ConnectedHealth

April 1, 2019

Response to Request for Information (RFI) Re: A Revised Telehealth and Digital Health Package

Dear Congressional Telehealth Caucus members and Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act sponsors:

ACT | The App Association's Connected Health Initiative (CHI) represents a broad consensus of healthcare and technology leaders seeking a policy environment that encourages the use of connected health innovations. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

CHI is a longtime active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease. CHI's advocacy reaches across the divisions of the Department of Health and Human Services, as well as other relevant agencies. Our members' digital health tools will enable the American healthcare system to deliver high-quality care, lower healthcare costs, and support American prosperity and job growth.

We applaud your outreach to interested stakeholders as you work toward reintroduction of a telehealth and digital medicine package. We share each of the goals expressed in your Request for Information (RFI) and look forward to working with each of your offices to craft solutions that—as we have laid out in testimony before the House Committee on Energy and Commerce and the Senate Health, Education, Labor, and Pensions Committee[1]—drive value for patients, caregivers, and taxpayers. Connected health services are essential tools to improve healthcare for all Americans while reducing rising healthcare costs. We appreciate your attention to these requests and look forward to collaborating on this vital issue.

Sincerely,

Graham Dufault
Connected Health Initiative

[1] Testimony of Morgan Reed, Executive Director, The Connected Health Initiative, Hearing on "Health Care in Rural America: Examining Experience and Costs," Senate Committee on Health, Education, Labor, and Pensions (HELP), Subcommittee on Primary Health and Retirement Security (Sept. 25, 2018), *available at* http://actonline.org/wp-content/uploads/2018-09-13-Testimony-CHI-House-EC-Health-Sub.pdf; Testimony of Morgan Reed, Executive Director, The Connected Health Initiative, Hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare," House Committee on Energy and Commerce, Subcommittee on Health (Sept. 13, 2018), *available at* http://actonline.org/wp-content/uploads/2018-09-13-Testimony-CHI-House-EC-Health-Sub.pdf.

I. Expanding Access to Telehealth and Remote Monitoring, Especially in Rural Areas and Improving Patient Outcomes, Whether by Expanding Access to Specialists or Other Providers or by Easing the Day-to-Day Patient Experience

Telehealth. We support the reintroduction of Sec. 11 of the CONNECT for Health Act, which would enable the Secretary of Health and Human Services (HHS) to waive "any restriction applicable to the coverage of telehealth services" under the relevant provisions of law.[2] Those restrictions, found in Sec. 1834(m) of the Social Security Act, are onerous and backward-facing. Except in pilot demonstration programs in Hawai'i and Alaska, 1834(m) prevents Medicare reimbursement for the use of telehealth unless the patient is at a qualified originating site (which excludes their homes) and located in either a "rural health professional shortage area" or in a county that is outside of a Metropolitan Statistical Area (MSA).[3] These restrictions pose a serious barrier to the adoption of live voice and video interaction between caregivers and patients. Out of approximately $1 trillion the federal government spends on Medicare each year, physicians billed just $29 million or so over the last year data were available. Where patients with private insurance can interact with their caregivers over live voice and video, Medicare patients are usually unable to exercise that option. Medicare patients must visit their physicians in person even when video or voice communication would be more cost-effective than incurring the time and resource costs necessary to travel to the office physically and linger in the waiting room.

Medicare rules should allow for more widespread adoption of telehealth because it is effective and helps manage costs. Often, caregivers generate the best results where they are empowered to use a combination of telehealth (that is, live voice and video) and store-and-forward digital health tools such as remote patient monitoring (RPM). For example, University of Virginia (UVA) Health System recently launched a telehealth- and remote monitoring-driven diabetes management program for rural patients with positive results. Over six months, the mean hemoglobin A1C levels of participating patients dropped from 9.9 percent—which indicates uncontrolled—down to a far more manageable 7.7 percent. Moreover, since UVA began its broader telemedicine program, it saved patients 18.3 million miles of driving, including 2.3 million miles in 2017 alone. But even though a combination of telehealth and RPM can be a potent mix, the definition of telehealth should remain tethered to the concept of "live voice or video" interaction. We, therefore, support the recent proposal from the Centers for Medicare and Medicaid Services (CMS) to recognize "communication technology-based services" that do not meet the Medicare telehealth services definition in 1834(m) of the Social Security Act. This regulatory separation between "telehealth" and "communication technology-based services" is a positive step and we encourage you to reinforce that distinction—while ensuring that CMS recognizes RPM in legislation—where possible.

