ConnectedHealth

Testimony of

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Before the

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Subcommittee on Primary Health and Retirement Security

"Health Care in Rural America: Examining Experiences and Costs"

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.

Your constituents in rural America face serious challenges in accessing cost-effective, quality care. Much of the problem is straightforward: people are further away from the healthcare services they need than in more densely-populated areas. This lack of access compounds the cost and effectiveness issues, further complicating the important task of addressing healthcare challenges in rural America. Enabled by a broadband internet connection, tech-driven tools that App Association and CHI members create must play a central role in bringing care teams to people where they are, and in facilitating greater patient engagement that lowers costs and improves outcomes through proactivity and prevention. But getting these technologies into the hands of patients and their caregivers is not a simple, one-step process. The U.S. healthcare system, bound up in labyrinthine, legacy regulations and payment policies, presents serious challenges to the incorporation of innovative tech-driven tools that offer the ability to make the best care available and accessible to all American located in rural areas.

This hearing takes place at a critical moment for healthcare in rural America. Moreover, this Subcommittee's wide-ranging jurisdiction from mental health and substance abuse to "health care disparities" puts it at the center of decoding the discrepancies between rural and urban healthcare. The costs of healthcare delivery continue to soar, and demographics are applying increasing 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.

Meanwhile, reports indicate that by 2025, the United States will face a shortfall of 46,000 to 90,000 physicians. [1] And while 20 percent of Americans reside in rural areas, only 10 percent of U.S. physicians practice there.[2] Compounding this shortage, of the 133 million Americans with chronic conditions, most are in rural areas. With 44 percent of rural hospitals operating at a loss—a 4 percent increase since 2017—almost one-third of them are at risk of closure. Not only does the closure of these hospitals cut off access to care for thousands of rural inhabitants, but each closure can also represent a 20 percent reduction of a rural area's local economy. The confluence of these resource, demographic, and geographic factors, along with buy-in from an unprecedented breadth of stakeholders who are recognizing the efficacy of the hardware and software technology tools available to medical professionals (not to mention what is being developed by American innovators like CHI members), makes now the right time to incent the adoption of these tools to address the looming American rural healthcare crisis.

In general, as we evaluate and suggest policy positions for decision-makers, we ask three fundamental questions. As we address the challenges to providing more cost-effective and higher-quality care in rural America, these questions are especially salient:

- **Does it drive value for patients?** Constituents anywhere likely take issue 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. But in rural areas of the country—where there are fewer caregivers per patient and higher rates of chronic disease, on top of an hour-long drive to the nearest care facility—the frustration is especially intense. Federal healthcare policies should enable innovators to make healthcare both more accessible and more effective for rural 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.[3] Accounting for the other necessary activities, they are left with only 27 percent of their time dedicated to direct clinical face time with patients. In rural areas, the shortage of physicians means each of them has less time to spare for paperwork and EHR data entry.

- **Does it drive value for taxpayers?** The current cost spiral—in which the healthcare system too often incents caregivers to care for the sickest patients in the most expensive settings—is unsustainable. The question we ask is not whether a policy makes care "cheaper." Instead, the question is whether a policy creates incentives for caregivers to avail themselves of cost-effective measures. Digital health tools will benefit rural Americans because providers that are able to use them are better equipped to meet cost challenges and reach patients where they are without having to travel. To improve outcomes in rural areas, healthcare 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 – and, increasingly, necessities – to the practice of medicine. Experts are referring to AI in the healthcare context as "augmented 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. And nowhere is this truer than in rural America, where the high rates of chronic disease and patients' distance from caregivers make telehealth and remote patient monitoring even more important. However, today, the policies dictating the use of technology have, in many ways, detracted from the time caregivers spend monitoring and engaging with patients, particularly because of the arcane nature of Medicare and Medicaid regulations and payment policies.

