ConnectedHealth

February 26, 2019

The Honorable Eric D. Hargan
Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, District of Columbia 20201

Dear Deputy Secretary Hargan:

ACT | The App Association's Connected Health Initiative (CHI) represents a broad consensus of healthcare and technology leaders who seek a policy environment that encourages the use of connected health innovations and ultimately supports an improvement in patient and consumer health. CHI works with Congress, the Department of Health and Human Services (HHS) and other regulators, policymakers, and researchers to inform policy that supports innovation, improves consumer and patient health outcomes through digital health tools, and keeps sensitive health data private and secure. Our members' products will enable the American healthcare system to deliver high quality care, lower healthcare costs, and support American prosperity and job growth.

We appreciate your continued work on ways to streamline improved patient outcomes and cost savings through removing unnecessary regulatory burdens or taking actions grounded in established congressional authority (i.e., do not require congressional action). As the leading representative of the connected health community, CHI identified numerous actions HHS can take to continue reducing these barriers. Appended to this letter, we offer a non-exhaustive list of key recommendations that we urge you to consider, provided alphabetically by agency name. We welcome the opportunity to discuss our views in more detail.

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,

Brian Scarpelli
Senior Global Policy Counsel

Andrea Benson
Policy Associate

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005

HHS Leadership

Many of the policy issues raised by the use of artificial intelligence/augmented intelligence (AI) require consideration of its impact on a wide range of stakeholders. The cultural, workforce training and education, data access, and technology-related changes will require strong guidance and coordination across a number of venues. Given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as steward of significant amounts of patient data, a federal healthcare AI strategy incorporating guidance on the issues below will be vital to achieving the promise that AI offers to patients and the healthcare sector. Other countries have begun to take similar steps (e.g., The UK's Initial Code of Conduct for Data Driven Care and Technology) and it is critical that U.S. policymakers collaborate with provider organizations, other civil society organizations, and private sector stakeholders to address AI's potential in healthcare.

Agency for Healthcare Research & Quality (AHRQ)

AHRQ plays an important role in developing knowledge, tools, and data needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions. CHI appreciates AHRQ's efforts to date to explore the cost savings and improved patient outcomes associated with digital health innovation through Evidence Reviews. Over the last year, CHI engaged with AHRQ to propose several Evidence Reviews to explore the benefits of digital health tools and services in the context of disease prevention, as well as medication adherence. As AHRQ is a trusted and valuable resource for legislative and agency policymakers, we believe such explorations play a key role in informing any potential regulatory action.

We encourage AHRQ to examine ways to explore the benefits of digital health tools, not just Medicare telehealth services (which are in practice a very limited set of live voice/video condition-specific services and do not include asynchronous products and services). AHRQ can do this today through completing new Evidence Reviews and other studies on such topics as quickly as practicable.

Centers for Medicare and Medicaid Services (CMS)

CMS has incredible opportunity to build on its recent recognition of the immense value of health innovations, including telehealth and remote patient monitoring (RPM), as well as other emerging technologies, that improve healthcare outcomes and secure significant cost savings.

Physician Fee Schedule (PFS)

In its CY2019 PFS, CMS activated and provided payment for three new Current Procedural Terminology® (CPT) Codes that capture the technical and professional elements of remote patient monitoring (RPM). CMS' efforts to provide unbundled coverage for RPM in Medicare Part B is a monumental step forward in advancing the use of digital health tools in the care of America's most vulnerable populations. Amid providing these new allowances and a range of related questions submitted by stakeholders, in the CY2019 final rule CMS committed to release further guidance to address details regarding new reimbursements for CPT Codes 99453, 99454 and 99457. This guidance, however, has not been issued to date and a number of questions and ambiguities remain. CMS can take steps to address these questions today by issuing supplemental guidance. Such questions and clarifications include:

- The CPT Code 99457 descriptor specifically says that "other clinical staff" time can be attributed to the required 20 minutes, but CMS text in the Physician Fee Schedule (PFS) final rule says 99457 cannot be billed incident-to. We believe this discrepancy to exist simply due to a drafting mistake by CMS. Clearly, clinical staff time for 99457 should be billed incident-to, under general supervision (rather than direct supervision), and should be allowed for clinical staff providing RPM services, similar to the exception CMS made for chronic care management (CCM) services. Like CCM, RPM services are most efficiently provided under general supervision and, for these codes to be implemented most effectively for patients and practices, RPM services provided by clinical staff should be billed incident-to under general supervision, where the physician or billing practitioner is not required to be in the same physical location as the clinical staff providing the monitoring. In many cases, practices would like to contract out the provision of RPM services, comparable to what they currently do for CCM services. Not allowing incident-to billing under general supervision will significantly impede the use of these services. We therefore request CMS make a technical correction to the CY2019 PFS to permit incident to billing of 99457 by clinical staff under general supervision.
- Confirming that devices can be used to execute these codes if they meet the definition of a medical device in the Federal Food Drug & Cosmetic Act (even if they enjoy enforcement discretion, *e.g.*, a general wellness product).

