*Submitted via electronic mail*

July 18, 2024

The Honorable Diana DeGette                    The Honorable Larry Bucshon, M.D.
U.S. House of Representatives                   U.S. House of Representatives
2111 Rayburn House Office Building             2313 Rayburn House Office Building
Washington, DC 20515                           Washington, DC 20515

Re: *Request for Information on Next Generation Cures Bill*

Dear Representatives DeGette and Bucshon,

On behalf of OCHIN, I applaud your continued leadership and appreciate the opportunity to offer input and feedback on the next iteration of 21st Century Cures proposals. OCHIN is a **national nonprofit health information technology and research network** comprised of over 2,000 community health care sites with more than 33,000 providers serving more than 6.1 million patients and includes Critical Access Hospitals (CAHs), rural and frontier health clinics as well as federally qualified health centers (FQHCs) and local public health agencies in 43 states. Both the 21st Century Cures Act and Cures 2.0 have been instrumental in advancing medical research and health care delivery, with provisions that pushed for greater interoperability, adoption of electronic health records, and funding to accelerate medical research. We are again at a critical time as artificial intelligence (AI) holds the promise of transforming healthcare operations and clinical practice but must be grounded in both algorithmic and distribution equity to overcome persistent health disparities. OCHIN urges prioritizing policies and funding in Cures 3.0 to: (1) modernize the health IT infrastructure for providers in rural and underserved communities, (2) build and scale community-based inclusive clinical trial infrastructure, and (3) ensure providers in rural and underserved communities are involved in the AI enterprise so the digital divide and disparities can be overcome.

## OCHIN: DRIVING INNOVATION, ACCESS, AND SELF-SUFFICIENCY

Since its inception in 2000, the OCHIN collaborative of community providers has focused on expanding access in underserved and rural communities to quality health care services through technology solutions, technical assistance, operational support, informatics, evidence-based research, workforce development and training, and policy. In the OCHIN network, over half of our members' patients are covered under Medicaid, 18 percent are uninsured, 53.6 percent live at or below the federal poverty level and one in three prefer a language other than English.

OCHIN is unique in the scale of clinical and social complexity data collected by our members to support their patients' care from underserved and rural communities and to strengthen public health. Notably, more than 2.75 million social risks screenings were completed in OCHIN Epic for over 1.5 million unique patients nationwide, which has produced the nation's largest EHR-embedded dataset on SDOH in primary care community clinics and allows providers and researchers to empirically assess how SDOH affect patient and population health.

In addition, OCHIN stewards the [ADVANCE Data Warehouse](#), nation's largest and most comprehensive database on health care and outcomes for communities systemically underrepresented or excluded from research. We provide the clinical insights and tailored technologies needed to expand patient access, connect care teams, and improve the health of rural and medically underserved communities. With over 510 million clinical summaries securely exchanged since 2010, OCHIN puts "one patient, one record" at the heart of everything we do to connect and transform care delivery. We ensure all health records flow seamlessly between patients and their many providers, giving clinicians greater insight into their patients' health and helping to complete the circle of care in rural communities. We also drive interoperability on a national scale through our growing health information network and automated electronic case reporting for public health.

## RECOMMENDATIONS

Building on the prior Cures' proposals and program–and consistent with two of the six themes you highlighted in your Cures 2.0 document from 2021, 1) Public health and pandemic preparedness, including increasing surveillance and testing capabilities, and 2) Centers for Medicare & Medicaid Services modernization including a greater ability to respond to the fast pace of technological and scientific advances–we urge you to advance the following initiatives and programs. We also provide additional details in the **Appendix.**

- **Strategically invest in building scalable community-based inclusive clinical trial infrastructure for providers in rural and underserved communities**. OCHIN has extensive experience engaging with providers in underserved communities to enroll their patients in clinical research, but the barriers and costs are prohibitive. In many cases it is not feasible for community health sites to participate due to staffing and capacity issues; lack of infrastructure for recruiting or consenting patients; limited capacity for rapid recruitment to meet study targets; and/or study budgets that did not include sufficient margin for infrastructure or capacity building to enable participation. The National Academies of Sciences, Engineering, and Medicine (NASEM) among other key stakeholders have outlined the urgent need to expand diversity and inclusion in clinical research, the potential to partner with community health centers (CHCs) to achieve this goal, and the need for additional resources to support these efforts.[1] However, CHCs and Critical Access Hospitals (CAHs) that provide care to our nation's most vulnerable patients, are often under-resourced and under-staffed, and unlike many academic health centers, typically do not have existing infrastructure to support research. **We urge you to ensure funding is allocated to expand both the infrastructure and the staffing support needed in a community clinic setting to support ongoing engagement.**
- **The digital divide remains pervasive for providers in underserved and rural communities that need access to modernized hosted certified health IT systems.** It has been over a decade that providers received funding to adopt electronic health records, and many continue to rely on what are now antiquated technologies that lack essential cybersecurity features. Modernized health IT systems are needed to achieve secure interoperability and electronic health information exchange, provide access to integrated telehealth and other virtual services. Further such systems are needed to optimize operations and financial sustainability through informatics and analytics that support transitions to new payment and delivery models. And,

