ConnectedHealth

Testimony of

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Before the

U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health

"Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

I. Executive Summary.

I am president of ACT | The App Association and current executive director of the Connected Health Initiative (CHI), an organization that has pulled together a broad consensus of healthcare stakeholders, including physician groups, patient groups, device manufacturers, software companies, venture capital firms, and research universities. We observe that Medicare, bound up in labyrinthine regulations and payment policies, presents serious challenges to the incorporation of tech-driven tools that can make healthcare more accessible and user-friendly.

This hearing takes place at a critical moment for American healthcare. Demographics are poised to apply new pressure to the system, as Baby Boomers move to Medicare. With the number of Americans over age 65 jumping from 40.3 million in 2010 to a projected 55 million in 2020—and up to 70 million in 2030—older Americans constitute an increasing percentage of the population. And as life expectancy increases, so does the expectation of staying home as we age. Currently, 87 percent of Americans over the age of 65 say they want to stay in their current home as they get older. The confluence of these demographic projections, along with buy-in from an unprecedented breadth of stakeholders who are recognizing the maturity of the technological tools at medical professionals' disposal, means the time is right to make substantial progress toward innovation-driven, value-based care.

As we evaluate and suggest policy positions for decision-makers, we ask three fundamental questions:

- **Does it drive value for patients?** When your constituents think about what they would change about healthcare, chances are they are fed up with a lack of access to care—from waiting in line to being unable to use the supercomputer in their pocket to manage their health. Medicare policies should enable innovators to make healthcare both more accessible and more effective for patients.

- **Does it drive value for caregivers?** Unfortunately, physicians report spending fully half of their time at work on electronic health records (EHRs) and other desk work.[1] Accounting for the other necessary activities, they are left with only 27 percent of their time dedicated to direct clinical face time with patients. It is critical that Medicare policies help caregivers spend more time with patients and less time at their computers.

- **Does it drive value for taxpayers?** The current cost spiral—in which Medicare incents caregivers to care for the sickest patients in expensive settings—is unsustainable. The question we ask is not whether a policy makes care "cheaper," rather, the question is whether a policy creates incentives for caregivers to avail themselves of cost-effective measures. Medicare policies should make cost-effective options the most attractive both for clinical and for financial reasons.

As the growth in demand for healthcare services outstrips supply growth, tech-driven tools like artificial intelligence (AI) are maturing from shiny objects into meaningful enhancements to the practice of medicine. In fact, experts are referring to AI in the healthcare context as "augmentative intelligence," a much more accurate description of its current and predicted future roles in the medical profession. Stakeholders across the healthcare field recognize that connected care can be a multiplier of—rather than an impediment to—caregivers' ability to treat patients. However, in many ways, the policies dictating the use of technology have detracted from the time caregivers spend with patients, particularly because of the arcane nature of Medicare regulations and payment policies.

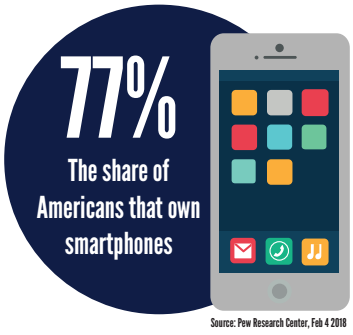
But all is not lost. In fact, other highly regulated industries have successfully overcome these obstacles and empowered innovators to drive convenience and cost-effectiveness. Financial services stands out as an example of an industry that features similar risks to those presented in the healthcare context. The misuse or misappropriation of financial accounts or information could have disastrous consequences, as could substandard healthcare or misuse of healthcare information. And yet, we can check our balances, transfer

funds, pay credit cards, and make any kind of purchase by a few taps on swipes on our phones. The financial services example illustrates that complex webs of regulation are not insurmountable. Why have we been unable to harness technologies like this in the healthcare context? The good news is that there is a path forward. There are numerous levers policymakers can pull to enhance value for patients, caregivers, and taxpayers alike. For example, policymakers should take the following steps:

