

March 1, 2019

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Labor, Education, and Pensions
428 Senate Dirksen Office Building
Washington, District of Columbia 20510

Dear Chairman Alexander:

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 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, and keeps sensitive health data private and secure. 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 appreciate the Senate Committee on Health, Labor, Education, and Pensions' (HELP's) efforts to "lower health care costs, incentivize care that improves health and outcomes of patients, and increase the ability for patients to access information about their care to make informed decisions."¹ As the leading representative of the connected health community, CHI identified numerous actions Congress and the federal government should take to enable cost-effective care that better connects patients and physicians. Appended to this letter, please find several brief suggestions for Congress and the executive branch, including requiring Medicare to support remote patient monitoring; waiving Medicare telehealth siting and other restrictions; promoting interoperability and streamlining privacy rules; providing tax advantages for certain wearables, apps, and software platforms; and modernizing rules under the Health Insurance Portability and Accountability Act (HIPAA) to ensure patients can control their own data and use it to benefit their health in today's digital economy.

¹ https://www.alexander.senate.gov/public/_cache/files/832a5a4d-b526-443b-ad26-d28b6106c40c/friend-final.pdf.

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,

A handwritten signature in black ink, appearing to read "Graham Dufault". The signature is fluid and cursive, with the first name being more prominent.

Graham Dufault
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I. Congressional Leadership in Artificial Intelligence / Augmented Intelligence

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. This is important to the Committee's inquiry here because estimates suggest that AI could improve healthcare outcomes by 30 to 40 percent² while creating annual savings of \$150 billion by 2026.³ Meanwhile, AI-driven voice recognition and natural language processing programs are already saving caregivers substantial amounts of time they would otherwise spend wrestling with electronic health record (EHR) systems or performing administrative tasks. One voice recognition company reports that it cuts down on fully 45 percent of the time healthcare professionals otherwise spend on EHR entries and other paperwork.⁴ In any future conception of healthcare in the next few decades, AI figures heavily into the equation because of its ability to assist caregivers and patients in their goals of improving outcomes while managing costs.

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. We are therefore pleased that the Department of Health and Human Services is convening roundtables to discuss a strategy for the federal government's approach to AI in healthcare. 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.

II. Require Medicare to Support Remote Patient Monitoring

Remote patient monitoring (RPM) has been, and will continue to be, an important part of a robust healthcare system. Several clinical studies demonstrated the role RPM plays in reducing costs and improving outcomes for patients, especially for extremely costly care arrangements associated with chronic conditions.⁵ Recently, our efforts have begun to pay off in advocating for coverage for RPM. In the calendar year 2018 Physician Fee Schedule (PFS), the Center for Medicare and Medicaid Services (CMS) distinguished between "remote monitoring" services and "telehealth," clarifying that the former does not face 1834(m)'s limitations and permitted separate payment for remote physiological data monitoring by activating and unbundling Current Procedural Terminology (CPT) Code 99091 ("physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver"). The code allows reimbursement to physicians and

² NICOLE LEWIS, ARTIFICIAL INTELLIGENCE TO PLAY KEY ROLE IN POPULATION HEALTH, MEDICAL ECONOMICS (2017), available at <http://www.medicaleconomics.com/medical-economics-blog/artificialintelligence-play-key-role-population-health>.

³ ACCENTURE, ARTIFICIAL INTELLIGENCE: HEALTHCARE'S NEW NERVOUS SYSTEM (2017).

⁴ <https://www.nuance.com/healthcare.html>.

⁵ Connected Health Initiative, Key Clinical Studies Demonstrating the Benefits of Connected Health Technologies, available at <https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5b6b2f50758d46b08c8e9fcd/1533751123403/Connected+Health+Effectiveness+Resource+080818.pdf>.

qualified healthcare professionals who rely upon remotely gathered physiologic data to monitor patients and is an important, but incremental, step forward.

Then, in the final calendar year 2019 PFS rule, CMS activated and will pay for each of the three new CPT billing 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 days; and treatment management services. They are an important step, but the Committee should be aware of potential issues that arise with their implementation. For example, 99457, which reimburses for treatment management services, states that it covers activities of clinical staff “incident to” the qualified health professionals in an office. However, the rationale of the rule includes a prohibition on billing for monitoring services rendered by clinical staff outside of qualified health professionals. The rule is, therefore, internally inconsistent. Unfortunately, providers are unlikely to bill the code if staff other than nurse practitioners and physicians are not allowed to perform the monitoring. Qualified health professionals’ time should not be spent monitoring data from patients who are not high priorities for care—they should be alerted when a problem does arise by the staff performing the initial monitoring. Efforts to ensure providers avail themselves of tech-driven tools that empower caregivers to provide cost-effective, higher-quality care to the right patients fall short if implemented in a way that ultimately discourages their adoption. We urge the Committee to take these implementation considerations into account when evaluating CMS activities related to RPM and other connected health modalities.

