CIVITAS
Networks for Health

January 2, 2023

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
ATTN: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

RE: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule (RIN 0955-AA05)

Dear Secretary Beccera and National Coordinator Tripathi:

Civitas Networks for Health (Civitas) appreciates the opportunity to provide feedback on the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule. Civitas is a national nonprofit collaborative comprised of more than 170 member organizations—health information exchanges (HIEs), regional health improvement collaboratives (RHICs), and business, technology, and services partners—using data and multistakeholder, cross-sector approaches to improve health for individuals and communities. We educate, promote, and influence both the private sector and policymakers on matters of interoperability, quality, coordination, and cost-effectiveness within the health system, while also supporting multi-site, grant-funded projects around the country.

Civitas members have become leaders in the development of a new paradigm known as the Health Data Utility Model (HDU). The HDUs emerging around the country represent an evolution in the structure of health information networks and value-added capabilities, combining the multi-directional data transmission infrastructure of incumbent statewide and regional HIEs with a wider array of quality improvement, analytics, community health and social service functions that in many places have been advanced by RHICs and related quality improvement organizations of varying sizes. The resulting nonprofit organizations—or partnerships of nonprofit organizations—comprising an HDU take advantage of scaling efficiencies across well-defined geographies to better serve their communities as secure information networks as well as platforms for the integration of new technologies. HDUs' multi-stakeholder governance arrangements position them as public assets and neutral system arbiters vis-à-vis private technology vendors, while distinct service areas enable them to achieve greater degrees of financial self-sufficiency through payer and provider fee schedules to supplement public contracts and formula dollars.

The success of the emerging HDU model to date is a credit to health stakeholders on all levels who recognize the benefits of participation, which in practice means willingness to share data in standardized formats or in accordance with various data use agreement protocols that enable the information to be integrated into the HDU and put to use. This willingness is not unusual once hospitals, doctors, insurers, public health authorities, and social service agencies understand the benefits (and Civitas' members commitment to security and privacy); however it is far from

universal, and given the ever-shifting dynamics of the health ecosystem it is always subject to cross-pressures and conflicting incentives. Despite ONC's progress toward realizing the information blocking provisions of the 21st Century Cures Act (42 U.S.C. 300jj-52)—notably, the 2020 Cures Act Final Rule (45 C.F.R. Part 171) and the Civil Monetary Penalties Final Rule (42 C.F.R. Parts 1003 and 1005) earlier this year enabling enforcement against health IT developers, health information networks (HINs), and HIEs—information blocking persists on a large scale. According to the findings of ONC's 2023 Health Information Organization (HIO) National Survey conducted by the UCSF's Division of Clinical Informatics and Improvement Research (CLIIR) in partnership with Civitas, 30% of HIO respondents (the vast majority of them Civitas members) have "routinely" or "sometimes" experienced information blocking over the past year. Respondents attributed 42% of this regular blocking to health systems, which resulted in the HIEs "missing information or difficulty providing services" an alarming 45% of the time.

Faced with this ongoing threat to the integrity of HIE and emerging HDU systems (and by extension, to the efficiency and quality of patient care), Civitas strongly supports the Proposed Rule establishing disincentives pursuant to the Cures Act for health care providers which HHS-OIG determines have committed information blocking. As described at length in the proposals, these disincentives exercise three existing Medicare statutory authorities held by CMS. Two of the three authorities involve "meaningful EHR user" determinations under the Promoting Interoperability Program for hospitals and CAHs (sections 1886(n)(3)(A) and 1886(b)(2)(B)(ix) of the Social Security Act) and the Promoting Interoperability category of the Merit-Based Incentive Payment System, or MIPS, within the Quality Payment Program (sections 1848(o) and 1848q of the SSA). The third authority uses conditions of the Shared Savings Program (section 1899(b)(2)(G)) that allow CMS to bar providers (including health systems functioning as Accountable Care Organizations) from participation due to "program integrity issues" and failure to comply with Shared Savings Program requirements, which would be amended to explicitly reference information blocking. HHS estimates that these measures would cost the median hospital violator $394,353 per payment year; the median MIPS-eligible clinician $686 and group practice $4,116; and the typical ACO participant (or health system ACO) any SSP-related revenue during the disincentive period.

Civitas' principal comment on the proposals in RIN 0955-AA05 is that they are not sufficient to address the gravity of the issue, given the continued pervasiveness of information blocking and the imperative to address it as comprehensively as possible if ONC's vision of wide-reaching interoperability and patient access is to be realized. Within just the specific "meaningful EHR use" categories of providers and Medicare program authorities covered under the Proposed Rule (namely, hospitals and Critical Access Hospitals via Promoting Interoperability and MIPS-eligible clinicians), the proposals' self-imposed limitations on the frequency of potential disincentive penalties are counterproductive. The reimbursement rates for acute care hospitals and CAHs in question would only be "downward adjusted" for lack of meaningful use as a consequence of information blocking once per EHR reporting period per calendar year, regardless of how many instances of information blocking HHS-OIG actually documents during that period. Similarly, MIPS clinicians and practice groups could commit multiple violations within the scope of an OIG determination and referral to CMS for a single performance period during one calendar year and would only suffer a single MIPS scoring penalty for that year.