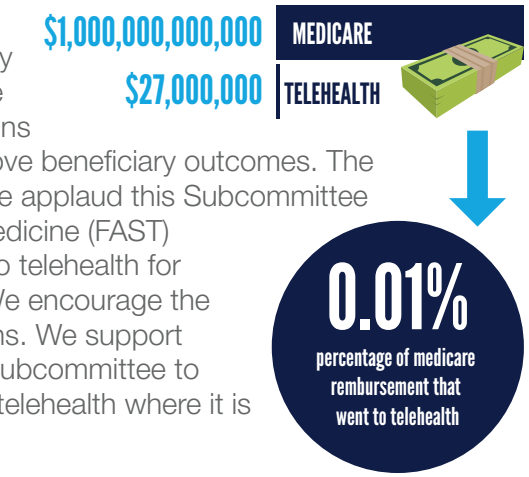
- First, policymakers should clarify that Medicare does not penalize—and in fact supports—the adoption of tech-driven tools that enhance efficiency and clinical efficacy, including by passing the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017 (H.R. 2556);
- Second, for practices that still use a fee-for-service model, the Centers for Medicare and Medicaid Services (CMS) should adopt billing codes that cover activities involving clinical enhancements using patient-generated health data (PGHD) and remote patient monitoring;
- Third, as more caregiving settings move from fee-for-service to value-driven models under Medicare, policymakers should file down 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;
- Fourth, Congress should peel away the overburdensome restrictions on telehealth under 1834(m) of the Social Security Act and consider requiring the Congressional Budget Office (CBO) to look beyond the 10-year budget window, including by passing the Preventive Health Savings Act (H.R. 2953);
- Fifth, policymakers should enhance interoperability and access to data through better guidance from the Office of Civil Rights (OCR) and finalize the "data blocking" rules; and
- Sixth, policymakers should support access to broadband, especially in rural areas—including using unlicensed spectrum—to enable connected health technologies to reach rural populations that suffer from high rates of chronic disease.

These are just a few examples of specific measures policymakers could take to enable advances in value for patients, caregivers, and taxpayers via innovations in connected and digital health tools.

II. Telehealth.



Too often, telehealth services – defined as two-way live voice and/or video in Medicare – are 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. In other words, telehealth is really only available where patients aren't. 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. The Subcommittee has already taken this on in specific ways. For example, we applaud this Subcommittee for the passage and enactment of the Furthering Access to Stroke Telemedicine (FAST) Act of 2017 (H.R. 1148) and for forwarding measures to expand access to telehealth for those impacted by opioid substance use disorder, including H.R. 5603. We encourage the Subcommittee to prioritize operationalizing the rollback of these restrictions. We support the Evidence-Based Telehealth Expansion Act (H.R. 3482) and urge the Subcommittee 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 do not propose to expand the definition of Medicare telehealth services beyond what CMS has interpreted from the statutory concept of telehealth—a live, interactive voice or video session. CHI strongly discourages any statutory changes that would expose new connected health modalities to the restrictions of 1834(m). We further note our appreciation and support for CMS' proposal in its draft Calendar Year 2019 Physician Fee Schedule to recognize of "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.

a. Value for Patients.

The mere thought of seeking preventive or prospective care may be exhausting for those who associate the healthcare experience with burdensome travel requirements, long waits, and other impediments to physician access. It is no surprise, therefore, that many patients who are sick or suffer from chronic conditions tend to wait for their illnesses to progress to a stage where it is more expensive and more difficult to address than if prevention and/or treatment had been provided earlier. And the experience could worsen, given trends in U.S. age demographic realities, guaranteeing that more Medicare patients will soon be seeking care from a system struggling to grow with the demand. Short-circuiting these tendencies to procrastinate in seeking care is only possible where access to care is enhanced, and we commend this Subcommittee for examining this area of need. The opportunities to enhance the value of healthcare are drastically increased for patients with smartphones, tablets, and other connected devices, representing an increasing majority of Americans, including Baby Boomers. This is especially true for rural Americans and those who otherwise lack convenient access to physical care.

b. Value for Caregivers.

Surveys reflect that caregivers want to reach more patients where they are. In fact, the University of Virginia (UVA) seeks to scale telehealth encounters to 60,000 per year over the next two years, and Cleveland Clinic similarly aims to reach 35,000 telehealth encounters over the course of a year. These plans are not unique, with the American Hospital Association finding that 65 percent of hospitals have implemented telehealth in at least one care unit, with that number expected to grow by another 13 percent.[2] Providers' proposed adoption of telehealth is good news for patients, but the benefits of Medicare telehealth services pales in comparison to the improved outcomes and cost savings associated with the use of further connected health products and services (discussed in further detail below).

c. Value for Taxpayers.

The benefits of telehealth for taxpayers are equally well-documented. The first 100 diabetes patients in the CHI steering committee member University of Mississippi Medical Center's (UMMC's) telehealth program, for example, collectively saved an incredible $336,184 in healthcare costs.[3] Using this data, cost analyses estimate that if 20 percent of Mississippi's diabetic population were enrolled in the telehealth program, it would save the state $189 million in Medicaid dollars.[4] The AMA further found through in-depth interviews with members of its Digital Medicine Payment Advisory Group (DMPAG)—of which I am a member—that instead of merely supplementing patient utilization, digital medicine offerings (including telehealth) substitute for otherwise more expensive healthcare services.[5] This evidence from practitioners contradicts the often-overstated fears that telehealth could lead to a bonanza of overutilization.