CMS also proposed to recognize “communication technology-based services” that do not meet the Medicare telehealth services definition in Section 1834(m). CHI supports this rationale and agrees that while 1834(m) must still apply to the narrow set of defined services that fall under its definition moving forward, any sweeping of new modalities in as Medicare telehealth services by CMS would harm the development of connected health technology innovations as well as their being made available to countless American Medicare beneficiaries. Across these three CPT codes developed to address chronic care remote physiologic monitoring, we urge this Committee to join CHI in encouraging CMS to provide as inclusive of a framework as possible to maximize the value of remote monitoring to Medicare beneficiaries. We believe that CMS can maximize the value of these new remote monitoring codes by, among other steps, clarifying that:

- Patient-reported data is included in the category of physiological data RPM devices CPT codes bill for and is considered a valid method of RPM in value-based models as well. In some cases, RPM can only be conducted where patients are able to self-report and verify the metrics caregivers are seeking in order to monitor their health.
- CMS will waive copay requirements for these new remote monitoring codes.

CHI is deeply engaged with CMS in its regulatory process to support these new codes’ activation and in attaining the clarifications above (along with others). However, this Committee should be aware of the clarifications that could be made and implementation challenges in case it sees fit to weigh in on the matter. We also note that there are other important proposals that hold great potential for the use of connected health technology on the proposed calendar year 2019 PFS,

such as CMS' proposed adoption of and payment for virtual check-ins and remote evaluation of recorded patient information; and payment for interprofessional consultations performed via communications technology such as telephone or internet. We urge this Committee to ensure that CMS continues to take steps forward, with needed changes and clarifications we have identified through our connected health community consultations, to realize the potential of connected health hardware and software innovations in its reimbursement policies. Moving forward, Congress should ensure that CMS releases and studies related claims data that will yield important and unique insights on the employment of these services.

In the context of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) implementation, we believe the Administration should consider the following:

- The process MACRA set up for CMS to approve physician-led models requires private sector stakeholders to submit proposals to the Physician Technical Advisory Committee (PTAC). Since the law's enactment, the PTAC has reported on 22 such models, positively recommending about half. The Secretary has positively reviewed all of those, but the Center for Medicare and Medicaid Innovation (CMMI) has run pilot models on none of them. We urge the Committee to inquire as to which parameters CMMI uses to determine whether or not it will conduct pilots for or implement any physician-led models. The alternative is for physician-led groups to ask Congress to approve their models in statute, an extremely expensive and time-consuming process that MACRA sought to avoid.
- Using an outcome-based approach, like those identified by Congress in MACRA (as opposed to an approach dependent on quantitative), 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 Incentive 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). 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.
- In the current final MACRA rule, CMS does not mention RPM or other connected health technologies as an acceptable means of connecting with patients as part of successful advanced alternative payment models (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. The Committee should be aware of this omission as a primary oversight body of MACRA's implementation.

III. Waive Medicare Telehealth Siting and Other Restrictions

The ability for rural Americans to engage with their caregivers via telehealth is central to a healthcare strategy that serves all Americans with the highest-quality, most cost-effective care. But unfortunately, telehealth services—defined as two-way live voice and/or video in Medicare—are too often not a meaningful option for Medicare caregivers and beneficiaries in the continuum of care. The barriers to using live voice or video as a means for patients and doctors to communicate are due to Section 1834(m) of the Social Security Act, which limits Medicare coverage for such telehealth services to highly specific “originating sites” and to areas with a healthcare professional shortage.

It’s no wonder, then, that of the approximately \$1 trillion the federal government spends on Medicare every year, a minuscule \$29 million or so goes toward telehealth. We encourage policymakers to find ways to remove 1834(m)’s backward-facing restrictions that prohibit Medicare caregivers from utilizing telehealth services to improve beneficiary outcomes. Congress has already taken this on in specific ways. For example, we applaud both chambers for the passage and enactment of the Furthering Access to Stroke Telemedicine (FAST) Act of 2017 (S. 431) and for forwarding measures to expand access to telehealth for those impacted by opioid substance use disorder, including provisions of this Committee’s Opioid Crisis Response Act (S. 2680 / H.R. 6). We encourage this Committee to prioritize operationalizing the rollback of geographic and site restrictions in 1834(m). We support the Evidence-Based Telehealth Expansion Act (H.R. 3482, which is also a section of S. 1016) and urge the Committee to consider proposals like this that would empower CMS to ease access to telehealth where it is fiscally and clinically responsible to do so.

