August 15, 2018

The Honorable Mike Kelly
Co-Chairman
Health Innovation Caucus
U.S. House of Representatives
Washington, District of Columbia 20515

The Honorable Ron Kind
Co-Chairman
Health Innovation Caucus
U.S. House of Representatives
Washington, District of Columbia 20515

The Honorable Markwayne Mullin
Co-Chairman
Health Innovation Caucus
U.S. House of Representatives
Washington, District of Columbia 20515

The Honorable Ami Bera, MD
Co-Chairman
Health Innovation Caucus
U.S. House of Representatives
Washington, District of Columbia 20515

Dear Representatives Kelly, Kind, Mullin, and Bera,

We applaud the Health Care Innovation Caucus for examining the barriers to and potential opportunities for tech-driven tools to lower costs and improve patient outcomes in the U.S. healthcare system via its recent request for information (RFI). While we believe the Centers for Medicare and Medicaid Services (CMS) has made significant recent progress toward these goals as it works to implement the provisions of the Medicare Access and CHIP Reauthorization Act (MACRA), there are many further areas of opportunity both for Congress and the Department of Health and Human Services (HHS). We share Congress' goal—as expressed in MACRA—to move the Medicare system from a largely fee-for-service model to one that rewards the value and cost-effectiveness of healthcare. We also applaud Congress for supporting the use of remote monitoring technologies to bring the Medicare system from quantity-based to quality-based.[1]

ACT | The App Association's Connected Health Initiative (CHI) represents a broad consensus of stakeholders in the connected health sector that create and leverage innovations to better the lives and health of patients across America. Although CHI does not offer connected health services as an organization, as representatives of companies that do provide such services, we are able to answer some of the high-level policy questions posed in the RFI. We hope these observations are helpful as the Caucus seeks to define Congress' next step for value-based care and the role technology-driven tools can play in advancing this goal.

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[1] *E.g.*, 42 U.S.C. 1395w-4(q)(2)(B)(iii)(III) (requiring CMS, for care coordination, to ensure the use of remote monitoring or telehealth).

Value-Based Provider Payment Reform.

- **What barriers in each of the following areas limit the full potential of innovation in Medicare and Medicaid?**
    - **Payment and Reimbursement**

One of the overarching barriers to payment policy keeping up with modern health tools is an uncertainty in the data that supports reimbursement and other monetary incentives for the adoption of tech-driven tools. While an existing (and growing) body of evidence demonstrates their ability to improve care and lower costs, because tech-driven tools—from voice recognition to chronic care management platforms—are newer, clinical and/or peer-reviewed data showing the efficacy of these tools is not as easy to come by as it is for more traditional healthcare strategies. The perceived scarcity of this data has led the Congressional Budget Office (CBO) to conclude in many cases that investments in advanced technology tools (which, in the parlance of Medicare regulations, fall under the definition of "remote patient monitoring," "store-and-forward," and other similar terminology) for treatment and preventive care measures are unlikely to result in savings. However, CHI urges this Caucus to recognize the strong evidence base that already demonstrates the efficacy and cost-savings associated with the use of cutting-edge remote monitoring tools.[2]

Studies have shown that providing remote care results in fewer hospitalizations, cost savings, and improved health outcomes. For example, a randomized control trial of telehealth and telecare services concluded that, "if used correctly telehealth can deliver a 15% reduction in emergency room visits, a 20% reduction in emergency admissions, a 14% reduction in elective admissions, a 14% reduction in bed days and an 8% reduction in tariff costs. More strikingly they also demonstrate a 45% reduction in mortality rates."[3] Perhaps the most promising application of remote monitoring is for patients with chronic conditions. A University of Ottawa Heart Institute study supports this proposition, finding that "telehome monitoring" cut hospital readmission for heart failure by 54 percent, with savings of up to $20,000.[4] But nowhere are the potential benefits of connected care more pronounced than in rural America. CHI steering committee member University of Mississippi Medical Center (UMMC) saved an impressive $339,184 in healthcare costs by using remote monitoring and telehealth just from the first 100 patients participating in its Diabetes Telehealth Network program. Cost analyses predict that if 20 percent of Mississippi's diabetic population was enrolled

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[2] CHI has worked across the health and tech communities to gather compelling studies which we have compiled into an "Effectiveness Appendix." *See* https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5b6b2f50758d46b08c8e9fcd/1533751123403/Connected+Health+Effectiveness+Resource+080818.pdf. Further, CHI continues to work with key parts of HHS, namely the Agency for Healthcare Quality Research, to advance the new literature reviews to promote the growing body of evidence regarding the efficacy of connected health innovations.

[3] "Whole System Demonstrator Programme, Headline Findings – December 2011," Department of Health, United Kingdom, *available at* https://www.gov.uk/government/publications/whole-system-demonstrator-programme-headline-findings-december-2011.

[4] University of Ottawa Heart Institute, Feb. 24, 2011, Press Release, *available at* https://www.heartandlung.org/article/S0147-9563%2807%2900084-2/fulltext.

in the program, it would bring $189 million in Medicaid savings to Mississippi each year.[5]

With plenty of available evidence supporting the case for tech-driven preventive health measures, we also urge the Caucus to support the Preventive Health Savings Act (H.R. 2953). This legislation would ensure that any of the committees with primary jurisdiction over healthcare issues could require CBO to look beyond its usual 10-year window to determine whether investments in preventive health will yield savings to the federal government. The 10-year window has been an impediment to Congress' efforts to move Medicare to a value-based system by ignoring the long-term benefits of remote patient monitoring and other preventive measures, especially for patients with unfortunate chronic conditions that are costlier if untreated with preventive measures.