To the extent that the cost savings telehealth could produce may not materialize for several years—insofar

as they are used for preventive care—the CBO's 10-year threshold is a barrier to adoption. For this reason, we support Chairman Burgess's and Rep. DeGette's Preventive Health Savings Act (H.R. 2953). Enabling committees to require CBO to analyze potential savings beyond the 10-year window for federal coverage of certain preventive measures would be a major step forward to unlocking the benefits of telehealth and other connected health modalities aimed at prevention.

III. Anti-Kickback Statute and Stark Law.

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. CHI notes its appreciation of the Department of Health and Human Service's (HHS') recent public solicitation for comments on the AKS and Stark Law's impact on innovation,[6] on which CHI has commented and urges this Subcommittee's to consider.[7]

We urge the creation of Stark Law exceptions that will responsibly facilitate the greater uptake of connected health innovations—be they hardware, software, or a combination of the two—throughout the continuum of care, including for Accountable Care Organizations. Moreover, the HHS' Office of the Inspector General (OIG) should 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 physician platforms for telemedicine is not violating the AKS. We have raised our views regarding the AKS previously in more detail and urge for their careful consideration by CMS.

CHI does not seek statutory changes to the AKS or the Stark Law; we believe HHS has clear authority to provide exceptions (in the case of the Stark Law) and much-overdue guidance (in the case of the AKS) to providers and other stakeholders, and we urge this Subcommittee to encourage HHS to take such steps as rapidly as possible.

a. Value for Patients.

The value of re-orienting the AKS and the Stark Law lies in enabling a user-friendly patient experience. The HHS' OIG has made some strides in this regard and recognizes the opportunities to create safe harbors that enable patients to access products and services that make their healthcare experience more effective and easier. For example, in its efforts to address fraud and abuse in Medicare and state health programs, OIG recognized in its December 2016 safe harbor rulemaking that "[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers," and assured that "we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending." Both the Inspector General and the Chief Counsel to the Inspector General have indicated that OIG is interested in exploring ways to permit greater flexibility for value-based arrangements, while still guarding against the problems the fraud and abuse laws were designed to prevent.

We believe that the 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 physician platforms for telemedicine is not violating the anti-kickback statute.

b. Value for Caregivers.

Small practices, in particular, could benefit from the extension of the Stark Law donation exemption (scheduled to expire in 2021) for interoperable technology, along with an expansion of this exemption to allow for donations aimed to improve the exchange of health data through innovative application programming interfaces (APIs) and other tools. Permitting such donations would assist smaller practices facing resource constraints to advance

value-based care using connected health technologies. Under current conditions, EHRs demand ridiculous amounts of time and energy on the part of physicians. Layering on another set of digital tools is not likely to help physicians unless those tools are woven into the continuum of care in an intuitive and user-friendly way. These attributes, in turn, are only achieved where they are woven into clinicians' treatment regimens.

In the case of the AKS, providers seeking to use connected health tools face the risk of liability under AKS should they provide those tools to their patients. Such tools are demonstrated to improve patient engagement and outcomes, as well as to save caregiver team resources. Without guidance from HHS on AKS as applied to the use of connected health technology (e.g., tablets, software platforms, etc.), no physician could be expected to take the risk of violating AKS, and AKS will remain a significant barrier to innovation in healthcare.

The barriers AKS and Stark Law present make the seamless integration of digital tools and caregiving difficult and in some cases impossible. Removing or reducing those barriers could dramatically enhance value for caregivers.

c. The Value for Taxpayers.

Congress' vision for value-based care, led by this Subcommittee, relies heavily on the development of risk-sharing models that are defined by flexible contracting arrangements. For example, a software company may partner with a device company to provide services to a mental health clinic. The contract between the software-device company joint venture and the clinic may contemplate higher or lower compensation for the joint venture depending on the effectiveness of the services and devices it provides the clinic. Unfortunately, this arrangement may run afoul of AKS, which prohibits the exchange of value in return for referrals or to generate healthcare program business.[8] Especially if the clinic is part of the joint venture, the Stark Law could also prohibit any value-driven discounts between the parties because it prohibits a physician from referring Medicare patients to an entity with which the physician has a financial relationship. These types of contractual arrangements—in which risk is shared, efficacy is rewarded, and ineffectiveness is penalized—are central to aligning value with Medicare's payment system. Identifying appropriate exceptions and mitigations for AKS and Stark Law prohibitions is, therefore, a key element of driving value for taxpayers as the system moves to value-based care. Without action by HHS, the AKS and the Stark Law will continue to present barriers to the use of connected health innovations and the demonstrated program savings their use brings.

IV. Clarification in Value-Based Models.

The value proposition for clarifying CMS' expectations and requirements in the context of the Quality Payments Program (QPP) is similar to that of providing exceptions to and reinterpreting the AKS and the Stark Law. Providers want to know that the adoption of tech-driven tools integrated into the continuum of care is welcomed by CMS and that such adoption will not disadvantage them from a Medicare coverage perspective or expose them to liability.

