CIVITAS
Networks for Health

August 2, 2024

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
2313 Rayburn House Office Building
Washington, DC 20515

Re: Stakeholder Input on Cures 2.0 (*Submitted electronically at cures.rfi@mail.house.gov*)

Dear Representatives DeGette and Bucshon:

Civitas Networks for Health (Civitas) appreciates your request for information (RFI) and the opportunity to provide input on the development of a new version of your Cures 2.0 legislation. We are grateful for the work you did to pass the original 21st Century Cures Act in 2016, and we are excited about your continued interest in developing innovative and improved policies to further advance the progress that health data capabilities and governance have made over the past eight years across the country for the benefit of patients, providers, and public health.

Civitas is a national nonprofit collaborative comprised of more than 175 member organizations—health information exchanges (HIEs), regional health improvement collaboratives (RHICs), and providers of services to meet their needs—working to use data frameworks, information infrastructure, and multi-stakeholder, 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 programs and projects around the country.

We are pleased to provide general discussion points addressing several key issues which have emerged since the original Cures Act and its landmark Title IV provisions on the delivery of health information, and which were not part of the 2021 Cures 2.0 bill and successor proposals. The Cures 2.0 proposal drove important reforms to federal biomedical research and pandemic preparedness but did not seek to revisit much of Cures' health IT jurisdiction. The rapid evolution and proliferation of digital health networks alongside extensive federal rulemaking to build out the 2016 Cures framework represents a unique and consequential opportunity for Congress to do so. At a time when the new post-*Chevron* regulatory environment has placed a premium on legislative review, the next iteration of Cures can be a vehicle to reinforce Congress' priorities in the health IT space and improve the effectiveness of enacted policies through the following measures:

***Information Blocking* –** Within Title IV of the 21st Century Cures Act, section 4004 created the first federal statutory definition of information blocking: "a practice that, except as required by law or specified by the Secretary pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information." The legislative text specifies the broad conditions and types of actions, subject to regulations, under which health IT developers, exchanges, networks and providers commit information blocking, and gives the Department of Health and Human Services (HHS) the power to investigate violators and impose penalties. The enforcement clauses that authorize the Department to impose fines (for developers, networks, and exchanges) and "disincentives" (for individual or grouped providers)

allow for significant discretion based on the extent of the information blocking violation and the scale of the resulting harm. Regulators at the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) began implementing section 4004 with the Cures Act Proposed Rule, finalized it in 2020 (45 CFR 170-171) and have since made major updates to its information blocking "exception" provisions and other Title IV components through the HTI-1 Final Rule and the recent HTI-2 Proposed Rule. ASTP/ONC and HHS Office of Inspector General (OIG) have also finalized the Information Blocking Civil Monetary Penalties Rule (42 CFR 1003 & 1005) as well as the Establishment of Disincentives Rule (42 CFR 171, 414, 425, & 495) in concert with the Centers for Medicare & Medicaid (CMS), which went into effect on July 31. These and related regulations represent an extraordinary volume of codification on a new subject in a short period of time, and Civitas appreciates HHS' work as essential to articulating the theory of information blocking established by the Cures Act and making it functional law to improve health data transmission in communities, regions, and states.

However, we can attest—because our members are the health information organizations on the ground effecting the transmission—that a few revisions are needed in order to ensure that rates of information blocking are reduced as effectively as possible, especially in certain sectors where the practice is most frequent (and does the most harm to patient care). Providers that are health systems, pharmacies, and commercial laboratories account for a large majority of the blocking encountered by Civitas members, and the practices they employ are deliberate, routine, and systematic (such as leaning on strategic affiliations with other health systems to slow sharing with other actors, throwing up artificial technical barriers, and outright refusals to share information) rather than isolated incidents or one-off mistakes. Though the Establishment of Disincentives Rule is newly in force, we are concerned that its use of HHS authorities will prove too limited to serve as a deterrent commensurate with the scale of the problem, which last year resulted in HIEs missing patient information or otherwise having service difficulties an alarming 45% of the time according to ASTP/ONC's own National Health Information Organization (HIO) survey.