Remote Patient Monitoring. We support the reintroduction of Sec. 6 of the CONNECT for Health Act, which would require HHS to make payment for RPM services, including through "unbundling, modification, or establishment of certain codes."[4] We acknowledge the progress CMS already made along these lines, including its decision to adopt and pay for Current Procedural Terminology (CPT) codes 99453, 99454, and 99457. These codes pay for the initial set-up and patient education on use of RPM equipment that measures physiological parameters (like weight, blood pressure, pulse oximetry, etc.); device supply with daily recordings or programmed alerts every 30

[2] The CONNECT for Health Act of 2017 (H.R. 2556 / S. 1016, 115th Cong.) Sec. 11.
[3] 42 U.S.C. 1395m(m)(4)(C).
[4] The CONNECT for Health Act of 2017 (H.R. 2556 / S. 1016, 115th Cong.) Sec. 6.

days; and treatment management services. These codes are well crafted to cover RPM in a variety of settings and clinical situations. Sec. 6 of the CONNECT for Health Act would codify the authority and mandate to adopt new codes like these and ensure that CMS continues to diligently pursue further payment models that support more cost-effective, high-quality care, especially for those in rural areas.

In addition to this important update to the statutory authority and mandates around the Physician Fee Schedule (PFS), we also recommend providing additional statutory guidance along these lines to ensure similar progress with respect to the Quality Payments Program (QPP). For example, one statutory section requires CMS to consider "use of remote monitoring or telehealth"[5] in setting forth "Improvement Activities" related to care coordination for MIPS participants. We recommend updating this provision to require CMS to consider "use of remote monitoring *and* telehealth," to more clearly require CMS to consider both important methodologies rather than *only* telehealth or *only* RPM. The case for RPM is as clear as it is for telehealth. For example, hospitals have sought ways of monitoring newborns remotely to enable parents to leave the hospital and still benefit from being under close supervision by a care team. Using Apple's HealthKit, hospital systems and app developers have been able to produce remote monitoring apps that use both patient generated health data (PGHD) and self-reported data to keep caregivers apprised of a patient's condition. Neonatal physicians, for example, are using Locus Health's newborn monitoring platform to keep a watchful eye on newborns that need attention but do not necessarily need to be in the hospital. This capability frees up hospital space for newborns who need it most while allowing parents much-needed rest at home with the peace of mind that their babies are still receiving high quality care.[6]

Unfortunately, although CMS enhanced incentives for fee-for-service providers to use connected health tools, none of its annual rulemakings to date have mentioned RPM or related connected health modalities, including those that build on or interact with certified electronic health record technology (CEHRT), in sections dealing with advanced alternative payment models (APMs). The problem with not mentioning these modalities at all in these rulemakings is that providers may decide that they are taking an unjustified risk in adopting such technologies when proposing an APM. If CMS doesn't mention those technologies, adopting them could be perceived as harmful to a proposed APM's chances of being adopted. To ensure that future rulemakings remove the disincentive for APM applicants to include connected health modalities in their models, you could amend the end of the definition of "Eligible alternative payment entity," at 42 U.S.C. Sec. 1395l(z)(3)(D) to provide that "(iii) The Secretary shall clarify that technology that builds on or interacts with CEHRT may help meet eligible alternative payment entity requirements. This may include remote communications-based technologies."

Enhancing Interoperability. Digital health tools such as clinical decision support, RPM, and even care coordination depend on the interoperability of healthcare providers' data systems. However, in order for technologies to be considered for advantaged status as certified electronic health record technologies (CEHRT), they must adopt certain standards adopted by CMS. CMS conducts rulemaking each time it adopts a new standard which may slow down the evolution of CEHRT.