Relatedly, the process by which the federal government recognizes new technologies and care modalities to fold them into the continuum of care is extremely long-winded. Nobody wants technology at the speed of government, but too often, that's what patients in the Medicare system get. Under the current procedure, the Center for Medicare and Medicaid Innovation (CMMI) must first approve a modality as something it has the authority and evidence base to begin testing it in a pilot project. Then, CMMI must obtain federal funding to carry out the study and create the study's parameters. After the study is conducted in a specific location drawing on a specific population with certain demographic characteristics, CMMI can finally issue the study, which is then thoroughly reviewed. After all of this, if the study stands up to review, the activities it covers might see Medicare reimbursement after at least a year of rulemaking exercises. Taken all together, this process can take 10 years. To put that in perspective, smartphones have been on the market for a decade, so imagine if we had to wait for CMMI to approve those before we could put them in our pockets. We would all have the first generation of iPhones, LGs, Galaxies, or Pixels. The current treatment of new technologies in the Medicare system is one that validates old ideas; it does not find new ones. We urge the Subcommittee to work with CHI to identify

opportunities for improving the process by which new technologies are approved and validated as cost-effective, clinically appropriate, and implemented with low risk of waste, fraud, and abuse.

The recent advancements made by CMS through both its Physician Fee Schedule (PFS) and QPP we have discussed above are significant, but they do not reduce the crucial role that CMMI plays (and will play) in exploring new innovations in Medicare and Medicaid. Nor do these changes alter the fact that, to date, the efforts of the CMMI in exploring the benefits of connected health technologies (both telehealth and remote monitoring) have been insufficient given the immense value these technologies provide. We support a new direction for CMMI and urge CMMI to truly explore these technologies potential as soon as possible through its efforts, building on recent advancements made in the PFS and QPP. CMMI should be ahead of this curve and not behind it. CHI commits to assist CMMI in any way possible to get to CMMI to the forefront of innovation in delivering care to Medicare and Medicaid beneficiaries.

a. Merit-Based Incentive Payment System (MIPS).

CHI supports CMS' efforts to incent the use of connected health innovations in the Merit-Based Incentive Payment System (MIPS) through providing modality-neutral approaches to Improvement Activities (IAs) and flexibility for program participants. For example, CHI supports CMS' adoption of CHI's proposed MIPS IA – IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care) for care coordination incenting providers to leverage digital tools that collect PGHD for patient care and assessment outside the four walls of the doctor's office using an active feedback loop.[9] CMS not only adopted the IA, but also assigned high weight and linkage to an Advancing Care Information bonus to it, signaling to providers that CMS acknowledges the important role connected health tools can play in improving health outcomes and controlling costs. This Subcommittee's Medicare Access and CHIP Reauthorization Act (MACRA) calls for an IA inventory that "shall include activities such as . . . remote monitoring or telehealth," and we encourage continued congressional oversight to ensure the continued adoption of IAs that pave the way for the adoption of digital tools.

CMS' previous policy of providing bonus points in the Promoting Interoperability (PI) category represented CMS' understanding that connected health innovations play a key role in improving outcomes and incent physicians to incorporate technology into their practice workflows and clinical activities. With regard to how connected health tools could better support the feedback related to participation in the QPP and quality improvement in general, we believe that the CMS' evaluation must reflect the fact that remote monitoring and telehealth—across patient conditions—offer key "health information technology [IT] functionalities," including the automatic collection and transmission of important biometrics for timely caregiver review and analysis.

Many CHI members develop truly unique applications that benefit both providers and patients. However, CMS' regulation that includes misplaced Certified EHR Technology (CEHRT) incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently across all MIPS components. For instance, the PI component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT.

This Subcommittee should ensure that CMS shifts away from rigidly requiring the use of CEHRT to an outcomes-based approach that would permit the use of non-CEHRT across the entire MIPS program. CMS should also seek to minimize administrative burdens (e.g., lengthy documentation reporting requirements) on Medicare caregivers. Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS-eligible clinicians to effectively demonstrate improvement through health IT usage. Further, changes in MIPS are inherently linked to other important rules CMS is responsible for, including the PFS which has recently begun to incent the use of asynchronous tools that will bring PGHD into care. Efforts to revise MIPS measures and objectives generally should be made in alignment with non-CEHRT use (e.g., remote monitoring technology) which can greatly improve patients' care and wellness. CHI commits to work with this Subcommittee to maximize the value of MIPS.

b. Alternative Payment Models.

