PREMIER TRANSFORMING HEALTHCARE TOGETHER®

December 16, 2019

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

The Honorable Fred Upton
House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Re: Cures 2.0 Call to Action submitted electronically via cures2@mail.house.gov

Dear Congresswoman DeGette and Congressman Upton:

On behalf of the 4,000 U.S. hospitals and health systems and more than 175,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to your Cures 2.0 Call to Action. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. The goal is to ensure provider access to accurate health information at the point of care to inform healthcare decisions and achieve best patient outcomes. This must be accomplished in a manner that minimizes administrative burdens on providers. Below we provide comments about ongoing oversight of the 21st Century Cures Act (Cures; Cures 1.0) implementation and then offer suggestions about Cures 2.0, especially in response to your focus on digital health.

Ongoing Oversight of 21st Century Cures Implementation and Cures 2.0

Premier supports Congress' efforts to advance medical research and foster innovations to develop cures. The 21st Century Cures Act was an important step forward in addressing several challenges impeding research, discovery, innovation and nationwide interoperability. As envisioned in Cures, the healthcare system needs to move beyond simply recording data in electronic health records (EHRs) and toward integrating and combining diverse data from disparate data sources. Interoperability across and among providers and sites of care, technologies (including remote monitoring and medical devices) is increasingly vital to care delivery. Without connectivity across the care continuum, data collection remains siloed and fragmented and does not provide the total picture necessary for healthcare providers and clinicians to deliver informed, evidenced-based and coordinated care.

We highlight several priority areas for your consideration as you continue oversight of the 21st Century Cures Act implementation and consider provisions for Cures 2.0:

- Ensuring health IT innovation and a competitive marketplace
- Increasing provider and clinician data availability, access and use
- Expanding efforts on patient matching and unique patient identifiers
- Accelerating and enhancing standards development, adoption and implementation
- Advancing interoperability across the care continuum
- Incorporating real-world evidence
- Ensuring access to quality home infusion services

Ensuring health IT innovation and a competitive marketplace

We urge immediate and ongoing Congressional action to further ensure a dynamic, competitive and innovative healthcare information technology (IT) ecosystem. Cures Section 4002 required that ONC develop and implement an Electronic Health Record Reporting Program. We are concerned that the Program has not yet been implemented and there is limited publicly available information about its status. Such a program could significantly improve the ability of clinicians and providers to compare and acquire health HIT systems that best meet their clinical and administrative needs and could lead to significant progress regarding patient safety[1] as well as EHR, usability, interoperability, and functionality. Furthermore, improvements to EHRs will help address unresolved clinicians' concerns and burdens.[2] Cures required the EHR Reporting Program to include the evaluation of certain functionalities of EHR systems including: security, usability and user-centered design, interoperability, conformance to certification testing, and other factors necessary to measure the performance of EHR technology.

Congressional attention and oversight is needed to ensure that EHR vendors publicly report on and demonstrate compliance with the U.S. Core Data for Interoperability (USCDI) and certified EHR (CEHRT) functionality; standards adoption and implementation; and confirm their integration and interoperability services and capabilities as well as their processes about data access and use. Additionally, greater transparency of EHR vendors' business practices and contractual terms and conditions is critical. Users need unfettered (public) access to freely available information about the EHRs implemented as part of the ONC certification program.

Increasing provider and clinician data availability, access and use

Achieving interoperability across the care continuum and assuring data availability at the point of care and within the clinical workflow must be a Congressional priority. We appreciate efforts by Congress and the Administration to expand patient and consumer access to their clinical and claims data via open application programming interfaces (APIs) and consumer-facing applications (apps). Ongoing evolution of digital technologies has introduced capabilities and advancements not previously contemplated in Cures. We urge Congress to ensure that providers and clinicians have timely and efficient access to data—especially real-time information on their patients at the point of care and within workflow[3]. Providers need robust, scalable, and interoperable health IT systems and EHRs to improve clinical decision making and deliver safe, coordinated and effective care and to improve outcomes. Importantly, Congress needs to ensure that providers and clinicians can implement and use any third-party applications of their choosing.