- That the new RPM codes can be used for remote monitoring in circumstances where a patient is not experiencing two or more chronic conditions (e.g., post-surgery monitoring), as the new codes are not CCM codes.
- What "interactive communication" means in the context of CPT Code 99457.
- Confirming that "patient-reported data" encapsulates not only automatically collected and transmitted physiologic data, but also data that is manually input to a remote patient monitoring software platform.

While there is a significant and growing body of empirical evidence showing the benefits of connected health technology for diabetes, this condition imposes a significant burden on CMS' Medicare program and its beneficiaries, with a spend of more than $104 billion every year treating this preventable disease.[1] However, diabetes is well-suited to digital medicine innovations because diabetes care requires interpretation of many kinds of data that can be captured through automation and biosensors. CMS can address the burden diabetes places on the Medicare program by:

- Including virtual diabetes prevention program providers who are CDC-recognized as part of the Medicare Diabetes Prevention Program (MDPP) under section 1115A(c) of the Social Security Act. CHI supports this proposed expansion, and the classification of the MDPP in Part B, as a timely and necessary step to address the diabetes crisis in the United States. CMS has already acknowledged the use of connected health tech products and services will be vital to the success of the MDPP.[2]

[1] https://blog.cms.gov/2018/04/30/cms-encourages-eligible-suppliers-to-participate-in-expanded-medicare-diabetes-prevention-program-model/

[2] *Id.* at 46417.

- Supporting virtual Diabetes Self-Management Training (DSMT), which would eliminate cost- and time-consuming barriers to utilization of DSMT. CMS should also define certified diabetes educators (CDEs) as providers of DSMT. A 2014 report by the American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance found an overwhelming majority of DSMT is carried out in primary care offices by non-"qualified diabetes educators."[3] CMS has the regulatory authority in the DSMT authorizing statute,[4] which states a certified DSMT provider is "a physician, *or other entity or individual designated by the Secretary"* [emphasis added] that provides DSMT and other Medicare services, to define a CDE. Recognizing CDEs as providers of DSMT care, including in telehealth, would help to address this gap in diabetes care.

Quality Payment Program (QPP)

In the context of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[5] implementation, we encourage the Administration to consider the following:

- Using an outcome-based approach, like those identified by Congress in MACRA, (as opposed to an approach dependent on quantitative metrics) can support the inclusion of telehealth and remote monitoring in providing patient care as any part the Quality Payment Program (QPP).
- In MACRA, Congress specified that telehealth and remote monitoring would be made available to ensure care coordination within the QPP Merit-based Inventive Payment System (MIPS) Clinical Practice Improvement Activities (IAs). Based on input from CHI, CMS adopted an IA under the MIPS program that supports doctors' review of patient generated health data (PGHD) in IA_BE_14 (*Engage Patients and Families to Guide Improvement in the System of Care*), a highly-weighted, Advancing Care Information Program-linked Improvement Activity which will drive the new value-based Medicare system forward in how millions of American Medicare beneficiaries are cared for. We support this important step by CMS and urge it to search for further opportunities to bring PGHD into the care continuum. CHI supports CMS' commitment to revisit the IA table periodically to ensure it makes necessary changes and seeks public input on the best process for making future changes.

[3] American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance. Adult Diabetes: Performance Measures. January 2014.

[4] 42 U.S.C. 1395x(qq)

[5] Medicare Access and CHIP Reauthorization Act of 2015, Public Law No. 114-10, 129 Stat. 87 (2015).