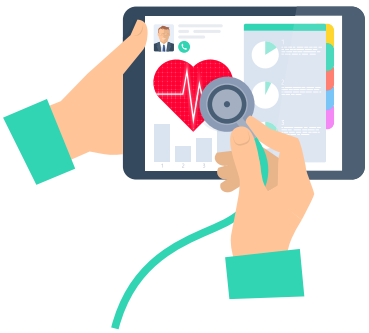
CHI also supports Congress' goal of realizing innovative Alternative Payment Models (APMs) and continues to work with stakeholders to find innovative alternatives to MIPS. APMs, with their financial and operational incentives, should demonstrate the best uses of remote monitoring or telehealth tools. To date, CMS has not discussed telehealth and remote monitoring's key role in the success of APMs in its heavily relied upon annual rulemaking. CHI maintains that this glaring oversight forces eligible clinicians, as well as other key stakeholders and organizations, to conclude that telehealth and remote monitoring do not have a role in APMs. We call on CMS to provide this crucial commentary and insight in the next final (CY2019) QPP rule. Such a step would also be consistent with CMS endorsement of telehealth and remote monitoring in MIPS.

Further, the current restrictions of 1834(m) are particularly inappropriate for APMs. We strongly support relieving APMs from the onerous Medicare telehealth restrictions in 1834(m). In a limited set of circumstances, CMS has taken steps to provide relief from section 1834(m)(4)(C) to pre-QPP APMs, demonstration projects, and Innovation Center models. For example, CMS provided this limited relief to Next Generation Accountable Care Organizations (ACOs). In addition, in the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, CMS waived the rural geographic requirement and allowed telehealth services to be covered in patients' homes or place of residence.

The ongoing annual MACRA implementation rulemaking presents CMS with a golden opportunity to endorse the use of connected health technology innovations in APMs and to provide waivers from all of 1834(m)'s restrictions. To attract participants to the APM program, the flexibility to utilize the range of connected health innovations can be a reward and a competitive advantage. APM quality and performance measures paired with the ability to collect and quickly analyze data collected through these tools will protect against fraud and Medicare's traditional fee-for-service utilization controls.

c. Value for Patients.

If an APM is allowed the flexibility to use connected health technologies for patients with specific at-risk chronic conditions, those patients would benefit from much more user-friendly and effective care. If CMS provides certainty for providers that it considers whether they integrate remote monitoring to improve quality, while reducing per capita total costs of care, providers will be more likely to adopt those measures as part of an APM and patients would benefit. CHI Steering Committee member UMMC adopted a remote monitoring strategy out of necessity, and the evidence shows improvements to outcomes as well as ease of use for UMMC patients. The 100 diabetes patients enrolled in the telehealth program saw a 1.7 percent reduction in their A1C levels, zero hospitalizations, and zero emergency room (ER) visits.



Similarly, MIPS programs that incorporate remote patient monitoring enable patients with chronic conditions to access better care in the form of remote monitoring and interactive care. CHI member company Podimetrics, for example, manufactures the SmartMat™, which—pursuant to clinical trials—can detect diabetic foot ulcers about five weeks before they present clinically. Diabetes patients at risk for developing a diabetic foot ulcer (DFU) may be required to undergo skin grafts or even amputations if DFUs develop. Preventive treatment is therefore exceedingly important for diabetic patients at risk for DFUs. Fortunately, MIPS providers should be more likely to adopt technologies like the SmartMat™ because the MIPS program recognizes the analysis of PGHD as an IA. Further improvements for patients could include shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach that would permit the responsible use of non-CEHRT by MIPS caregivers. CMS should also seek to minimize administrative burdens (e.g., lengthy documentation reporting requirements) on Medicare caregivers. Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS eligible clinicians to effectively demonstrate improvement through health IT usage while also measuring such improvement.[10]

d. Value for Caregivers.

Increased flexibility in the APM and MIPS programs would produce obvious benefits for caregivers, most notably by allowing them to access the technologies of their choice, in a manner that augments—rather than impedes—their ability to practice medicine. Moreover, effective use of RPM technologies allows providers to prioritize patients with more urgent needs, in many cases guided by the software. This is especially true if CMS were to allow MIPS providers to use technologies beyond CEHRT. In its proposed Query of Prescription Drug Monitoring Program (PDMP) measure, CMS has acknowledged the use of health IT beyond CEHRT. Providers' use of this technology is also important in the MIPS context, so we would support CMS allowing providers the flexibility to adopt technologies that build on CEHRT, for example. This enhanced flexibility and choice for caregivers would make integration of tech-driven tools using PGHD more user-friendly and enable them to see the full potential of these tools to enhance the caregiving experience and reduce EHR and desk time.

e. Value for Taxpayers.