All is not lost. Other highly regulated industries have successfully overcome these obstacles and empowered innovators to drive greater effectiveness, convenience, and cost-efficiencies. 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 with a few taps or 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. Policymakers can pull a number of levers to enhance value for patients, caregivers, and taxpayers alike. For example, policymakers should take the following steps:

- First, policymakers should ensure that healthcare policies do not penalize—and in fact support—the adoption of tech-driven tools that enable physicians to engage meaningfully with physically distant patients, including by passing the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017 (S. 1016);

- Second, policymakers should support access to broadband, especially in rural areas—including using unlicensed spectrum in the television band, often referred to as "TV white spaces"—to enable connected health technologies to reach rural populations that suffer from high rates of chronic disease;

- Third, Congress should remove the overburdensome restrictions on telehealth under 1834(m) of the Social Security Act, particularly those unreasonably restricting Medicare telehealth services to a limited set of geographies and those prohibiting the home from being an originating site;

- Fourth, Congress should ensure that the cost savings associated with the use of connected health innovations are accounted for, and require the Congressional Budget Office (CBO) to consider cost savings

associated with the prevention of disease as well as looking beyond the 10-year budget window by passing the Preventive Health Savings Act (S. 2164);

- Fifth, the Centers for Medicare and Medicaid Services (CMS) – as well as state Medicaid policymakers – should adopt billing codes that provide reasonable support for caregivers using tools to bring patient-generated health data (PGHD) and timely AI-driven analysis of that PGHD into patient prevention and treatment activities;

- Sixth, 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;

- Seventh, policymakers should also incentivize 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;

- Eighth, 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); and

- Ninth, the Department of Health and Human Services (HHS) Office of Civil Rights should provide, through regulatory reforms as well as guidance, clarity as to the obligations of covered entities and business associations under the HIPAA law with respect to the technology in use today as well as emerging technology.

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. And while our focus today is on government policies and programs, it is important to recognize that the Medicare and Medicaid system, for better or worse, is a bellwether for the state Medicare and Medicaid programs as well as private payers. Due to its sheer spending power, along with some other factors, the policies adopted in the Medicare and Medicaid system will have a heavy impact on all aspects of the American healthcare system.

CHI commits to working with each member of this vital Subcommittee to improve the care every American has access to and receives across its rural communities.

II. Bringing Connected Health Technology Innovations into the Medicare Reimbursement System

The reimbursement policies across Medicare programs, particularly the Physician Fee Schedule (PFS), must evolve rapidly to provide access to improved care for rural Americans. Traditionally, the Medicare system has provided significantly limited reimbursement for Medicare telehealth services—in effect a live voice or video call only—which are subject to the backwards-facing and onerous restrictions in Section 1834(m) of the Social Security Act, which I discuss in greater detail below. But even worse, the Medicare system entirely ignores the diversity of hardware and software technology tools past live voice and video, which offer even greater benefits. CHI has long argued, before Congress and through direct engagement with CMS, for the system to move forward and embrace the power of remote monitoring innovations across its programs.

As more Medicare services and funding shifts to a value-based paradigm, the PFS will remain an important means of reimbursing rural providers for healthcare services for rural 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 spend 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.

At CHI, we have been putting our money where our mouth is on reimbursement. For example, I continue to serve as an appointed expert on the American Medical Association's Digital Medicine Payment Advisory Group (DMPAG), a collection of experts in digital medicine services as well as coding, valuation, and coverage that advance opportunities to bring the use of digital tools into the delivery of care through Current Procedural Terminology® (CPT) changes and additions, among other efforts. The DMPAG's work has resulted in new CPT codes that capture both the technical and professional aspects of remote 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]).[4]

The DMPAG developed the three codes described above through concerted and thoughtful deliberations. 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, with the RUC relying on a 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. Rural populations tend to have higher rates of these kinds of patients,[5] so the codes are especially important for rural patients and their caregivers. Below, I discuss how important it is that CMS utilize these new remote monitoring codes.

a. Medicare Telehealth Services

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. 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. 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 Subcommittee 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 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 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 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.