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[1] Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research, Committee on Women in Science, Engineering, and Medicine, Policy and Global Affairs, National Academies of Sciences, Engineering, and Medicine. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. (Bibbins-Domingo K, Helman A, eds.). National Academies Press; 2022:26479. doi:10.17226/26479

advancing innovation and delivering 21$^{st}$ Cures leveraging the benefits of rapidly developing artificial intelligence (AI) systems cannot happen without modernized systems. **As part of the Cures 3.0, we urge you to direct federal agencies, such as the United States Department of Agriculture (USDA), to streamline and simplify the agency's community grants programs and clarify that these funds can be used to modernize health IT systems including through software.** We also urge you to incorporate the Equal Access to Specialty Care Everywhere (EASE) Act of 2024 (H.R. 7149/S. 4078), which would fund the technological infrastructure as well as the creation of a dedicated network of specialists delivering virtual services to test whether such a model will improve access to specialty care.

- **Driving national digital data and technical standards is critical for innovation, particularly AI innovation.** Currently, there is a rapidly growing number of state standards and laws related to privacy, and increasingly, related to AI oversight and regulation. Many of these state laws regulate health care activities adding costly and complex compliance requirements layered over federal requirements. It is critical that Congress take the lead in establishing federal standards in this area while also continuing to support the advancement of other digital data and technical standards.

- **Ensure the development of AI standards and policies that champion algorithmic and distribution equity.** Using AI in healthcare does not come without risk. While the flurry of regulatory and technical standards from both the federal and state levels are well-intended, it creates regulatory complexity. Added complexity makes it even more challenging to address adverse bias AI which can include systemic exclusion resulting from cost prohibitive requirements. Currently, stakeholders – including the least resourced- are left to piece together the varied requirements. **We encourage Congress to prioritize investments in resources for providers in underserved and rural communities to develop, implement, and maintain strong governance structures and training for health care AI applications consistent with Fair, Appropriate, Valid, Effective, Safe (FAVE) principles.** Building in these safeguards protects against harm from AI and exacerbating existing inequalities. Furthermore, resourced-strapped providers in rural and underserved areas cannot leverage AI on their own. **We urge Congress to fund the establishment of regional innovation hubs that provide resource training and support for AI technology adaptation for providers in underserved and rural communities, as well as, create targeted grants and funding opportunities to enable providers to adopt and integrate AI.**

OCHIN welcomes the opportunity to provide technical assistance and data to support your work. Please contact me at stollj@ochin.org if you have any questions.

Sincerely,

Jennifer Stoll
Chief External Affairs Officer

**Enhancing Research Readiness and Capacity**

- There is increased national recognition of the need for more inclusive and representative clinical research and the potential for community-based primary care health centers to partner in filling this gap. In many cases, CHCs and CAHs cannot participate in studies and clinical trials due to issues such as staffing and capacity issues; lack of infrastructure for recruiting or consenting patients; limited capacity for rapid recruitment in order to meet study targets; and/or study budgets that did not include sufficient margin for infrastructure or capacity building to enable participation. Uncertain policy and funding environments where health centers have experienced tremendous changes and challenges, including high staff turnover and workforce shortages since the COVID-19 pandemic, have also prevented successful participation in clinical trials and research. **To meaningfully overcome structural inequality in health care research, OCHIN urges you to provide sufficient funding for research activities involving primary and critical access sites serving underrepresented communities.** We further urge Congress to prioritize new strategies for participating in patient-level clinical trials, including offering adequate budgets to support robust patient and clinic engagement, and input to methods and data sources to ensure relevance and inclusion. For example, Congress could direct PCORI into funding and encouraging collaborations between CHCs, CAHs, and more established health systems to build scalable models for clinical trial recruitment and participation in CHC settings. Such partnerships could help develop CHCs and CAHs readiness and capacity for clinical trials research.