In Cures, Congress required ONC to develop new criteria for EHRs to make health data available via open, public, standardized APIs. We urge Congress to clarify that EHR vendors must also deploy open APIs for clinicians and providers for data access and connectivity to third-party applications. Such APIs will help improve data exchange and communication between and among clinicians and providers and between clinicians and their patients. Additionally, open standardized APIs will enable clinicians and

[1] Pew Charitable Trusts How the New Electronic Health Record Reporting Program Could Improve Patient Care https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/12/how-the-new-electronic-health-record-reporting-program-could-improve-patient-care
[2] National Academies of Sciences, Engineering, and Medicine. 2019. Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being. Washington, DC: The National Academies Press. https://doi.org/10.17226/25521.
[3] Horvath, K., P. Sengstack, F. Opelka, A. B. Kitts, P. Basch, D. Hoyt, A. Ommaya, P. Cipriano, K. Kawamoto, H. L. Paz, J. M. Overhage. 2018. A vision for a person-centered health information system. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/201810a

providers to connect and use third party applications of their choosing thus facilitating their ability to implement real-time clinical decision support as well as prospective and retrospective data analytics tools to enhance the quality, efficiency and safety of care. This is critical to value-based healthcare delivery that emphasizes integrated and coordinated care for patients.

Additional Congressional action is needed to recognize that providers and clinicians need to be able to add enhanced capabilities and functionality (i.e., risk stratification, electronic prior authorization, case management, referral management, care coordination, decision support, data analytics, population health management, clinical surveillance, registries, enterprise analytics, and patient engagement) beyond certified EHRs. Such Congressional action will help foster innovation by ensuring data for analytics, research and innovation. Congressional action is also needed to direct CMS and ONC to expand the technologies, applications and use of health IT beyond EHRs) that are recognized as acceptable solutions that meet the Promoting Interoperability Program requirements.

There is a compelling case for integrating clinical and claims data especially given the transformation to value-based care and advanced payment models. For example, an ACO's success depends on the timely exchange and transfer of patient information and coordination of patient care. Since Medicare beneficiaries have the right to seek care from any provider that accepts Medicare, it can be a challenge for ACOs to monitor the services received by their aligned patients.

Recent (ONC and CMS) rulemaking represent progress but are insufficient. Provider and clinician timely and efficient access to claims data is critical for successful industry transformation to value-based care. We appreciate CMS' pilot projects that allow access to Medicare data, such as the Blue Button 2.0 for patients; the Beneficiary Claims Data Access (BCDA) for accountable care organizations; and the Data at the Point of Care (DPC) for fee-for-service providers. We urge additional Congressional efforts to ensure that providers and clinicians have access to and use of all public and private sector claims data for the individuals and populations under their care.

Expanding efforts on patient matching and unique patient identifiers

Innovation and industry progress have been stifled due to a narrow interpretation of the language included in Labor, Health and Human Services (HHS), and Education and Related Agencies Appropriations Act (Labor-HHS) bills since FY 1999 that prohibits HHS from adopting or implementing a unique patient identifier. Ongoing policy impediments to patient matching and identification continue to put patients at risk, increase costs to the healthcare system, maintain inefficiencies in care delivery and care coordination, and undermine efforts to achieve nationwide interoperability. While the 21st Century Cures Act required and GAO issued a report[4] about patient matching, Cures did not directly address creating unique patient identifiers. Nevertheless, efforts to lift the Congressional ban and support for these efforts continue to gain momentum.[5] For example, as part of their recent proposed rulemaking, ONC and CMS issued requests for information regarding how CMS and ONC could improve patient identification. In June 2019, the U.S. House of Representatives passed H.R. 2740, the FY 2020 Labor-HHS bill, which included a Premier-supported amendment that strikes the language that prohibits HHS from spending any federal dollars to promulgate or adopt a national patient identifier.

[4] HEALTH INFORMATION TECHNOLOGY: Approaches and Challenges to Electronically Matching Patients' Records across Providers
GAO-19-197: Published: Jan 15, 2019. Publicly Released: Jan 15, 2019.
[5] Pew Charitable Trusts Enhanced Patient Matching Is Critical to Achieving Full Promise of Digital Health Records
https://www.pewtrusts.org/-/media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf

We urge Congress to take concrete steps to address the unrelenting challenges associated with patient matching as part of its continuing oversight of 21st Century Cures Act implementation as well as its consideration of Cures 2.0. Congress should, at a minimum, lift the existing ban and direct ONC, CMS and other agencies (such as NIST) to identify and adopt technologically sound and trustworthy solutions to accurately match patients to their records.