CMS' mis-categorization of counties as non-rural also presents a serious hurdle to usage of Medicare telehealth services. For example, several rural counties in Virginia are considered rural for the purposes of the Federal Communications Commission (FCC) and the U.S. Department of Agriculture (USDA), but they are not considered rural under CMS' definition. As a result, local health facilities in these counties are eligible for rural programs under FCC and USDA support programs but are ineligible for telehealth services. To be clear, these counties are very rural and very remote. Instead of trying to force federal agencies across the government to agree on a definition "rural," however, CHI recommends that Congress systematically repeal the originating site and other restrictions to telehealth use. Instead, policymakers should ensure that telehealth is a viable alternative for patients and caregivers in situations where live voice or video is the more cost-effective and high-quality option.

Facility	City	County	USDA	USAC/FCC	Medicare Telehealth Payment Eligible?
Konnarock Family Health Center	Damascus	Washington	Yes	Yes	No
Clinch River Health Services	Dungannon	Scott	Yes	Yes	No
Carilion Giles Community Hospital (CAH)	Pearisburg	Giles	Yes	Yes	No
Tri-Area: Floyd	Floyd	Floyd	Yes	Yes	No

i. 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. These frustrations are worse in rural areas. It is no surprise, therefore, that many rural 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.

ii. Value for Caregivers

Surveys reflect that caregivers who serve rural Americans 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 over the next year. [6] Providers' proposed adoption of telehealth is good news for patients, but the benefits of Medicare telehealth services pale 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).

iii. Value for Taxpayers

The benefits of telehealth for taxpayers are equally well-documented. For example, in a recent telehealth program done by CHI steering committee member University of Mississippi Medical Center (UMMC), the first 100 patients with diabetes collectively saved an incredible $336,184 in healthcare costs.[7] 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.[8] 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.[9] 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 Sen. Angus King's Preventive Health Savings Act (S. 2164). 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.

Telehealth is not just a means for caregivers to engage with patients more often to provide preventive care that saves taxpayer dollars by avoiding more costly care. Live voice and video are also important in other settings. For example, studies estimate that physicians perform over 700,000 knee replacements per year, a number that is projected to increase to almost 3.5 million by 2030. Perhaps the most important part of knee replacement surgery is physical therapy (PT), but patients who live a significant distance from a PT facility have difficulty attending PT sessions due to busy schedules, transportation costs, and other factors. People who have gone through PT to recover from surgery, or know someone who has, understand that engagement with a PT professional during the process is important and taking the time to go to a PT appointment is difficult. Research shows that PT by telehealth—referred to as "telerehabilitation"—correlates to "a total cost of care that was less than expected and to an increased probability of discharge home."[10] Telehealth benefits are therefore not limited to prevention but they also add value for taxpayers by increasing the cost-effectiveness of services like post-surgery PT, especially for patients in rural areas.

b. Remote Communications Technologies

Recently, our efforts have begun to pay off in advocating for coverage for remote monitoring. In the calendar year 2018 PFS, 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 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 qualified healthcare professionals who rely upon remotely gathered physiologic data to monitor patients and is an important, but incremental, step forward.

Then, building on the hard work of the DMPAG and the results of the CPT Editorial Board process that resulted in new CPT codes for chronic care remote physiologic monitoring, in the proposed calendar year 2019 PFS, CMS proposed to activate and pay for each of the three new codes. CMS has 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 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.

- 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). 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 Subcommittee 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 how these services are being employed.

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.[11] 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 and Medicaid 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 Congress to ensure that CMS takes these necessary steps.

III. A New Direction for the Center for Medicare and Medicaid Innovation (CMMI)

The process by which the federal government recognizes new technologies and care modalities to fold them into the continuum of care has proven to be a difficult and lengthy process. Nobody wants technology at the speed of government, but too often, that's what patients in the Medicare system get. For example, when it is examining new models, the Center for Medicare and Medicaid Innovation (CMMI) must first resolve that model as something over which it has sufficient authority, as well as an evidence base, in order 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-wide adoption after at least a year of rulemaking exercises. Taken all together, this process can take up to 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 Congress 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 PFS and Quality Payments Program (QPP) we have noted 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 working with this Subcommittee to assist CMMI in any way possible to get to CMMI to the forefront of innovation in delivering care to Medicare and Medicaid beneficiaries.