A quick review of the recent changes made to reimbursement and quality payment policies will help define and put into context the remaining barriers:

- Since MACRA's passage and under Congress' oversight, CMS has already taken important steps to incorporate connected health tools that save lives and reduce costs through its Physician Fee Schedule (PFS) rulemaking last year when it unbundled Current Procedural Terminology® (CPT) code 99091 to provide payment for the use of remote monitoring tech.
- And as these strides are made toward moving Medicare past its legacy of fee-for-service payment, CMS has also been, again pursuant to MACRA, shaping its Quality Payment Program (QPP): last year, as part of the QPP's merit-based incentive payment system (MIPS) rules, CMS adopted an Improvement Activity (IA) that CHI proposed—IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care)—which incents providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA urges providers to ensure that any devices they use to collect patient-generated health data (PGHD) do so as part of an active feedback loop. CHI is especially encouraged that CMS assigned high weight and linkage to an Advancing Care Information bonus to this IA, signaling to providers that CMS acknowledges the important role connected health tools can play in improving health outcomes and controlling costs.

We commend CMS for taking these and other pro-connected health steps that will improve the care every Medicare beneficiary receives while also reducing program costs and urge Congress to ensure CMS continues in this direction. In this regard, we are hopeful that the Caucus takes a leading role in voicing Congress' preferences.

While good progress has been made, CHI also urges this Caucus to agree that much work remains to be done if we are to remove remaining barriers to adoption of tech-driven tools and ultimately realize MACRA's vision of a value-based Medicare system. Bipartisan legislative options exist today that can drastically reduce barriers to the use

[5] http://www.connectwithcare.org/wp-content/uploads/2017/06/2016_Outcomes_Clinical-1.pdf.

of cutting-edge innovations in Medicare and Medicaid. For example, the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act (H.R. 2556) is a careful and balanced approach that would lift Medicare's arduous limitations on the use of telehealth, enable the use of RPM technology for patients with chronic conditions, safeguard that new payment models will incorporate connected health technologies, ensure that these advanced solutions are a part of the Medicare Advantage program, and address discrete issues associated with the treatment of Americans who suffer strokes and who require dialysis treatment. CHI supports its passage, either in part or in whole, and commits to work with the Committee and Congress widely to advance the legislation.

Further, with CMS currently contemplating its next steps as far as needed changes to both the PFS and QPP, this Caucus's RFI is being issued at a crucial time. CHI notes that there are a number of encouraging proposals in the draft calendar year (CY) 2019 PFS/QPP this Caucus should ensure CMS adopts, such as CMS' proposal to activate three further remote monitoring codes that CHI contributed to the development of and that, if adopted, will further support the use of remote monitoring innovations in the Medicare program. Further, CMS is considering additional changes to the MIPS program to give due credit for using connected health technology innovations in care delivery when calculating a MIPS score. Such proposals should move forward, incorporating the thoughtful feedback of the connected health stakeholder community. Further areas, however, such as Alternative Payment Models (APMs) under the QPP, merit greater focus by CMS so that a clear message is sent to all stakeholders that remote monitoring tools should serve a key role in the success of future innovative APMs. CHI continues to examine CMS' proposed rule for further opportunities for realizing Congress' vision of a value-based Medicare system, and we commit to assisting this Caucus by identifying opportunities for improvement as it moves forward.

At the request of the White House, CHI has examined the numerous opportunities for regulatory reform and improvement possible today and without congressional action.[6] Many of these areas fall within the Medicare and Medicaid system, while others directly impact the ability of Medicare and Medicaid caregivers to deliver the best care to American beneficiaries. For example, we note that HHS' Office of the Inspector General could provide more clarity as to the appropriate use of software platforms in light of the Stark Law and anti-kickback rules. In addition, we suggest that HHS consider removing unnecessary barriers to market entry for the electronic prescription of controlled substances. We urge this Caucus to examine the areas of regulatory opportunity we have identified in the context of this RFI and to consider how it may spur HHS to take advantage of these opportunities.

[6] CHI's letter with its wide range of recommendations on ways to advance the uptake of digital health innovations without congressional action was transmitted to the White House in May of 2018, and is available at https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5af9fcde758d468cf8ccb6f4/1526332639008/05102018_Connected-Health-Initiative-Input-to-WH.pdf.

How can Congress help the Centers for Medicare and Medicaid Innovation Center (CMMI) achieve its purpose of developing testing and innovative payment and delivery models?

Please see, attached as Appendix A, CHI's filing with CMS on its CMMI New Direction proceeding. Contained in that comment are suggestions for CMMI to make improvements on its own to the CMMI models with an eye toward better fostering innovative payment and delivery models.[7] However, the Caucus could consider weighing in with CMMI to signal Congress' support for actions it may be considering but not yet committed to taking.

In addition to these suggested improvements, CHI notes that CMMI has opted not to move forward with a virtual diabetes prevention program (VDPP) pilot program. CHI would support such an expansion as soon as practicable, which we believe is possible today under CMMI's existing authority. In support of this view, please see attached as Appendix B a letter co-signed by CHI arguing for the adoption of a VDPP.

We appreciate the Caucus's continued focus on ensuring that CMS carries out its statutory mandate under MACRA. With respect to any of the potential actions of CMS, CMMI, or any other agency, expressing the Caucus's views on the record could be persuasive and helpful in achieving our shared goals. With Congress' oversight, and the Health Innovation Caucus's leadership in particular, we believe that tech-driven tools will play a key role in producing higher-quality, more cost-effective health outcomes for patients.

Sincerely,

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[7] These CHI comments are also available at https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5a3acaea085229e1ec4ee719/1513802476621/chi_comment_re_cms_cmmi_new_direction_final__w_appendix__112017.pdf.