Enabling MIPS providers and APMs to adopt tech-driven tools like remote patient monitoring and care coordination platforms helps effectuate MACRA's goal of aligning participating providers' incentives with those of taxpayers. By using a software platform like the one by CHI Steering Committee member Rimidi—which enables diabetes patients and their care teams to manage diet and other inputs in real-time and with customizable settings—MIPS providers and APMs can more effectively create an environment that responds to patients' needs in a cost-effective manner. A failure to either acknowledge digital medicine in APM rules or reward it in MIPS scoring dissuades providers from selecting tools that can enhance cost-effectiveness and clinical efficacy. At the same time, the incentives that exist in a fee-for-service system—where providers are tempted to order services like imaging and lab tests because each is reimbursed separately—are not present in the same way with MIPS scoring or APM rules. The incentives in MIPS are for the provider to implement IAs and report on quality measures (which are designed to improve cost-effectiveness and clinical efficacy) that increase its score. Similarly, the rules incent APMs to implement quality measures demonstrating cost-effectiveness and high-quality care. Digital tools that enable providers to treat and consult patients in less costly settings, more directly, and with greater customizability help providers achieve the APM and MIPS goals so rules governing the programs should avoid dissuading providers from using them.

Further, we completely disagree with the notion that a service provided by a caregiver using digital tools raises inherently more serious waste, fraud, or abuse risks than if the service were provided in person. In fact, in addition to the benefits described above, enabling the use of digital tools in value-based settings provides a more streamlined and accurate way of tracking transactions, patient engagement, and service provision. Thus, digital tools can actually help assure taxpayers that the products and services Medicare pay for are put to their proper use in ways that are unavailable without them.

V. Fee-for-Service Updates to Facilitate the Transition to Value-Based Care.

As more Medicare services and funding shifts to QPP, the PFS will remain an important means of reimbursing providers for healthcare services for Medicare patients. But one key component to an effective transition is for the PFS to acknowledge and support modern digital health modalities so that providers who rely on the PFS can be reasonably compensated for adopting efficiency- and quality-enhancing digital health tools. A failure to cover the time clinical staff spends in providing care using PGHD, or resources spent integrating software platforms and devices that help facilitate preventive care, would have the perverse effect of pushing providers to spend valuable time and resources on less cost-effective care measures when conditions are worse and where settings are costlier.

In its 2018 PFS rulemaking, CMS distinguished between "remote monitoring" services and "telehealth," 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, which has several limitations, allows reimbursement to physicians and qualified healthcare professionals who rely upon remotely gathered physiologic data to monitor patients.

CHI strongly supports CMS' current proposals to activate each of the three new CPT codes developed to address chronic care remote physiologic monitoring (990X0 [Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment]; 990X1 [Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days]; and 994X9 [Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month]).[11] Each of these codes was developed through concerted and thoughtful deliberations of the DMPAG, which is comprised of experts in digital medicine services as well as coding, valuation, and coverage. The DMPAG, in turn, submitted applications for the creation of these new codes to the independent CPT Editorial Panel which vetted and approved the applications for new codes. The CPT Editorial Panel considered, among other relevant factors, significant supporting clinical documentation. We understand that the AMA's relative value scale (RVS) Update Committee (RUC) undertook a valuation of these codes to which CMS has access. We urge this Subcommittee to ensure that CMS covers, prices, and pays for those new CPT codes utilizing the RUC information. The RUC relied on an existing body of evidence demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, and those facing access barriers due to geography, limited mobility, or medical fragility. Moving forward, this Subcommittee should ensure that CMS release and study related claims data that will yield important and unique insights on how these services are being employed.

Across these three CPT codes developed to address chronic care remote physiologic monitoring, we urge 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 physiological data collected via automated remote monitoring technology fits within CMS' definition of physiological data.
- A device used can be caregiver- or patient-provided and need not be prescribed. Requiring that the provider order such a device via a prescription may exclude devices already in use/available, and would reduce needed flexibility in use of 990X0, 990X1, and 994X9 services for both caregivers and patients.
- An established relationship between a provider and a patient exists after such a relationship is created by a provider in that practice.

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).

Separately, the Home Health Prospective Payment System (HH PPS) is a payment program for home health agencies (HHAs) which is relevant to this hearing. In its current draft HH PPS rule, CMS proposes to include evidence-based remote patient monitoring expenses used by an HHA to augment the care planning process as allowable administrative costs that are factored into the costs per visit.[12] Such a change will ensure that use of remote patient monitoring is fairly considered 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. However, CMS proposes to define RPM very narrowly 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." This description does not fully capture RPM elements such as the supply of devices; set up and instruction; data collection [attended, unattended with algorithmic alerts, and unattended]; transmittal; and report preparation

of quantitative results. Further, it makes more sense to use a consistent definition of RPM across its beneficiary programs (e.g., consistency with recently proposed technical codes 990X0 and 990X1). We have asked CMS to shift away from its definition proposed in the draft rule and to align this definition of remote patient monitoring with that proposed for 990X0 and 990X1 and urge this Subcommittee to ensure that CMS takes these necessary steps.