**Investment in Modernized Health**

- **Too many providers in rural and underserved communities are using dated, fragmented technologies that lack essential cybersecurity features and hinder consistent and secure access, exchange, and use of standardized, uniform electronic health information.** There is an urgent need for investments to upgrade health IT systems of providers in rural and underserved communities that must be met before interoperability as well as strong cybersecurity measures can be realized. **OCHIN specifically urges you to direct the USDA to streamline the community grants program and clarify that funding the adoption and maintenance of modernized certified hosted health IT is consistent with congressional intent.** In addition, through the farm bill reauthorization and appropriations process, Congress is also able to clarify that the community grants program covers software licenses as an essential component of infrastructure investment on an ongoing basis. Congress could also direct some of the previously authorized and appropriated broadband funding allocated for these purposes as well to ensure safety net providers and the patients they serve are not left behind. These are prerequisites to closing the digital divide. Modernized systems are needed to solutions, including AI, which will drive improved clinical outcomes and experiences of care, increase operational efficiency, reduce provider burden, strengthen public health, and improve regulatory and operational compliance.
- **Modernized health IT is key to not only furthering interoperability but maintaining a strong cyber infrastructure and cybersecurity defense practices.** Additionally, providers must have access to modernized health IT to benefit from essential 21$^{st}$ cybersecurity features. With the aftermath of the February Change Healthcare cyberattack leaving many providers reeling in its wake, it is more important than ever to secure our nation's critical infrastructure, which houses

our citizens' private and sensitive healthcare information, from criminal elements and adversarial nation-states as well as support sharing of information on cyber incidents to support patient care and safety.

- **OCHIN recommends Congress pass the EASE Act of 2024**, which would fund a virtual specialty network demonstration that would include funding for the technological infrastructure and technical assistance needed to modernize providers health IT, which in turns allows for the creation of a dedicated virtual network of specialty clinicians that accept referrals from safety net providers. The virtual specialty network would utilize a range of virtual modalities (including clinical decision support, eConsults, and telehealth, for example) and coordinate care with primary care clinicians.

## Alignment of Data Standards at the State and Federal Level

- The lack of a standard approach to digital data and technical standards causes inconsistencies in data classification and collection, challenges in tracking progress over time, and undermine interoperability and seamless data sharing across organizations and care settings. The cost of harmonizing and implementing different standards is increasingly cost-prohibitive and complicates compliance, increases administrative burden, and drives burn-out while undermining sustainability of providers in underserved communities. Reporting requirements must be automated where possible and aligned across all programs for the many providers cross-participating and more substantially burdened. Accelerating the development, testing, and use of these standards should lead with demographic, public, health, and social risk-related data elements and include funding for technical standard testing among providers in rural and underserved communities. **Critical funding is necessary to create, and test standardized and validated elements and data collections tools**, especially in rural and underserved communities who otherwise would bear the cost burden of testing, a financial challenge they cannot afford to take on.
- The flurry of state-level regulation around health data privacy, sexual orientation and gender identity, and reproductive health has created **a complex regulatory landscape** that make it challenging for healthcare providers to administer a legally compliant medical record. This hinders coordination of care as compliance means healthcare providers must resort to data segmentation, creating conflict with federal goals and regulations.

## Ensuring Algorithmic and Distribution Equity in AI

- **No single, uniform federal law exists specifically governing AI currently exists**. Successful adoption of AI systems requires harmonized federal and state regulatory requirements, in addition to uniform, inclusive digital data and technical standards. In addition to investing in a clear governance structure, we recommend Congress to direct ONC to play an expanded role as a convener, coordinator, and communicator of AI related federal and state requirements impacting health care given the rapid proliferation of AI uses in this sector. The myriad of federal agency activities related to AI as well as the proliferation of state privacy laws and recent new AI related laws such as the Colorado Consumer Protections for Artificial Intelligence and California's and Utah's AI BOT laws make it challenging for providers, especially those least resourced, to figure out how to comply.
- Collaborating and sharing tools and capabilities to enable system evaluation and surveillance helps achieve algorithmic and distribution equity in healthcare. It also fosters trust in healthcare AI and ensures those in rural and underserved communities are not left behind. **Using AI in**

**healthcare does not come without risk.** To build and invest in strong and effective AI educational programs, we encourage establishing partnerships with community organizations to educate and involve end-users in the development and feedback process for generative AI technologies, which is another way of ensuring their voices are heard and included. Providers in rural and underserved areas will also benefit from regional innovation hubs that provide resource training and support for generative AI technology adaptation. Ensuring AI systems reflect the voices of providers and patients in underserved and rural areas requires concerted efforts to integrate community integrations into learning networks and in decision-making spaces, allowing for education and involvement of end-users in the development and feedback process for AI.