IV. Ensuring that Value-Based Care Models Realize the Potential of Connected Health Technology Innovations

While the billing practices of Medicare providers are very important, the future shape of the new value-based system envisioned by Congress in the Medicare and CHIP Reauthorization Act of 2015 (MACRA) is arguably even more so. The value proposition for clarifying CMS' expectations and requirements in the context of the use of tech-driven hardware and software tools in the QPP is simple. Whether participating in the Merit-based Incentive Payment System (MIPS) or an Alternative Payment Model (APM), rural providers need to know that their adoption and use of technology tools are welcomed by CMS and that such adoption will not disadvantage them from a Medicare coverage perspective or expose them to liability. In turn, adopting these tools better enables providers to engage with rural patients in more dynamic and cost-effective ways.

b. Merit-Based Incentive Payment System (MIPS)

CHI supports CMS' efforts to incent the use of connected health innovations in MIPS through providing modality-neutral approaches to Improvement Activities (IAs) and flexibility for program participants. For example, CHI appreciates 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.[12] CMS not only adopted the IA, but it 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 in MIPS. MACRA reflects this Subcommittee's 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 and other incentives that pave the way for the flexible adoption of digital tools.

For example, CMS' previous policy of providing bonus points in the Promoting Interoperability (PI) category represents CMS' understanding that connected health innovations play a key role in improving outcomes and incenting 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.

Yet 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.

Congress 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 working with this Subcommittee to maximize the value of MIPS.

c. Alternative Payment Models

CHI also supports Congress' goal in MACRA 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 have strongly urged CMS to provide this crucial direction and rationale in the next final (calendar year 2019) QPP rule. Such a step would also be consistent with CMS endorsement of telehealth and remote monitoring in both the PFS as well as MIPS, and it would be a crucial step for rural Americans.

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.

A1C LEVELS

9.9% **1.7% Drop** **7.7%**

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. The availability of a wide range of options to reach patients at home is crucial for rural caregivers.
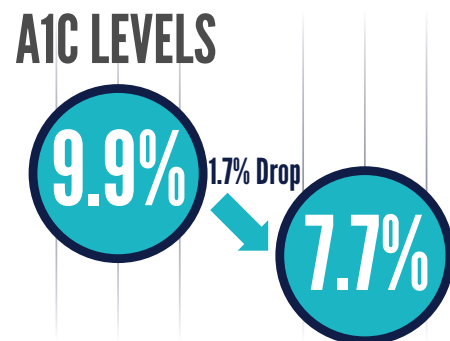
d. Value for Patients

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. Rural patients especially would benefit from the reduced need to travel long distances to see their doctors and from the ability to engage with physicians from their homes. 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.
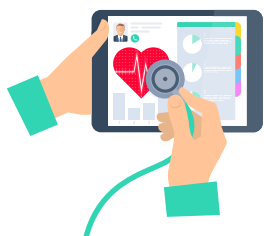
We discuss UMMC—which is a Health Resources and Services Administration (HRSA)-designated Telehealth Excellence Center—in detail above, but it makes sense to describe the benefits connected health tools have produced for UMMC patients. UMMC adopted a remote monitoring strategy out of necessity, and the evidence shows improvements to outcomes as well as ease of use for UMMC patients. The first 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. [13] The monitoring program involved patients using a tablet and sensors to track symptoms and blood glucose levels. In a similar project, UVA partnered with a Federally Qualified Health Center (FQHC) to conduct a diabetes management program for rural patients. The program involved telemedicine, remote patient monitoring, and tech-driven care coordination. The results thus far have been remarkable: over six months, the mean hemoglobin A1C levels (a marker for diabetes control) dropped from 9.9 percent—which indicates uncontrolled—down to a far more manageable 7.7 percent. Moreover, since UVA began its broader telemedicine program, it has saved patients 18.3 million miles of driving, including 2.3 million last year alone.