VI. Access to Data and Interoperability.

The efficacy of precision medicine, population health, clinical decision support—and AI driven tools in particular—is dependent in large part on the availability of massive data sets. The free flow of information and interoperability are therefore important, potentially life-saving conditions. CHI is committed to advancing health data interoperability throughout the continuum of care.

Electronic health information and educational resources are critical tools that empower patients to engage in their own care. 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 two-way open 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 interoperability 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, this Subcommittee 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 CEHRT and CEHRT systems. A good example of industry-led efforts to establish standardized implementation of a standard is the Argonaut project, which helps standardize the implementation of the Fast Healthcare Interoperability Resources (FHIR) standard. But even private sector efforts like Argonaut can become too focused on compliance-driven efforts in order to meet perceived regulatory requirements. There must also be an incentive to communicate and pass information from one party to another. We also note that MACRA[13] provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics.

We believe this Subcommittee shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD. We strongly encourage this Subcommittee to ensure HHS' interoperability efforts prioritize data generated by patients outside of the traditional care setting. Providers serving the beneficiaries of federal health plans will come to expect access to seamless and secure patient data across the care continuum, 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."[14] Moreover, we would support efforts to incent software developers and patients to make use of Medicare claims data. This Administration's Blue Button 2.0 initiative, which would help make this claims data usable via APIs to developers is a good start and this Subcommittee could supplement those efforts by ensuring that Medicare covers tools that enable patients to use, analyze, and share their claims data.

A diversity of APIs are emerging to assist in bringing PGHD into the continuum of care, but we stress that not all of these are necessarily well integrated with EHRs. While CEHRT will be required to support APIs, many vendors will enable "read only" access, allowing for data to only flow out of the EHR rather than both in and out. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards. Creating "special effort" to develop applications and undue burden and costs for our members. CHI reiterates our concern with, and lack of confidence in, any

presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability.

Further, privacy laws like the Health Insurance Portability and Accountability Act (HIPAA) also tend to—contrary to the name of the law itself—impede the portability of a patient's data from one provider to another. Although we do not suggest statutory changes to HIPAA, we have urged HHS' Office of Civil Rights (OCR) to provide updated and clear guidance to covered entities and business associates such that providers may observe the spirit of HIPAA's requirements without fear of "gotcha" enforcement tactics. CHI supports OCR's use of the fines it collects through enforcement for proactive educational efforts by OCR to improve the privacy posture of covered entities and business associates, rather than simply using those funds to bring further enforcement actions.

Within Medicare, moving away from the Meaningful Use program's "pass/fail" approach, CMS has adopted a Promoting Interoperability scoring regime that is less prescriptive and burdensome. CHI continues to work with CMS to ensure that compliance burdens for PI participants are as low as possible to maximize participation, and we support proposed changes to the PI scoring regime and measures proposed with increased flexibility and lower compliance burdens in mind (e.g., scoring measures at the objective level; and moving away from numerator/denominator scoring, and instead utilize a yes/no attestation; and aligning the hospital and physician PI programs by extending the 50-point score standard – recently finalized for hospitals in the IPPS – to physicians). The Subcommittee could encourage CMS to adopt the scoring approach across beneficiary programs to promote simplicity and certainty for digital health stakeholders.

CHI, like many others, is anticipating ONC's release of its draft information blocking rulemaking required under the 21st Century Cures Act. As information blocking is defined in law, we see the rule providing key insights into what is not info blocking. For example, CHI believes that the rule should make it clear that an entity is not data blocking in the event that patients cannot access their entire medical record through a mobile app and cannot receive their entire medical record in a format of their choosing (e.g., an app). This data may be limited for a few reasons, including security concerns regarding their own system(s) or recipient's system(s), as our members rely on strong encryption to protect sensitive health data; data segmentation (for privacy); and lack of access to information (e.g., no connectivity). While the 2015 Edition CEHRT includes API functionality that requires patients have access to at least the common clinical data set (CCDS), which is 21 data elements, expectations about what can be accessed through an app may need to be managed. CHI commits to work with this Subcommittee, HHS, and other stakeholders in encouraging the use of APIs that pull more than CCDS. Further, CHI anticipates the information blocking rulemaking to clarify:

- What constitutes "special effort" in eliminating blocking and promoting interoperability;
- How "should have known" is defined;
- How patient access is measured;
- How its rulemaking interacts with HIPAA requirements, ONC certifications, the Trusted Exchange Framework and Common Agreement (TEFCA), etc.;
- What constitutes a "violation," and the informal and formal pathways to complaint adjudication;
- Whether OCR will offer safe harbors utilizing constructs such as the TEFCA/ U.S. Core Data for Interoperability (USCDI), the ONC Interop Standards Advisory, etc.;

This Subcommittee may also be able to help by ensuring that CMS works in concert with sister agencies that are working to address the same issues now. For example, the National Coordinator for Health Information Technology (ONC) is currently developing TEFCA and U.S. Core Data for Interoperability (USCDI) to advance interoperability, on which CHI has provided its detailed input; further, an information blocking rulemaking must be advanced by ONC at some point. The Federal Trade Commission also plays an important role. We urge the Subcommittee to ensure that the agencies within HHS align their approaches and to ensure that they minimize compliance burdens on affected stakeholders. As such, CHI supports CMS' proposal to have participation

in the TEFCA qualify as a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. CHI strongly supports incentives to ensure the secure exchange of information. We urge that reporting requirements present as low a burden as possible and that the new CMS rules do not have the effect of incentivizing taxing data dumps that have little practical value.