- Through the development of the Advancing Care Information (ACI) and Meaningful Use (MU) programs, CMS should reduce the reliance on CMS program participation and the use of Certified Electronic Health Record Technology (CEHRT). The Health Information Technology for Economic and Clinical Health (HITECH) Act incented physicians to purchase and use electronic health records (EHRs). Digitizing medical records has helped reduce issues associated with paper charts and records, including legibility, access, and loss. However, excessive regulation and overly-prescriptive federal requirements have created unintended consequences. Program participants are now bound to use poorly-functioning CEHRT products—built primarily to measure and report on CMS requirements—and are disincentivized from adopting truly useful technology. CMS should identify methods to reduce the overreliance on CEHRT in its programs and allow for physician and patient choice to drive the adoption and use of health IT products, such as by leveraging the value of connected health technology innovations that build on CEHRT. Through rulemakings such as its Inpatient Prospective Payment System, CMS has the ability to broaden current measures to focus on functions that physicians find useful rather than narrowly outlining how certain technology must be used. CHI welcomes the opportunity to provide further detail to CMS.
- Through MIPS, CMS should give Medicare Advantage (MA) health plans the flexibility to use telehealth and RM services as a basic benefit of service. Under its existing authority, CMA can provide a menu of remote monitoring or consumer-oriented information technology categories that primary care and specialty doctors would use for care improvement.
- CHI believes CMS should share our vision of a diverse array of connected health products and services, including telehealth and remote monitoring, playing an integral role in the success of APMs. However, in the current final MACRA rule, CMS does not mention these technologies in this context, nor in their role in the success of APMs. We believe CMS' total omission of connected health technologies in the APM section of the final MACRA final rule is a missed opportunity to improve care and reduce costs through new innovative APMs.
- Medicaid waiver authority can be used to encourage states to ask for waivers to include dual eligibles in their telehealth programs and establish programs for dual eligibles like Diabetes Prevention Programs, as age appropriate.
- CMS should also waive Medicare's telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and alternative payment models (APMs), including payment bundles and medical home demonstrations.

Medicare Shared Savings Program

CMS should exercise its statutory authority under 42 U.S.C. 1395jjj(f) in the case of the Medicare Shared Savings Program to waive payment and program requirements as appropriate to allow for one-sided and two-sided risk models under a waiver of telehealth restrictions. This would help providers that use APMs to reduce costs and meet statutory requirements. CMS recently exercised relevant waiver authority on several aspects of telehealth for two-sided risk models only. Doing so more broadly would further the success of APMs.

Medicare Advantage (MA)

CMS has recently proposed an MA rule that addresses proposed "additional telehealth benefits" as part of basic MA benefits per the Bipartisan Budget Act of 2018, Pub. L. 115-123 (BBA).[6] CHI agrees that these should be defined as services furnished by MA plans for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Social Security Act and have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange. We specifically support providing MA plan sponsors with the discretion to make the determination that the telehealth services are clinically appropriate as opposed to limiting coverage to only those services CMS covers under the telehealth benefit. However, we urge CMS to note that the definition only applies to telehealth under Medicare Part B, which specifies two-way audio and visual real time and interactive services. Furthermore, CMS should note that all other virtual services such as remote patient monitoring are not considered telehealth and therefore are not subject to restrictions as CMS has stated recently in the CY2019 PFS and the 2019 Home Health Rule. As a result, MA plan sponsors are already able to include other virtual services, including remote patient monitoring, in the basic benefits so long as considered clinically appropriate, providing a pathway to use innovative digital tools in MA.

[6] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (83 FR 54982).

CHI also notes that in this draft rule, as required by Section 50323 of the BBA, CMS proposes to allow MA plans to cover Part B benefits provided via electronic exchange as "additional telehealth benefits" and as a basic benefit as defined in § 422.101. Created by the BBA, section 1852(m) of the Social Security Act allows MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020, and to treat such services as basic benefits for purposes of bid submission and payment by CMS. The BBA limits these authorized "additional telehealth benefits" to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) and have been identified for the applicable year as clinically appropriate to furnish through "electronic information and telecommunications technology." In its efforts to implement the BBA, CMS has noted in the preamble that "[e]xamples of electronic information and telecommunications technology (or 'electronic exchange') may include, but are not limited to, the following: secure messaging, store and forward technologies, telephone, videoconferencing, other internet-enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication." We strongly urge CMS to rescind this preamble language and leave the proposed regulatory language as outlined: "[e]lectronic exchange means electronic information and telecommunication technology."

CMS must re-approach its implementation of Section 50323 of the BBA to ensure MA's alignment with CMS' established approaches to Medicare telehealth services, as well as to remote patient monitoring and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions. Further, we urge CMS to expressly state that remote patient monitoring technologies may be included as part of basic MA benefits and are not subject to 1834(m).

Home Health Prospective Payment System (HHPPS)

CHI supports CMS' proposal in the CY2019 HHPPS rule to include remote patient monitoring expenses used by a Home Health Agency (HHA) to augment the care planning process as allowable administrative costs that are factored into the costs per visit. Such a change ensures that remote patient monitoring is utilized on a cost per visit basis when it is used by an HHA to augment the care planning process and will result in a more realistic HHA Medicare margin calculation. CHI agrees with CMS that remote patient monitoring will be helpful in (1) augmenting HHA services in the patient's plan of care; (2) enabling HHAs to more rapidly identify changes in a patient's clinical condition and to monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care; and (3) augmenting home health visits.