The structure of these disincentives as written would seem to suggest that HHS regards most information blocking as one-off mistakes or isolated incidents removed from providers' decision-making, rather than deliberate and systematic attempts to limit access to otherwise shareable data. ONC's own HIO National survey results attest to this reality for HIEs, 45% of whom reported that health care providers are engaged in blocking as a policy choice through "strategic affiliations" with other health systems, and 25% of whom said that providers use transparently "artificial" technical or process barriers to put off exchange and undermine interoperability. Another 40% of survey respondents described outright "refusals to exchange patient information." The Proposed Rule's intention to effectively cap disincentive applications to single instances within the relevant reporting and payment windows without carrying forward penalties for serial violations may not meaningfully affect the calculations of the worst violators.

The larger problem with HHS' disincentive proposals concerns the limitations on the types of health care providers to be disincentivized. The Department explicitly states in the Proposed Rule that "we believe optimal deterrence of information blocking calls for imposing appropriate disincentives on all health care providers," and interprets "appropriate disincentives" in the text of the Cures Act to mean any exercise of existing agency authority over "health care providers" as defined in the 2020 Cures Act Final Rule. Yet as written, the proposals capture only short-term acute care hospitals and critical access hospitals subject to Medicare Promoting Interoperability; the MIPS-eligible categories of clinicians and clinician-groups, and ACO health system-provider participants in the Shared Savings Program. These actors comprise a critical mass of the health system, but they do not represent a monopoly on either health care delivery and patient services or clinically and epidemiologically relevant health data. The Cures Act Final Rule definition of "health care provider" based on 42 U.S.C. 300jj(3) also includes federally-qualified health centers and community health centers (FQHCs/CHCs), skilled nursing facilities, long-term care facilities, pharmacies, and laboratories—all of which are key exchange partners for health data utilities around the country, and vitally important for HDUs' core value proposition as comprehensive, accountable hubs for patient records and data applications in their service areas.

Pharmacies and commercial laboratories are particularly relevant in this context, given how nearly a third of HIEs in the HIO National Survey reported that these providers are responsible for a large share of "routine" information blocking encountered outside hospitals and physician groups. Prescription and diagnostic lab data is integral to patient medical records and to the wider matrix of epidemiology, population health, and financial information, which is why Civitas HIEs and emerging HDUs have made great efforts to expand connectivity for pharmacy and lab use cases, including statewide "universal PDMPs." ONC has likewise made improving pharmacy interoperability and the integration of e-prescribing into exchange networks an agency priority, commissioning a task force through its Health Information Technology Advisory Committee (HITAC) in 2023 that recommended an increased focus on bi-directional messaging capabilities to link pharmacies with clinicians and public health authorities (among other measures).

Leveraging wider HHS and CMS authorities to establish additional "appropriate disincentives" that target pharmacies and commercial labs would be an effective means of advancing the Department's interoperability and deterrence goals—and the program architecture required to do so already exists. Over 64,000 pharmacies nationally participate in Medicare Part C and Part D networks (Medicare Advantage and prescription drug plans), while over 48,000 pharmacies and

3,900 independent clinical laboratories nationwide were enrolled in Medicare Part B as non-institutional providers in 2021, the last year of CMS statistics available. Since finalizing a series of Medicare policy and technical reforms in 2018 (CMS-4182-F), CMS has exercised its broad authority to set, administer and refine Part C and Part D contract terms under SSA sections 1860(D)-12(b)(3)(D), 1871, and 1102 to institute a "preclusion list" system for revoking prescriber and provider participation in the program. Using the list, CMS can and does act proactively to ban Medicare Advantage sponsors of Part C plans from paying pharmacies and pharmacists for "conduct detrimental to the best interests of the Medicare program."

At the agency's discretion, such conduct has included billing fraud, the use of false or misleading information in official communications, nonpayment of existing Medicare debts, and felony convictions; there is no obvious reason that CMS cannot consider pharmacy information blocking as a condition for preclusion or add it to the list under 42. C.F.R. section 422.2 via rulemaking. Likewise, CMS could choose to "go bigger" and cast a wider enforcement net over all pharmacies in Part D networks; clinical labs reimbursed alongside outpatient providers under Part B; and other program participants by amending the overall Medicare revocation and enrollment denial criteria under 42 C.F.R. section 424.535 to make information blocking defined in 45 C.F.R. Part 171 one of the explicit "reasons for revocation." These criteria and the associated "reenrollment bar" regulations (which prevent revoked providers from participating in Medicare again for 1-10 years, per agency determination) are substantively amended on a regular basis through the annual Physician Fee Schedule and other updates. As recently as July 2023, CMS proposed and subsequently finalized as part of its 2024 PFS (CMS-1784-F) new discretionary authority to cite civil judgements against providers under the False Claim Act as "reasons for revocation," as well as a wholly new 60-day "stay of enrollment" status for providers who are non-compliant with at least one section 424.535 regulation, but who the agency feels have sufficient short-term corrective potential.

ONC and CMS have collaborated in the past on unified approaches to implement interoperability policy and regulatory changes, and an issue as detrimental to health and health care system outcomes as information blocking deserves no less.

Thank you again for the opportunity to comment. Please do not hesitate to reach out to Civitas if we can be a resource as we work together to achieve a community-governed, interoperable health data system to improve health and healthcare outcomes.

Sincerely,

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