VII. Providing Broadband Infrastructure to Support a Connected Health Continuum.

CHI supports the efforts to provide much-needed infrastructure for broadband connectivity generally, and in the healthcare context specifically, particularly in rural parts of the United States that face both chronic diseases (e.g., diabetes, heart disease, and COPD) and a lack of accessible health care facilities.[15] For example, in Mississippi, the American Diabetes Association approximated that 371,662 Mississippians (15.4 percent of the state's adult population) live with diabetes and about 810,000 Mississippians (37.5 percent of the state's adult population) have pre-diabetes blood glucose levels.[16] Despite alarming rates of diabetes, Mississippi has only 53 physicians per 100,000 people, painting a dire picture for the treatment of this otherwise manageable condition.[17] Nationally, every year, physicians diagnose 1.5 million Americans with diabetes, adding them to the 30.3 million Americans already battling the disease. More than 320 million people in the United States could require health care services at any time.[18]

As of last year, about 8 percent of Americans still lack access to broadband.[19] Meanwhile, new and innovative internet of things (IoT) technologies and deployments, requiring robust mobile broadband connections, are almost ubiquitous in today's economy.[20] And of the approximately 24.5 million Americans who continue to lack access to broadband,[21] most are in rural areas. Compounding the issue, rural Americans also suffer from higher rates of chronic disease than in metropolitan areas[22]—conditions that can be improved substantially with connected health tools like remote patient monitoring and telehealth. The critical nature of the healthcare sector mandates that improvements be made to America's critical infrastructure, and this includes broadband infrastructure and measures to give healthcare providers the ability to use connected health technology products and services throughout the continuum of care, both inside and outside the doctor's office.

CHI supports increased connectivity for rural health care and recognizes the Federal Communications Commission's (FCC) role in this respect. While the Commission's Rural Healthcare Fund (RHCF) has been a useful means for connecting eligible healthcare facilities, support for connectivity to enable remote monitoring is lacking to the detriment of countless rural American patients in need. The FCC has identified numerous barriers to broadband infrastructure deployment and has recently proposed several measures to address these barriers.[23] The FCC has committed to close the digital divide by establishing a "Gigabit Opportunity Zone" program, which would "bring broadband and digital opportunity to our nation's most economically challenged areas."[24] Even more recently, the FCC has proposed to establish a Connected Care Pilot Program to provide broadband services
to connect rural patients with healthcare facilities utilizing cutting-edge remote monitoring tools. CHI has urged the Commission to continue this trajectory to ensure that the necessary infrastructure is in place to facilitate more innovative mobile broadband solutions. We remain committed to assisting this Committee and the FCC in bringing the power and utility of the connected-health revolution to every American.

As the FCC considers options for greater broadband connectivity, it is important that the FCC utilize every spectrum resource it has available, whether licensed or unlicensed. For example, television white spaces (TVWS), unused portions of the television band, have the proven capabilities to deliver broadband connectivity to wide-ranging areas, without sacrificing bandwidth strength or speed. More importantly, TVWS does not require an extraordinary amount of infrastructure to deploy as TVWS-enabled broadband simply requires a TVWS device that can connect to an existing transmission tower, even if it is many miles away. Several pilot programs have even shown that TVWS-enabled devices do not require grounded electricity to be functional. Lastly, TVWS bands can help ease the programmatic strains associated with "last mile" connections, helping paying consumers avoid unnecessary increases in USF service charges on their next phone bill. We urge FCC action to unlock the ability to use TVWS for rural healthcare connectivity.

VIII. Conclusion.

Digital medicine can save lives—but only if we let it. Inextricable from the story of connected health is the fact that the American healthcare system for decades was driven not by value but by a constant stream of services. Now, digital medicine could help revolutionize healthcare as mobile technology has fundamentally improved banking. Alternatively, bureaucratic inertia and red tape could keep the cloud-plus-mobile improvements that have redefined our daily lives in countless other ways forever on healthcare's sidelines. We applaud the Subcommittee for shedding light on the existing barriers to the adoption of innovative means of enabling an American healthcare system that is more valuable to patients, providers, and taxpayers alike.

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