We discourage proposals to expand the definition of Medicare telehealth services beyond what CMS has interpreted from the statutory concept of telehealth—a live two-way voice or video session. Statutory changes that would expose new connected health modalities to the restrictions of 1834(m) would be unforced errors. We further note our appreciation and support for CMS’ proposal in its draft Calendar Year 2019 Physician Fee Schedule to recognize “communication technology-based services” that do not meet the Medicare telehealth services definition in Section 1834(m). While 1834(m) must still apply to the narrow set of defined Medicare services that fall under its definition moving forward, any inclusion of new modalities as Medicare telehealth services would harm the development of connected health technology innovations as well as their being made available to countless American Medicare beneficiaries. CMS should also waive Medicare’s telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and APMs, including payment bundles and medical home demonstrations.

IV. Promote Interoperability

A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called “store-and-forward”) technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the integration of PGHD into EHRs. Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector, and help eliminate information silos, data blocking, and barriers to patient engagement.

Interoperability must not only happen between providers, but also between RPM products, medical devices, and EHRs. A great example of interopm

perability between systems, devices, and networks can be seen in the communications technology industry, which has flourished globally. In addition to testing and finding consensus on industry standards, the Office of the National Coordinator for Health Information Technology (ONC) should prioritize encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This practice could also be used to measure the interoperability of EHR products. A system demonstrating “widespread interoperability” will provide useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must also be an incentive to communicate and pass information from one party to another.

Policymakers should enhance interoperability and access to health data through promulgating highly-anticipated information blocking rules per the 21st Century Cures Act as well as through establishing further incentives for health data interoperability (e.g., the Trusted Exchange Framework and Common Agreement). Policymakers should continue to promote ONC’s efforts towards an interoperable healthcare system.

We believe ONC shares CHI’s vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized. We strongly encourage ONC to ensure that its efforts prioritize the sharing of data generated by patients outside of the traditional care setting across the continuum of care. In addition to patients expecting access to their own health data, providers serving the beneficiaries of federal health plans will come to expect seamless access to secure patient data, where “[i]ndividuals are able to seamlessly integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service terms.”⁶ Further, ONC’s work to develop the trusted framework should incorporate and build upon the vision it set forth in its Interoperability Roadmap and PGHD framework.

The success of value-based care models depends heavily on bi-directional interoperability of healthcare data. To reward better outcomes and cost-effective approaches to care, providers must be able to utilize two-way APIs to access, share, and make meaningful use of data about their patients. True interoperability involves not just the ability to access data, but also the ability to use it and manipulate it for the user’s purposes and to benefit the patient. Knowing the whole story is important for providers and payers to understand the best treatment plan or prevention measures for patients, as well as for patients who seek greater engagement in their own care. Data from previous care settings becomes more important in value-based care because the viability of the provider depends on outcomes. The process to arrive at these outcomes becomes more efficient with care plans tailored to patients’ medical history, genetics, and other factors.

This is especially true for providers in rural areas, where there are fewer physicians serving people who live further away from care. Because of these geographic challenges, rural providers need data that shows which care plans or prevention and treatment measures are likely to work—and which aren’t—for the patients they see. Physicians spend about half their time doing paperwork and grappling with EHRs that create friction in their workflow. With fewer caregivers per capita and greater distances in less urban parts of the country, a system that traps physicians in endless stretches of administrative busywork is even more costly for rural patients. Caregivers simply don’t

⁶ ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* at 73.

have the time. Value-based care models enable providers in rural areas to divert resources to where and when they are needed most. The ability to access and analyze data on patients and populations is central to the ability to deliver cost-effective, high-quality care.

The private sector is making strides to assist with the interoperability of data across EHRs and other platforms, and a diversity of APIs are emerging to assist in bringing PGHD into the continuum of care. For example, Health Level Seven International (HL7) is a standards-setting organization comprised of stakeholders from across the healthcare spectrum that has developed the Fast Healthcare Interoperability Resources (FHIR) standard. This is a “light, thin” standard that attempts to homogenize a relatively small subset of data formats and elements across different data users in the healthcare system. The FHIR standard also comes with an API to facilitate the exchange of EHRs. To effectuate the adoption of FHIR, HL7 launched the Argonaut Project, which is also working on standardizing more granular aspects of data formatting and field entries.

It is important that incentives align in such a way that they encourage the adoption of data field and format standards like FHIR, without strict mandates that could lock in standards that fail to keep pace with innovation. Data field and format standardization is likely to change as better data set management develops. Eventually, EHRs and other vendors should provide for two-way APIs that allow software developers to both download data from large sets held by the EHR *and* upload that data into the system. This two-way capability will be central to ensuring that 1) patients will benefit from newer innovations as quickly as possible and 2) interoperability will evolve more naturally with developments in software and hardware. Healthcare providers usually work with a wide variety of vendors, from device makers to software companies, and ensuring they all work together to paint an accurate and seamless picture for caregivers is critical, especially for value-based care models.