However, CHI strongly urges CMS to align its proposed HHPPS definition of "remote patient monitoring" in the Draft CY2019 HHPPS with that captured in CPT codes 990X0 and 990X1. While CMS correctly and proactively distinguishes between "remote monitoring" services and "telehealth" in this and other rulemakings, in the Draft CY2019 HHPPS, CMS borrows heavily from CPT code 99091 to propose a definition for "remote patient monitoring" as the "collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA." In describing the collection of physiologic data, CPT code 99091 does not optimally describe remote monitoring, as CMS acknowledges in the 2018 Physician Fee Schedule final rule ("…we believe that activating CPT code 99091 for separate payment under Medicare for 2018 will serve to facilitate appropriate payment for these services in the short term…"), underscoring how this code and its descriptor do not accurately capture remote patient monitoring elements. Moreover, in the 2019 Proposed Physician Fee Schedule CMS proposes to activate and pay for newly created and appropriate remote monitoring codes that originated from the collaborative work of the American Medical Association's Digital Medicine Payment Advisory Group (DMPAG) and various digital health stakeholders including CHI. Providers of remote patient monitoring services will benefit greatly from the creation of these codes, should CMS correctly activate and cover these services. Importantly, these new codes provide for the supply of devices; set up and instruction; data collection (attended, unattended with algorithmic alerts, and unattended); transmittal; and report preparation of quantitative results. CHI suggests that CMS, in the HHPPS, contribute to a common definition of "remote patient monitoring" across its beneficiary programs (e.g., consistency with technical CPT codes 990X0 and 990X1). We therefore urge CMS to shift away from the definition it proposes in the Draft CY2019 HHPPS, and to align its definition of remote patient monitoring in the Draft CY2019 HHPPS with that proposed by 990X0 and 990X1.

Centers for Medicare and Medicaid Innovation (CMMI)

CHI appreciates CMMI's recent announcement of new models but remains concerned that CMMI is not adequately focused on exploring innovative technological healthcare delivery mechanisms. A 21st century healthcare system should embrace the array of new technologies available, such as remote patient monitoring technologies and asynchronous store-and-forward methods, which enable the delivery of healthcare solutions beyond the four walls of a hospital room or doctor's office.

In addition to recognizing the statutory burden of 1834(m), CMMI should work to reduce the burdens for potential applicants. CMMI should articulate consistent requirements that are applicable to all models being tested, rather than developing separate requirements for each. The burden for applicants and participants could be reduced through uniform processes, expectations, principles, and rules that span models like population health and chronic conditions that are being tested. To align payers with the goals of the CMMI models and incent their participation, CMS should build upon the QPP to encourage the development of models that are based on existing structures and payment models and allow existing networks to apply as Advanced APMs to make these entities eligible for Medicare bonuses and programs like MIPS and the QPP. In exploring the benefits of telehealth as defined in 1834(m), CMS should use its established authority to waive the backward-facing and outdated restrictions. CMMI should also focus on exploring new and innovative remote monitoring technologies (which are not telehealth under 1834(m) and therefore do not face its geographic, originating site, etc., restrictions). We further urge CMMI to build upon the successes of the Veterans Health Administration in its use of connected health technologies.

CMS should further exercise its statutory authority, such as 42 U.S.C. 1315a(d)(1), in the case of CMMI Models to waive payment and program requirements as appropriate to allow for one-sided and two-sided risk models under a waiver of telehealth restrictions. This would help providers that use APMs to reduce costs and meet statutory requirements. CMS recently exercised relevant waiver authority on several aspects of telehealth for two-sided risk models only. Doing so more broadly would further the success of APMs.

CMMI should also recognize and build upon the incredible successes of some Medicaid systems, such as the University of Mississippi Medical Center and the University of Virginia's Karen S. Rheuban Center for Telehealth. In these states (and some others), Medicaid programs have taken steps to support not only telehealth but—more importantly—remote monitoring innovations that bring PGHD into the continuum of care based on demonstrated improvements to patient outcomes and significant cost savings. CMMI can and should play a crucial role in proliferating these successes.

CHI supports CMMI's ongoing consideration of public input on new directions it should take to improve its operations, and we have provided detailed views to CMMI during its consultation process.[7]

[7] Letter from CHI to DEA Assistant Administrator John Martin (Apr 19, 2018), *available at* https://bit.ly/2jHwAXT.

