing the incentive and financial alignment to provide this holistic, patient-centered care. **The bottom-line is that Medicare beneficiaries benefiting from the care ACOs provide could be denied access to those benefits without an opportunity to provide input on decisions which impact them. This result is tantamount to**

punishing Medicare beneficiaries without recourse. On this basis alone, the Task Force believes this proposal should be withdrawn.

If this proposal were to move forward, the Task Force asks ONC and CMS to clarify the impact of a clinician's information blocking violation on their group practice and the ACO in which the group practice participates. For example, if a clinician in a group practice with a single tax identification number ("TIN") is found to violate the information blocking prohibition, does that mean the violation could be the basis for sanctioning the ACO in which that group practice participates? What about if the ACO includes as participants other group practices with separate TINs? The Task Force believes at the very least that while the conduct of one clinician may impact their group practice, it should not affect an ACO that operates with multiple group practices with separate TINs. Instead, the impact of the violation should be narrowly tailored so as not to harm all beneficiaries served by that multi-TIN ACO.

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The Task Force appreciated the opportunity to comment on the Proposed Rule. Should you have questions about our letter or desire additional information, please contact Task Force Executive Director Jeff Micklos at jeff.micklos@hcttf.org.

Regards,

Eric Fennel
Vice President, Network Strategy and Value-Based Solutions
Aetna, A CVS Health Company

Claire Mulhearn
Chief Communications & Public Affairs Officer
agilon health

Sean Cavanaugh
Chief Policy Officer
Aledade, Inc.

Stephanie Quinn
Executive Senior Vice President, Advocacy, Practice Advancement and Policy
American Academy of Family Physicians

Patrick Holland
Chief Financial Officer
Atrius Health

Ashley Yeats, MD
Vice President of Medical Operations
Blue Cross Blue Shield of Massachusetts

Todd Van Tol
Executive Vice President, Health Care Value
Blue Cross Blue Shield of Michigan

Troy Smith
Vice President of Healthcare Strategy & Payment Transformation
Blue Cross Blue Shield of North Carolina

Laura Fox
Director, Payment Innovation
Blue Shield of California

Zak Ramadan-Jradi
Vice President, Network Management
Cambia Health Solutions

Stephanie Finch
Senior Solutions Lead
Clarify Health

Wesley Wolfe
Executive Director, Market and Network Services
Cleveland Clinic

Emily Stewart
Executive Director
Community Catalyst

Amy Kaszak
Executive Vice President of Strategic Initiatives
Curana Health

Mark McClellan, MD, PhD
Director
Duke Margolis Center for Health Policy

Angelica Jewett
Vice President, Value Based Solutions
Elevance Health

Ashley Ridlon
Vice President, Health Policy
Evolent Health

Frederick Isasi
Executive Director
Families USA

Richard Lipeles
Chief Operating Officer
Heritage Provider Network

Andy Marino
Senior Vice President, Plan Networks
Honest Medical Group

David Nace
Chief Medical Officer
Innovaccer

Anthony Barrueta
Senior Vice President, Government Relations
Kaiser Permanente

Ryan Anderson, MD
Vice President, Clinical Care Transformation
MedStar Health

Sinsi Hernández-Cancio
Vice President for Health Justice
National Partnership for Women & Families

Alan Balch
CEO
National Patient Advocate Foundation

Joy Burkhard
Executive Director
Policy Center for Maternal Mental Health

Seth Edwards
Vice President, Population Health and Value-based Care
Premier

Melanie Matthews
CEO
PSW

Srin Vishwanath
CEO
OPN Healthcare

Jordan Asher, MD, MS
Executive Vice President, Chief Clinical Officer
Sentara Health

Signify Health

Jim Sinkoff
Deputy Executive Officer and Chief Financial Officer
Sun River Health

Emily Brower
SVP Clinical Integration & Physician Services
Trinity Health

Garon Meikle
Chief Financial Officer
UAW Retiree Medical Benefits Trust

Judy Zerzan-Thul, MD
Chief Medical Officer
Washington State Heath Care Authority