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[5] 42 U.S.C. 1395w-4(q)(2)(B)(iii)(III)

[6] *See, e.g.*, https://www.apple.com/105/media/us/healthcare/2019/cE249dd1_58dc_487a_880b_6a1bc197cc43/films/uva-childrens-hospital/healthcare-uva-childrens-hospital-tpl-cc-us-20190307_1280x720h.mp4.

You could include a provision that directs CMS to establish a predefined yearly process for standards rulemaking and comment—still providing necessary stakeholder input while at the same expediting adoption of the latest interoperability standards. This would help CMS quickly adopt new standards to match those that are being used in the private sector, helping avoid situations where vendors would need to use older standards to qualify as CEHRT.

II. Encouraging easier and expanded use of existing telehealth and remote monitoring technologies, many of which suffer from low uptake rates

Tax incentives. Last year, Americans heard an announcement about the upgraded sensors and other technology in popular smartwatches. Technology has advanced to the point where the devices on our wrists can now take accurate electrocardiogram readings. As an initial matter, it would make little sense if Americans could not send these accurate readings to their physicians and work the data their devices gather into the continuum of their own care.

We also urge you to incent the purchase of software and hardware technology by requiring the Internal Revenue Service (IRS) to include such innovations as allowable medical expenses designated by the IRS in IRS Pub. 502, thereby making their purchase eligible using flex savings accounts (FSAs) and health savings accounts (HSAs), providing consumers with the flexibility to lower their healthcare costs.[7] Such an incentive would help rural Americans—especially those at risk for chronic conditions—access preventive digital medicine proven to produce positive results.[8]

Telehealth and RPM for Specific Conditions or Scenarios. Studies have shown that RPM and telehealth can significantly improve adherence to respiratory therapy. Similarly, RPM and telehealth improve outcomes for patients with chronic conditions including heart failure and diabetes. Notwithstanding our call for broad reimbursement for RPM and a general waiver of telehealth restrictions, we urge you to include a specific waiver from the 1834(m) telehealth restrictions—and a specific requirement for CMS to provide payment mechanisms—for diabetes, heart failure, and respiratory and physical therapy. Evidence shows that each of these use cases helps manage overall costs per patient while leading to better patient outcomes.[9] This approach likely includes designating qualifying respiratory therapists as telehealth practitioners under the Medicare program by, for example, adding those practitioners to the relevant statutory list.[10] We would also support provisions that aim to test any of these condition specific concepts in pilot programs.

Lastly, technological advancements in diabetic retinopathy screening have produced successful results, enabling care teams to better screen for the condition. Unfortunately, diabetic retinopathy

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[7] *E.g.,* by amending the definition of "medical care" at 26 U.S.C. Sec. 213(d)(1) to include such expenses.
[8] The Connected Health Initiative has drafted proposed legislation to accomplish this additional FSA/HSA coverage, which we have named the Wearable Equipment Adoption and Reinforcement and Investment in Technology (WEAR IT) Act.
[9] *See* Key Clinical Studies Demonstrating the Benefits of Connected Health Technologies, Connected Health Initiative, *available at* https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5b6b2f50758d46b08c8e9fcd/1533751123403/Connected+Health+Effectiveness+Resource+080818.pdf.
[10] *See* 42 U.S.C. 1395m(m).

is both the leading cause of blindness and vision loss in adults between 20 and 74 years old and will affect nearly 80 percent of people living with diabetes. You could include a provision to ensure that Medicare covers diabetic retinopathy screening for patients with diabetes in the primary care setting.

III. Conclusion

We appreciate that this committed group of bipartisan, bicameral Members of Congress is exploring suggestions from a wide range of stakeholders to streamline federal healthcare rules to better empower providers, innovators, patients, and consumers to control costs and better manage care. Tech-driven tools play an important role in the improvement in quality and cost-effectiveness of healthcare. Ensuring that CMS, Congress, and other federal agencies create a legal landscape that supports—rather than hinders—the use of these tools is, therefore, of utmost importance.