Durable Medical Equipment (DME)

For DME, CMS has established that "therapeutic continuous glucose monitors (CGMs)" can be billed to CMS for both the DME component and an all-inclusive supply allowance. However, Medicare's local contractors have issued a coverage determination that will result in rejection of the supply allowance if a smart tablet- or smartphone-compatible app is used in conjunction with the CGM device and biosensors. This interpretation by Medicare contractors was not dictated by law and resulted in a programmatic policy that ignores the many efficiencies of secure connected technologies that have the ability to ease the burdens on patients while reducing costs to Medicare in DME payments. CMS clearly has the ability to change their course under existing authority and appears to have intervened to address the decisions of local Medicare contractors in this specific instance. However, CHI strongly urges CMS to ensure that the use of dual-use connected technology as DME is permitted widely.

Drug Enforcement Administration (DEA)

CHI urges the Drug Enforcement Administration (DEA) to reduce its regulations to foster innovation and competition in the electronic prescribing of controlled substances (EPCS),[8] particularly as the opioid epidemic continues to grow. These regulations currently prevent innovators, and particularly small business innovators, from participating in the EPCS market. Specifically:

- The DEA's requirements under section 1311.116 that require testing by a DEA-approved certifying body are unnecessarily rigid. CHI recommends that digital healthcare innovators be given the flexibility to demonstrate compliance with DEA biometric subsystem requirements through attestations and documentation that demonstrates their compliance, while also being able to utilize testing by a DEA-approved certifying body. Such flexibility would preserve DEA oversight of EPCS service providers while eliminating a rigid and costly compliance barrier for digital health innovators.
- The DEA's requirements under section 1311.116 require the co-location of EPCS software with the physician's device in order to issue an electronic prescription. Advancements in technology make the need for co-location unnecessary and this requirement ignores the advent of secure cloud computing-enabled approaches that allow independent devices to perform the same task. Removal of this requirement would make EPCS offerings more efficient and affordable for clinicians.

[8] Comments of CHI, *CMMI: Innovation Center New Direction* (Nov 20, 2017), *available at* https://bit.ly/2jHwAXT.

Food and Drug Administration (FDA)

The FDA, as the regulator of medical devices, has incredible opportunity to improve patient outcomes at reduced costs through reform of, and necessary clarifications to, its regulatory process. CHI continues to work with the FDA to remove barriers to innovation through revisions to guidance documents and other important policy changes, including in supporting the development of the Software Precertification Program. Overall, we commend the FDA's risk-based approach to the regulation of medical devices, including its use of enforcement discretion for low-risk devices.

CHI notes several ongoing challenging developments, however, that should be re-evaluated by the FDA:

- **Clinical Decision Support (CDS) Software** – we continue to be concerned with the FDA's proposed approach to CDS, which has yet to be finalized. The guidance requires significant revisions to reduce barriers to innovation in software being used for clinical decisions per Congress' intent in the 21st Century Cures Act. Areas needing revision include: the draft guidance's definition of CDS; key terms such as "a pattern or signal from a signal acquisition system" and "physiological signals;" and FDA's new proposed approach to the "independent review" of the basis for the recommendations presented by CDS, including its proposed approach to exclude "proprietary" algorithms from ever enjoying enforcement discretion.
- **Prescription Drug-Use-Related Software (PDURS)** – CHI is concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the PDURS in recently-released draft guidance,[9] which would divert from the Center for Devices and Radiological Health's (CDRH) work to modernize the FDA's approach to the regulation of Software as a Medical Device (SaMD). For example, CDER's approach to PDURS would take a situation-based approach, as opposed to the CDRH's risk-based approach to SaMD. Further, CDER's proposed approach to PDURS would expose software developed by a drug company to significantly longer approval timeframes, placing PDURS at an arbitrary disadvantage to SaMD overseen by CDRH. We recommend that the FDA's approach to PDURS be brought into alignment with the widely-supported approach developed by CDRH for SaMD.

[9] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25206.pdf.

- **Artificial/Augmented Intelligence (AI) and Machine Learning (ML)** – Because of AI and ML's incredible potential to improve treatments and patient outcomes, CHI believes that the FDA must directly address the role of AI and ML in a new standalone guidance document. Innovative medical software will likely utilize AI and machine learning to improve the software's processes, and it is important that the FDA ensure that a scalable, risk-based approach be taken to regulation and enforcement discretion. Industry, and software developers in particular, will benefit from the FDA's directly addressing AI and machine learning in this guidance.