Accelerating and enhancing standards development, adoption and implementation

We appreciate increased attention to data and interoperability standards and related requirements for CEHRT. However, limited standards adoption and inconsistent EHR vendor implementations continue to hamper data exchange and keep nationwide interoperability out of reach. We urge Congress to require ONC, CMS and other agencies such as NIH[6], to more actively support, advance and accelerate health data and interoperability standards development, adoption and implementation. We urge heightened focus on:

- Enhancing efforts to prioritize, develop and implement payor-to-provider use cases (i.e., for public sector and commercial claims data access)
- Developing use cases to ensure availability of (clinical and claims) data for more robust population health data analytics and data aggregation
- Addressing the transmission of data to and from EHRs (read-write capabilities) beyond the Cures' 1.0 requirement relating to registries[7]
- Accelerating implementation of bulk data transfer (via Bulk FHIR); CDS hooks and other standards (such as to operationalize read-write capabilities to get data into and out of EHRs) needed to ensure data access, availability and use, especially for value-based care and advanced payment models

Advancing interoperability across the care continuum

Advancing interoperability across EHR systems and care settings can unlock barriers to data sharing and care coordination between health systems, physician group practices, independent physicians, and post-acute care settings. Ongoing measurement to understand the current status of HIT adoption by providers and the ability of providers to share information across the continuum will be important in understanding the effectiveness of interoperability initiatives. Post-acute care (PAC), behavioral health (BH), and home and community-based services (HCBS) providers were not eligible for the Medicare and Medicaid EHR adoption incentives created by the HITECH Act. Given the cost of EHR systems and lack of actualized support for interoperability from the vendor community, investment in health IT has been limited among PAC, BH, and HCBS providers. Long term (LT) and PAC often do not have EHRs, or at least do not have CEHRT. Congress could explore ways to incentive PAC, BH, and HCBS providers to more readily adopt health IT in support of wider efforts to standardize patient data, improve care quality and reduce costs. To provide these incentives Congress could direct the CMS Innovation Center to develop a pilot program to provide a prospective payment for PAC, BH, and HCBS investment in health IT resources to advance

[6] Request for Information (RFI): Use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR) for Capturing and Sharing Clinical Data for Research Purposes https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-150.html

[7] Cures 1.0 Section 4005 Requires EHRs to be technically capable of transmitting to, receiving and accepting data from registries as a condition of certification in accordance with standards recognized by ONC.

interoperability. The demonstration(s) should support investment in health IT, while evaluating pilots through measurement of interoperability and patient outcomes.

Incorporating real-world evidence

The 21st Century Cures Act required FDA to create a program for evaluating the use of real-world evidence (RWE) to support the approval of a new indication for an already-approved drug and help support or satisfy post approval study requirements. FDA had previously addressed the use of RWE regarding medical devices in 2017. RWE is valuable in conducting comparative effectiveness research to determine which products have the best outcomes for subsets of patients and can potentially be used in the regulatory decision-making process. Finally, RWE is important for assessing the cost-effectiveness of a product and understanding the total cost of care for specific disease states often treated with different products. Gaining insight into safety, efficacy, patient outcomes and cost-effectiveness of products is integral to addressing concerns from stakeholders, including providers, clinicians, researchers, patients, and payers regarding the introduction of products in the marketplace and encouraging their adoption. As Congress builds on its initial RWE work at FDA and other federal agencies, we encourage Congress to include actions to address the heightened need for information governance, including privacy and security, data access, data integrity and quality, and data stewardship, which are especially critical given the increasing array of data sources (such as EHRs; remote monitors; third party apps; and patient-generated or mediated data) and types (such as genomic; clinical; administrative; financial; and patient-reported) as the health IT eco-system moves toward nationwide interoperability.