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—a population that comprises a disproportionately high percentage of rural residents. 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.

e. Value for Caregivers

Increased flexibility in the APM and MIPS programs would produce obvious benefits for rural 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, the 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.

f. 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 in rural areas 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 rural 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 rural 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. 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.[14] 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.[15] 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. [16] 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.[17]

As of last year, about 8 percent of Americans still lacked access to broadband.[18] Meanwhile, new and innovative internet of things (IoT) technologies and deployments, requiring robust mobile broadband connections, are almost ubiquitous in today's economy.[19] And of the approximately 24.5 million Americans who continue to lack access to broadband,[20] most are in rural areas. Compounding the issue, rural Americans also suffer from higher rates of chronic disease than in metropolitan areas[21]—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 FCC's 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.[22] 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."[23] Even more recently, the FCC has proposed to establish a Connected Care Pilot Program to provide $100 million for 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.

VI. 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 HHS' recent public solicitation for comments on the AKS and Stark

Law's impact on innovation,[24] on which CHI has commented and urges this Subcommittee to consider.[25]

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.

g. 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.

h. 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.

i. The Value for Taxpayers

Congress' vision for value-based care 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.[26] 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.

Costs associated with non-emergency medical transportation (NEMT) and emergency transportation can add up in rural areas. Patients must use NEMT to reach regularly scheduled appointments such as dialysis for patients with renal disease. Longer distances between patients and care facilities in rural areas mean costs for NEMT and emergency alike can range much higher in less densely populated areas. According to one estimate, about 30 percent of the U.S. population can only reach appropriate urgent care via air transport, which is a major cost driver in the U.S. healthcare system.[27] Certainly, some proportion of urgent care trips is attributable to chronic conditions that respond to preventative management. Enabling rural providers to use remote patient monitoring and other connected health modalities would reduce the overall costs associated with expensive, yet preventable, emergency trips in rural areas. Moreover, software-facilitated engagement could help defray NEMT costs by reducing the need to pay for transportation for patients to distant providers.

VII. Providing Incentives for Patients to Bring Patient-Generated Health Data into Their Care

With incremental progress already taking place, and even further progress likely, in providing caregivers incentives to use cutting-edge technology to bring PGHD into their care decisions, we must also ensure that we do not forget the other crucial part of the care continuum formula: the patient. CHI urges this Subcommittee to join us in seeking to provide consumers and patients across rural America 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.

Earlier this month, Americans heard an announcement about the upgraded sensors and other technology in popular smartwatches. 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.

VIII. 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[28] 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 Congress to ensure the federal government's 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."[29] 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 Congress 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 previously 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 actions. CHI would support appropriate reforms to allow OCR to use 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). Congress could encourage CMS to adopt the scoring approach across beneficiary programs to promote simplicity and certainty for digital health stakeholders.

CHI, like many others, was pleased to hear that the National Coordinator for Health Information Technology (ONC) sent 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 working with this Subcommittee, HHS, and other stakeholders in encouraging the use of APIs that pull more than CCDS. Further, CHI anticipates that the information blocking rulemaking will 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.

Congress may also be able to help by ensuring that sister agencies working to address interoperability coordinate appropriately. For example, ONC is also currently developing the TEFCA and U.S. Core Data for Interoperability (USCDI) to advance interoperability, CMS is continuing to establish its role in interoperability, and

the Federal Trade Commission also plays an important role. We urge Congress to ensure that the agencies within HHS, and other federal actors, align their approaches and to ensure that they minimize compliance burdens on affected stakeholders. For example, 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.

IX. Conclusion

Digital medicine can save lives, especially in rural America—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. This model has exacerbated the healthcare challenges in rural areas. Now, digital medicine could help revolutionize rural healthcare, just 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 state of healthcare in rural America and granting us the opportunity to advocate for 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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