V. Provide Tax Advantages for Certain Wearables, Apps, and Software Platforms

Policymakers should also incent patients themselves to bring connected health innovations into their own care by making appropriate changes to the tax code to allow software apps and platforms, as well as wearable monitoring devices, to qualify as eligible medical expenses under the tax code. CHI urges this Committee to join us in seeking to provide consumers and patients across the nation with the ability to more easily acquire and use the software and hardware available today to get more engaged in managing their own health and, once diagnosed, treatments.

Many popular watches on the market are being upgraded with sensors and other technology. Technology is advancing 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 rural Americans could not send these accurate readings to their physicians and work the data their devices gather into the continuum of their own care.

Importantly, policymakers have the opportunity 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. Such an incentive would help rural Americans—

especially those at risk for chronic conditions—access preventive digital medicine proven to produce positive results.

VI. Modernize Rules Under the Health Insurance Portability and Accountability Act (HIPAA)

CHI submitted comments to the Office of Civil Rights (OCR) on the HIPAA request for information (RFI) request to streamline the rules and to promote patient engagement with their health. Potential changes to the HIPAA rules, as well as related rules such as the information blocking report and Trusted Exchange Framework and Common Agreement (TEFCA) proceeding, are key pieces to the larger shift towards a value-based system, and necessary for care coordination to function. OCR can make major inroads in this respect by ensuring its regulations are technology neutral and outcome-driven (i.e., not locked into certain technologies). Past these formal recommendations, we also urge OCR to engage in ongoing outreach to the range of stakeholders affected by the HIPAA rules, including the developers and range of users of connected health technologies. For example, we recommend that OCR convene a working group to investigate whether current rules or internal practices within a large organization hinders data sharing for research and population health initiatives due to misperceptions about HIPAA. These regulatory processes should result in more clarity for providers, technology makers, and patients to understand how all stakeholders can most efficiently make healthcare information interoperable without incurring liability while allowing for seamless care coordination. Better, more responsible access to data would enable more innovative healthcare tools that help providers control costs and deliver better services for consumers and patients across the nation.

We encourage OCR to issue guidance specifically related to text messaging and chat services like Microsoft Teams as soon as practicable. Such guidance would help HIPAA covered entities understand how they may or may not use text messaging and chat services in the course of patient care, including care coordination and communication with family and caregivers, and decrease fear of HIPAA violations leading to OCR enforcement. Similarly, CHI encourages OCR to provide clarity as to how push notifications will be treated under HIPAA.

VII. Stark Law and Anti-Kickback Statute

The Anti-Kickback Statute (AKS) and Stark Law are prime examples of well-intentioned laws that frustrate CMS' progress as it seeks to evolve Medicare from fee-for-service to value-based care. We agree with CMS' assessment that the Stark Law and AKS provide important anti-fraud protections for Medicare. However, they are both out of date and present barriers to innovation, and considerations for new exceptions to the laws are needed.

As more caregivers move from fee-for-service to value-driven models under Medicare, policymakers should modernize regulatory vestiges—like features of the Anti-Kickback Statute and the Stark Law—intended to reduce fraud, waste, and abuse that specifically result from fee-for-service practices. We believe that the Office of the Inspector General (OIG) could provide clarification on questions regarding anti-kickback laws to reflect realistic engagement program requirements. Such issues include ensuring that giving patients a device (e.g., a tablet) to communicate with a care team is not considered patient inducement; or that providing physicians with platforms for telemedicine is not violating the anti-kickback statute. Reducing barriers to value-based care presented by AKS and the Stark Law is important to the Committee's inquiry in this case because value-based care should help control Medicare costs while driving high-quality care.

In its fall Semiannual Report to Congress, OIG declined to propose new safe harbors in response to public comments, stating that they required more study and that questions about the application of the anti-kickback statute should be addressed on a case-by-case basis like the advisory opinion process.⁷ OIG's position is particularly challenging for digital medicine and mHealth applications where the provision of data and/or data analytic tools may be considered an illegal inducement even when they have no inherent or standalone value. This leaves stakeholders in a cycle where health care providers are unwilling or unable to pay for data (either because it is not a reimbursable expense or expectations that access to data or data platforms should be free after one has paid for equipment or last-mile connection, and vendors and manufacturers are barred from providing data or data services as part of a paid-for product or service).

VIII. Conclusion

We appreciate that the Senate HELP Committee 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.

⁷ OIG Semiannual Report to Congress—April 1, 2017, through September 30, 2017, Appendix G, available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf>.