For enforcement to have real teeth, it must effectively account for repeat violations. Hospitals, Critical Access Hospitals (CAHs), and large clinician groups which are found to have engaged in information blocking after the requisite HHS-OIG investigation should have their scores in their respective Medicare electronic health record (EHR) meaningful use programs downward-adjusted in such a way as to account for multiple violations within a calendar year, rather than a single Promoting Interoperability (PI) Program or Merit-based Incentive Payment System (MIPS) penalty regardless of the number of documented blocking incidents. Just as importantly (if not more) for curbing the frequency of blocking along the full length of the care delivery pipeline, HHS should leverage the significant Medicare program authorities at its disposal to create disincentives that target pharmacies and commercial labs, including through the terms of Medicare Advantage (MA) plan contracts. The recent HTI-2 Proposed Rule clarifies that both types of providers are in fact "health care providers" under the Cures Act Final Rule; yet without tailored enforcement mechanisms this recognition can have little effect. HHS is reportedly considering new rounds of disincentive rulemaking soon, and while we look forward to working with the agencies on these efforts, we feel that a future iteration of Cures 2.0 offers an opportunity for legislators to consider bringing more directness to the section 4004 disincentive provisions.

TEFCA—Arguably no piece of Cures Act Title IV represents a more significant long-term exercise of federal power in the health information space than the "Trusted Exchange Framework and Common Agreement" (TEFCA) pursuant to section 4003. The section defines "interoperability" as that which enables the secure and lawful exchange of electronic health information between different health information technology (health IT) systems "without special effort on the part of the user," and then proceeds to outline the development of "a trusted exchange framework, including a common agreement among health information networks nationally" under ASTP/ONC's direction as the primary vehicle for realizing interoperable network exchange. In the years since Cures' enactment (and especially since 2021), the agency and its "recognized coordinating entity" (RCE) contractor have made major strides toward developing the foundations of TEFCA as a set of baseline capabilities for different health data sharing scenarios, organized around a group of ASTP/ONC-approved "Qualified Health Information Network" (QHIN) entities as the primary entry points and arbiters of the TEFCA system extrapolated from section 4003 legislative language. The first parts of TEFCA's QHIN-mediated exchange functionality went live in December 2023, and ASTP/ONC has continued to produce operational and technical content designed to expand its breadth and depth, including the *Common Agreement 2.0* in April and the *Treatment Exchange Purpose Standard Operating Procedure* in July of this year.

Civitas and many of our members have engaged extensively with ASTP/ONC leaders on TEFCA, and a few Civitas members have been deeply involved in QHIN development. We are excited by TEFCA's potential to meaningfully streamline certain aspects of health data exchange and raise the bar for technical standardization and baseline levels of interoperability nationwide. However, the technical baselines in question—such as facilitated Fast Healthcare Interoperability (FHIR) capabilities—have long since been met by Civitas HIEs themselves, while technical complications for data transmission have emerged from "live" TEFCA that HIEs must invest their uncompensated time and resources to manage. These include problematic instances of "data duplication" caused by queries from HIE participants who are also QHIN participants, as well as the patient identity resolution challenge of QHINs defaulting to the master patient indices (MPIs) of multiple HIEs at once (requiring additional HIE "filtration" of QHIN queries by geography). ASTP/ONC and its RCE are attempting to fix these glitches at the same time as they assemble blueprints for new TEFCA services that Civitas members already provide in their state and regional service areas, leading to confusion among stakeholders and duplication of effort.

TEFCA is a voluntary framework consistent with the section 4003 authorization that "nothing…shall be construed to require a health information network to adopt the trusted exchange framework or common agreement" and that it "shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks." Yet in the period since TEFCA went live, ASTP/ONC has begun moving toward an apparent exception in the statute which allows that "federal agencies contracting or entering into agreements with health information exchange networks…may require the adoption" of TEFCA. In practice, the agency does not need to go as far as specific HIE contracts. Its efforts to reportedly push TEFCA as a condition of participation in programs at CMS and the Centers for Disease Control and Prevention (CDC) for providers and public entities risk creating a *de facto* federal "TEFCA mandate" for large segments of the health data pipeline before the system is ready, and contrary to Congress' intent. The prospect of "Cures 2.0" legislation is a chance for lawmakers to explore resetting the balance

between TEFCA and established non-federal health information sharing infrastructure by clarifying the extent of HHS' authority to require TEFCA, and by focusing the collective efforts of all stakeholders on the system's most productive applications, such as public health authority connectivity.

Patient Matching—In drafting Title IV of the Cures Act, Congress recognized that low patient match rates—the ability of health system actors exchanging data to accurately and reliability collate information on the same person from different electronic health records—were a critical weakness that threatened the viability of the entire digital health enterprise. Accordingly, section 4007 required the Government Accountability Office (GAO) to conduct a survey of "current methods used for patient matching based on performance"; review the status of matching "policy and activity" at ASTP/ONC; and solicit recommendations from a wide array of non-federal stakeholders. GAO spent two years collecting input from standards development organizations, HIEs, HIT developers, quality improvement experts, healthcare providers, and state public health authorities attesting to the importance of best practices around data "hygiene," administrative process improvements and purpose-adapted digital tools. The resulting report (*Health Information Technology: Approaches and Challenges to Electronically Matching Patients Records Across Providers)* was delivered to Congress in 2019, and floated ideas such as a national patient identifier and federally standardized data sets (particularly for demographic data) alongside ASTP/ONC's public-private interoperability fora which were part of its preliminary work on TEFCA.