Ensuring access to quality home infusion services

Value-based care, population health management, new payment models, new technology, digital health, and consumerism are changing healthcare delivery and expanding the care continuum from acute care settings into alternate sites, including home-based care[8] (i.e. the spectrum of health and social services that can be provided in the home)[9] and home healthcare (i.e. the Medicare skilled home health benefits delivered by Medicare-certified home health agencies)[10].

Congress enacted home infusion policies within the 21st Century Cures Act, and we urge Congress to consider additional action as part of Cures 2.0 to resolve issues with CMS' interpretation of the law. Cures changed the payment structure for infusion drugs under the Medicare Part B durable medical equipment (DME) benefit and importantly included a long sought-after policy to create a Medicare payment for the professional services associated with home infusion therapy for Part B DME infusion drugs (Section 5012). However, this does not start until January 1, 2021, creating a lengthy and inappropriate four-year gap in implementation.

The average sales price (ASP) policy enacted as part of Cures created immediate and significant reimbursement reductions for infusion providers without sufficient coverage for the cost of services associated with administering infusion drugs in the home. Premier/Innovatix conducted a survey of its membership shortly after the legislation passed and shared the results with congressional offices. We heard clearly from our infusion members that Cures was likely to push beneficiaries into other, higher-cost

[8] Landers S, Madigan E, Leff B, et al. The Future of Home Health Care: A Strategic Framework for Optimizing Value. Home Health Care Manag Pract. 2016;28(4):262–278. doi:10.1177/1084822316666368
[9] Issue Brief: Medicare Advantage
Facilitates Innovative Care in the Home Issue Brief August 2018 https://www.bettermedicarealliance.org/sites/default/files/2018-08/CareInTheHome_2018_08_30%20ISSUE%20BRIEF.pdf
[10] https://www.medicare.gov/coverage/home-health-services

settings for their care delivery. Numerous respondents also said they would be forced to discontinue services for existing patients. Beneficiaries who receive home infusion therapy are often susceptible to infection and other adverse clinical outcomes, making the home the ideal site of care for treatment, not a physician's office, skilled nursing facility or a hospital. Home infusion is a safe and effective alternative to inpatient treatment that may provide beneficiaries with options to maintain their lifestyle and work activities.

In response to infusion industry concerns about the misaligned start dates enacted under Cures, Congress passed Section 101 of the Medicare Part B Improvement Act of 2017/ the Medicare Home Infusion Therapy Access Act of 2017 (H.R. 3178/ S. 1738) as part of the Bipartisan Budget Act of 2018 (P.L. 115-123). However, CMS defined "infusion drug administration calendar day" in both the CY 2019[11] and 2020[12] home health/home infusion final rules to restrict payment to when a skilled professional is in the patient's home for both the temporary and permanent home infusion services benefits. This definition is a significant departure from the intent of the BBA and Cures. CMS' latest final home health rule, which maintains its definition of "infusion drug administration calendar day," underscores the need for additional Congressional action. Requiring a skilled professional be in the home for a reimbursement to occur is inconsistent with other public payors and misinterprets the fundamental practice of home infusion. We urge Congress, as part of Cures 2.0 to amend the definition of an "infusion drug administration calendar day" to eliminate the requirement that a skilled professional be in the home for reimbursement to occur and define the term as the "day on which home infusion therapy services are furnished on the day of infusion drug administration," as Congress originally intended.

Summary

The Premier healthcare alliance appreciates the opportunity to submit ideas about Cures 2.0. We applaud Congress' vision of advancing medical research, fostering ongoing medical and technological innovations and achieving interoperability to help improve patient care and save lives. We look forward to working with Congress to transform care delivery and improve patient outcomes, especially as the U.S. health system embraces innovations for personalized healthcare, discovers new cures, therapies and products and transitions to value-based care and payment.

If you have any questions regarding our comments or need more information, please contact me or Meryl Bloomrosen, Senior Director, Federal Affairs, at meryl_bloomrosen@premierinc.com or 202.879.8012. We look forward to continued dialogue. Thank you again for providing us the opportunity to offer ideas.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance

[11] CMS-1689-FC, https://www.govinfo.gov/content/pkg/FR-2018-11-13/pdf/2018-24145.pdf
[12] CMS–1711–FC, https://www.govinfo.gov/content/pkg/FR-2019-11-08/pdf/2019-24026.pdf