More than five years later, substantial progress toward more comprehensive and capable health information sharing frameworks has not solved the patient matching problem. Mismatched patient data still accounts for an estimated one-third of all rejected insurance claims, costing the healthcare system $6 billion annually and the average hospital $1.5 million, according to an industry survey. As it was in 2019, HHS remains barred from spending any federal money on a "national patient identifier" by Section 510 of the annual Labor-HHS appropriations bill, despite bipartisan attempts to repeal the language in question (and notwithstanding the sound logistical arguments against creating the identifier). TEFCA has evolved into its own system intended to facilitate health information exchange across use cases on top of existing infrastructure but does not address the patient matching issue.

The best solution still at hand is leveraging federal expertise and industry partnerships to develop standardized data sets for "accurate and precise patient matching to track patient match rates and document improvement over time," as envisioned by the bipartisan MATCH IT Act (H.R. 7379). Introduced by Reps. Mike Kelly (R-PA) and Bill Foster (D-IL) with diverse backers, this bill would fulfill the GAO report's recommendation by directing ASTP/ONC to create national-standard sets defining duplicate records, overlaid records, instances of multiple matches found, and intra-system mismatch rates. The derived "minimum data set" would be incorporated into the United States Core Data for Interoperability (USCDI) baseline as well as the required benchmarks for the Medicare Promoting Interoperability programs and ONC's health IT certification program, with target match rates above 90%. As a short, straightforward, and effectively cost-free measure (reducing mismatch costs more than pays for itself), the MATCH IT Act would be an ideal addendum to any larger Cures 2.0 legislative package.

Health Data Utilities—With a more thoroughly digitized health system and the proliferation of ever-more complex uses for health data to enhance patient care and public health, nonprofit HIEs around the country have had to grow and expand their capabilities to keep pace. Nearly all Civitas HIE members have moved beyond basic point-to-point connections between doctors' offices and into a wider range of value-added services for different types of clinical and non-clinical participants: acute and specialty care hospitals, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs), Skilled Nursing Facilities (SNFs) and Long-term Care Facilities (LTCFs), Accountable Care Organization (ACO) clinician groups, public and commercial payers, public health authorities, first responders, research institutions, social service agencies, and other community-based organizations. In doing so, they have become leaders in the development of a new and innovative paradigm known as the Health Data Utility (HDU) model. The HDUs emerging around the country represent an evolution rather than a revolution in the shape of health information networks, but the HIE-to-HDU transformation is substantial; it combines 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.

Operationally, HDUs are distinguished by a highly developed multi-stakeholder governance structure with official sanction at the state, local and/or tribal government levels—not unlike many public utilities that operate other types of critical infrastructure for specific geographies. This arrangement helps HDUs build and retain community trust and enhances their partnerships across the health landscape. Such buy-in is especially valuable when collective challenges like consent management, cybersecurity concerns, and artificial intelligence demand that health ecosystems work together through common frameworks and shared media of exchange. From the federal government's perspective, HDUs complement and enhance public health data exchange initiatives already underway, such as the CDC's Data Modernization Initiative (DMI), by providing a single source to connect health systems with public health departments, claims data, prescription drug monitoring, community organizations, and social service providers to share information in real time. The pillars of the CDC's current public health data strategy—addressing gaps in public health data, interoperability, actionable data, and improving outcomes for all—require close alignment of information sharing mechanisms that HDUs have already achieved on the state level. The future that ASTP/ONC envisions for TEFCA likewise runs through HDUs, which despite the technical issues created by QHIN exchange are best positioned to make TEFCA's public health use case a reality.

Future iterations of Cures 2.0 legislation should consider the evolution of the HDU model to improve public health data exchange alongside existing public health infrastructure and other public health agency initiatives. The HDU model was years away when the 21st Century Cures Act was enacted in 2016, and still a brand-new concept when the 2021 Cures 2.0 bill was put forward. The next version of Cures can place itself at the forefront of health data development and interoperability by updating its legislative language so that "health data utility" is refenced alongside "health information network," "health information exchange," "health information organization," and other legacy terminology. Particularly in the context of public health programs (such as pandemic preparedness demonstrations and funding for state and local health authorities), the inclusion of HDUs will ensure the progress made over the last several years reaches its full potential.

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 public health and health care outcomes.

Sincerely,

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